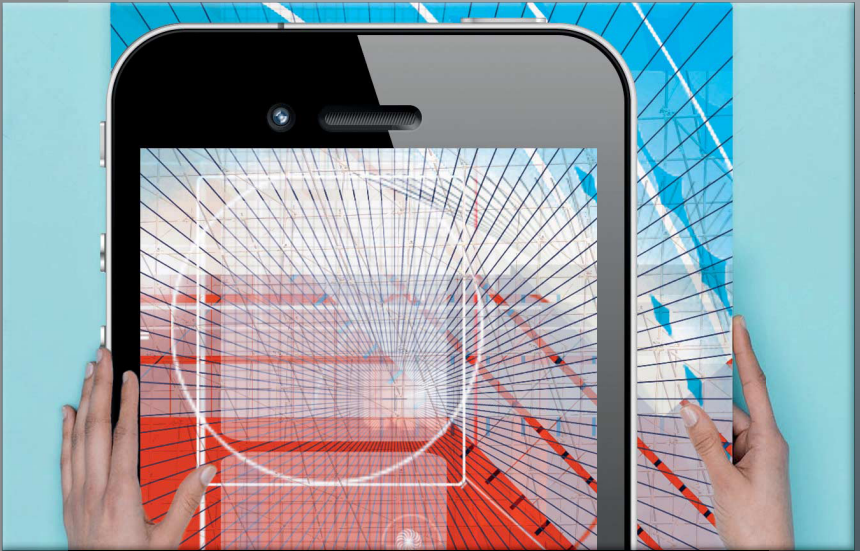# Improving Usability, Safety and Patient Outcomes with Health Information Technology

From Research to Practice

Editors: Francis Lau
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Information technology is revolutionizing healthcare, and the uptake of health information technologies is rising, but scientific research and industrial and governmental support will be needed if these technologies are to be implemented effectively to build capacity at regional, national and global levels.

This book, *Improving Usability, Safety and Patient Outcomes with Health Information Technology,* presents papers from the Information Technology and Communications in Health conference, ITCH 2019, held in Victoria, Canada from 14 to 17 February 2019. The conference takes a multi-perspective view of what is needed to move technology forward to sustained and widespread use by transitioning research findings and approaches into practice. Topics range from improvements in usability and training and the need for new and improved designs for information systems, user interfaces and interoperable solutions, to governmental policy, mandates, initiatives and the need for regulation.

The knowledge and insights gained from the ITCH 2019 conference will surely stimulate fruitful discussions and collaboration to bridge research and practice and improve usability, safety and patient outcomes, and the book will be of interest to all those associated with the development, implementation and delivery of health IT solutions.

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Preface

Health information technologies (IT) are revolutionizing and streamlining healthcare and their uptake is rising dramatically. The variety and range of technologies and software applications is considerable and there is increasing demand for implementation of health IT in hospitals, clinics, homes and in the virtual space of mHealth, pervasive healthcare and social media. However, to effectively implement these technologies scientific research and industrial and governmental supports must be strongly in place in order to transform health care and build capacity at the regional, national and global levels.

The conference will take a multi-perspective view about what is needed in order to move technology along to real sustained and widespread use in moving research findings and approaches into practice. Solutions range from improvements in usability and training, to need for new and improved design of information systems, user interfaces and interoperable solutions, to governmental policy, mandates, initiatives and need for regulation. In addition, greater interaction will be needed among industrial, governmental and academic partners.

We believe that the knowledge and insights gained from the ITCH 2019 conference will stimulate fruitful discussions and collaborations among the participants in ways that can bridge research and practice to improve the usability, safety and patient outcomes through innovative and responsible application of health IT solutions.

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Contents

Review of Mobile Apps for Prevention and Management of Opioid-Related Harm

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Abstract. Opioid-related harm is a major public health concern in Canada and abroad. There is a growing market of mobile apps that focus on preventing and managing opioid-related harm. The use of mobile health technologies is a promising intervention that can assist with addressing the problem. The aim of this paper is to examine the current state of the mobile app market with respect to prevention and management of opioid-related harm. This will involve a review currently available opioid apps for the major operating systems (iOS, Android, Windows CE and BlackBerry OS) and examine the number of released apps, service providers, operating systems, target user groups, purpose of app, range of features, location, use of evidence, interface, languages, cost and licensing model, and user ratings.

Keywords. mHealth, mobile applications, communication technology, information technology, opioid, narcotic, analgesics

1. Introduction

Opioids are natural or synthetic substances that are used for pain management in clinical settings, but are also produced and consumed for non-medical reasons. [1] The most common opioids prescribed for pain management include: hydrocodone, oxymorphone, morphine, codeine, and fentanyl. [2] Although opioids can be effective for pain management, these medications are highly addictive and can lead to dependence (i.e. particularly when they are used through different methods (injected or snorted) at a higher dose. They can also be addictive when there are prescribed over an extended period of time. [3] The aim of this paper is to examine the current state of the mobile app market with respect to the prevention and management of opioid-related harm. More specifically, this paper reviews currently available opioid apps for multiple operating systems and examines apps in the context of service providers, operating systems, target user groups, purpose of app, features, location, use of evidence, interface, languages, cost and licensing models, and user ratings.

2. Background

Opioid-related harm such as addiction and overdose have become a major public health crisis in Canada and around the world. Canada is the second leading country in per capita

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rates of prescription opioids, second only to the United States. [4] In Canada, opioid-related deaths have been increasing across the country over the past decade. [5] Recently released data from Public Health Agency of Canada indicates there were 1,036 opioid-related deaths in Canada between January and March 2018, in which 94% were unintentional or accidental. [5] Between January 2016 and March 2018, it is estimated that 8,000 Canadians lost their lives to an opioid-related overdose. [5]

Opioid-related harm is increasing the pressure on the Canada's health care system. The Canadian Institute for Health Information (CIHI) reported that opioid-related harm increased emergency department visits and hospitalizations. [6] Between 2007–2008 and 2016–2017, the rate of hospitalizations due to opioid poisoning increased by 53%. [6] In 2016–2017, more than half of hospitalizations for opioid poisonings were considered accidental and almost one-third were a result of purposely self-inflicted. [6] Data from the provinces of Alberta and Ontario indicate that rates of ED visits more than doubled in Alberta and increased by almost half in Ontario between 2012–2013 and 2016–2017. [6]

Governments and public health agencies have put in place several strategies in an attempt to respond to the opioid crisis. These strategies include: public methadone clinics, antagonist therapy for opioid maintenance, education and guidelines for prescribers, prescription drug monitoring programs, patient education programs, support for medications to reverse opioid overdose, education and training for caregivers on management of overdose. [7] In 2019, the Government of Canada announced an investment of CAD $100 million over five years, with CAD $22.7 million for the Controlled Drugs and Substances Strategy to combat the opioid crisis. This included $30 million over five years for the Harm Reduction Fund, which supports community initiatives to reduce infection disease among drug users. An additional 1.5 million over 5 years was invested for new supervised consumption sites across Canada. [8] Technology-based interventions such as mobile phone interventions (mHealth) are increasingly being used for substance abuse and addiction. [9] There are a growing number of clinical interventions that are being provided via mobile devices. mHealth has a significant potential to play a key role in preventing and managing opioid-related harm provided the apps can prevent opioid related harms.

3.   Methodology

To examine the current state of mobile health technology with respect to prevention and management of opioid- related harm, we conducted an electronic search in July of 2018 of the official app stores for the iPhone operating systems, Android (Google Play), (iOS; itunes), Windows Phone (Windows Store), Blackberry OS (Blackberry World). The terms 'opioid' OR 'opiate' were used to search each store.

4.   Findings

The findings are grouped into themes provided below:

Number of released Apps: In total, there were 243 results yielded from the search that was done across stores (i.e. 151 results from Google Play, 90 results from App Store, 2 results from Microsoft Store, and 1 result from Blackberry World). After a review of

all the results, 27 apps were found to target the prevention and management of opioid-related harm.

Service Provider: The service providers for the 27 apps ranged from product vendors, not for profit organizations and government entities. The majority of the apps were supplied by product vendors (n=19 apps). There were four apps that were sponsored by government organizations and three apps that are sponsored by Not-for Profit organizations. For one app, service provider information was not available.

Provider Mobile Apps: The majority of the 27 apps are available in the Android and iOS operating systems. In terms of operating systems, fifteen apps were Android and 24 apps were iOS based. Twelve apps were available as either Android or iOS operating systems. No relevant apps were found in the Microsoft Store or Blackberry World.

Target Audience: There were a wide range of target audiences or potential users for these apps including individuals using opioids, caregivers and support groups, clinical practitioners, governmental organizations, first responders, pharmacies, volunteer responders and the general public. In many cases, the mobile apps were developed for multiple audiences. The majority of apps were developed for opioid users (n=21), in which 10 were for those using opioids and those who were at risk of addiction. Eleven apps were developed for opioid users in addiction recovery, four for opioid users at risk of overdose, and one for opioid users at risk of infectious disease. Five apps targeted both opioid users at risk of addiction and in addiction recovery. There were 13 apps whose primary users would be clinical practitioners. For the remaining apps that were identified ten of these apps were developed for first responders, nine focused on providing supports for caregivers and supporters, seven apps for governmental organizations, six apps for pharmacies or prescription medication providers, and two apps for volunteer responders. In total, there were ten apps that were designed for the general public.

Purpose of App: There were several reasons for the development of mobile apps. Apps were developed as clinical decision support for clinicians, to generate statistical data, to create directories, to provide education and information, to support user self-management, to aid in communication with social network, and to provide an emergency response. Apps ranged from having one purpose to four. No app had all the interventions described above. There were 12 apps with one purpose, nine apps with two purposes, four apps with three purposes, and two with four purposes. The majority of the apps were developed to *educate and inform* users (n=20 apps). Eight of the apps focus on providing *self-management support* for opioid users that have been prescribed medication for pain and/or for those in recovery. Six apps focused on *communication* between opioid users and a network of opioid users or between opioid users and clinicians and/or support providers. Six of the apps provided a *directory* of services and programs for users. Four of the apps provided health care practitioners with guidelines and tools to assist with *clinical decision support*. Three apps were focused on preventing death (i.e. when an individual has overdosed by sending an *emergency response* to local pharmacies, a network of opioid users or caregivers). Only two apps focus on collecting and reporting of *statistical information*.

Features: To meet the purpose of the app, there were several app features offered to users. These features included: multi-media content, maps, self-monitoring information tracking, location tracker and alerts, gamification, communication with clinical and support providers, social network chat, data analytics and reporting.

Multimedia Content: *Education and information* took the form of text, images, and video clips. The presented content included information about: opioids (i.e. types, uses, side effects, causes and types of pain), strategies to prevent opioid dependence, information about opioid dependence, self-management during opioid use and early addiction recovery, motivation and inspirational messaging, medication and safety information, signs of overdose, how to respond to an overdose, prevention of infectious disease, and how to use the app. Eight apps provided *guidelines* information. Of the eight apps, five apps provided prescribing information about opioids for chronic pain by health care practitioners. One app supported clinicians with a calculator to determine opioid dosage. Another app aided practitioners with risk stratification for each patient based on a morphine equivalent dose range, as well as pain and function scores. This app also automated Prescription Drug Monitoring Program (PDMP) checks. Here, the app helped to track who was prescribing and receiving controlled substances and services as well as how much is being prescribed and how often. Another app provided first responders with operational response protocols for fentanyl analogs. Two apps offered self-help guides to opioid users during addiction recovery. One app provided information on activities that increase endorphin production for those individuals in early recovery. Another app used a 12-step guide and medication assisted treatment (MAT) concepts to help recovery patients stay active and on track.

Self-Monitoring Information Tracking: Six apps allowed opioid users to track their own information. For those recovering from opioid addiction, three apps provided self-monitoring tools. One app's access to a progress tracker, allowed for the tracking of obstacles in recovery (stress, anger, and anxiety) and strategies used to tackle challenges (meditation, honesty, and exercise). Another app tracked daily health reports for an individual health care practitioner and provided access to a Life Map Journal which assisted the person with their understanding of how they ended up in their situation and what lies ahead. Another app provided access to a journal, but its main function was to keep track of lists, action plans, and discoveries. For those using opioids and at risk of addiction, there were two apps with self-tracking features. One app provided access to tools and charts to track medications, create pain diaries, and document pain using pain diagrams. Another app recorded patients taking their medication. This information was made available to clinicians involved in their care. One app was designed for users that were at risk of infectious disease. This app tracked five key behaviors related to opioid use that are important to maintaining health and provided graphical feedback on the behaviors being tracked.

Maps: Six apps provided users with maps. Five of these apps provided maps for services and programs in the local community and one app provided information on local pharmacies that carry NARCAN® (naloxone HCL) Nasal Spray. The nasal spray is a FDA-approved form of naloxone used to reverse an opioid overdose in an emergency.

Location Tracker and Alerts: Three apps tracked the location of the opioid user. One of these apps monitored the activities of individuals who were at risk of overdose from opioids. In the event of an overdose, the app activated a network of nearby volunteer responders (individuals that are part of group network of people who were at risk of overdose from opioids or other contaminated drugs, and the people who want to keep them safe) to respond to the emergency. Another app physically monitored inactivity by an opioid user. In the event that a user was not moving or responding to prompts by their device, the app would send an alert to the user's social network of caregivers and/or support group. Another app allowed for registered carriers of Naloxo to locate an opioid

user who had overdosed when an alert was received. This app enabled carriers to see where the emergency is and get directions using their smartphone. If the requestor has entered their phone number (usually done on app install, prior to the emergency) the naloxone carrier would also receive a number and could call the requestor.

Gamification: Gamification is an application that consists of applying game playing elements to non-game context to promote engagement and achieving certain outcomes. Three apps provided users with gamification. One app was an informational app for the general public. It provided weekly challenges that allowed users to learn about opioids (e.g. why they are addictive, and how to recognize and respond to an opioid overdose). This app allowed users to work towards winning prizes. Another app focused on those users with an opioid addiction and used daily challenges to assist them with the decision to stop opioid abuse. These activities included learning skills that stop opioid use and strategies to move ahead. The app had a journal that allowed users to keep track of lists, action plans, and discoveries. Both of these apps had a subscription licensing model. One additional app was available. At no cost, the app provided a suite of information and tools to help people recovering from opiate addiction through MAT. The work included a feature that rewarded individuals for regularly checking their app.

Communication with Health Care and Support Providers: Three apps provided opportunities for individuals in addiction recovery to directly communicating with their health care practitioner. These apps were offered in conjunction with opioid treatment programs and clinics in the United States. One app was an integral part of a program that focuses on a specific approach to recovery. This app allowed patients to communicate with their support system. Another app was used by a specific clinic in the United States, which allowed patients to communicate with their doctor. The app also provided users with access to weekly video conferences with a doctor, therapist, life coach and fellowship group. Another app was designed to assist people utilizing MAT in order the help them recover from opioid addiction. The app allowed users to contact coaches, both from the user's social support group and health professionals.

Support Network Chat: Two apps reviewed allowed opioid users to communicate with other opioid users and/or their support group. One app allowed opioid users at risk of overdose to communicate with other individuals at risk of overdose from opioids or other contaminated drugs, as well as people who want to keep the opioid users safe. This app allowed app users to keep track of inactivity – a way of monitoring for a potential overdose. Another app provided users in recovery with access to a peer support system through an anonymous social network. This app provided an opportunity for like-minded individuals to connect with and support each other.

Data Analytics and Reporting: Two apps were used for data analytics and reporting. One app was a real-time mobile and desktop application that could be used by first responders and citizens to enter overdose incident data. The app has a data repository that stores overdose incident data for all participating countries and offers a comprehensive reporting system that allows users to create custom queries by substance(s), provider, location, demographic, intervention type and outcome data. The app was intended to serve as an epidemiological indicator to provide incidence and prevalence data on opioid overdose data at a city, county, state and national level. Another app reported and analyzed data for first responder departments throughout the United States to track the administration of Naloxone for an opioid overdose.

Location: Four apps were developed for a particular geographical location, program or clinic in the United States. Two apps were geographically focused on the North

Carolina (i.e. the counties of Alamance, Caswell, Chatham, Guilford, Montgomery, Orange, Randolph and Rockingham) and New York City in the United States. One app focused on a program in Pennsylvania (Williamsburg) and another app focused on a physician practice in Lakewood, New Jersey. One app was found that was available to patients that are part of the health care organization that sponsors the app.

Use of Evidence: Six service providers reported the use of evidence to develop app content. Sixteen service providers did not state whether evidence-based information was used to inform their apps. For five apps, the use of evidence is not applicable since the app was used for emergency response or data analytics.

Interface: Only one app had an interface that allowed for personal motion sensing capabilities by a user.

Languages: Twenty-four apps were exclusively offered in the English language. Two apps offered services in two languages (English and Spanish) and one app provided services in three languages (English, German and Afrikaans).

Cost and Licensing Model: The majority of the apps (24 apps) were available at no cost. One app had no cost for (90 days). After 90 days, a subscription model would take effect. For this app, the standard rate per user is $99/month. If an upgrade took place within the first 30 days of the trial, the cost was $69/month. Within 60 days, it was $79/month and before seven days (prior to a trial expiring), the cost was $89/month. One app had a one-time cost of $1.99 and another required a monthly subscription of $9.99.

Rating of Apps: Since the majority of the apps were in their infancy. The number of reviews were small or non-existent. In addition, it was hard to determine how many of the reviews were legitimately written by people that were using the app. Nonetheless, on a scale of 1-5, one app was rated between 1-2, another was rated between 2-3, and yet another app was rated between 3-4. Eleven apps were rated in the range of 4-5 and 13 are not rated at all.

In summary, there were a number of themes that emerged in a review of apps designed to support opioid addicted users, caregivers and the health professionals who provide care. In the next section of this paper, that authors review our findings in the context of the published literature.

5. Conclusions

Our review of mobile apps for the prevention and management of opioid-related harm indicates that there are just over two dozen apps available on the market. The majority of these apps were developed by for-profit health care providers. Since the apps are relatively new, there are a limited number of user ratings associated with each app. This indicates that the market is in its infancy and that there are further opportunities for governments, not-for-profit providers, and for-profit providers around the world to sponsor the development of new mobile applications or to enhance existing apps developed to address opioid-related harm. The users of these mobile apps are mainly opioid users, but they also include caregivers and support groups, clinical practitioners, governmental organizations, first responders, pharmacies, volunteer responders and the general public. In the majority of cases, the mobile apps were developed for English-speaking users. This creates a disadvantage for non-English speaking individuals. Future product developments should consider inclusion of multiple languages. On the other hand, the majority of the apps were available at no cost, which prevents disparity related to income.

The apps were designed to provide education and information to users, self-management support, communication and directories, clinical decision support, emergency response, and collection of statistical information. No one mobile app included all of the above features or functions. For this reason, an individual interested in the role of apps in opioid management would need to identify those apps that would be suitable to use based on opioid and/or caregiver user needs. To avoid redundant app features, there is a need for software developers to expand their offerings of opioid management features or for new developers to create a product that is inclusive of an opioid user's health and safety needs. Several mobile app features focus on preventing opioid related harm. The most common app feature was multi-media content for education and information sharing. Several of these apps provided guidelines on opioid prescribing, but less than a third of the apps cited the evidence that was used to guide app content development. Maps and self-monitoring information tracking were the next most available features found on opioid apps. Location trackers and alerts, gamification, and communication with health and support providers are the next most common features. Only one location tracker app had an interface that detected movement of an individual. The apps for communication with health care and support providers were limited to interactions with specific programs or clinics. Support network chats, data analytics and reporting were the least common features available for opioid mobile apps. Based on our review of opioid app features, the authors identify several opportunities for future development of mobile apps related that can be used to prevent and manage opioid-related harm. Product developers should consider the following:

- Directories and maps that allow users to locate services and programs in all counties, states, and countries
- Evidence-based self-management protocols and checklists for those recovering from opioid addiction
- Location tracking and alert functionality that sends an emergency response for suspected opioid overdose to first responders
- Use of artificial intelligence to predict when an individual will relapse so an emergency response can be generated. There is currently one product vendor that is working on this technology [10]
- Communication features for any practitioner involved in the care of opioid users regardless of geographical location or sponsoring program or organization
- Sensory monitoring of physical movement by health care and support providers caring for opioid users
- Educational content and information that is evidence-based and includes best practices. This information should include up-to-date information on the 'opioid crisis'

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9

Axe the Fax: What Users Think of Electronic Referral

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Abstract. Long wait times for elective services are seen as one of the major challenges for Canadian healthcare. Canadians report that they wait longer for specialists than citizens in other countries. The main reason for this is that the referral process is poorly coordinated and leads to delays in care. Electronic referral (eReferral) is seen as a potential means of improving the referral process and enabling faster access to care. There is the potential for national implementation of eReferral in Canada to help achieve this aim. However, existing initiatives have encountered challenges with user adoption and users have continued to use fax. A validated tool was used to survey both users of fax as well as users of eReferral. These two groups of users were then compared. Most family physicians using fax were satisfied overall with the process. This highlighted how challenging any change of this engrained technology will be. There were, however, some significant areas were eReferral was superior to fax. This included response time, the overall quality of referral information, completeness of the information, the timeliness of the information, and the format and layout. There is an opportunity to leverage these findings to support the adoption of eReferral and help reduce wait times.

Keywords. Wait times, electronic referral, eReferral, fax

1. Introduction

Canadians cherish their health care system with 94% calling universal health care a source of collective pride [1]. However, there exist a number of challenges. Long wait times for elective services are seen as one of the three major challenges for Canadian health care [2]. Canadians report that they wait longer for specialists than citizens in other countries [3].

In many cases, long wait times are the result of a poorly designed process as opposed to a lack of capacity [4-6]. Evidence from jurisdictions other than Canada suggest that replacing fax with electronic referral (eReferral) can improve the referral process by increasing the number of complete referrals, reducing inappropriate referrals and ultimately helping reduce wait times [7-9]. Little evidence has been synthesized about the Canadian experience with electronic referral, and the most recent environmental scan, which was conducted based on evidence until early 2013, concluded that there was little data on referral systems in Canada [10]. Without replacing fax and adopting electronic referral systems the potential benefits, including reducing wait times, cannot be realized.

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Canada Health Infoway, a not-for-profit organization, which has as its members the federal, provincial and territorial Deputy Ministers of Health has recently launched an ambitious access initiative to create a gateway that will enable a health technology ecosystem across Canada [11]. One proposed service that may be part of this ecosystem is electronic referral. Before implementation begins, it will be important to understand the experiences of Canadian users with electronic referral so as to understand if users will abandon faxing and adopt electronic referral.

2. Review of the Literature

A literature review of Canadian studies and reports was conducted and highlighted a number of benefits of electronic referral and also the challenges encountered [12-18]. Electronic referral systems can be easy to use, lead to improvements in the referral process, improve the quality of referral, improve the management of patient care, support more equitable access, and decrease wait times [12-18]. There are, however, also a number of challenges in using electronic referral. There is poor adoption of electronic referral systems among Family Physicians, there is a higher information requirement to complete an eReferral, eReferral systems are not connected with other systems, there are a lack of specialists on these systems, users of eReferral are often not engaged in the development or deployment process, there are potential significant cost of these systems, training is inadequate, and there are technical barriers [12-18].

No studies in Canada used a validated questionnaires to survey eReferral users. Also, no studies directly compared eReferral users to users of fax. This research aims to add to the existing literature by directly comparing users of fax to users of electronic referral using a validated questionnaire.

3. Methods

3.1. Participants and Recruitment

Participants were Family Physicians from a local health region in Ontario that had an electronic referral system. Understanding the perspectives of these participants was important as expansion of electronic referral in the area was being contemplated. These users were engaged in this study from March 2017 to December 2017. There were 2 groups in this study:

- Group 1 – Family Physicians referring to hospital outpatient services who had not used the electronic referral platform
- Group 2 – Family Physicians referring to hospital outpatient services who had used the electronic referral platform

This was a matched cohort study where users of eReferral were compared to users of fax.

The electronic referral system was a web-based system that launched directly from the Family Physician's electronic medical record. Patient demographic and medical data was auto-populated and the Physician was automatically signed in. The system also allowed for direct access through an online portal to both initiate and receive referrals.

This study was approved by the Human Research Ethics Board at the University of Victoria. All participants were provided a $20 gift card for participation in the survey.

Twenty Family Physicians who used fax to send referrals were sent surveys. Six Family Physicians responded for a 30% response rate. Twenty-two Family Physicians, all those using eReferral in the region, were sent the survey. Nine Family Physicians responded for a 41% response rate.

3.2. Procedure

The System and Use Survey (SUS) developed by Canada Health Infoway [19] is a validated tool that captures user perceptions of health information systems. It is aligned to the Canada Health Infoway Benefits Evaluation Framework as well as the micro dimensions of the Clinical Adoption Framework developed by Lau et al [20]. These dimensions are system quality, information quality, service quality, use and user satisfaction, and then quality, access, and productivity under net benefits. Results were analyzed within these dimensions.

The System and Use Survey (SUS) was modified for the use of fax and eReferral. Both are types of information systems and thus the SUS is appropriate for use. The surveys were put on Fluid Surveys (FluidSurveys, Ottawa, ON) and questionnaires were emailed to participants. Fluid Surveys stores data in Canada.

3.3. Analysis

Characteristics of the study population were collected. A matched cohort approach was used for survey data. The results from the eReferral group were compared with the fax group for questions that were the same for both groups. Since the SUS contained questions with ordinal variables and the expected value in each cell was less than five (as tested for each comparison), a Fisher's exact test was used. The XLSTAT (v2018.5, Addinsoft, Paris) statistical program was used which runs within Microsoft Excel (Microsoft, Washington).

4. Results

The group of Family Physicians using electronic referral (FP using eR) was compared to the group of Family Physicians using fax (FP using Fax) in terms of gender, computer proficiency, length of time in practice, family practice organization type, and clinic location. A Fischer's exact test was used and there was no statistically significant difference between the groups in any category.

4.1. Dimensions of User Satisfaction and System Quality

The overall user satisfaction was not significantly different between Family Physicians using fax (FP using Fax) and those using eReferral (FP using eR). In terms of system quality, the only statistically significant result was regarding response time of the status of referral (see Figure 1). All Family Physicians strongly or moderately agree that the response time for the status of referrals is acceptable through eReferral, with the exception of only one physician stating this is not applicable. For Family Physicians

using fax, three were not sure if response time from the hospital about their faxed referral was acceptable, while two physicians moderately agreed that the response time was acceptable and one physician felt that this was not applicable.
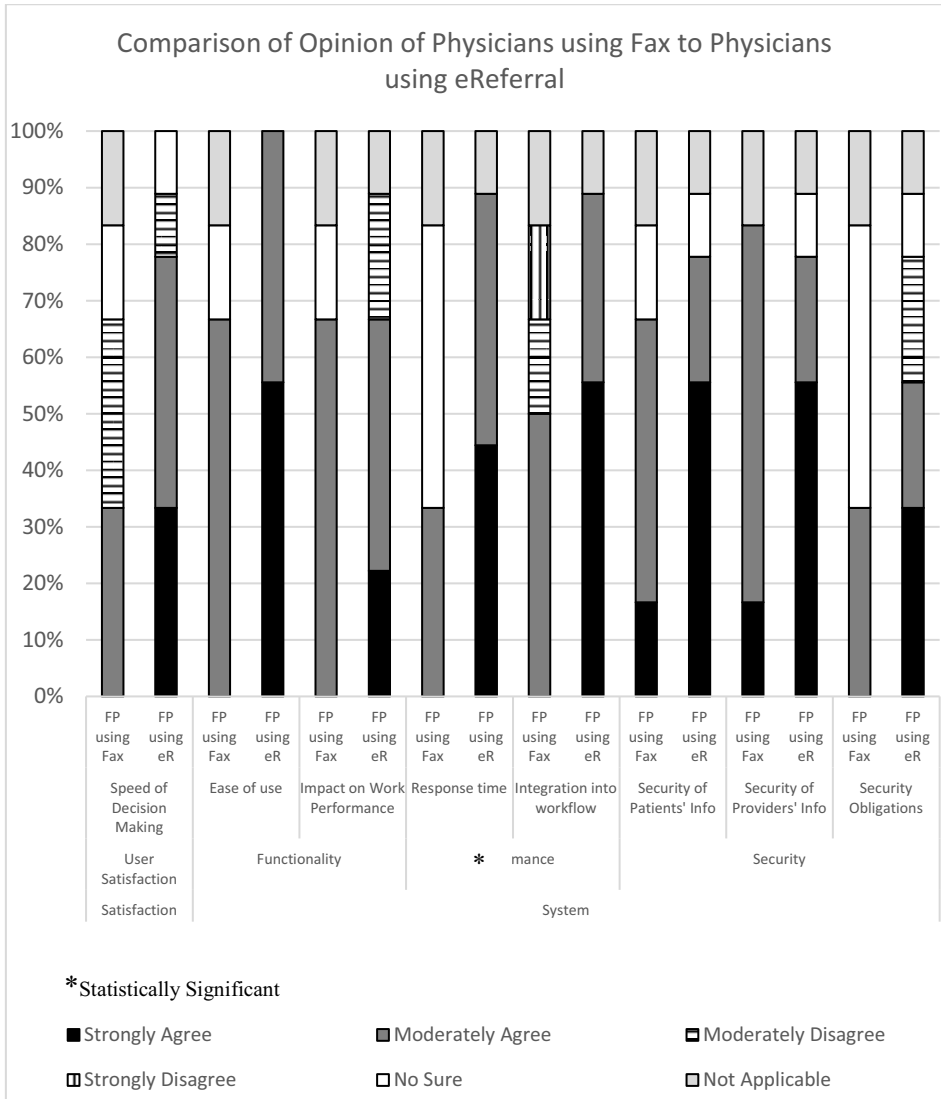
Figure 1: The Opinion of Family Physicians using Fax compared to Family Physicians using eReferral about User Satisfaction and System Quality

4.2. Dimensions of Information Quality

For the dimension of Information Quality there were 3 statistically significant results (see Figure 2). Eight of the Family Physicians using eReferral strongly or moderately agreed that the information coming back to them from the hospital about their referral is

complete with only one moderately disagreeing while those that are using fax had a mixed opinion of the completeness of the information coming back. In addition, seven of the Family Physicians using eReferral strongly or moderately agreed that the information (e.g. Status of Referral, tests available) from hospital is timely, with one Family Physician moderately disagreeing and one selecting not applicable. On the other hand, there was a mixed opinion from those using fax with three physicians saying they are not sure if the information is timely, one physician moderately agreeing that the information is timely, one moderately disagreeing with this, and one stating it is not applicable. Finally, all Family Physicians using eReferral strongly or moderately agree that the format and layout of the referral information from the hospital is acceptable, while half or three of the physicians using fax moderately disagree that the format and layout is acceptable, while two were not sure and one felt it was not applicable.
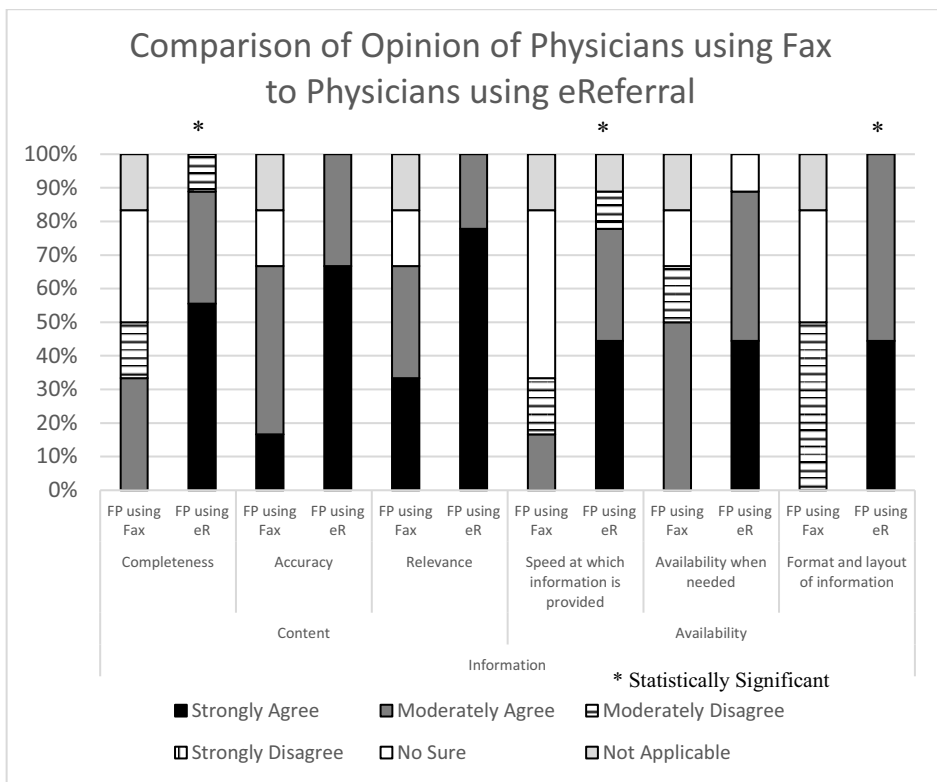
Figure 2: The Opinion of Family Physicians using Fax compared to Family Physicians using eReferral about Information Quality

4.3. The Likelihood to Recommend

There was a statistically significant difference between eReferral and faxed referral with regards to likelihood to recommend the solution to a colleague (see Figure 3). All Family Physicians definitely or probably would recommend eReferral to a colleague. For fax,

two-thirds of Physicians would probably recommend fax, while one-third would probably not recommend fax and one-third was equivocal.
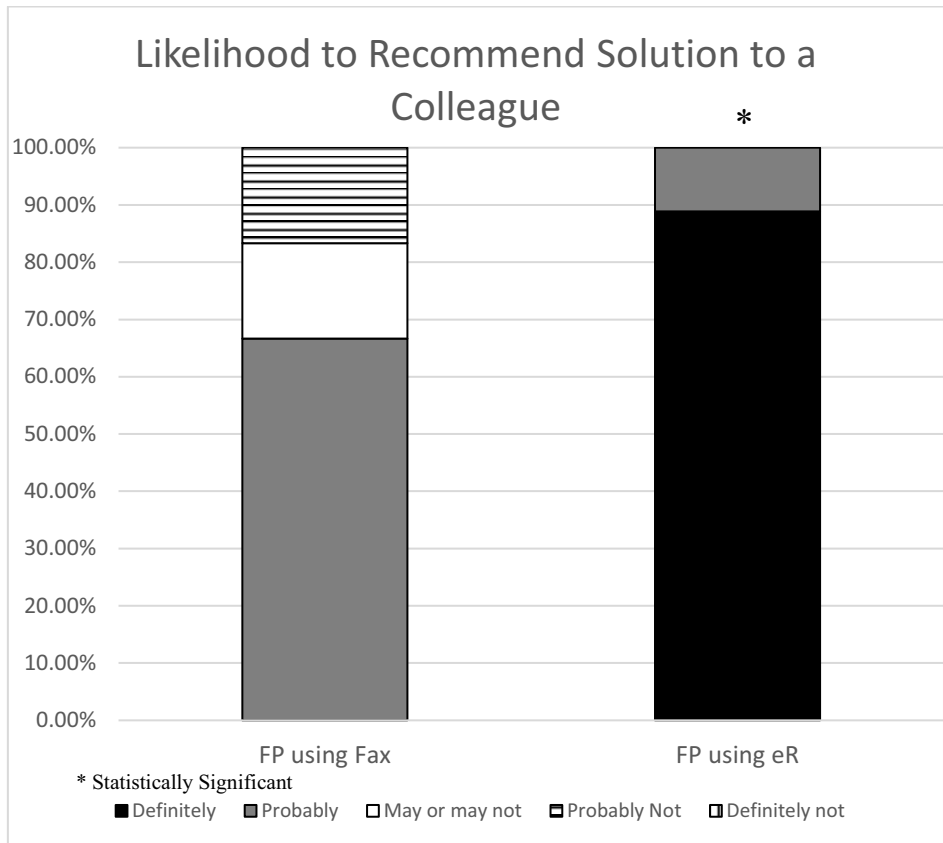
Figure 3: The Likelihood to Recommend Fax or eReferral to a Colleague for Family Physicians

5. Discussion

The group of Family Physicians using eReferral was matched with those using fax. Computer proficiency was part of the measures that was compared. Although not equivalent, attitude towards computer use is seen as an important factor in the successful use of information systems [21] and could bias the opinion of those using eReferral. However, since computer proficiency was similar, the groups did not seem biased in this regard.

The overall user satisfaction was not significantly different between Family Physicians using fax and those using eReferral. It seems that there is no overall impetus or burning platform for physicians to switch away from the fax machine.

In terms of the dimension of System Quality, the only statistically significant result was regarding response time of referral status. This finding did not appear in the literature

review so a new benefit has been identified.. Electronic referral seems to provide more timely information back to referring clinicians as they track referrals.

For Information Quality, overall Family Physicians felt the information coming back to them from the hospital through electronic referral is complete while those that are using fax have a mixed opinion of the completeness of the information coming back. This aligned with the finding in the literature in terms of process improvements and more complete information coming back to the referral sender [13, 17]. Family physicians using eReferral also felt that the information (e.g. Status of Referral, tests available) from hospital about their referral is timely. There was a mixed opinion from those using fax. This may by due to the fact that Family Physicians have more awareness of the referral process through eReferral or that the information is indeed more timely. This benefit was not captured in the literature. This aligns with the System Quality benefit of the response time of the eReferral system being seen as more favorable compared to fax. Finally, all Family Physicians using eReferral agreed that the format and layout of the referral information from the hospital is acceptable, while those using fax had a mixed opinion. This was also not found in the literature.

There was a statistically significant difference between eReferral and Faxed referral with regards to likelihood to recommend the solution to a colleague. All Family Physicians would recommend eReferral to a colleague. For fax, two-thirds of Physicians would probably recommend fax, while one-third would probably not recommend fax and one-third were equivocal. This positive impression of eReferral is not captured in the literature. The Likelihood to recommend a company to a friend/colleague has been seen as the best predictor of growth of a company [22]. This also indicates that clinicians are willing to put their reputations on the line to recommend electronic referral [22]. It should be mentioned that it was surprising to see two thirds of Family Physicians would probably recommend fax to their colleagues. This may again speak to the fact that fax is an established process that Physicians feel works well.

6. Conclusion

Long wait times across Canada present a major challenge for the Canadian health care system. Electronic referral can help improve the referral process and reduce wait times. However, the electronic referral system needs to be adopted to accomplish this. This study contributes valuable information about Family Physician's perspectives of electronic referral as compared to fax. Fax presents a high bar that may be hard for electronic referral to overcome. However, there were a few areas that were identified where electronic referral has advantages that may be used to support adoption. Further study is required with a larger sample size to more fully understand Family Physician perspectives of electronic referral.

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Early Usability Assessment of a Conversational Agent for HPV Vaccination

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Abstract. With the emerging use of speech technology in consumer goods, we experimented with the application of conversational agents for the communication of health information relating to HPV vaccine. Research have stated that one-to-one contact between providers and patients have a variety of positive influences on patients' perception towards vaccines, even leading to uptake, compared to paper-based methods. We implemented a Wizard of Oz experiment that counsels adults with children (n=18) on the HPV vaccine, using an iPad tablet and dialogue script developed by public health collaborators, and for early testing of a prospective conversational agent in this area. Our early results show that non-vaccine hesitant parents believed that agent was easy to use and had capabilities needed, despite the desire for additional features. Our future work will involve developing a dialogue engine to provide automated dialogue interaction and future improvements and experimentation for the speech interface.

Keywords. Conversational agents, vaccine, HPV, Wizard of OZ, counseling, speech interfaces, voice user interfaces

1. Introduction

Human papillomavirus (HPV) is a virus that causes several types of cancers including cervical, head and neck, anal, penile, vaginal, and vulvar. The primary preventive measure is the HPV vaccine which is recommended for all adolescents at 11-12 years of age. In the state of Texas, the vaccination coverage rates are low, at 33% (39.7% for girls; 26.5% for boys), compared to the national rate of 43%, yet both are still lower than the Healthy People 2020 target of 80% coverage [1].

Provider vaccine counseling appears to be the most effective educational method [2,3] and preferred by some patients [4], but the amount of time and resources needed to effectively communicate is an impediment on busy health care providers [5].

Nonetheless, speech is the most natural way for humans to communicate [6] and consume information [7]. Conversational user interfaces, or conversational agents (CA), is an emerging technology trend [8]. Harnessing CA for health communication could consistently and systematically perform dialogue tasks while alleviating the communication burden of the provider and supplement the delivery of health information, specifically related to the HPV vaccine. But how would potential end-users perceive it? We propose the following questions:

- How would parents with a child under 18 assess the usability (*ease of use*, *efficiency*, and *expected capabilities*) of a voice user interface for HPV vaccine counseling application?
- Would the parents' vaccine hesitancy have an impact on the usability of an HPV vaccine conversational agents?
- What are the features and requirements that users desire in order to be feasible?

Our aim is to gather preliminary assessment knowledge of a vaccine-centric CA to help refine our idea of utilizing an automated CA for HPV counseling at a clinical environment. For our early assessment and data collection process, we employed the Wizard of OZ protocol that simulates speech interfaces with a potential user who thinks they are interacting with an automated machine or robot [9]. It allows us the evaluate the usability and acceptability of the system rather than to measure the quality of an entire system.

2. Material and Method

2.1. Dialogue Script

Dialogue Script. We utilized an HPV vaccine survey called the Carolina HPV Immunization Attitudes and Beliefs Scale (CHAIS)[10] that contains survey items categorized by the Health Belief Model, a behavioral change model that has been used in numerous vaccine intervention studies. This provided us with an initial baseline of talking points to communicate HPV vaccine information to prospective users, and possibly enough information that could nudge the participant towards vaccine uptake. For the time being, the latter is an area we will explore at a later study.

Each survey item from CHAIS communicated a piece of knowledge about the HPV vaccine. For each piece of knowledge, we developed dialogue utterances that initiated a discussion about that piece of information. For example, in the survey, there is a question that asks, "How effective do you think the HPV vaccine is in preventing cervical cancer?" The question expresses the notion that the HPV vaccine prevents cervical cancer effectively, which helped us construct dialogue that initiates the conversation by expanding on that concept, e.g. "If your child is vaccinated with the HPV vaccine it will protect against various HPV viruses which causes many precancerous and cancerous lesions in males and females."

After developing the first draft of the script, we conferred with public health experts and experts who work directly with patients at Texas Children's Hospital to refine the script. The working draft used for the study segmented the dialogue into different sections of the health belief model and included an introductory section that included small talk to segue into the main counseling section. From advisement of our experts, we avoided complex information that would be best handled by the users' provider. Additionally, for potentially complicated discussion about dosage, we kept it brief and emphasized that the user should seek their provider for more information.

There was also a "pursuit" section in the event that participants did not want to talk about the vaccine. An example of pursuit might be a provider stating, "If (s)he were my child, I would definitely go ahead with the vaccination," as opposed to just accepting parental resistance (in which no vaccine is given) or mitigating their original recommendations (e.g., delaying the vaccine). Previous studies have found that when

physicians continued to pursue their original vaccination recommendations toward vaccine-hesitant parents (VHPs), significantly more VHPs ultimately accepted the physician's vaccination recommendations [11,12]. This indicates the importance of persistence in vaccine counseling, and we incorporated it into our dialogue to maximize the likelihood that the users would become receptive to the HPV vaccination.

In addition, we developed a dialogue sequence to handle questions during the session. The answers for prospective questions were based on our previous work of creating a patient-centric vaccine ontology knowledge [13] from VIS documents - a paper flyer provided to patients at the time of inoculation . These answers would be provided in simple triples of subject, predicate, object format, e.g. "HPV vaccine has 3 doses". For any question that was outside of the scope of the knowledge base we resorted to canned responses that encouraged the user to ask that question to their provider.

2.2. Software System

We developed an iPad and Mac platform application system to perform the Wizard of OZ experiment. The iPad application (Figure 1 (l)) served as the user-facing speech interface that the participant will interact. The tablet communicated with a separate laptop application through Bluetooth connectivity. The laptop application was a GUI tool that enabled the operator to copy and paste from the script or type out utterances (for unanticipated user responses) to the iPad (Figure 1 (r)). The text is transmitted directly to the tablet, where the tablet speaks, using text to speech (TTS), to the participant. The iPad tablet can capture the participant's speech using offline speech recognition where it is transcribed and sent to the laptop application. We utilized offline speech recognition to ensure if there were any personal information spoken that it would not be transmitted to any external server. The GUI laptop tool collects a chat log of the interaction between participant and the software system and save it in a secured drive. The tablet application was developed using proprietary Apple's iOS SDK and the desktop application was also developed using Apple's MacOS SDK.

Figure 1. (l) Tablet speech interface using the Siri voice profile, (r) desktop application that provides the tablet's utterances. Both applications were connected peer-to-peer via Bluetooth.

2.3. Experimental Method

Our study was approved by UTHealth's Internal Review Board [1] and conducted from February to July of 2018. Flyers were posted across the campus to advertise for

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[1] The University of Texas Health Science Center's Committee for the Protection of Human Subjects approved this study (HSC-SBMI-17-0533).

participants. During that time period, we recruited 18 participants, who were adults with at least one child under age of 18. This is primarily because the HPV vaccine is an adolescent vaccine that is administered between the ages of 11 through 18, and the parent is the decision maker for the child. Each participant was escorted to a private room by the data collector assistant and completed a pre-assessment survey that included basic information about the subject and a Parent Attitudes about Childhood Vaccines (PACV) survey[14] that measures vaccine hesitancy. Adjacent to the room, another researcher, the operator, was seated with the desktop application and the dialogue script.

After completing the pre-assessment survey, the experiment started, and the participants went through the simulated automated counseling system with the operator coordinating the interaction through the guidance of the dialogue script. At the end of the simulated counseling session, we administered a usability survey voice user interfaces provided by [15] that had three questions pertaining to the aforementioned usability variables, and we collected the free text comments from the participants which were later segmented by positive and negative comments.

3. Results and Discussion

Out of the 18 participants, one refused further participation and one experienced technical difficulty, and overall, the final count of participants was 16. Of these 16 participants, 6 spoke English as a non-primary language. There was an equal number of healthcare professionals or researchers and non-healthcare professionals or researchers. 9 of the participants attended had a graduate degree. Most people have children below 10 years of age.

The PACV survey measured parent attitudes about childhood vaccines. Each answer had a value and a raw score was obtained for all of the questions. That score was then converted to a score that measured vaccine hesitancy. A score of 0-50 represents not vaccine hesitant, 50-80 represents vaccine hesitant, and 80-100 represents very vaccine hesitant. All 16 of the participants were considered not vaccine hesitant, which prohibited us to measure the impact of vaccine hesitancy on the usability of the voice interface.

On a scale from 1-7 [2], there was an average score of 5.4 (σ=1.59) for *ease of use* and an average of 4.5 (σ=1.46) for the *expected capabilities*. Most of the participants relatively disagreed with the statement that the system was *quick and efficient* with an average score of 3.3 (σ=1.85) on a scale from 1-7 [2]. On average, participants relatively agreed that the system was easy to use and had the capabilities that they expected. However, the perceived slowness was attributed to how fast the remote operator responded to the user's utterance.

The Pearson's correlation coefficient (r) was used to quantify the linear correlation between two variables in order to investigate if the score of one variable affected the other in a linear fashion. Correlation coefficient is a continuous number ranging from -1 to 1, with -1 stands for perfectly negative linear relation, and 1 stands for perfectly positive linear relation. For interpretation purpose, we classify the absolute values of correlation coefficients of less than 0.30 as "small or no correlation", values of [0.30, 0.50] as "weak correlation", values of [0.50, 0.70] as "moderate correlation", and values

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[2] 7-strongly agree, 6-agree, 5=agree somewhat, 4=neither agree nor disagree, 3=disagree somewhat, 2=disagree, 1=strongly disagree

of [0.70, 1.00] as "strong correlation". Also, we calculated the Fisher's z' transformation to obtain a normal distribution for our correlation calculation.

As a result of this correlation analyses, we found the weak correlation between the *ease of use* and the *efficiency* of the system with an estimate of 0.34 (95% CI [-0.18, 0.72], with two-sided p-value of 0.197), the moderate correlation between the *ease of use* and the *expected capabilities* of the system with an estimate of 0.63 (95% CI [0.08, 0.82], p-value=0.024), and the moderate correlation between the *efficiency* and the *expected capabilities* with an estimate of 0.55 (95% CI [0.20, 0.86], p-value=0.007), where the 95% CI were computed by proper use of Fisher's z transformation [16]. In summary, these analyses suggested that the score given for the *expected capabilities* has a moderate effect on the scores given for the *ease of use* and *efficiency*.

The written comments from the participants can be separated into two broad categories, negative and positive. The negative comments mainly concerned five things: the response time, the repetitiveness, the lack of visuals, the need to humanize the system, and the inability to answer all questions. The biggest concerns were regarding the response time and the repetitiveness. Most people wrote that the system needed to improve its response time and that it repeated the same points. People also stated that adding graphics would help with the overall look, improve interaction, and make it less uncomfortable. Some people also stated that they would prefer speaking to a person or a system that sounded more humanlike. The positive comments mainly regarded four things: the interactivity, how informative it is, the accessibility, and the clarity of the system. Most people enjoyed the interactive aspect of the system and how it understands them and encourages them to ask questions. Many people also stated that the system provided useful information on the HPV vaccine and reinforced the important points. Not only did the system offer useful information, it also stated the information clearly, had a clear voice, and was very straightforward and easy to operate.

While we received some encouraging positive comments, there were some useful suggestions that could lead to an improved user experience. The responsiveness issue was an important aspect. Because we were copying and pasting or typing responses to be transmitted wirelessly that may have had a slight latency impact on perceived responsiveness. It also highlights that if the system were to be automated and utilized artificial intelligent components, the system would need to be relatively quick in responding to the user's utterance. Another was better usage of graphics or visualizations to complement the dialogue. Recently, we have been experimenting with the use of visualizations of emotions which could be used to augment the interface [17,18]. Lastly, the aim of the speech system is to alleviate some of the communication challenges at a clinical environment. Some of the users expressed a desire to speak to a human. Our belief is that the important discussion points, like personal contextual health information as it pertains to vaccines should be handled by the provider to avoid confusion. Throughout the dialogue, we emphasized that user should confer with the doctor for more nuanced and specific information, especially since we envision this conversational agent to be stationed as a kiosk or tablet in the waiting room.

4. Conclusion

From our study of 16 participants, who were not vaccine hesitant, we determined that parents found that a vaccine conversational agent was relatively easy to use and had the capabilities. Most participants found the agent to be slow and this is mainly due to

responsiveness of the WOZ remote operator. Nonetheless, the feedback highlighted the importance for automated vaccine conversational agents to be responsive with utterances and with the suggestions from users, we have collected future features and improvements to better develop an automated CA. Currently, work is underway in developing an ontology-driven dialogue engine and lightweight question-answering component to answer natural language questions.

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Towards Developing an eHealth Equity Conceptual Framework

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Abstract. Early implementation of electronic health records and patient portals had great promise of addressing the widening disparities in health. However, recent research has found that not only are these disparities persisting, but the differences in health outcomes between populations are increasing. Addressing this gap specific to ehealth calls for attention to health equity. Health equity approaches reveal the systematic and societal structures that contribute to preventable and unjust outcomes for different populations. To conceptualize and apply a health equity approach within ehealth, we propose the eHealth Equity Framework (eHEF). Derived from the World Health Organization's conceptual framework for actions on the social determinants of health, eHEF can be useful for public health practitioners, researchers, policymakers and information technology designers to keep health equity agenda at the forefront of all stages of health information technology lifecycle.

Keywords. digital divide, ehealth, health equity, health disparities, health information technologies (HIT), patient portals, social determinants of health

1. Introduction

Equity in health is achieved by targeting health disparities, defined as potentially avoidable, systematic differences in health between groups of people who are differentially (dis)advantaged socially [1, 2]. In the context of ehealth, health equity acknowledges the complex factors (e.g., socio-economic status, gender, ethnicity, race, digital divide, health literacy) that can lead to the unequal provision of care and unfair differences in health outcomes. In the United States (US), health equity has been declared as a foundational goal within the development and implementation of patient portals. The US Institutes of Medicine report '*Crossing the Quality Chasm'* (2001) references equity as one of the six aims at the core of rebuilding healthcare delivery [3]. In Canada, where patient portals are in the early stages of development and implementation, policy documents provide limited examples of bringing together concepts from ehealth and health equity [4]. Within the academic literature, frameworks addressing chronic disease, health literacy, and social determinants of health, have been extended into ehealth models with a potential to target health disparities [5-7]. Each of these factors are significant to conceptualize health equity within ehealth context, but on their own are not sufficient in addressing inequities inadvertently perpetuated by health information technologies (HITs). Although there has been increased recognition of health equity within ehealth

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literature and practice, we were unable to find a framework that provides a comprehensive conceptual resource for considering health equity in ehealth interventions.

We contend that in order to systematically study, understand, and influence how patient portals (and other HITs) are helping to achieve equity in health for diverse populations of HIT consumers, especially for patient groups bearing the highest burden of disease and illness, a comprehensive and theoretically-robust framework / model is needed. In this paper, we will present our initial attempt to derive such a model, the *eHealth Equity Framework (eHEF)*. We will use examples from research on patient portals to introduce and demonstrate eHEF's application in research, policy and practice.

2. The eHealth Equity Framework

Our eHealth Equity Framework (eHEF) (see Figure 1) arises from the public health perspective. eHEF builds upon the World Health Organization's "Conceptual Framework for Action on the Social Determinants of Health" (CSDH) [8, 9] and brings together the concepts of health equity, social determinants of health inequities and ehealth. In Figure 1 the underlined text and dotted arrows indicate the changes to the original framework. We first describe some key assumptions of the CSDH focusing on concepts that are either shared or distinct between the two frameworks. We then proceed to discuss various components of eHEF with references to the original CSDH.

2.1 Background

CSDH takes a life course perspective in recognizing how social, economic and political context influence health outcomes. It represents concepts that are shared within health equity and ehealth literature: governance, policy, education, occupation, income, gender, ethnicity and race, behavioral, psychosocial and biological factors. CSDH also offers considerations that may be less recognized within ehealth interventions, particularly societal and cultural norms and values and material circumstances. CSDH focuses on the distribution of health and well-being (Figure 1; right box) and
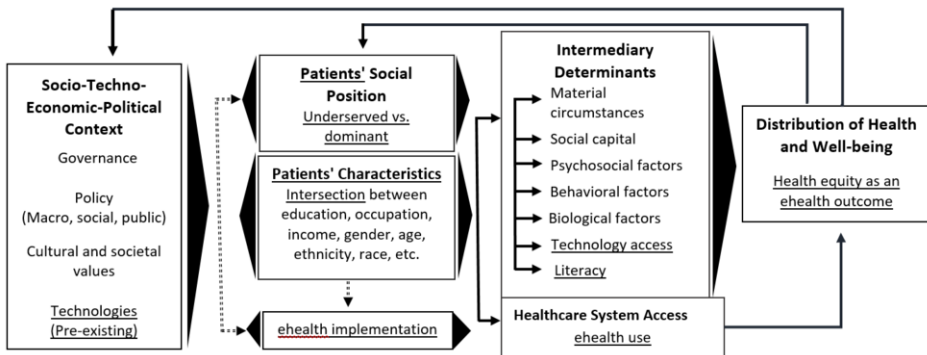
Figure 1: eHealth Equity Framework (adapted from Solar & Irwin, 2007)
Underlined words and dotted arrows indicate changes from original model

emphasizes how the delivery of an intervention can generate different outcomes between populations; thus suggesting the necessity of applying a health equity lens from policy through to practice. The large triangular arrows attached to the boxes are preserved from the CSDH, and represent direction and magnitude of the mechanisms that influence the distribution of health and well-being. The thin arrows create feedback loops, suggesting that the framework is not to be interpreted as a linear model, but as a web of relations.

Importantly, in the original CSDH framework, technology is not viewed as a distinct concept. Indeed, CSDH was intended to shift away from the predominant "technology-based medical care", and acknowledge the broad social processes that influence patient outcomes [9]. In contrast to the absence of technology in the original socially-focused CSDH framework, we have integrated technology throughout eHEF (see Figure 1). Although a full exploration of this integration is beyond the scope of the paper, there are three important considerations for arguing that the technical and the social are not mutually exclusive: 1) Equating technology with predominant medical care models, although commonplace, limits an examination on how technology can apply to, or even is intrinsic to, social models of care. We suggest that CSDH's assumption about technology dichotomizes the social and the technological in a way that is theoretically and practically problematic [10]. This assumption also discourages an examination of health equity within ehealth; 2) Solar and Irwin, the authors of CSDH, justifiably critique medical models that overlook the role of social structures for health and wellbeing [9]. Their argument can be extended to ehealth: we should be attentive to the risk of technological interventions that are intended to improve patient outcomes, but result in supporting the dominant, already healthier populations; and 3) The CSDH framework was conceptualized during the emergence of social media, and thus the relationship between information technology, health and social processes may not have been fully realized during conceptualization. In the past decade, there has been increased recognition that technology can be a determinant of health, and yet also applied as a strategy to address health inequities [11, 12].

Thus, to reflect the complex intersection between ehealth and health equity, technology has been conceptualized throughout all eHEF stages. Matching with the life course perspective of CSDH, the lifecycle of information technologies has been incorporated throughout each stage of eHEF, from the pre-existing technologies, through to implementation, use, and outcomes. We are drawing on Silver, Markus and Beath [13] to define various stages of ehealth life cycle: pre-existing technologies refers to the existing technological infrastructure that can be both enabling and constraining for different patient populations. Implementation refers to the initiation, acquisition, introduction and adaptation stages. Use refers to who uses the system and for what purpose, while recognizing the unintentional and differing individual consequences of this use. Outcomes are specific to equity, and can be applied both proactively in designing equitable ehealth strategies, and reactively to evaluate distribution of health and well-being after ehealth implementation.

2.2 Socio Technical Economic Political Context

The left of Figure 1 indicates the socio-techno-economic-political concepts that are often conceptualized within health informatics as system-level considerations: policy, governance, cultural and societal values and pre-existing technologies. Patient portal-specific policy examples include the '*US meaningful use legislation for electronic health records*' and clinical guidelines that have informed the development of electronic health

records (EHRs). Governance represents how each country, province, state or medical clinic may administer, manage and interpret policies and guidelines to support health care practices. A distinction within eHEF is that it is foremost an equitable model of care, with an ideal outcome being patient-centered care, where *all* patients are respected. Governance structures guided by patient-centered care may not necessarily lead to equitable outcomes, as they may represent the values of the dominant patient population. Governance processes and policies sensitive to health equity concerns, would involve ehealth strategies that move beyond blanket approaches, and recognize that additional resources should be dedicated to underserved populations. This perspective, where health is viewed as a "collective social concern", demonstrates a particular value. How this value is enacted by society can impact what supports are dedicated to different populations and illness groups. Stigma and discrimination may be perpetuated when a society views health primarily as an individual's responsibility while not acknowledging the influence of socio-techno-economic-political processes. The relationship between values and ehealth is demonstrated by patient portals use by people with HIV. The historical and ongoing stigma towards this illness has resulted in limited use of patient portals due to concerns of potential confidentiality breaches in having sensitive health information online [14]. An ehealth equity perspective recognizes the specific barriers in use of patient portals for people with HIV and includes strategies to address these concerns: building trust in the technology through policies specific to security protections, and limiting how online records are reported that may inadvertently disclose a diagnosis to family members [14].

eHEF adds '*technologies – pre-existing*', to acknowledge the influence existing technologies have on the implementation of emerging HITs. To use patient portal as an example there are technologies internal (e.g. EHRs) and external (e.g. broadband internet) to the healthcare system that determine which populations may receive the greatest benefit in terms of quality of care and outcomes. As EHRs were designed by and for educated, white professionals, and presuppose high level of literacy and skill, there is a risk that patient portals will embrace the language and preferences of a population with the highest levels of education and socioeconomic status [15]. An ehealth equity approach would acknowledge the significance of these foundations, and develop policies that not only view equity as an overarching goal, but provide strategies throughout all HIT stages to address how these foundations impact underserved populations.

2.3 Patients' Social Position and Patients' Characteristics

The second set of left-most boxes (Figure 1) represent factors often categorized as the social determinants of health: examples include education, occupation, income, gender, age, ethnicity, race and geographic location. Research on patient portals commonly measures and reports demographic factors as indices of health inequities, potentially implying a deterministic relationship between "personal" characteristics such as race and portal utilization. However, in CSDH an important distinction is made by referring to these characteristics as 'social determinants of health *inequities*'. That is, rather than considering determinants as being 'personally-entrenched', they are recognized as socially-mediated factors. Consequently, the emphasis is on addressing unjust conditions that result from social processes [9].

Building upon this, and to prevent misinterpreting these demographic factors as individual and unavoidable predictors of health outcomes, in eHEF we have opted to emphasize equity rather than social determinants of health. '*Intersection*' has been added

to connect these determinants of health inequities within 'patients' characteristics'. We aim to reflect the complexity of these factors, and to discourage applying them as a series of check-boxes. 'Patient' has been added within this section to emphasize that it is patients' social position and characteristics that should be prioritized, rather than dominant voices from traditional healthcare stakeholders. The added dotted arrows further indicate the relationship between the three boxes: when patients' social position and characteristics are not considered during ehealth implementation, marginalization may be reinforced for populations that are already underserved. Ehealth equity interventions sensitive to these concerns would involve implementation strategies that allow for customization to the needs of different populations. For patient portals this could be having an adaptable design where reading level and information can be individually tailored to match patients' characteristics [16].

2.4 Intermediary Determinants Of Health

The second set of boxes from the right in Figure 1 represent factors that CDSH references as the intermediary determinants of health. Healthcare system access is included to emphasize its role in being a health determinant. Often perceived at the individual level, other determinants include biological, psychosocial and behavioural factors. Material circumstances represent the financial means in obtaining a safe physical environment, healthy foods and warm clothing [9]. Not commonly recognized within ehealth, this "consumption potential" provides distinct insights for consumer health informatics, in considering where one lives and what one can afford can impact ehealth use.

While different iterations of CSDH have included the concepts of social cohesion and social capital, we opted for social capital in eHEF. Social capital aligns with shared decision-making approaches in developing trustful and cooperative relationships, while acknowledging the power differentials that are introduced at the socio-economic and institutional level [8]. Two specific additions within eHEF are technology access and literacy, to represent the crossover between health equity, health literacy and digital divide in considering how health disparities may be conceptualized. The analysis of these concepts is beyond scope of this paper, however, both health literacy and digital divide have been considered in the development of eHEF. Although both of these concepts are familiar within ehealth literature, health equity was selected as the overarching concept within eHEF in order to capture the complex relationship between system-level processes, health, information and technology. Literacy forms a distinct category within this section to reflect how system and societal processes influence the multiple forms of literacy (i.e. health, information, computer, media, numeracy, and science literacy) [6]. Literacy was chosen over health literacy, to emphasize that literacy required to effectively use HITs is far more complex than educating and developing skills in understanding purely health-related information [17]. Also of note in this section is that *access* has been referenced in terms of both technology and healthcare. Whereas technology access may include access to the internet, a computer, digital technologies, etc., it is not synonymous with healthcare access. This separation allows for awareness of how information technologies outside of the formal healthcare system can influence health outcomes, and how enrolment, use of patient-centered HITs requires considering personal access to technologies.

3. Conclusion

eHEF is intended to provide a frame to think comprehensively about a multi-faceted health equitable approach across all stages of the HIT lifecycle. For example, the preliminary model is being applied in a scoping review we are currently completing on *'how patient portals are addressing health equity'.* This is how one can apply an ehealth equitable approach using Figure 1: locate the HIT stage within eHEF, extend to the factors within the shared section, and then follow the arrows to understand the broader considerations. Through this process it can illuminate the proximal factors that need to be incorporated to address health inequities, while also drawing attention to possible unintended consequences through distal interactions.

eHEF can be of benefit to: 1) policy-makers in developing ehealth equity strategies with populations that are experiencing health disparities; 2) researchers in not only applying HITs for measuring the social determinants of health, but in evaluating how HITs impact the digital divide; 3) public health decision-makers in not viewing technological and social processes as a dichotomy, but considering how ehealth applications can address health inequities; 4) health providers such as physicians, nurses, and allied personnel in being mindful of health disparities in the context of using HITs; 5) HIT designers in recognizing how the foundations of pre-existing technologies, and patients' social position need to be explicitly considered in ehealth implementation and; 6) patient populations that experience the poorest health outcomes, by revealing how socio-techno-economic-political processes need to be acknowledged in order to achieve equitable distribution of health and well-being.

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Factors Associated with Increased Adoption of a Research Data Warehouse

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Abstract. The increased demand of clinical data for the conduct of clinical and translational research incentivized repurposing of the University of Arkansas for Medical Sciences' enterprise data warehouse (EDW) to meet researchers' data needs. The EDW was renamed the Arkansas Clinical Data Repository (AR-CDR), underwent content enhancements, and deployed a self-service cohort estimation tool in late of 2016. In an effort to increase adoption of the AR-CDR, a team of physician informaticist and information technology professionals conducted various informational sessions across the UAMS campus to increase awareness of the AR-CDR and the informatics capabilities. The restructuring of the data warehouse resulted in four-fold utilization increase of the AR-CDR data services in 2017. To assess acceptance rates of the AR-CDR and quantify outcomes of services provided, Everett Rogers' diffusion of innovation (DOI) framework was applied, and a survey was distributed. Results show the factors that had impact on increased adoption were: presence of physician informaticist to mediate interactions between researchers and analysts, data quality, communication with and engagement of researchers, and the AR-CDR's team responsiveness and customer service mindset.

Keywords. Clinical Data Warehouse, AR-CDR, electronic health records, clinical data repository, clinical research

1. Background and Significance

Clinical enterprise data warehouses (EDW) emerged to fulfil organizational data needs with the aim to integrate and improve quality of data. The enormous amounts of data captured through electronic medical records (EMR) motivated the adoption of EDWs as means to discover new knowledge that could improve patient care. Some organizations use EDWs to actively improve the care of specific patients as soon as they are hospitalized [1]. Many healthcare organizations are already reaping the benefits of a data warehouse and recognizing its value in support of research [2].

The University of Arkansas for Medical Sciences (UAMS) decision to develop an in-house data warehouse was necessitated by the diversity of silo clinical and administrative data sources, and the need to support the increased demand for clinical and transitional research. Implemented in 2011, the data warehouse at UAMS had less than favorable acceptance, and UAMS' leadership decision to move the EDW's home to the department of biomedical informatics in 2016 to address the growing data needs of

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researchers led to improved utilization. The decision to rebrand the EDW to the Arkansas Clinical Data Repository (AR-CDR) is an indication of UAMS commitment to maintain a competitive advantage in the healthcare space by leveraging its rich data sources to drive innovative clinical research. With the AR-CDR, researchers no longer need to collate data from disparate systems to answer their research questions.

2.   Objective

The paper characterizes the factors that contributed to increased adoption of the AR-CDR, and can be categorized as: (1) Technical: incorporating more subject areas into the AR-CDR improved data quality and efficiency of query fulfilment, (2) Behavioral: empowering researchers with use of self-service cohort estimation tools, and (3) Organizational: assembling a team, including a physician informaticist, with focus on customer service improved relationship and trust with researchers.

3.   Methods

3.1.   Implementation of the Clinical Data Warehouse

The laborious task of linking data from UAMS' clinical, ancillary, and administrative systems motivated the implementation of the first EDW in 2011, with the arching goal of streamlining the process of reporting. The deployment of the EDW followed three phases: (1) Integration of clinical and financial systems, (2) Integration of the Epic electronic medical record (EMR), and (3) Repurposing of the EDW to support Clinical and Translational Research.

3.1.1. Integration of Clinical and Financial Systems (2011 to 2014)
In support of the clinical and translational science award (CTSA), data warehouses emerged as a necessity to facilitate medical research for either efficient recruitment of research participants or secondary use of clinical data to discover new knowledge. In response, UAMS' data warehouse included a subset of clinical subject areas that were sufficient to answer operational questions. It included patients' information and demographics, diagnoses, charges, laboratory and medication data. The ETL (extract, transform, and load) process extracted data from four clinical systems: Centricity, SunRise and AllScripts, SoftLab, and GE EMR; and two financial systems: MeKesson and Siemens.

Shortly after deploying the data warehouse, UAMS launched I2B2 (Informatics for Integrating Biology & the Bedside) for research cohort estimation. I2B2 is a self-service tool that provides a de-identified subset of EMR's clinical attributes such as patient diagnoses, medications, and laboratory results and aims at accelerating research studies initiation.

3.1.2.   Integration of Epic EMR (2014 to 2016)
The adoption of Epic EMR in 2014 replaced legacy clinical systems and became the mainstay system for charting ambulatory and inpatient encounters. The data warehouse ETL was redirected to extract data from EPIC Clarity data repository without enhancing the EDW with new clinical subjects. By 2016, data incompleteness of the EDW resulted in decreased utilization due to repeated data quality discrepancies.

3.1.3. Arkansas Clinical Data Repository (2017)

In 2016, the EDW was renamed the Arkansas Data Repository (AR-CDR) to reflect UAMS' new direction to provide a comprehensive research data platform that ties clinical and disease registries. The AR-CDR's new home, the department of biomedical informatics, leverages the department's faculty rich mix of expertise in clinical and informatics domains. In addition, a dedicated support team, made up of analysts and developers, was assembled and is led by a physician informaticist. With the newly assembled team, a series of face-to-face interviews were conducted with researchers to assess their data needs and understand their experience with the retired EDW. Overall, researchers expressed, in descending order, their dissatisfaction with quality of data, technical staff unfamiliarity with clinical terminology, inadequacy and non-intuitiveness of the I2B2 tool, and insufficient communications and with the technical team.

In response to researchers' feedback, we held several individual meetings with researchers and presented at several clinical departments meetings to introduce the AR-CDR's enhancements and informatics tools, including: (1) addition of surgery and anesthesia, health literacy, social history, oncology, and obstetrics and gynecology subject areas; (2) Integration of tumor and trauma registries, and tissue bio-specimen; and (3) Deployment of TriNetX[2], a web-based, self-service cohort estimation tool. In addition, a simple, streamlined research data request fulfilment process was implemented, and installed RedMine[3], a web-based open source project management tool, to track and document research data requests, user and group communications, and technical and content enhancements.

3.2. Everett Rogers' Diffusion of Innovations

In order to assess researchers' acceptance of the AR-CDR, we applied Everett Rogers' [3] stages of diffusion of innovation (DOI) framework to evaluate the stages researchers' passed through to access and use the system. Rogers' framework estimates adaptors of new technology can be categorized as innovators (2.5%), early adopters (13.5%), early majority (34%), late majority (34%) and laggards (16%) [3].

3.3. Arkansas Clinical Data Repository Survey

In order to evaluate researchers' impressions of the AR-CDR, in comparison with the retired EDW, we implemented and distributed a 14-question survey to assess: 1) quality of service, 2) workflow efficiency, 3) usefulness of data, 4) publication and grant submissions, and 5) user satisfaction.

4. Results

The positive transformation of the AR-CDR was achieved by conducting campus-wide campaign to showcase the system's capabilities and to demonstrate the cohort estimation tool functionality. Between January 01 and December 31, 2017, the AR-CDR and the cohort estimation tool were presented to 156 people: 110 individual researchers, 10 small

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[2] https://www.trinetx.com
[3] https://www.redmine.org

group presentations, and 3 faculty department meetings. Adoption rates of the AR-CDR were higher than Roger's framework across all categories except for late majority and laggards: innovators (7%), early adopters (22%), early majority (38%), late majority (30%) and laggards (3%), Figure 1.
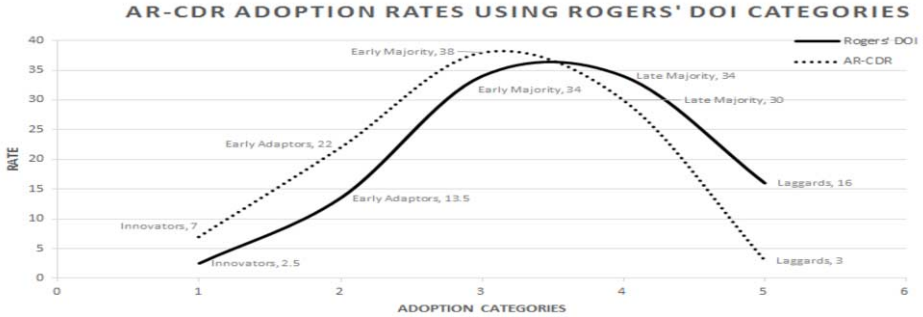
Figure 1. AR-CDR adoption rates as compared to Rogers'

The number of IRB-approved research queries received in 2017 was four times (99 queries) of what was received on average (25 queries) in each 2015 and 2016, and 37 researchers executed 455 cohort estimation queries. Out of the 60 researchers surveyed and received data from the AR-CDR in 2017, two researchers were no longer at UAMS; and, 32 of 58 completed the survey for a response rate of (55%). Survey respondents were classified into two groups based on their date of awareness of either the EDW or AR-CDR: *Group* 1: January 2017 to December 2017, (n = 27), included respondents who became aware of the AR-CDR for the first time; and, *Group* 2: Before January 2017, (n=5), included respondents who knew of the EDW before it transitioned to the AR-CDR.

Both groups highly rated the AR-CDR quality of service, Figure 2. Group 2 satisfaction edged higher than group 1 in spite of their disappointment with the retired EDW. Both groups reported that data provided to research queries were of high quality and had high concordance with clinical systems, and their research queries were completed within reasonable time. While group 1 submitted most number of research queries: 57% submitted one research query and 43% submitted at least two research queries, group 2 researchers submitted at least four research queries each. Outcome of queries showed that 100% of group 2, compared to 60% of group1, submitted for either grant or publication, and 40% of group 1 used data for hypothesis generation.

5.   Discussion

Of the 156 users who knew of the AR-CDR, 105 received access to the cohort estimation tool, 37 executed at least one query, and 60 submitted at least one IRB-approved query, totaling 99 research queries. We believe the factors that contributed to increased throughput of the AR-CDR in 2017 were organizational- placing the AR-CDR in the department of biomedical informatics and leveraging clinical and informatics expertise were key in establishing trust and collaboration with researchers; behavioral -
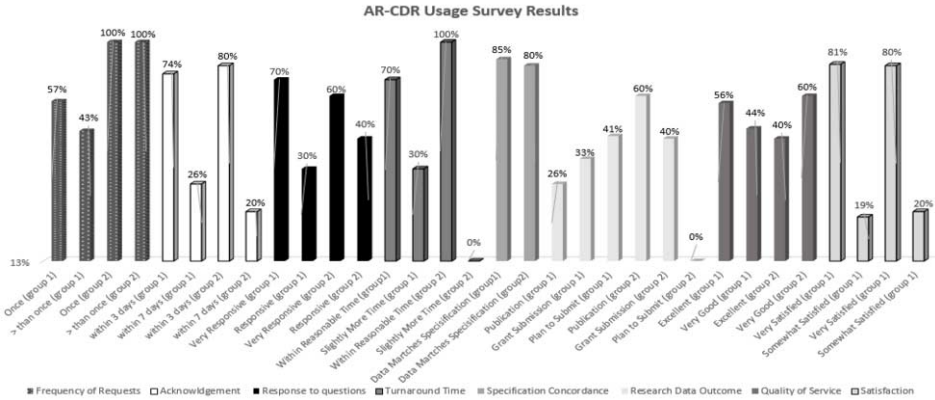
Figure 2. Survey results: comparing the two surveyed groups based on their responses to the eight categories.

establishing rapport through frequent meetings and communications, and setting realistic expectation with researchers were necessary to build professional relationships; and technical - deploying new self-service tools and enhancing the AR-CDR content empower researchers to use for clinical and analytical studies. Continued demand and use of the AR-CDR depends on the provisioning of quality data and informatics tools.

6.   Acknowledgement

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Adoption Strategies for Electronic Patient Portals: Employing Advanced Data Mining and Analytics

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Abstract. Patient portals are becoming increasingly available at medical institutions, worldwide. Reporting of patient portal adoption strategies is scarce. A multi-institutional health network in Toronto, Canada is seeing great success with its portal adoption by patients, with an annual adoption rate of almost 65%. In the literature, annually adoption rates in Canada range between 5% and 10%. This significant difference and high adoption is attributed to a multifactorial approach that includes a dedicated operations team to engage with patients and staff, a co-design approach for portal development and more recently, new data-driven strategies to affirm and recommend promotion approaches. Advanced data mining and analytics are promising tools to help improve the adoption rate. This paper will describe five analytics tools used to describe and potentially improve patient portal adoption rates.

Keywords. Patient portal, personal health records, adoption, big data, data mining, data analytics, consumer informatics

1. Introduction

Globally, online patient portals are increasingly becoming commonplace at medical institutions [1]. Patient portals enable its users to access their personal health records (PHRs) that are tethered to institutional electronic health records (EHRs) in addition to a variety of other activities, such as receiving appointment notifications, communicating with health care providers, and sharing PHRs with family or other providers [2-3]. As medical institutions actively move towards patient-centric approaches, patient portals have become popularized to promote patient engagement and subsequent self-care, enhance patient-provider relationships, and improve health care quality (convenience, satisfaction, patient safety and clinical efficiency) [4]. Although growing, evidence regarding patient portals is immature, particularly as it pertains to adoption [1].

Currently, patient portal adoption across single and multi-institutional health systems in Canada range between 5%-10% annually [2]. Seminal patient portals, such as

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the Kaiser Permanente and Veterans Health Administration portals in the United States, have achieved higher rates, particularly after the deployment of additional portal features [2]. For instance, registrations on Kaiser Permanente's portal drastically increased from 9% to 27% after integrating PHR functionality in 2006 [5]. The most recent reported adoption rate by Kaiser Permanente is now 70% [6]. We are currently operating under the generally accepted adoption definition of at least one login or activated account [1]; although recognizing its limitations, we are working on refining this definition. At the University Health Network (UHN) in Toronto, Canada, the annual adoption rate is 64.8 %, with 43,000 'myUHN' patient portal registrations during the first 14 months.

UHN is a multi-institutional health system, consisting of 4 patient sites (Toronto General Hospital, Toronto Western Hospital, Princess Margaret Cancer Centre, Toronto Rehab Institute). During this period, all sites cumulatively reported 1,129,346 clinic and day/night care visits and 122,578 emergency visits [7]. We sought to employ advanced data mining and analytics strategies from other industries (i.e. retail and finance), starting in May 2018, to better understand myUHN users and patient flow and to ultimately increase our adoption rate. This paper will describe five analytics tools used to describe and improve adoption rates.

2. Advanced Data Mining and Analytics Tools and Techniques

myUHN was developed and its promotion implemented into hospital workflows with a user-centered design approach [8]. myUHN features are: real-time access to PHRs and laboratory testing results, appointment notifications, wayfinding for clinic information and patient education, and creating proxy accounts[2]. To gain access to myUHN, patients are offered a registration code at almost all client-facing areas, including clinics, imaging, phlebotomy, and information desks. myUHN is a fairly new service and staff education is ongoing. In order to ensure our patients needs are met, patients can also obtain codes over the phone by contacting the myUHN Support Operations line. This makes our adoption rate the proportion of codes registered over the codes offered. This code offering structure was selected based on a key needs assessment finding: patients preferred to receive registration codes at any site as opposed to a single, centralized area along with having the option to call in if a code was not offered in person. To determine the patterning of our code offers and registrations, we use:

- Dashboards
- Moving Averages
- Network Diagrams
- Offer Rate
- Market Penetration

2.1. Dashboards

Dashboards are interactive, easily modifiable cross-sectional views of inputted metrics [9]. In utilizing this tool, we were able to make our data presentation more dynamic and to disseminate critical knowledge in real-time for stakeholders to engage with and understand the adoption-related data.

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[2] https://www.uhn.ca/PatientsFamilies/myUHN

2.2. Moving Averages

Moving averages are defined as "smooth data" or "bending trendlines" in using the average over a specified period of time to lessen or eliminate the impact of outliers in a data set [10]. By visualizing and interpreting data in a smoothed fashion, we are able to identify and account for anomalies, capturing adoption more accurately. Anomalies identified in our adoption data were national or statutory holidays, and not the hypothesized seasonality. For each national or statutory holiday, the appearance of the data would indicate a great increase/high adoption. However, this increase is not reflective of an increase in registrations, but rather a significant decrease in the number of codes offered to patients that day. With this consideration, a moving average would be more informative than the traditional, annual or cumulative adoption rate.

We determined that using a 90-day average is a suitable period of time whereby it is short enough to show a trend signal, yet long enough to 'smooth out' anomalies (Fig 1). Notably, this 90-day moving average for adoption rates demonstrates that the total registrations were proportional to the number of codes offered to patients. Similar to adoption rate, we used a 90-day average to track total registrations at each site. With this metric, we were able to identify significant actionable trends that were otherwise not seen when analyzing the monthly or yearly aggregates.
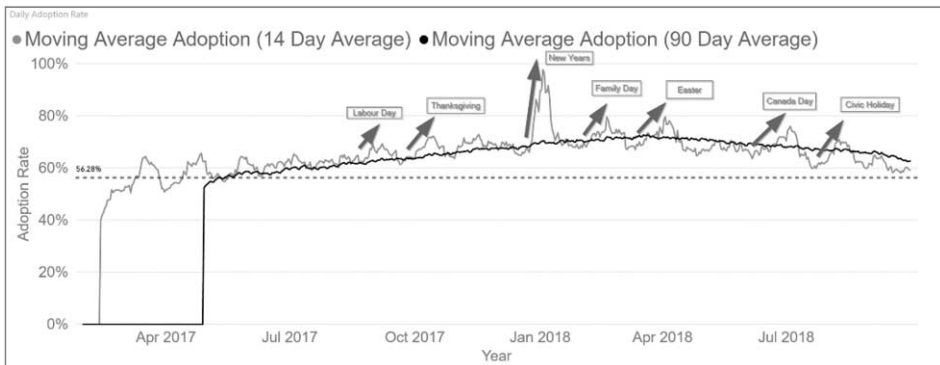
Figure 1. Adoption Rate – 'Smooth' 90-Day versus 14-Day Moving Average.

2.3. Network Diagram

Although informative, moving averages for adoption rates and total registrations do not speak to who myUHN users are, what proportion of clinic visitors are myUHN users, and the frequency in which clinics are accessed. Through an exploratory data analysis process in which two separate datasets (myUHN system activity and clinical visit data) were compared in multiple combinations and variations, we learned that myUHN users were patients who came to UHN more frequently than non-users and that there are several highly connected clinics with significant patient overlap within the network.

We used a network diagram to understand the interconnectivity between clinic populations and to see this relationship between myUHN patients and the clinics they access (Fig 2). To understand this figure, imagine each line as being a patient who had

an appointment at a particular clinic. The circles are the clinics themselves, where the size of the circle represents the number of patients who accessed this clinic. This patient could have had attended multiple appointments at multiple clinics; hence, the proximity between each of the circles.

This imaginative figure visualizes at a very high level which clinics are common to various groups of patients. By supplementing the operations team knowledge and expertise about how the patient flow works, we strive to deliver very focused efforts to increase the awareness of myUHN in highly connected environments. A great benefit in utilizing this tool is the removal of technical and statistical aspects of the analysis from the ideation process, so that all team members may engage with the data, and over time better integrate findings to make more effective, actionable plans.

Our network diagram illustrates that clinics/areas with high adoption also had greater patient overlap with other clinics/areas. From this, we learned two facets to inform adoption strategy:

1. Our initial adoption strategy was limited and did not leverage patient flow, as UHN patients, regardless of portal usage, visited more than one clinic/area across multiple sites.
2. 33.8% of myUHN registration occurred on the day they received the code. This is reasonable as information burden is a common occurrence when patients visit hospitals. Since we are not electronically reminding patients to complete myUHN registration after they are given a code, the data displayed in the network diagram shows the high-traffic, linked clinics/areas. The network diagram can be used as guidance, for clinics with the greatest overlap. These areas, in our case, Imaging, are encouraged to re-offer myUHN codes to patients, resulting in a higher re-issue rate. The number of code re-issues to patients has increased from 8.5% to 19.2% as a result of the operations team gaining leadership support to actively promote the portal and performing in-service staff training in these high-traffic, linked areas.
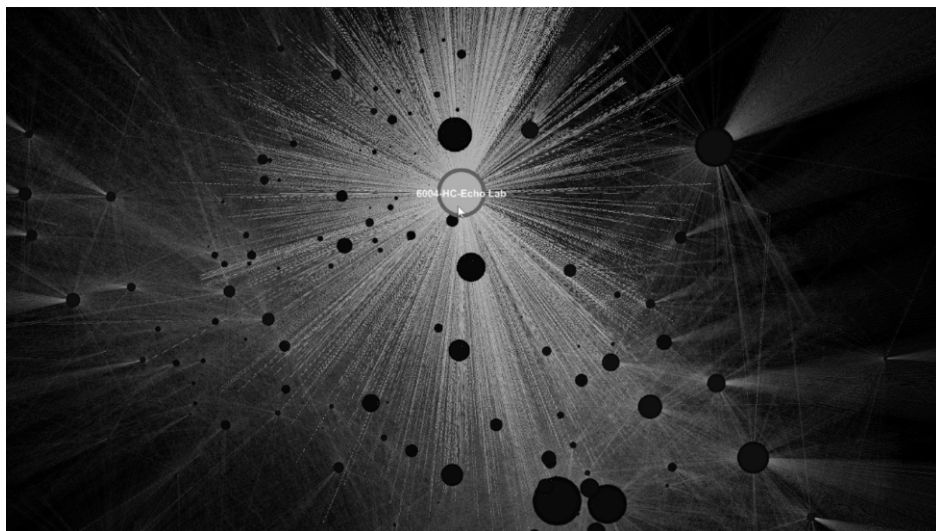
Figure 2. Network Diagram of Adoption Rate Distribution Across UHN Clinics/Areas.

2.4. Offer Rate and Market Penetration

To determine what proportion of the clinic populations were myUHN users, we used offer rate and "market" penetration. Offer rate is the percentage of registration codes offered to non-myUHN users (total number of registration codes offered to patients over total number of non-myUHN users). This term is commonly referred to as 'capture' or 'conversion' rate [11]. "Market" penetration is the proportion of myUHN users that have visited a particular care site or clinic within the hospital network (Fig 3). This information allows us to gauge what percentage of each clinic's population have yet to sign-up and use the portal. By using "market" penetration as a key metric, we are able to determine the carrying capacity of each clinic/area. Carrying capacity is the ability of our environment (current human resources, technology limitations and support infrastructure) to issue registration codes and to support patient demand without adding additional resources. As the market penetration approaches its maximum carrying capacity, the growth rate, in this case, incremental growth in registrations drastically slows as the proportion of myUHN users in a clinic's population increases (i.e. logistic growth). Knowing these metrics could elucidate any clinics that may not be promoting the portal and help guide myUHN operations efforts, including environmental scans, before using resources and delivering additional staff trainings. In time, high-traffic and interconnected clinics may develop a more standardized process in their clinic workflow to ensure registration codes are offered more consistently.
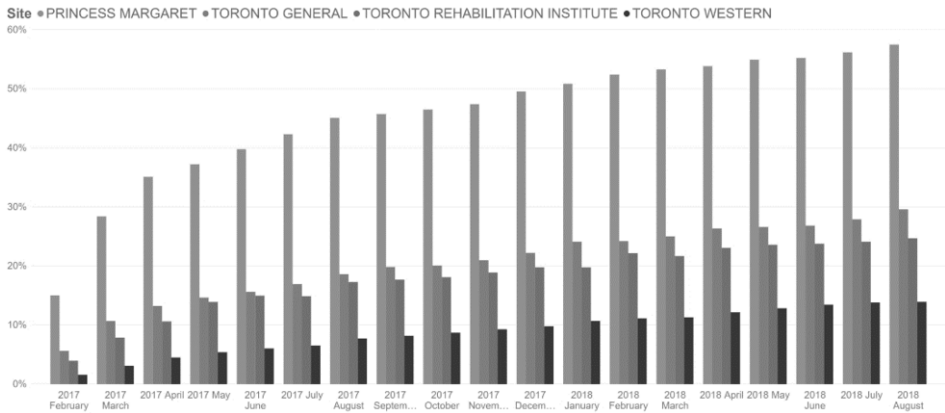
Figure 3. Market Penetration Across Each UHN Site.

3. Conclusion

The adoption rate of myUHN is remarkably higher than the reported average in both large and small-scale health systems in Canada. Data exploration and data-driven strategies appear to indicate further success, yielding significant knowledge about patient flows at UHN service areas. This knowledge can be leveraged to reinforce as well as tactically prioritize and deploy operational management approaches such as patient and staff engagement, training and marketing. The novelty of utilizing these advanced data

mining and analytics tools and techniques provides a very exciting opportunity to fulfill our obligation to all health service users to deliver the highest quality of health care.

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Advancing Telehealth Nursing Practice in Oncology: Factors Affecting Nurse Use of Electronic Symptom Management Guidelines

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Abstract. Oncology, telehealth nursing practice is growing. There has been an increased use of telehealth systems to support patients living with cancer in the community. In this study we explore the impact of integrating electronic symptom management guidelines (eSMGs) and electronic health records (EHRs) upon oncology, telehealth nursing practice. Ten nurses participated in clinical simulations and post-clinical simulation interviews. Participants' identified that several factors that influenced the use of SMGs including nursing experience and experience in using the eSMGs.

Keywords. Telehealth, nursing, health informatics, clinical simulations

Introduction

Electronic Symptom Management Guidelines (eSMGs) are increasingly being used by nurses to help patients self-manage their chronic illnesses and to provide patients with follow-up care during and after treatment. Guidelines are statements that make recommendations. Guidelines optimize patient care and are informed by a systematic review of the evidence-based literature. Symptom management guidelines focus on the prevention or treatment of the symptoms of disease (including the psychological, social and spiritual aspects of disease). eSMGs are guidelines that are provided in electronic form [1]. One of the key innovations in the area of eSMG use is the application of eSMG's to cancer patients' management in the context of oncology, nursing telehealth practice. Over the past few years, oncologic organizations that treat patients have integrated eSMG's into telehealth nursing practice and electronic health record (EHR) system use with the intent of improving patient care and caregiver support in managing patient symptoms arising from cancer and its treatment. To better understand the impact of such an integration of eSMG's and EHRs on nursing practice, a qualitative study was conducted. In this research the authors studied how nurses working in telehealth cancer care used eSMG's and EHRs. Nurses were asked to participate in clinical simulations and/or interviews to learn about the effect of these technologies on their practice.

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1. Background Literature Review

Symptom Management Guidelines (SMG's) are an important support for nursing practice. Symptom management guidelines or clinical practice guidelines provide clinicians (e.g. physicians, nurses) with recommendations about the care of patients with specific health conditions [1]. Over the past 10 years, clinical practice guidelines have been translated into electronic form. Electronic clinical practice guidelines, a form of decision support, can be used by nurses at point of care to support decision-making. Decision support systems (DSS) can be active or passive. Active DSS provide suggestions and support using automated alerts or reminders that arise when a health care professional fails to complete parts of the EHR or order a laboratory test, diagnostic imaging test or medication, if there is a difference between the guideline and the ordering practice [2]. Passive DSS present information in a way that allows the health professional to view the information without disrupting the process of care [1,2]. eSMG's, a type of passive DSS, are being increasingly integrated into oncology nurse telehealth practice; for example, as an: (1) external resource in the form of a guideline available via the World Wide Web (WWW) used in addition to an EHR, (2) embedded in the EHR as info-buttons, and (3) as an integrated DSS within an EHR [1,2]. To date research has demonstrated that the use of DSS can lead to reduced medication error rates, improved quality of patient care, reductions in the cost of care, changes in clinician actions and decision making, promotion of preventative screening and the use of evidence-based recommendations for prescribing of medications [2,3]. Much of this prior work has focused on physician and nurse use of DSS in acute care settings [2] and in telehealth settings with a focus on general health issues of citizen callers [4-6]. Fewer researchers have examined DSS's use by oncology nurses in telehealth practice. In the current work, we examine the use of eSMG's by telehealth nurses in oncology settings.

2. Methods

A mixed method study involving clinical simulations and interviews was conducted.

2.1. Sample

Oncology nurses who work in telehealth nursing settings were invited to participate in the study via email invitations and presentations at staff meetings at a large multi-site oncology treatment organization. A total of ten telehealth nurses agreed to participate in the study.

2.2. Setting

The clinical simulations were conducted in an office similar to the offices used by telehealth nurses. This was done to ensure the ecological validity of the clinical settings and the representativeness of the findings [5]. Study participants were seated at a desk, and provided with access to a telephone and computer that could be used to access the organization's EHR and eSMG's via a website [see 4-7] (see Figure 1 below).

Figure 1. Clinical Simulation Setting
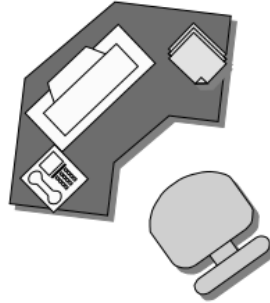
2.3. Materials

The EHR provided data about two types of fictitious oncology patients: a patient with constipation and a patient with febrile neutropenia. eSMGs provided information about managing constipation and febrile neutropenia. Expert clinicians selected one easy case (i.e. constipation) and one difficult case (i.e. febrile neutropenia) for nurses to respond to during the clinical simulation to obtain information about how nurses' react to differing levels of patient case difficulty. The easy case was presented first and the difficult case was presented second to stimulate information seeking and to reduce learning and carryover effects [6,7]. After participants took part in clinical simulations, they were interviewed [8].

2.4. Procedure

After the oncology nurses consented to take part in the study, they received a phone call from an individual playing the role of a constipation patient first and then a patient who had febrile neutropenia. In each case, the actor described her symptoms while speaking with the nurse on the telephone. Nurses reviewed the EHR and the eSMG's as they would in their work setting. The nurse and actor discussion was audio recorded. The nurses' interactions with the EHR and eSMG's were recorded using HyperCam® screen recording software. Following this, a short post-clinical simulation interview took place with each participant. All of these interviews were audio recorded. Participants were interviewed about verbalizations that the researcher did not understand, and any activity that the participants' undertook while interacting with the eSMG's and the EHRs that was not understood by the researcher for the constipation and the febrile neutropenia fictitious patient cases [8].

2.5. Analysis

All clinical simulation and post-clinical simulations interview recordings were transcribed. Transcripts were annotated with participant interactions with the eSMG's and the EHR. Transcripts were later uploaded into NVivo®. Following this, the transcripts were coded using a content analysis approach. The unit of analysis consisted of words, phrases and paragraphs that represented one concept. These concepts were then classified into categories and themes using the constant comparative method.

3. Findings

3.1. Demographic Characteristics

Ten nurses participated in the study (see Table 1 below). The average age of participants was 36.5 years. All were female and their level of education ranged from Baccalaureate prepared through to Masters. The average number of years participants' worked was 6.4 years.

Table 1. Demographic Characteristics

Sample Characteristics	Percentage (Frequency)
Age	Average Age = 36.5
Sex	100% Female
Level of Education	Bachelors of Nursing and Masters of Nursing
Years of Nursing Experience	Average – 6.1 years

3.2. Clinical Simulation and Post-Clinical Simulation Interview Results

Researcher reviews of clinical simulations revealed there was variability among nurses in terms of the type and amount of eSMG information used. Nurses identified that the guidelines supported their work and patient care, but that several factors influenced their use of the eSMGs in the post-clinical simulation interviews. Participants noted these factors influenced the frequency of eSMG's use. For example, all of the nurses (n=10) identified that telehealth nurse and oncology nursing experience influenced their use of the eSMG's. Nurse participants indicated that as their familiarity with telehealth nursing practice and/or the oncology increased, they relied less on the eSMGs to guide their work, having learned about patient symptom management over time. Experience in using the eSMG's was also important. Experienced and novice nurses developed competencies in using the eSMG's so they were used less often as the content of the guideline was learned over time. This knowledge also helped with quickly finding information. It was noted by some study participants that there was a need to be aware of updates to the guidelines so periodic checks of online guideline materials was necessary. Some participants suggested that the organization could develop ways to notify nurses of changes to the guidelines to enhance awareness of the presence of new information. In other cases participants stated that tools such as Google® scholar could be used to identify decision aids and other electronic guidelines for use in practice. Lastly, nurses noted that as the complexity of the patient's condition increased so would the use of the guidelines to support decision making. These factors are outlined in the Table 2 below.

Table 2. Factors Influencing Nurse Use of eSMG's

Factors
Nurse experience in telehealth and oncology
Nurse experience in using eSMGs
The presence of updates and changes to the guidelines based on research evidence
The availability of other electronic tools to provide additional information
Complexity of the patient conditions.

Both clinical simulations and post-clinical simulations enabled the collection of complementary data that provided differing types of insights and information about oncology, telehealth nurse use of eSMGs.

4. Conclusions

The use of eSMGs remains an important aspect of oncology, telehealth nursing practice in modern health care settings. Much of the research to date has focused on physician use of eSMG's. Less research has examined the use of eSMGs in conjunction with EHRs and in oncology nurse telehealth practice settings. In this study, we learned that a number of factors influence the frequency of eSMG use. Broadly, these factors were nurse and patient-related as well as organizational in origin. The nurse's clinical, telehealth and prior eSMG experience all influence how and when such guidelines are used. Alternatively, patient characteristics also have a role in influencing usage. The inherent uniqueness of each patient and the complexity of each patient's health condition remains important. Others have suggested the complexity of a patient's condition has an influence on eSMG use. Lastly, some nurses suggested that eSMG use was dependent on the availability of eSMG and other organizational tools that could be used by nurses. Limitations of this study include small sample size. In summary there remain a number of factors that influence technology use by oncology telehealth nurses. Future research needs to address the role of differing types of guideline representations on nurses' acquisition and ability to use guideline-based knowledge while interacting with patients during a telephone call.

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Reason for Use: An Opportunity to Improve Patient Safety

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Abstract. The objective of this study is to understand how the reason for use (RFU) or the indication for medications are used, its effects on the decision-making process, the implications, and the willingness among prescribers, pharmacists, and patients to share RFU information. Methods, semi-structured interviews were conducted to retrieve the information needed from a total of 60 participants. Results, pharmacists, prescribers, and patients generally have positive opinions about including RFU information in their communications. Conclusion, there is a general agreement among participants that sharing RFU information will improve patient safety.

Keywords. Reason for use, medication prescriptions, patient safety, patients, pharmacists, prescribers

1. Introduction

In 2011, the Canadian healthcare system spent $2.6 billion on preventable medication-related hospitalizations[1]. More than 7% of Canadians and almost 1 in 3 seniors take five or more prescribed medications, a situation commonly referred to as polypharmacy[2,3].Half of patients taking multiple medications do not take their medications as prescribed, and between40% to80% of the information communicated verbally by healthcare professionals is forgotten by the patient[4,5].This situation leads to preventable adverse drug events and directly impacts patient safety.

The access to information on electronic medical records (EMRs) by Ontario pharmacists is often limited[6]. Pharmacistsalso do not have access through their respective pharmacymanagementsystems (PMSs) to relevant information, such as indications for medications or reason for use(RFU), lab reports, and radiology reports[7].Poor communication of direct diagnostic knowledge within healthcare teams negatively affects patient safety[8].On many occasions, pharmacists need to fill in the gaps, which increases the opportunities for medication errors, especially for medications that have multiple RFU or when the patient is unable to communicate the RFU.

When assessing opioid prescriptions, for example, it is a requirementto ensure appropriate and safe prescribing [7]. In a survey of Ontario pharmacists[8],86% are concerned about their patients who are taking opioids, due to early prescription refills,

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suspected double-doctoring, and requests for a replacement for lost medication. The same study points out that pharmacists have difficulties reaching physicians in 43% of the occasions, 28% of the physicians did not return their calls promptly, and 56% were unwilling to share the therapeutic plan with the pharmacist. One of the research conclusions emphasizes the need to improve physician-pharmacist communication[8]. Kerestecioglu [1]found similar issues showing that physicians and pharmacists want a direct way of communication between their systems.

The authors of this article consider RFU to be a valuable piece of information that has the potential to solve the lack of communication among healthcare providers in the circle of care. Furthermore, including RFU in communications between healthcare providers will have a positive impact on patient safety and medication adherence, while supporting a patient-centered care approach.

This paper focuses on the description and analysis of data retrieved from interviews that were conducted with pharmacists,prescribers, and patients.The objective of this paper is to understand how the reason for using a medication might be shared between members of the healthcare team to enhance communication, decision making, and patient safety.

2. Methods

Pharmacists, prescribers (i.e., physicians and, nurse practitioners) and patients were interviewed using an interview guideline. The questions in the interviews were grouped into three sections: demographics, how participants interact with the current system, and their expectations and feelings towards including RFU on prescriptions as mandatory practice. The interviews included questions outside of the scope of the article objective; hence, only relevant questions are presented in Table1 for the analysis.

Table 1. Questions selected among the three interview questionnaires.

Participants	Questions
Patients	How do you find out what your medications are for?
	Who shares RFU information with you? Prescriber? Pharmacist? When?
	Was there a time in which knowing the RFU was helpful? Please, tell me more.
	How do you feel about sharing RFU with the pharmacist?
	How would knowing RFU information change your ability to make decisions?
	Do you have any concerns about sharing RFU information? If so, what?
Prescribers	Do you ever record the RFU? If so, where? Do you ever include RFU on prescriptions?
	Do pharmacists need to know RFU information?
	If the RFU is not given to the pharmacist, how do you think they figure out that information? What could a pharmacist do with this information?
Pharmacist	How do you typically identify the RFU?
	What are the advantages of having RFU information?
	Was there a time in which you could have used RFU?
	Do you have concerns about sharing RFU information? If so, what?

The sample included60 participants in total which included prescribers, pharmacists, and patients. Physician and pharmacist participants were randomly selected among members of the Ontario College of Pharmacists (OCP) and College of Physicians and Surgeons of Ontario (CPSO), who actively practice in Kitchener-Waterloo, Mississauga, or the Toronto area. Patients were recruited using posters and through Waterloo Research Aging Participant Pool (WRAP) and were selected based on: being older than 18 years, currently taking prescribed medications (preferably three or more), and self-administering these medications.

A qualitative and descriptive analysis was conducted for the data retrieved from the interviews. Many questions were posed with answers that were yes/no/it depends; if participants answered 'it depends' they were invited to expand on their answer, turning into an open-ended answer. Some of the open-ended answers are shared below; quote selections were made based on how well the participant's opinions illustrated the problem relative to the question asked. All the open-ended answers were analyzed by the authors of this paper, and key terms/themes were extracted.

3. Results

3.1. Sample Description

Statistics regarding the sample composition are shown on Tables 2 and 3.Eighty-five percent (n=17/20)of pharmacists had used more than one PMS. The most popular PMS was Kroll (80%) followed by HealthWatch (70%), in a list of 12 various PMSs used. Eighty-five percent (n=17/20) of prescribers were family doctors, and twenty percent (n=4/20) worked in more than one practice. The most popular types of practices in a list of ten are presented in Table 3. Ninety-five percent (n=19/20) of prescribers had used more than one EMR system, and the most popular system used was Practice Solutions (PS)(70%) from TELUS Health.

Table 2. Demographic data of participants (20 prescribers, 20 pharmacists and 20 patients).

Participant	Age/Experience		Gender		No. of Meds		Kepta List of Meds		
	Mean	Range	Female	Male	Mean	Range	No	Yes	%
Patients	59	23- 89	10	10	4.65	1- 10	6	14	70
Pharmacists	9.63	1- 25	11	9	-	-	-	-	-
Physicians/ NP	10.60	1 -33	8	12	-	-	-	-	-

Table 3. Other demographic data of prescriber and pharmacist participants

Participant	No. of Pharmacy/ Practice in which participant's work			Type of Pharmacy/ Practice	PMS/EMR used per participant			
	One	Two	Three	(n)	(n)	Mean	Range
Pharmacists	15	5	-	Independent (12) Chain Store (12) Hospital (1)	Kroll (16) HealthWatch (14) Filware (8) Others (17)	2.80	1- 4
Prescribers	16	2	2	Family health team (5) Independent (4) Emergency (4) Community health center (4) Others (8)	PS (14) OSCAR (9) Meditech (7) Nightingale (6) Others (26)	3.73	1 - 7

3.2. Current System

Table 4 shows how patients discovered what their medications were for, and the number of sources used. Some of the comments explaining these behaviours were:"The doctors don't tell you, they just prescribe it…unless you explicitly ask them. They tell you to take it at such time…even when you explicitly ask them some don't tell you. So, you end

up Googling it.”; and “I start with the prescribing physician, then get more information from the pharmacist.”

Table 4. Clues on how patients interact with the current system.

Source used to identify RFU			Was RFU ever shared?		When was RFU shared?	Importance of knowing RFU
(n/20)	Mean	Range	Yes	No	(n/20)	(n/20)
Pharmacist (8)	1.55	3 – 0	17	3	New meds (15)	Very important (19)
Physicians (16)					Refill (1)	Important(0)
Support Materials (2)					Annual reviews (3)	Moderately important (1)
Online (5)					Upon asking (7)	Slightly important (0)
						Not important (0)

According to Table 4, RFU information is typically shared with patients when they get a new medication, on asking a healthcare professional, during an annual medication review with their pharmacist, or when they are refilling a medication. Patients described RFU as a vital piece of information; 75% (n=15/20)of patients agreed with the statement:“I do not take a medication that I don't know. I make sure I know what I am taking."

Information regarding adding RFU onto a prescription is presented in Table 5.Threeprescribers stated that they regularly add RFU, while half said they may add RFU depending on the situation, and the remaining seven stated that they never include RFU. They noted that they included of RFU on the prescription was due to the following reasons: off-label medication use, avoiding patient confusion, allowing a pharmacist to double check the dose, or for a patient who is taking multiple medications. Over half of the prescribers recorded RFU under the section notes or label instructions in their EMR. Those who did not record the RFU mentioned that they did not do so due to time restraints, or because they did not want to confuse patients when medications had multiple indications.

Table 5. Prescriberbehavior and opinions toward RFU

RFU recorded in EMR		The prescription includes RFU			Pharmacist needs to know RFU		
Yes	No	Yes	No	It depends	Yes	No	It depends
11	9	3	7	10	12	2	5

The last column in Table 5 shows prescribers’ opinions regarding whether pharmacists need to know RFU information. A prescriber supporting a ‘yes’ responses aid, “I think it's for safety reasons. The more information that's shared the safer the situation is going to be for the patient.They might be in a better situation to be able to pick up on potential medications that might be prescribed unnecessarily or may have some good suggestions to offer.”

Table 6. Strategies to identify RFU, what pharmacists do and what prescribers believe a pharmacist does.

Strategies	Pharmacist(n/20)	Prescriber (n/20)
Educated guess	20	14
Self-search	7	3
Ask patients	20	13
Call prescriber	1	4
Check EMR/EHR	1	

Table 6 shows the processes that pharmacists take to determine RFU information when it is not given, and the beliefs prescribers have on how pharmacists find this information. Independent and chain store pharmacists have indicated they make use of at least two of the strategies presented in Table 6 to identify RFU when it is not given to

them. The hospital pharmacist interviewed stated that they check the EMR/EHR, rather than infer it (educated guess).

When prescribers were asked about what pharmacists could do with RFU information, their responses were: check the dosage, counsel the patient, check for errors or drug interactions, make drug suggestions, and check for patient adherence and safety. Some prescribers stated:"Pharmacists have an expertise clinically that would be beneficial to provide recommendations (to physician) if they knew reason for use all the time.";"I think they could reinforce with the patient why they've been prescribed that medication, how to properly use it and just clarify a lot of questions"; and,"It would enhance care, reduce risk.…They may be able to pick up on potentially unnecessary medications a little easier...If they had reason for use."

Pharmacists were asked how beneficial it would be if they had access to RFU information. Their responses were: a great deal (n=10), quite a bit (n=6), and somewhat (n=4). They were also asked what the advantages were. Some of their replies were:"For example, we are dealing right now with the recall of valsartan, as we know it can be used for so many indications, if I had reason for use I could suggest the right conversion to another drug, yeah there are a lot of advantages";"It will help with the approach to follow with the patient, catch drug errors, prescribing errors."; and "I will be able to clinically assess the prescription a lot better. I will be able to catch dosing errors. If I knew it, it would be ultimately safer for the patient."

When the pharmacists were asked if there was ever a time, they could have used RFU information, the answer was 'yes'80%(n=16/20) of the time. One of the responses was: "It would save some time. When people use medications for off label reasons. If they have that on the prescription, I'd be like, 'Okay, that's an off-label use.' Sometimes it scares the patient. 'Yeah, it's supposed to be used for this.' And they're like, 'But I'm not using it for that. Does that mean I have this condition?' 'No, no, no. It can also be used for other things. 'You explain it to them and they get it, but it would help a lot."

3.3. What if the RFU Were Mandatory

When patients were asked how RFU information would affect their ability to make decisions about their medications, they indicated they would be more informed (n=20), would adhere better to the treatment (n=6), and make better decisions about taking their medication (n=5). Some answers were "If you know the reason for use and you no longer have the symptoms, you no longer have to take it anymore"; and "If something doesn't seem to be working, I can look at: why this was prescribed in the first place...and I can go more prepared into making better use of the physicians' time as well, and I can say, 'I am still having this issue …, can we talk about that?'"

Some patients (n=3) and pharmacists (n=4) indicated that they have concerns about sharing RFU information. Those concerns were related to confidentiality and privacy; some of the statements were: "The main concern, is that sometimes oversimplifying an indication can make the thing more complex, assumptions can be made rather than going to the patient and asking them to get more details, it might be that when I look at this word (RFU), then I will not look at other factors as well and that is the main thing" (pharmacist response) and"Unfortunately, I can see it (privacy reasons) for elementary school kids and middle school kids because they'll kill each other with this sort of private information.If they get a hold of it, they might want to

persecute one another. Maybe privacy must protect certain groups. Adults? I fail to get upset because somebody knows something about me" (patient response).

4. Discussion and Conclusion

The way in which the current system works demonstrates holes in the communication strategies between pharmacists, patients, and prescribers which can lead to preventable medication errors. This study confirmed the potential for RFU information to enhance communication among patients, pharmacists and prescribers, as well as willingness to share RFU within the healthcare team.

Even though the data indicates that it is possible to use RFU to improve communication, it would be necessary to consider the concerns expressed regarding privacy and confidentiality.

Acknowledgement

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Linking Health Records with Knowledge Sources Using OWL and RDF

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Abstract. This paper describes a method by which the Web Ontology Language (OWL) can be used to specify a highly structured health record, following internationally recognised standards such as ISO 13606 and HL7 CDA. The structured record is coded using schemes such as SNOMED, ICD or LOINC, with the coding applied statically, on the basis of the predefined structure, or dynamically, on the basis of data values entered in the health record. The highly structured, coded record can then be linked with external knowledge sources which are themselves coded using the Resource Description Framework. These methods have been used to implement dynamic decision support in the open source cityEHR health records system. The effectiveness of the decision support depends on the scope and quality of the clinical coding and the sophistication of the algorithm used to match the structured record with knowledge sources.

Keywords. OWL, RDF, Dublin Core, EHR, ISO 13606, HL7 CDA, Knowledge, Clinical Coding, SNOMED.

1. Introduction

The Web Ontology Language (OWL) [1] is a key component of the Semantic Web activity of the World Wide Web Consortium (W3C) [2]. OWL can be used to specify highly structured models, where the representation of the model as an ontology of distinct, yet connected, statements (axioms) adds the ability to link with other semantic data sets and to use Description Logic reasoners to check consistency and to infer relationships [3].

For the Electronic Health Record (EHR), the most widely used generic models for representation are ISO 13606 [4] and HL7 CDA [5]. We have shown previously how an OWL ontology model, encompassing both ISO 13606 and HL7 CDA, can be used as the foundation for a structured EHR [6].

Another cornerstone of the Semantic Web is the Resource Description Framework (RDF) [7] which provides a mechanism to annotate any addressable resource with meta data, regardless of whether that resource is accessible by the author of the meta data, or not. RDF is often used in conjunction with the Dublin Core standard [8], which defines a set of fifteen commonly used metadata elements, such as title, description, subject and publisher We will show in the next section how RDF and Dublin Core can be used as a standard method for adding clinical coding to any knowledge source.

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According to Musen at al, "the requirements for excellent decision making fall into three categories: (1) accurate data, (2) pertinent knowledge, and (3) appropriate problem-solving skills" [9]. For a clinical decision support system,as opposed to a decision making system, the problem-solving skills are left to the realm of the clinician; the job of the computer is to represent data accurately and present pertinent knowledge to the decision maker.

This paper describes a relatively simple, yet effective, method for presenting pertinent knowledge, evidence or advice to clinicians at the point where decisions are made. In cases where the EHR is well structured, carries clinical coding and is being used as the primary means of documenting the clinical process, it is possible to extract the clinical context of the EHR session, match that context with relevant, coded, knowledge sources and then retrieve the knowledge for presentation within the EHR session.

The next section outlines the method by which this is achieved using OWL, RDF and Dublin Core; the following section presents the results of applying the method in the open source health records system, cityEHR.

2. Methods

The method for linking health records with knowledge sources, as shown in Figure 1, requires a structured representation of the clinical record, dynamic coding of the record to describe the clinical context, a map of coded knowledge sources,, and use of that map to match the clinical context with the most relevant knowledge sources.
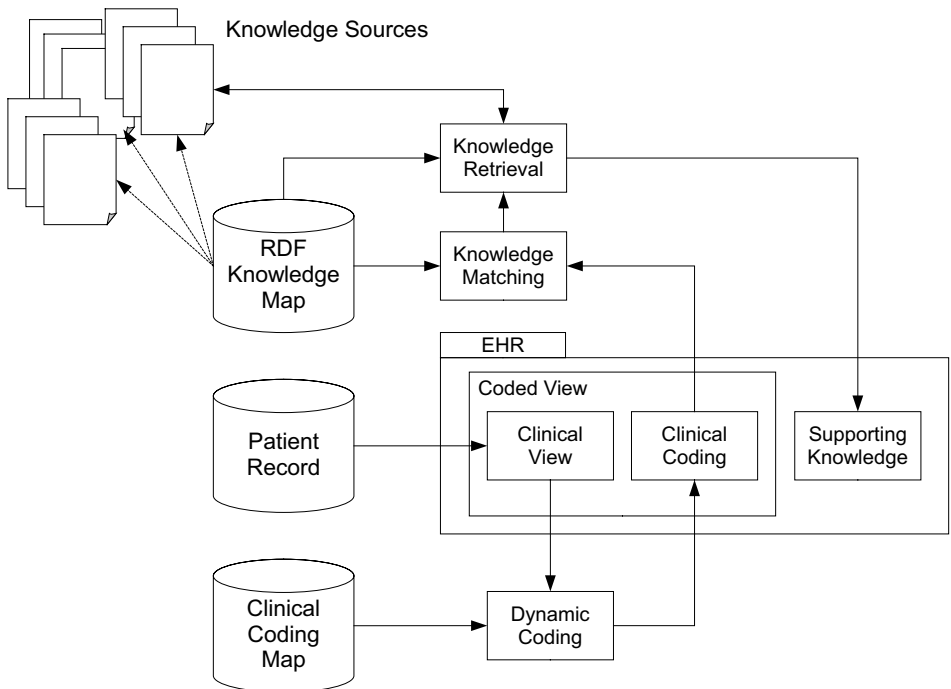
Figure 1. Clinical Decision Support Using Clinical Coding

The clinician runs a session in the EHR and interacts with a Clinical View which is a combination of information fed from the stored Patient Record and new information created within the session. The Dynamic Coding process uses the structure of the Clinical View, the specific information it contains and the Clinical Coding Map to generate a Coded View. The coding is used as input to the Knowledge Matching process which compares it with the RDF Knowledge Map to generate a set of Uniform Resource Locators for the Knowledge Sources, which are then used by the Knowledge Retrieval process to deliver Supporting Knowledge into the EHR session.

2.1. Ontology Representation of the Health Record

The ISO 13606 standard specifies a hierarchical context for any clinical data stored in the health record. The data are recorded in Elements which belong to Entries; an Entry is the lowest level of meaningful clinical context (often referred to as a 'clinical statement'). Further context can be provided by organising Entries within Sections, which are collected in Compositions. Generally, the Composition serves as the unit of storage in the EHR but further clinical context can be applied by organising Compositions within Folders. The Folder level organisation can be applied in a dynamic manner, so that a Composition may appear within multiple Folders, simultaneously. So a Folder could represent, for example, the specialty of the clinical user, an episode of care or a long term condition of the patient.

```
<Declaration>                                          <ObjectPropertyAssertion>
    <Class IRI="#ISO-13606:Entry"/>                        <ObjectProperty IRI="#hasContent"/>
</Declaration>                                             <NamedIndividual IRI="#ISO-13606:Entry:BMDData"/>
<Declaration>                                             <NamedIndividual IRI="#ISO-3606:Element:BMDMeasurement"/>
    <NamedIndividual IRI="#ISO-13606:Entry:BMDData"/>   </ObjectPropertyAssertion>
</Declaration>                                          <ObjectPropertyAssertion>
<ClassAssertion>                                           <ObjectProperty IRI="#hasContent"/>
    <Class IRI="#ISO-13606:Entry"/>                        <NamedIndividual IRI="#ISO-13606:Entry:BMDData"/>
    <NamedIndividual IRI="#ISO-13606:Entry:BMDData"/>      <NamedIndividual IRI="#ISO-13606:Element:TScore"/>
</ClassAssertion>                                       </ObjectPropertyAssertion>
<DataPropertyAssertion>                                 <ObjectPropertyAssertion>
    <DataProperty IRI="#hasDisplayName"/>                  <ObjectProperty IRI="#hasContent"/>
    <NamedIndividual IRI="#ISO-13606:Entry:BMDData"/>      <NamedIndividual IRI="#ISO-13606:Entry:BMDData"/>
    <Literal xml:lang="en-gb">DXA Scan Results</Literal>  <NamedIndividual IRI="#ISO-13606:Element:ZScore"/>
</DataPropertyAssertion>                                </ObjectPropertyAssertion>
```

Figure 2. Structured Health Record Using OWL/XML

Figure 2 shows a small part of the ontology that defines a structured health record. #ISO-13606:Entry is declared to be a class and #ISO-13606:Entry:BMDData to be an individual which belongs to that class and has a display name of "DXA Scan Results" as declared in the DataPropertyAssertion. Three ObjectPropertyAssertions are then used to assert that the #ISO-13606:Entry:BMDData entry contains three elements: #ISO-13606:Element:BMDMeasurement, #ISO-13606:Element:TScore and #ISO-13606:Element:ZScore. The full model of a structured health record contains many thousands of assertions of this type, defining the full set of ISO 13606 Compositions that can be used to record patient information.

2.2. Static and Dynamic Coding of the Structured Health Record

An OWL/XML ontology representation can also be used to model clinical coding and the association of codes with ISO 13606 entries in the record, as shown in Figure 3.

```
<Declaration>                                          <Declaration>
  <Class IRI="#CodingSystem:SNOMED"/>                    <Class IRI="#CodePoint"/>
</Declaration>                                         </Declaration>
<Declaration>                                          <Declaration>
  <NamedIndividual IRI="#Code:SNOMED:64859006"/>         <NamedIndividual IRI="#CodePoint:BDMData:64859006"/>
</Declaration>                                         </Declaration>
<ClassAssertion>                                       <ClassAssertion>
  <Class IRI="#CodingSystem:SNOMED"/>                    <Class IRI="#CodePoint"/>
  <NamedIndividual IRI="#Code:SNOMED:64859006"/>         <NamedIndividual IRI="#CodePoint:BDMData:64859006"/>
</ClassAssertion>                                      </ClassAssertion>
<DataPropertyAssertion>                                <DataPropertyAssertion>
  <DataProperty IRI="#hasDisplayName"/>                  <DataProperty IRI="#hasCondition"/>
  <NamedIndividual IRI="#Code:SNOMED:64859006"/>         <NamedIndividual IRI="#CodePoint:BDMData:64859006"/>
  <Literal xml:lang="en-gb">Osteoporosis</Literal>      <Literal>BMDData/TScore lt -2.5</Literal>
</DataPropertyAssertion>                               </DataPropertyAssertion>
<DataPropertyAssertion>                                <ObjectPropertyAssertion>
  <DataProperty IRI="#hasCode"/>                         <ObjectProperty IRI="#hasCode"/>
  <NamedIndividual IRI="#Code:SNOMED:64859006"/>         <NamedIndividual IRI="#CodePoint:BDMData:64859006"/>
  <Literal>64859006</Literal>                            <NamedIndividual IRI="#Code:SNOMED:64859006"/>
</DataPropertyAssertion>                               </ObjectPropertyAssertion>

                                                       <ObjectPropertyAssertion>
                                                         <ObjectProperty IRI="#hasCodePoint"/>
                                                         <NamedIndividual IRI="#ISO-13606:Entry:BMDData""/>
                                                         <NamedIndividual IRI="#CodePoint:BDMData:64859006"/>
                                                       </ObjectPropertyAssertion>
```

Figure 3. Clinical Coding Using OWL/XML

The first set of assertions defines the clinical code for Osteoporosis from the SNOMED coding scheme (www.snowmed.org). The second set of assertions defines a CodePoint, which assigns the SNOMED code 64859006 (Osteopososis) to the ISO 13606 Entry for BMDData, with the condition that TScore is less than -2.5. This set of assertions is sufficient to implement dynamic coding of the BMDData Entry; a similar set without the hasCondition data property assertion would be used to implement static coding (i.e. the code would always be assigned to the Entry). The expression in the Literal string for hasCondition uses the W3C standard XPath language, with BMDData/TScore representing the TScore Element of the BMDData Entry.

2.3. Coding Knowledge Sources Using RDF and Dublin Core

The RDF Knowledge Map contains a set of metadata assertions as triples of subject-predicate-object. The RDF XML coding shown in Figure 4, uses the rdf:about attribute to represent the subject, which is any addressable resource (in this case a clinical guideline for Osteoporosis from the National Institute of Health and Care Excellence).

```
<?xml version="1.0" encoding="UTF-8"?>
<rdf:RDF xmlns:rdf="http://www.w3.org/1999/02/22-rdf-syntax-ns#"
         xmlns:dc="http://purl.org/dc/elements/1.1/" dc:title="Knowledge Map">

    <rdf:Description rdf:about="http://pathways.nice.org.uk/pathways/osteoporosis">
        <dc:subject rdf:datatype="http://www.snomed.org">391068001</dc:subject>
        <dc:description rdf:datatype="http://www.snomed.org">
           Hip dual energy X-ray photon absorptiometry scan T score
        </dc:description>
    </rdf:Description>

    <rdf:Description rdf:about="http://pathways.nice.org.uk/pathways/osteoporosis">
        <dc:subject rdf:datatype="http://www.snomed.org">64859006</dc:subject>
        <dc:description rdf:datatype="http://www.snomed.org">Osteoporosis</dc:description>
    </rdf:Description>

    <rdf:Description rdf:about="http://pathways.nice.org.uk/pathways/osteoporosis">
        <dc:subject rdf:datatype="http://www.snomed.org">312894000</dc:subject>
        <dc:description rdf:datatype="http://www.snomed.org">Osteopenia</dc:description>
    </rdf:Description>

</rdf:RDF>
```

Figure 4. RDF Knowledge Map Using RDF and Dublin Core

The Dublin Core dc:subject element represents the predicate for subject metadata from the SNOMED vocabulary (defined by the rdf:datatype attribute) and the content of that element represents the object, which in this example is the SNOMED code assigned to the Osteoporosis guideline. The example in Figure 4 shows the assignment of three SNOMED codes to the Osteoporosis guideline; the full Knowledge Map for a clinical specialty would contain thousands of codes.

3. Results

The methods described above were used to implement new features in the open source cityEHR health records system, for creating and managing RDF knowledge maps, dynamic coding of the health record and presentation of supporting knowledge.

3.1. Creating and Managing RDF Knowledge Maps

In cityEHR, RDF knowledge maps can be created and edited manually or can be imported from external maps (perhaps generated as the result of Natural Language Processing on targeted web resources). The maps are stored as indexed XML documents that can be searched efficiently using the W3C standard XQuery language.

3.2. Coding of the Health Record

For the cityEHR runtime system, the ontology-based definition of the structured record is transformed from OWL/XML into a set of HL7 CDA XML documents which are linked to a corresponding set of automatically generated forms using the W3C XForms standard; these forms are then used for interaction with the clinical user.

Similarly, the ontology-based Clinical Coding Map is transformed into a set of HL7 CDA code elements, that are inserted into the XForm that represents the current clinical view. Static coding (without conditions) is inserted directly; dynamic coding is made by transforming the conditions expressed in the ontology definition into full XPath expressions that are linked to the structure of the HL7 CDA document in the XForm and are then evaluated as clinical information changes, as part of the standard XForms implementation.

3.3. Retrieval and Presentation of Knowledge

The first step in retrieving knowledge, is to extract the clinical coding associated with the clinical statements at the Entry level, then less specific context at the Section, Composition and Folder levels of the ISO 13606 structure. The extracted codes are then used to match with codes in the RDF Knowledge Map, to find relevant knowledge sources.

The algorithm used to make this match can be more or less sophisticated. The simplest algorithm merely retrieves all knowledge sources that are coded with any of the same codes extracted from the clinical context. More sophisticated algorithms can rank the knowledge sources based on the number of matching codes, or use an understanding of the relationships between clinical codes (for example the codes for Male and Female are disjoint).

The matches on knowledge sources are returned as URLs (the URLs specified by the rdf:about attributes in the RDF Knowledge Map). To present the knowledge in the cityEHR session, the URLs are passed to a web service which accesses each URL and returns the content found there. If the content is in PDF format it is returned directly; if it is in HTML format then the content is returned using the Beautiful Soup HTML scraping library [11].

4. Conclusions

Structured health records, associated clinical coding and maps of coded knowledge resources can be represented using the Semantic Web standards OWL and RDF. These representations can be transformed to drive an EHR system, where clinical coding is applied statically or dynamically to the structured health record, then extracted as a representation of the clinical context and used to retrieve relevant knowledge to support clinical decision makers. The effectiveness of this method depends on the quality and extent of the clinical coding maps and the sophistication of the algorithms used to match clinical context in the EHR session with the coded knowledge sources.

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59

Embedding Health Literacy Tools in Patient EHR Portals to Facilitate Productive Patient Engagement

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Abstract. Many health care providers have opened their EHR systems to patients in order to increase information sharing and patient participation. Accessing to EHR has offered the promises of improving patient understanding, engagement, and outcomes. Although patients generally appreciate the access to their health records, currently, most EHR systems are used as data storage and communication tools and their potential for promoting productive patient engagement have not fully developed. There is a need to develop and incorporate effective health literacy tools into EHR patient portals, helping patients interpret their health data, understand their medical conditions and treatment plans, make informed decisions, and take proper actions. We will examine the challenges that patients face in using EHR portals, then provide two innovative health literacy solutions for facilitating productive patient engagement: (a) an embedded semantic medical search engine that provides reliable and contextualized health information support, and (b) an integrated AI voice chatbot that answers patients' questions and provides on-demand self-care advice. Other approaches that can add benefits to patients in the context of using EHR will also be described.

Keywords. Electronic health records (EHR), patient EHR portal; health literacy, health information, embedded health information tools, contextualized medical search, AI voice chatbot, patient education, patient engagement, clinical outcomes

1. Introduction

Health information technologies, particularly Electronic Health Records (EHR) is seen as a key driver of value-based and patient-centered care. At present, the majority of EHR systems available in North America hospitals are mostly used as data storage and communication tools typically consisting of patient health histories, lab test results, diagnostic images and reports, as well as physician's notes. The benefits of EHR for physicians seem clear: improving productivity, coordinated care, patient safety, physician-patient communication, and patient education.

In recent years, many health care providers have opened their EHR systems to patients in order to increase information sharing and patient participation. Although patients generally appreciate the access to their health records, current EHR systems have not yet shown substantial evidence for improving patient understanding, engagement, and outcomes. As all EHR platforms were developed for physicians and as it takes years of professional training to understand the kinds of clinical information contained, patients face many challenges in using such systems. Some studies even reported

negative impact on patients, especially on people with limited health literacy. There is a need to develop and incorporate effective health literacy tools into EHR patient portals in order to facilitate productive patient engagement, bringing EHR to its full potential.

In this paper, we define EHR patient portals as Electronic Health Records (EHR) systems that provide access for patients to view their health histories, lab test results, diagnostic images and reports, as well as physician's notes. We will examine the challenges that patients face in using such EHR portals, then provide two innovative health literacy approaches for facilitating productive patient engagement: (a) an embedded semantic medical search engine that provides reliable and contextualized health information support, and (b) a AI voice chatbot that answers patients' questions and gives them advice on their health conditions. Other approaches that can add benefits to patients in the context of using EHR will also be described.

2. Problems in Implementing and Using EHR Patient Portals

Productive patient engagement through EHR portals requires patients to have the basic health literacy, which is the capacity to obtain, understand, and use health information in their healthcare. Patients with limited health literacy often have difficulty in understanding medical terminology used in lab reports, doctor's notes and other content (Chen, Zheng, et al., 2016). In addition, patients with limited health literacy and limited English proficiency often experience suboptimal communication and health outcomes (Ratanawongsa et al., 2017). In particular, such patients often felt overwhelmed by the complexity of health data, which often cause confusion and anxiety, especially when they receive abnormal test results via the EHR patient portals (Giardina, Modi et al., 2015). The adoption and utilization of EHR patient portals has been relatively low. According to a recent report (Heath, 2018), even 52% Americans have access to their EHR, only 28% Americans viewed their medical records. The top reasons for not viewing patient health records are (a) wanting to speak with providers in person (76%), and (b) limited perceived need to view medical records (59%). In order to increase patient use of their EHR, the patient portals need to offer additional content that is perceived useful by patients. Adding health information content that is actionable, educational, and interactive may better inform, educate, and engage patients, increasing the likelihood for them to use the EHR. Furthermore, given the prevalence of low health literacy in the population and the challenges that patients face in using EHR portals, tools that improve patients' understanding of EHR data and treatment plans, as well as their basic health literacy may prove valuable.

3. Two Health Literacy Tools for Facilitating Productive Patient Engagement

Several approaches have been taken to improve physician-patient communication and patient education in the context of patient EHR use. Using secure text messaging and email communications between doctors and patients are among the most popular ones. Such physician-patient communication can be carried out either inside or outside the EHR platforms, and both work very well. However, such an approach requires significant amount of work by the physicians, adding workloads on physicians who are already at risk of burnout. In addition, it is difficult to implement this method as a general

approach to meeting all health information needs of patients at all time, the EHR systems need to have a built-in mechanism to satisfy patients' information needs in timely fashion.

Basic health literacy education for the general public is often achieved through self-directed learning. Contextualized instruction and on-demand learning are two important strategies for developing understanding and supporting problem solving in this form of learning (Pari, 2003). To address challenges indicated above, we provide two innovative health literacy solutions for facilitating productive patient engagement: (a) an embedded semantic medical search engine that provides reliable and contextualized health information support, and (b) an integrated AI voice chatbot that answers patients' questions and provides on-demand self-care advice. Other approaches that can add benefits to patients in the context of using EHR will also be described.

3.1. An Embedded Semantic Medical Search Engine that Provides Contextualized Health Information Support

Incorporating a semantic medical search engine in patient EHR platforms provides a way for patient to access contextualized health information needed for them to make sense of test reports, treatment plans, and other EHR content. We are recommending semantic search engine because such search engines have built-in rules to identify, prioritize, and select health information for facilitating patients understanding, informed medical decisions, and proper self-care. These rules can also address questions that patients often have, such as why, when, and to whom a given medical intervention is effective or ineffective. This may help patients better understand their health data, treatment plans, and self-care tasks. We have developed such a semantic search engine which can be used in EHR via API and the details of this search engine were described elsewhere (Chen, Decary, 2017, 2018).

Beside conducting health information search in the context of viewing their health records, patients can access contextualized information through hyperlinks. The hyperlinks can provide explanations on test reports, physician notes, or the relationship between an abnormal test result (e.g., high glucose level) and the way to change it (e.g., diet, exercises, or drug). Depending on the needs and preference of patients, such a contextualized search tool can be used to help patients learn things they perceive as useful.

3.2. An Integrated AI Voice Chatbot that Answers Patients' Questions and Provides On-demand Self-care Advice

We are now at a unique time in human history where AI-powered voice technology has matured enough to make a difference in people's lives and that AI voice medical chatbots can be developed to provide on-demand and personalized self-care advice to patients. Such voice chatbots can make it easier for patients to obtain, understand, and use health information, improving their self-care as well as their treatment outcomes.

We are working on several specialized AI voice medical chatbots to provide self-care advice for various chronic conditions and surgical procedures. Such chatbots can engage in human-like natural conversations with patients via both voice and text, answering open-ended questions and providing personalized self-care advice. They can be deployed to all computer platforms, AI Assistant devices, smartphones, and many popular messaging and social media platforms. They can also be expanded into other

languages than English. Two video snippets of our AI voice chatbot prototypes can be viewed online (Chen & Decary, 2018).

Although these chatbots are developed as stand-alone applications, they can be integrated into patient EHR platforms to help patients understand their health data, treatment plans, as well as lifestyle modifications needed for successfully managing their health conditions. As many health organizations are seeking effective digital health tools to promote productive patient engagement, improve treatment outcomes, and reduce health care costs, we believe AI voice-activated medical chatbots will become an important and integral part of patient EHR platforms.

3.3. Other Approaches

No matter how smart technology may have become, there are always situations in which patients need additional support and resources beyond what is offered by the technology. In such cases, patients should be able to engage in secured communication with their primary care providers; they should also have access to immediate telehealth consultation when they fail to understand medical information that is crucial for their treatment plan. At present, some health providers have offered such services as integral parts of their patient digital health care ecosystem, ensuring the continuous support and care to their patients.

4. Future Directions

The advances in AI and digital health technology have offered the real potential to transform global health care. However, currently, in Canada, the EHR adoption rate is very low. Although 85% Canadian primary care physicians are using EHR, only 15% Canadians have access to their health records (Canada Health Infoway, 2018), which is much lower than the 52% access rate by Americans (Heath, 2018). Besides opening EHR portals to Canadians, we need to understand barriers that Canadians face in adopting EHR and take effective approaches to overcome such barriers. In particular, we need to consider the importance of health literacy when selecting, designing, and utilizing patient EHR platforms. In addition to medial search engines and AI voice chatbots, other features can be added to EHR to make EHR more useful and effective. For instance, providing diagnostic and predictive analysis using population EHR data, incorporating online health services (e.g., telemedicine, e-booking, and e-prescription) will enable us to develop a new type of EHR platforms, and eventually an intelligent, integrated, and connected consumer digital health care ecosystem.

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Applying the Behavior Change Technique Taxonomy to Mobile Health Applications: A Protocol

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Abstract. The lack of standardized descriptors of behavior change facilitators in mobile health apps makes it difficult for clinicians and consumers to quickly evaluate the potential of a mobile health app. The Behavior Change Technique Taxonomy (BCTT) was developed to evaluate health interventions for the presence of behavior change techniques. This paper describes the methods used and methodological results in applying the BCTT to commercially available mobile health apps in the respiratory and sleep domains.

Keywords. mHealth, mobile health applications, consumer health informatics, behavior change

1. Introduction

Over 325,000 mobile apps are now available through the major app stores, yet the majority have less than 5,000 downloads [1]. Unlike traditional health interventions that have originated from clinicians or clinical researchers, mobile health apps are often developed commercially with little clinician or consumer input. While the intent is to improve health outcomes, the evidence in using mobile health apps for this purpose is limited [2]. Evaluating the effectiveness of mobile health apps has been hindered by limited examples of sustained adoption, particularly by individuals who could receive the greatest benefit. Mobile health adopters tend to have higher education-levels, stronger self-reported health and be more physically active [3,4]. In a systematic review on engagement with mobile health apps, lack of motivation was identified as a potential barrier, with key behavior change facilitators being notifications, personalized interventions, feedback, social comparison, and clinician influence [5]. However, there are limited examples of best practice approaches and tools that can evaluate the presence of behavior change facilitators in app design [2]. This makes it difficult for clinicians and consumers to quickly evaluate the potential of a mobile health app.

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There is overlap between these described facilitators and behavior change techniques (BCTs). BCTs are understood to be the "active ingredients" within health interventions; the smallest identifiable strategies that are likely to produce a specific behavior change [6]. Over the past decade, the Behavior Change Technique Taxonomy (BCTT) has been developed and applied in evaluating the presence of BCTs within healthcare interventions [2,7,8]. BCTT development was a top-down, bottom-up approach, that involved a literature review looking cross behavior change theories and a Delphi survey with expert behavior change researchers. The BCTT includes 93 individual behavior change techniques (BCTs) within 16 categories, with common categories being goals and planning, feedback and monitoring, social support and reward and threat. Since its development, the BCTT has been used to evaluate the presence of BCTs across numerous health interventions and in different delivery mechanisms. In the literature, it has been noted that it can be difficult, yet not impossible, to identify the individual BCTs within an intervention due to incomplete descriptions of the interventions, outcomes or populations [6]. In a recent scoping review, the authors were able to identify 135 studies that identified BCTs and assessed effectiveness [6].

This research team has used the BCTT to initially map interventions from our original clinical trials to a telehealth kiosk, a new delivery mechanism [9,10]. While mapping the conversion to a new technology, it was noted that the technology itself introduced unique considerations. Some BCTs in the original intervention studies could not be replicated in the telehealth kiosk, while the technological functions offered opportunities for new BCTs to be introduced. Additionally, the telehealth kiosk could have potentially replicated some of the social support functions that have been traditionally categorized as human interactions.

To further understand the distinct considerations for applying the BCTT within consumer health, in this research pilot study, we retrospectively applied the BCTT to mobile health apps within two domains (respiratory and sleep). The research question was: *'Can the Behavior Change Technique Taxonomy be used to reliably describe the functions/features of mobile health apps that are designed to influence a person's health outcomes?'*. This research differs from prior BCTT research as the team evaluated the delivered content of mobile health apps rather than evaluating researchers' written descriptions of the intended interventions. This paper describes the methods used and methodological results in applying the BCTT to commercially available mobile health apps versus in-person health interventions described in the literature.

2. Methods[3]

2.1. Preparation

Prior to coding all three coding researchers completed a 25-hour online BCTT training course that encompassed tutorials, six graded practice sessions and two assessment tests [11]. In addition to the BCTT online training resources, the research team developed a BCT-App Codebook which contained data collection steps and standardized persona data. Two domains, respiratory and sleep, were initially chosen for review, as these had not been included in the original BCTT development, and no examples were found that

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[3] This research was approved by the University of Victoria Human Ethics Research Board (17-228).

applied the BCTT in evaluating sleep or respiratory health apps. The steps prior to coding each domain involved:

- Defining the search strategy and inclusion/exclusion criteria for locating relevant apps in the domain;
- Conducting an environmental scan (sufficient number of apps to review, creating standardized persona data);
- Developing an online survey tool to facilitate data entry for each of the 93 codes (Figure 1) and data analysis;
- Creating the timeline for app review: at least two reviewers were assigned to each app, and the team was scheduled to meet after evaluation of each set of five apps.

Figure 1. Example of the First Category in the BCTT-App Coding Survey

2.2. Data Collection

Each reviewed app was downloaded onto a smart phone by the coder. Standardized persona data were used where possible. Data was collected through screenshots that recorded interactions with the apps. Screenshot data were stored on a secure server at the University of Victoria. Depending on the environmental scan, the interaction period with each app varied between three and seven days. Apps that were identified as having weekly functions were scheduled for longer interactions.

If an app was available on Android and iPhone, both versions were evaluated by at least two coders. One coding survey that detailed each BCT was filled out for each app by the coder. A second coding survey was submitted if subsequent interactions with an app yielded additional BCTs. A three-point system was used for coding (0 = not present;

1 = may be present, unsure; and 2 = present, confident). For the "Social Support" construct, additional modifiers were included in the survey so coders could indicate the source of the social support (0 = technology; 1 = person unknown; and 2 = family or friend). Open text for each BCT was included so coders could write field notes and indicate which screenshots corresponded to their codes for a BCT.

2.2.1. Inclusion/Exclusion Criteria

Exclusion criteria - Apps were excluded from the data set if:
- Did not focus on the patient as the user;
- Was a diagnostic tool;
- Provided only educational or background information on the disease (no user interactivity);
- Only provided music or sounds for relaxation;
- Was not available in English or in Canada

Additional exclusion criteria specific to the sleep domain:
- Only function was an alarm clock;
- Less than a four star rating on the app store.

Inclusion criteria - Apps needed to have the following characteristics to be included in the data set:
- Reference the sleep or respiratory domain (i.e. chronic obstructive pulmonary disease (COPD) or asthma) in the introduction/overview of the app;
- Focused on behaviors (e.g. breathing, sleep, physical activity, etc.) or monitoring indicators of the illness (oxygen saturation, etc.);
- Free apps on Google Play or iTunes designed to be used on a mobile device.

2.3. Data Analysis

The study design was an iterative process where the protocol, codebook and online survey were adapted to address the areas of discrepancies identified during research team meetings. This resulted in progressive changes to analysis procedures. The initial protocol outlined that reliability in coding was to be assessed using Cohen's κ with a criterion of 0.75 for agreement. However, during evaluation of the first domain, respiratory apps, percent agreement was used as there was considerable variation in confidence level of coding (1 and 2's). The variability in the survey results for the sleep apps, resulted in the team completing analysis through consensus conferences.

3. Results

The quality of respiratory apps affected the ability to effectively apply the BCTT, as few apps demonstrated presence of BCTs. When the coders switched to the second domain (sleep), there was greater diversity in the BCTs that were identified within the apps, with representation across multiple categories. However, agreement on coding the apps was not achieved. A consensus conference revealed a unique consideration in BCTs that focused on monitoring and how they may be interpreted for technological applications.

For example, "biofeedback" was defined as an external device that monitors physiological or biochemical state [11]. There was disagreement whether apps that monitored snoring rates and breathing patterns were sufficient to meet this definition. Similarly, "self-monitoring of behavior" was defined as establishing a method for the person to monitor their behavior [11]. It was unclear initially whether an app that encouraged a person to place the phone at the bed side each night to monitor a person's movement should have been coded for this BCT.

The issues for consensus in the second set of sleep apps were specific to concepts in the domain rather than the BCTT definitions. For example, for apps that featured alarm clocks there was disagreement as to whether the time setting feature within an alarm clock was sufficient in meeting the criteria of 'setting a goal'. Additionally, the team discussions revealed that apps involved different categorizations for changing sleep patterns. For some apps sleep was viewed as the *outcome* in developing better sleep patterns, where the *behavior* to be changed focus on alcohol consumption, physical activity, and caffeine intake. Other apps conveyed the sleep pattern (e.g. oversleeping) as the *behavior* change, where an alarm would wake the person within an ideal phase of the sleep cycle. The second consensus conference for the sleep domain resulted in further instructions being added to the BCT-App Codebook and refinement of definitions and domain-specific examples within the BCT-App Coding Survey. Additionally, a disagreement area-specific test set was created to evaluate the modifications before assessing the next app set.

4. Conclusions

Based on these experiences, the following recommendations are made for evaluating BCTs in mobile health apps:

1. Conduct a pre-evaluation environmental scan of the domain to identify the persona information needed;
2. Plan for consensus conferences for coders with each new domain. Consensus conferences should be held after a small set of mobile health apps (<10) has been independently reviewed to identify domain specific issues;
3. Utilize data collection tools that reinforce BCT definitions and give domain examples where appropriate.

Assessing presence BCTs through mobile health use, introduces is a key methodological limitation. Only the displayed functions or interactions of mobile health apps can be coded, as the intentions of the app developers cannot be inferred from the apps themselves. This will decrease the potential for false positives in coding BCTs, but does mean that intended behavior facilitators may not be recognized if the intended interaction is not delivered fully or in the manner intended.

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Patient Empowerment: The Role of Technology

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Abstract. Patient empowerment is a buzzword that has gained much currency in recent years. It is defined as a process that helps people gain control over their own lives and increases their capacity to act on issues that they themselves define as important. This paper outlines the problems faced by the current medical model of patient empowerment and proposes a unique framework for patient empowerment that provides guidance on how health technology supports or detracts from empowering patients and families. The paper provides an ethical lens for physicians, policymakers, patients, and families in the health care system to consider the central role of the principles of autonomy and justice in patient empowerment. This paper also discusses how technology can be used to further patient empowerment and patient-centeredness of health care systems.

Keywords. patient empowerment, health technology, communication technology in patient empowerment

1. Introduction

Patient empowerment is a buzzword that seems to have gained much currency in the health care sector over the last decade [1, 2]. However, there does not appear to be a consistent definition of patient empowerment in the literature [3]. This varying terminology leads to confusion and disillusionment of the importance and role of patient empowerment [4]. Critically this leads to an inability to devise and test technological interventions effectively [5]. How can we implement a health technology, if we can't agree on a definition?

The Financing Sustainable Healthcare in Europe report provides a useful pointer to the underlying philosophy of patient empowerment [6]: "(1) the having and sharing of power, and (2) sources of power and ways to increase power. Empowerment can serve the goals of the empowered (e.g., greater pride and self-worth), and of the empowering agents (e.g., empowering employees as a way to foster productivity)."

Empowerment is the ability for individuals to have a voice at the table. It centres care around patients' preferences and increases their autonomy rather than their conformity [7]. This paper proposes some new ideas about what is necessary *and* sufficient for larger scale patient empowerment where information technology can play a transformative role.

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2. Problem Identification and Resolution Process

We conducted a scoping review of peer-reviewed and grey literature on patient empowerment in MedLine, Google Scholar and Google. We reviewed 32 articles until we reached saturation. We used the British Design Council's Double Diamond method [8] to identify key problems with patient empowerment and then narrowed them down to 5 major problems. We then explored potential solutions to the problems, noting that some problems were already being solved by other organizations, such as PCORI [1], but several were partially solved and one has not been addressed in any substantive manner.

3. Problems Patients Face in the Current Medical Model

In general, patients appear to face five major problems when attempting to self-manage their chronic disease or participate in the healthcare system.

1) They have little or no voice to influence the system for their own needs. Currently, services are negotiated by payers and providers, not patients or their advocates.
2) Patients have limited access to or control over their own medical information. Patients have limited transparency on who has access to their data.
3) Even if patients did have access and control of their data, they are still at a knowledge and information disadvantage when interacting or negotiating with payers and providers.
4) Patients have little say in how the main value creating activity in health care, research, is conducted, although efforts are underway to resolve this [1]. Patient data is controlled by the organizations that conduct the research.
5) Patients do not receive any of the benefits, including monetization of data, from the use of their data. In a world where data is increasingly an appreciating asset, this does not seem fair nor equitable [9].

These problems are not addressed by current empowerment models [3].

4. Initial Principles Development

The initial patient empowerment principles were developed through an iterative process of developing solutions for each of the above-mentioned problems. We identified several drivers for efforts to increase patient empowerment:

1) Cost reduction ("people need to look after themselves to lower costs")
2) Better health outcomes ("it's for their own good"),
3) Greater system efficiency ("less resources used if patients look after themselves")
4) Improve patient autonomy, control and participation in benefits (i.e., it's the right thing to do).

We quickly realized that cost reduction and system efficiencies are system benefits and can become coercive, if taken to their limits. Even achieving better health outcomes, while seemingly benign and positive, can also become coercive if those who have greater knowledge recommend interventions in the 'patient's best interest'. Any approach that

can be coercive, by definition cannot lead to patient empowerment. Thus, we conclude that patient empowerment must come from an ethical driver [10, 11].

Ethical principles such as autonomy and justice should be the driving factors of patient empowerment. Patients must be autonomous agents of their own health and patient empowerment should be conducted through justice and equity for all patients. This approach has significant implications for how we approach patient empowerment and provides guidance about how technology can help patients control access to their data, level the playing field with regard to knowledge and information and help them participate in the benefits that are derived from the use of their data.

5. Principles of Patient Empowerment

We believe there are 3 areas where technology can support patient empowerment in keeping with an ethical approach that is not self-contradictory.

5.1 Access and Control

Access refers to the possession of one's own health care data. Access to data is important because without it, patients are unable to control interest in their own health care. People need to understand what needs improving before they can take steps to help themselves. Most patients are not even aware that they have the right to ask for their medical records [12]. The idea of ownership of data has been highlighted in Canada by the First Nations Information Governance Centre [13]. This group has implemented standards for how First Nations' data should be collected, used, and shared. The four parts of their framework are ownership, control, access, and possession (OCAP). OCAP$^{®}$ is part of the First Nation's efforts to exert self-determination. The principles of OCAP$^{®}$ also relate to all Canadians. All citizens have a right to access their own health data and exert self-determination for their health. The ethical principle of autonomy is strengthened by providing patients greater access and control over their own data, greater transparency on who has access to their information and how and for what purpose it is being used [14].

5.2 Knowledge and Information

Patient empowerment should give people the power to control their own health care. It needs to give them the knowledge, education and information to use that data in their own best interests. The current patient-provider relationship is paternalistic and needs a shift towards a more collaborative, two-sided relationship. This means that physicians need to help patients understand their condition and what they can do to treat it at home. Patients need tools to support health literacy, navigation of the health system and knowledge about their disease and its treatment. Patients want to be empowered and can be empowered in the process of treatment decision-making [13]. The principle of autonomy is furthered by helping patients level the information and power gaps inherent in healthcare, while ensuring safety from negative or highly stressful information [10, 11, 15].

5.3 Shareholding

Shareholding is a new idea in the health world which, to our knowledge, has not been previously described. What we propose is that all organizations that profit from a patient's data pay out a 'dividend' to the patient. This is already seen in the retail industry, where companies reward customers for their data through loyalty programs [16].

This concept encourages for-profit companies to compensate those who contribute to making their profits. People's information is currently being used by genomics companies and the pharmaceutical industry with no tangible benefit to those whose data was used. The monetization of data should go beyond paying for data when received. Rather, institutions should share the profits they make with the people whose data they used. Shareholding is a concept that is consistent with the ethical principle of justice in health care.

6. Role of Information and Communications Technology in Patient Empowerment

To improve patient access and control over data, patients need new technologies that allows them to download their data at will, that can tag and track their data to give them greater transparency over where their data goes, who uses it and for what purpose. They also need new technologies to allow them to give and revoke permissions for the use of their data. Although blockchain technologies are overhyped in healthcare, this is one area where they may have a role in providing transparency and control over data for patients. The blockchain, properly implemented, would allow patients to see who had a copy of their data, see who was requesting their data and for what purpose and grant or deny access to their data based on their own preferences and inclinations.

To enable greater knowledge and information, patients need access to tools that can improve their health literacy, their knowledge about their own diseases and what options they have to control them. To support patient autonomy, physicians need scalable and sustainable tools to help them understand a patient's readiness for change so that patients lead the way, rather than the other way around. Physicians also need tools to help them engaged in shared decision-making with their patients. Patients also need tools that can help them understand their own motivations and engage themselves in caring for themselves. Patients and caregivers also need access to technology that can help them navigate the health system so they can get the best care in the most efficient way.

To enable shareholding, the blockchain and other data tracking technologies may play an important role by allowing patients and companies to track where a patient's data went, by whom it was used and what benefit a company may have derived from it.

7. Conclusion

This paper makes a contribution to the patient empowerment literature by pointing out that patient empowerment must be approached from an ethical perspective, rather than from one driven by cost-cutting, system efficiency or even improved patient outcomes. This ethical perspective provides guidance about which technologies are required and how they could be used to promote patient empowerment. The transformative and force-

multiplicative role of technology in patient empowerment should not be underestimated, as it is the only way that patients can level the playing field and control their own health destinies.

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Improving Usability, Safety and Patient Outcomes with Health Information Technology
F. Lau et al. (Eds.)

75

Data for Adherence Decision Support

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Abstract. Technological interventions aimed at addressing medication non-adherence have shown some promise but do not deliver the full potential of an Internet of Things based Adherence Decision Support (ADS) system due, in part, to a lack high-resolution definition and measure of adherence. This paper presents a novel methodology and pilot study aimed at collecting data to support an AI-based measure of adherence. The pilot study results demonstrate the viability of the methodology and that a full-scale study could provide meaningful data to support to an AI-based ADS system.

Keywords. medication adherence, decision support, Internet of Things, health information technology

1. Introduction

Medication prescriptions are a common form of medical intervention recommended by health care professionals. In 2014 prescription medications accounted for approximately 12.7% of all health care spending in Canada [1]. It is desirable to ensure that these medications are consumed as intended to improve health care outcomes and reduce further expenditure. Medication adherence is the extent to which an individual's medication consumption complies with the agreed upon recommendations from a health care provider [2]. Notably, this definition requires that the patient *agrees* with the health care provider and is *compliant* with the recommendation(s). While both are important aspects adherence, this paper focuses primarily on compliance under the assumption that the patient agrees. The relationship between adherence, agreement, and compliance has been explored in previous work [3].

Medication non-adherence remains an unsolved problem, in large part, due to its complex multi-faceted nature containing medical, social, economic, and technical aspects [4]. Thus far, no complete solution has emerged to address non-adherence and while a "silver bullet" for non-adherence is unlikely, technological interventions when coupled with other forms of intervention have been shown to improve medication adherence [5]. Recent developments of Connected Health and Internet of Things (IoT) enabled devices aimed at improving adherence typically provide simple reminder and rudimentary tracking capabilities [2]. While these technologies are useful they are not

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context-aware and fail to adapt to variation in the user's lifestyle and medication taking behaviours.

1.1. Adherence Decision Support Systems

Ideally, a context-aware adherence system should support a user's medication taking behaviours by adapting to changes in their day-to-day routines while considering how a medication interacts with the body (half-life, etc) and other medications. IoT technologies allow Adherence Decision Support (ADS) systems to observe many aspects of a user's behaviour and provide real-time decision support regarding when to take medications. Consider a prescription for Glargine which should be taken before bedtime, if the user does not take their medication prior to getting into the bed the system might make a recommendation based on an IoT bed sensor and a medication consumption history from an IoT enabled insulin device. Other similar ADS functions can be imagined.

An important prerequisite for an ADS system is the ability to determine what constitutes adherent v. non-adherent behaviour. ADS recommendations should be aimed at improving the user's adherence, i.e., an ADS should not only provide a reminder functionality but also provide recommendations to not administer medication when it would lead to decreased adherence. In essence, ADS systems require a means of *measuring* adherence for a given user's context. Many adherence measures have been proposed, however, most do not provide sufficient resolution to facilitate real-time decision support. In previous work, a high-resolution adherence measure that could be integrated into an ADS system was developed [6] (see Figure 1).
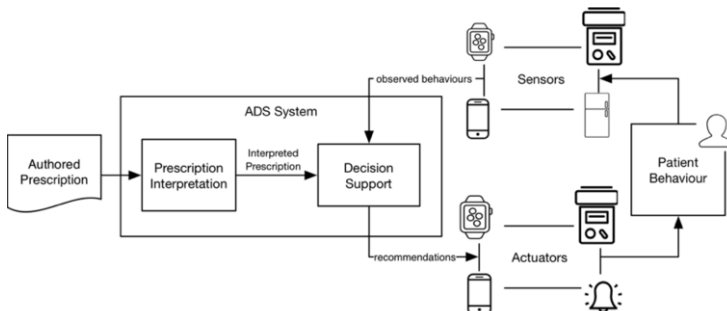
Figure 1. Architecture of ADS system.

An Authored Prescription (AP) is a prescription provided by a health care professional (e.g., "take 81 mg of Aspirin once per day"). APs, even in an electronically structured data format, are not appropriate for an ADS system since they usually contain implicit assumptions about how to administer the medication. For example, a *once daily* prescription might mean take once per calendar day or once every 24-hours; both interpretations are potentially valid but only one is likely to be correct from a medical perspective. Adherence measurements based on an incorrect prescription interpretation might lead to medically unsafe ADS recommendations.

To address the gap between APs and the computational abilities of ADS systems a step called *Prescription Interpretation* is used to produce an Interpreted Prescription (IP) that has a single unambiguous meaning and is suitable for the measurement of adherence in an ADS system. While present work is limited to manual prescription interpretation, it is ideally an evidence-based automated process that uses a combination of a database of prescription information and professional opinions.

1.2. Objective

An important research question concerning the feasibility of developing any AI-driven, automated interpretation of authored prescriptions is whether there actually exists consensus between different prescribers on how to interpret authored prescriptions. If this is the case, adherence measurement models may be constructed by aggregating interpretations from individual prescribers. Additionally, the aggregate prescription information must be expressed in a way that is conducive to computational measurement of adherence. This paper reports the results of a pilot survey of prescribed medications aimed at collecting data to support prescription interpretation. Our preliminary results show that the collected data can be used to define mathematical adherence scoring functions to be used in connected ADS systems.

2. Method

An online survey of providers asking participants to describe adherence scenarios for a range of prescription medications was conducted. A sample of participants were recruited through existing professional networks of practicing physicians. Participants were directed to a web survey.

The survey contained demographic and practice questions as well as quantitative questions presented as "adherence scenarios". For each scenario (short patient history, prescription, and medication administration history), participants were asked to indicate the range of time in which the *next* dose of medication should be administered while remaining adherent (compliant) to the prescription. Participants indicated their response using a sliding graphical scale as shown in Figure 2. The previous dose of medication is represented by a black marker (100 mg at 8:00). Participants indicated the earliest time the next dose could be administered using the green marker (~17:00) and the latest time the next dose could be administered using the red marker (~24:00).
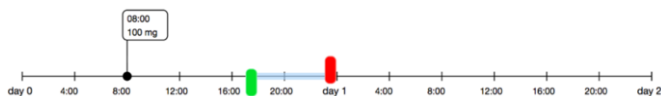
Figure 2. Sample graphical scale used by survey participants to indicate an adherent time range.

A total of ten adherence scenarios were shown to participants (see Table 1). Responses were excluded if they met one of the following criteria: 1) the response range included a previous administration implying a double dose would be compliant, or 2) the response range did not include (within a 10% margin) the expected next administration time based on the original AP. The remaining responses were aggregated to form an "expert consensus" regarding for when the next dose of medication should be administered. The aggregate data were reviewed and validated by three external experts with experience in medications and information systems. The aggregate expert consensus data was manually abstracted into one or more fuzzy functions (based on the mathematical concept of fuzzy sets [6]). This is somewhat analogous to finding a trend line in a linear data set. The resulting fuzzy functions approximate the expert consensus data and are concisely representable for the purposes of computationally computing a compliance measure.

Table 1. Adherence scenario prescriptions presented to survey participants.

Author Prescription	Time of Previous Dose(s)
Nitrofurantoin 100 mg twice daily	8:00
Ramipril 2.5 mg once daily	10:00
Hydromorphone 4 mg every 4 hours as needed	6:00, 10:00, 14:00
Marvelon 1 tablet once daily	9:00
Glargine 10 units at bedtime	22:00
Moxifloxcin 400 mg every 24 hours	12:00
Caphalexin 500 mg four times a day	8:00, 12:00
Warfarin 7mg once daily	9:00
Penicillin V 500 mg three times a day	9:00, 17:00
Hydromorphone Contin 9 mg twice daily and Hydromorphone 4 mg every 4 hours	8:00 (9 mg), 14:00 (4 mg)

3. Results

In total, 73 individuals responded to the survey, however, only 33 participants completed all questions. Most participants (n=66) were resident physicians with remaining participants having less than 5 years of experience (n=3), 5 to 10 years of experience (n=2), and greater than 10 years of experience (n=2). Most participants practiced in a family medicine office (n=59) with the remaining participants practicing in a specialist office (n=4), family medicine in a hospital (n=7), or being a specialist in a hospital (n=3).

Figure 3 shows the aggregate results for two prescriptions and the corresponding fuzzy functions. Other results may be found in [6]. These figures show the percentage (vertical axis) of survey participants whose response range included a time (horizontal axis). This also demonstrate a degree of agreement between participants for each time interval. For example, Figure 3a shows that ~60% of responses indicated that 21:00 is an appropriate time to administer the next dose of Penicillin V given that the previous doses were at 9:00 and 17:00.
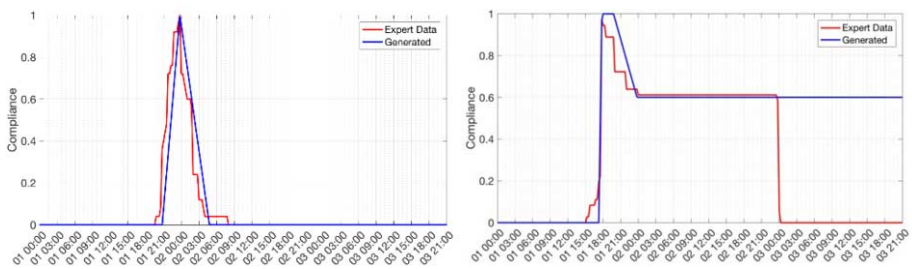
Figure 3. Aggregate results for two prescriptions: a) (left) Penicillin V 500 mg three times a day (prev. doses at 9:00, 17:00), b) (right) Hydromorphone 4 mg every 4 hours as needed (prev. doses at 6:00, 10:00, 14:00).

4. Discussion

This pilot study demonstrates the feasibility of the method as a form of data collection to support an ADS. The pilot study also demonstrates a degree consensus between participants and shows promise for the use of the study methodology to support an AI-

based ADS system. For example, the results shown in Figure 3a can be used to define administration frequency of "three times a day" for a Penicillin V prescription. Specifically, the time between doses should be at least five hours and no more than ten hours, however, the optimal time is between seven and eight hours. While this conclusion may be obvious to a human interpreting the AP, it is important to have an evidenced-based semantic definition of "three times a day" when conducting automated prescription interpretation and measuring compliance. Further, there appears to be variation in the curves based on the medication class. This would not be evident if considering only prescription dose frequency (e.g. twice a day) or medication half-lives.

Developing an ADS system using this approach would require a considerable amount of expert consensus data. However, an appropriate information architecture can be used to reduce the amount of data required. Archetypes of different aspects of prescriptions can be created and studied individually and then combined to during prescription interpretation. For example, the data in Figure 3a can be used to derive for timing of antibiotic administration. Other archetypes might consider relationships to meal times or bed times. Crowd sourcing data collection allows this method to scale.

This study was intended as a pilot survey to determine the feasibility of obtaining expert consensus data to support ADS systems. As such, there are some weaknesses in the methodology that should be addressed prior to a full-scale survey. First, participants were not screened to determine if they were in fact practicing physicians; this was mitigated to some extent by only circulating the invitation to private online communities. Second, an online survey does not allow the researchers to ensure participants fully understand the requested task, therefore, some responses might not accurate; the exclusion criteria were created to address this concern. Finally, since this data collection method is novel, it is not clear how to standard statistical methods to assess the power of the results can be applied, future work should explore alternative statistical methods.

5. Conclusion

This pilot study of practicing physicians explored the viability of collecting expert consensus data to support AI-based ADS systems. The results indicate that larger scale surveys, with minor methodological changes, could provide meaningful inputs to an automated prescription interpretation process in an ADS aimed at improving patient's day-to-day medication adherence.

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FHIRForm: An Open-Source Framework for the Management of Electronic Forms in Healthcare

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Abstract. Electronic Forms (E-Forms) for data capture are vital for most health information systems in public health and clinical research. Standardized electronic forms ensure accurate data collection, consistent form rendering, easy maintainability, and interoperability. Adopting an innovation research method we explore the challenges of standardized data capture in healthcare and offer a pragmatic solution. We appraise existing standards and software to propose the list of requirements for an ideal E-form framework. Our proposed solution leverages FHIR specification and existing open-source software tools. We discuss how our open-source solution can be extended collaboratively and discuss its value using InterRAI instruments as examples.

Keywords. E-Form, FHIR, InterRAI

1. Introduction

Electronic forms (hereafter E-Forms) remain the standard method to acquire user entered data in health information systems (HIS). E-Forms are vital for clinical research (case report forms) [1], order sets for patient management [2] and public health [3]. It is common for healthcare organizations to realize after expensive HIS installations that a comprehensive system for end-to-end data management from data collection to analytics is challenging to implement. An end-to-end form-based data capture and analytics is important for public health and clinical research organizations that have unique data management requirements. The standardization of the content, structure, and workflow enable effective sharing of E-Form assets between these organizations in a system independent manner.

There is a growing emphasis on deriving knowledge from patient data that requires the application of knowledge management principles and frameworks. In this paper, we apply the innovation action research method [4] to the problem of structured health data

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capture. First, we review some of the commonly used standards and frameworks in this domain. Next, we propose a list of requirements for an ideal E-Form framework.

This is followed by a description of a novel framework and its instantiation using existing standards and open-source tools. Then we describe a potential value of our solution using InterRAI [5] as an example. Finally, we briefly evaluate our solution as a software artifact.

2. Existing standards and solutions

There are several standards for semantic data collection in healthcare. The ISO 13606 standard is a two-level modelling approach for semantic interoperability [6]. It segregates information level (represented by the reference model) from the knowledge level, (represented by the archetype model) [7]. The advantages of ISO 13606 include a formal definition of clinical data structure, simplified terminologies and scalability [8]. The openEHR specification [9] is an extension of ISO 13606 with a focus on content. In addition to the reference model and the archetype formalism defined as restrictions on the reference model shared with ISO 13606, openEHR defines an archetype query language, service models, and APIs.

The Multilevel Healthcare Information Modeling (MLHIM) [10] Specifications extends on the multi-level modelling approach introduced by openEHR. In MLHIM, Reference and Data Models are represented in the traditional XML Schema Definition format. Since data models allow the creation of data instances that need to be valid in perpetuity, they are immutable and unique, ensuring data validity of longitudinal records. MLHIM uses RDF within the XML schema in a unique way to define the semantics that provides semantic interoperability [11].

Next, we describe existing software solutions for semantic data capture and manipulation.

The Clinical Knowledge Manager (CKM) is the repository management system for openEHR [12]. It is a Web 2.0 tool that supports the online collaboration of domain experts to create and publish archetypes. The ADL Workbench is a tool for manipulating the archetypes and templates written in the Archetype Definition Language (ADL). It can reference any model such as openEHR and ISO 13606 [13].

Research Electronic Data Capture (REDCap) is a web application for building and managing online surveys and databases mostly for research studies [14]. REDCap supports data entry, data validation and export/import operations, and has a shared repository of data collection forms. Open Data Kit (ODK) is an open-source solution for data collection using mobile platforms. It is designed to be useful in resource-constrained areas with poor connectivity, by saving submissions locally before syncing them with the server [15].

Existing standards focus on structure, content and semantics but not on form presentation and rendering. The lack of a suitable standard made most health information systems rely on proprietary standards for form management. In the next section, we discuss the list of requirements that we consider important for an ideal E-Form framework based on our experience and a review of the above standards.

3. Characteristics of an ideal E-Form framework

An ideal E-Form framework should have the following features:

1. A centralized repository is needed for hosting E-Forms. The vendor systemsshould retrieve the forms in real-time from the repository. This would allow Eform maintainers to update forms and push the changes efficiently to downstream systems.
2. The E-Forms should ensure semantic interoperability so that E-Forms can beshared across health service providers (HSP) seamlessly. This will also enhance cooperation between analytic teams.
3. Form elements should be maintained independently and shared across forms forconsistency and ease of maintenance.
4. The forms should be rendered consistently with enough information incorporatedin the E-Form to facilitate accurate rendering.
5. The form submissions should be standardized so that the information can be submitted to various systems simultaneously. This would ensure accurate data collection at various levels.
6. The E-Forms should support procedural logic so that the rendering system canperform calculations and implement hide/show of elements.
7. The E-Forms should ensure patient safety.
8. The rendering engine should be generic enough to be easily incorporated into anyHIS.

In the next section, we describe how we used existing standards and open-source tools to propose a software instantiation.

4. Approach

We adopted Fast Healthcare Interoperability Resources (FHIR) as the standard for representing form structure and content. FHIR resources were chosen based on their support for 80% of common use cases. Extensions can be used to bridge the gap for the remaining 20%. FHIR has been successfully used for a variety of use cases outside of conventional interoperability such as exchange of clinical study data [16].

We propose a software framework for E-Form management, using FHIR specification and open-source tools for editing, serving and rendering E-Forms. *FHIRForm* is an FHIR Questionnaire including extensions for managing form related procedural logic. The E-Form components are independently managed as FHIR DataElements that are injected into the Questionnaire. The FHIRForm framework (Figure 1) is a software stack for managing E-Form workflow with the following components.

1. A FHIR server.
2. A FHIR resource editor.
3. A FHIR client that can render the FHIR Questionnaire as a web form.
4. FHIR Extensions and other resources.

The FHIR server is a Spring-Boot application based on University Health Network's HAPI-FHIR Server, available as open-source[17]. The FHIR resource editor (FRED)

[18] is an open source web application that enables users to edit JSON FHIR resources and FHIR bundles. We have improvised and integrated it into the FHIR server so that FRED is served by the same server instance and can directly edit FHIR resources on the
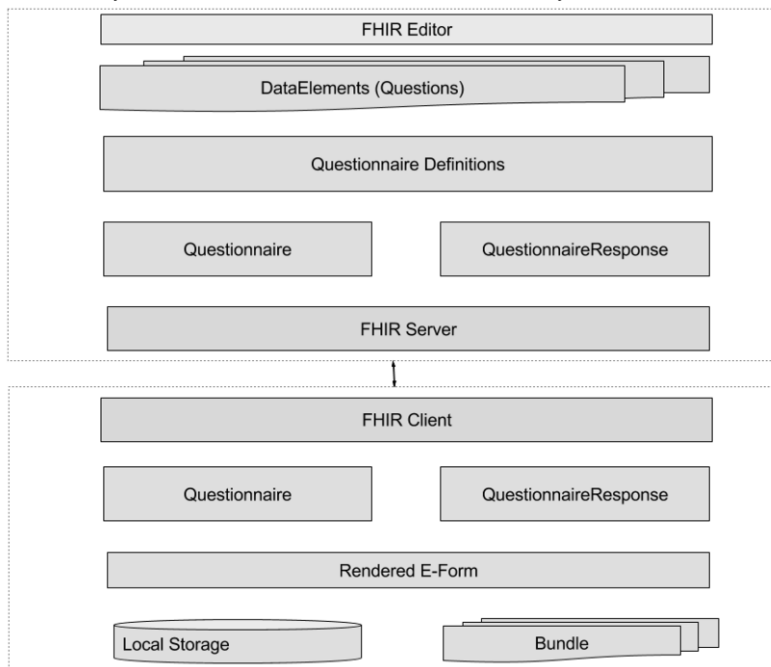
Figure 1. FHIRForm Framework

server. The FHIR client application is a generic rendering engine that can be incorporated into other web frameworks [19].

The FHIRForm framework is open-source for collaborative development [20]. In the next section, we describe a typical use case of our FHIRForm framework.

5. Use case

InterRAI [5] is an international collaboration of researchers that strives to standardize the collection and interpretation of high-quality health data. In addition to data collection forms, InterRAI instruments have outcome measures, assessment protocols, casemix algorithms, and quality indicators. Though InterRAI does not propose a well-defined content representation and presentation standard, its forms have a consistent organization. Each data point is defined separately and incorporated into semantic blocks that are shared across forms. InterRAI tests and certifies vendor implementations of data collection software. Unfortunately, its overlap with other assessment and registration forms such as patient demographic data leads to double data entry [21].

The FHIRForm framework would enable InterRAI to improve the maintainability of their instruments and to make the testing of tools more efficient. The individual items in each instrument could be maintained as FHIR DataElements that can be injected into an E-Form at the time of the request. The paper forms could be discontinued, and the vendors with credentials could access the instruments from the server. The data collected

can be submitted to any FHIR compliant system as a QuestionnaireResponse resource. InterRAI has scales and algorithms associated with its instruments that require specific handling [22]. Customized FHIR extensions may be necessary to handle the specialized rendering of scales and algorithms.

6. Discussion

End to end solutions for E-Form management do not exist, leading to different standards and proprietary frameworks that cause interoperability problems. Data collection forms in healthcare may require embedded procedural logic [23] for functions such as hiding, disabling or showing parts of a form based on the response received for a previous field, calculating scores based on responses, and displaying alerts. The XML and JSON used in a FHIR resource can be used to define procedural logics with extensions. The two commonly used procedural logic used in healthcare forms are the *IF..THEN..ELSE* logic. This requires logical gates such as *OR* and *AND* and operators such as *'Equals'*, *'Lesser than'* and *'Greater than'* as described by Bethke et al [24].

The transformation of data-centric decision making to knowledge-centric decision making requires a common data model (CDM) for data aggregation. We are currently working towards adopting The Observational Medical Outcomes Partnership (OMOP) CDM for data persistence. The OMOP CDM is supported by observational health data sciences and informatics (OHDSI) with a set of data visualization and analytics tools [25].

Finally, we use Hevner's design science research guidelines [26] for the preliminary assessment of the software artifact that we created. The outcome of our research is a prototype software stack for E-Form management (design as an artifact) to mitigate current inefficiencies (problem relevance). Design evaluation is based on structural and functional testing of our software according to a typical use case. Our predominant research contributions are requirements analysis of the ideal E-Form framework and the linking of existing open-source software into a framework. Our design involved searching the existing standards and software systems to ensure research rigor. Communication of research is important in Hevner's guidelines and innovation action research [4]. Our results are relevant to both clinical-oriented and technology-oriented audiences.

We propose a pragmatic framework for the end to end management of electronic forms in healthcare. The framework leverages existing open-source software and standards to realize a cost-effective and efficient solution to create, maintain and share forms. Data collected using this framework ensures semantic aggregation and sharing at various levels. The work on the rendering engine is still in progress, and we seek help and guidance on this topic from the open-source community.

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Death: The Simple Clinical Trial Endpoint

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Abstract. Death, as a biological phenomenon, is well understood and a commonly employed endpoint for clinical trials. However, death identification and adjudication may be difficult for pragmatic clinical trials (PCT) that rely upon electronic health record and patient reported data. We propose a novel death identification and verification approach that is being used in the ToRsemide compArisoN with furoSemide FOR Management of Heart Failure (TRANSFORM-HF) PCT. We describe our hybrid approach that includes gathering information from clinical trial sites, a centralized call center, and National Death Index searches. Our methods detail how a possible death is triggered from each of these components and the types of information we require to verify a triggered death. Our different trigger / verification elements collectively define the TRANSFORM-HF PCT's definition of a death event. .

Keywords. clinical trial, death, heart failure, national death index

1. Introduction

Delaying death by administering therapeutic interventions is a major clinical research objective. Clinical trial investigators select death as both a safety and efficacy endpoint because it is objectively measurable and serves as the ultimate test for new therapies.[1-3] However, death identification and adjudication processes can be quite different for explanatory trials (conducted in an idealized setting that gives the intervention the best chance to demonstrate benefit) and pragmatic trials (conducted in real-world settings to determine whether the intervention will have benefit in actual practice).[4] In traditional explanatory trials, sites typically are responsible for identifying study subject deaths, and a centralized Clinical Events Committee adjudicates the types of death. However, death identification and adjudication may be more complicated for pragmatic clinical trials (PCTs) that rely upon patient data collected for other purposes (e.g., from the electronic health record [EHR] as part of routine care or claims processing) or data collected from patients (e.g., directly by patient report or indirectly from patient devices). If these are the only PCT data sources, unless a patient dies during a health care encounter, their death data are not routinely available to a PCT.

Explanatory clinical trial investigators typically learn about a patient death when the patient cannot be contacted and a study coordinator contacts a proxy to schedule a study visit or when the study coordinator searches the internet to determine the patient's current

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location. In addition, there is no timely and comprehensive national death database in the United States (US) that easily can be linked with EHR records. We propose a novel death identification and verification approach that is being used in the ToRsemide compArisoN with furoSemide FOR Management of Heart Failure (TRANSFORM-HF) PCT: funded by the National Heart, Lung, and Blood Institute (U01HL125511-01A1), registered with ClinicalTrials.gov (NCT03296813), and approved by the Duke University Medical Center Institutional Review Board (Pro00080595).

2. TRANSFORM-HF – Study Description

TRANSFORM-HF is a randomized, unblinded, two-arm, multi-center PCT of patients hospitalized for new or worsening heart failure. Approximately 6000 patients will be enrolled at approximately 50 US Study Sites and we expect to observe more than 721 death events. Enrolled patients are randomized in a 1:1 allocation ratio to either oral torsemide OR oral furosemide and receive a prescription for one of these oral loop diuretics prior to index hospitalization discharge. Post-discharge data collection is performed by the Duke Clinical Research Institute's (DCRI) Call Center using a centralized follow-up procedure. There are no in-person study-specific patient follow-up visits. The full details on disease background and eligibility are described in the clinical study protocol.[5]

3. Death Event Ascertainment

All-cause mortality (defined as death after randomization) is the TRANSFORM-HF primary endpoint. Enrolling Study Sites are responsible for ascertaining patient deaths occurring during the index hospitalization period, and the DCRI Call Center is responsible for patient death ascertainment during the follow-up period. Because patient death ascertainment may be imprecise using these methods alone, TRANSFORM-HF also will rely upon National Death Index searches as a secondary source for patient death information.

3.1. Site Ascertainment

If a TRANSFORM-HF patient dies during their index admission, the Study Site is responsible for triggering and verifying the death event. This occurs by entering patient death information into the trial's electronic case report form (eCRF). The Site then sends a copy of the patient's discharge summary to the DCRI Call Center. The discharge summary will note the patient's discharge status as expired (see Figure 1).

3.2. Call Center Ascertainment

The DCRI Call Center will conduct follow-up interviews with patients at 30-days, 6-months, and 12-months following randomization. All patients will be followed for a minimum of 12 months. Patients enrolled early in the course of the trial will have extended follow-up, up to 30 months for the first 500 patients.

If the call center cannot reach a patient to schedule an interview, they will follow the steps outlined in Figure 1 to determine the patient's vital status. This is a two-phase process during which the call center first obtains information (a trigger) that a patient death may have occurred. During the second phase (verification), the call center obtains source documents to verify that a patient death has occurred. If a source document cannot be obtained, the patient is considered an unconfirmed death.
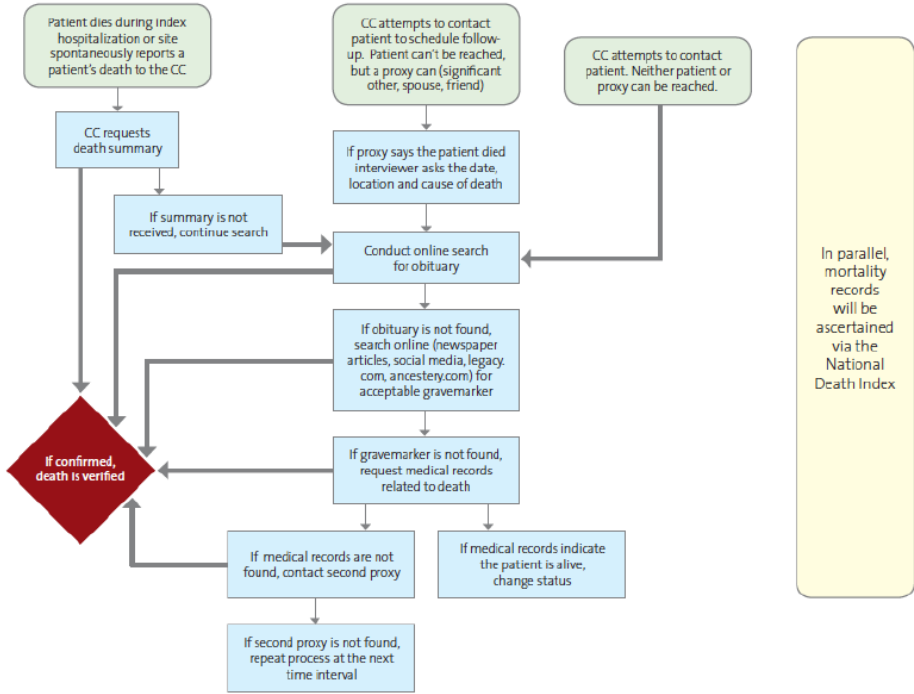
Figure 1. Study Site and Call Center Death Ascertainment.

TRANSFORM-HF patients complete Medical Release and Patient Contact forms during their enrollment. In the Patient Contact form, patients list their personal contact information plus that of spouses and friends or relatives not living with them who may be contacted as a proxy in their absence. If a proxy says the patient has died, this serves to trigger the death verification process for that patient. If proxies cannot be contacted to verify the patient's vital status, the DCRI Call Center will conduct online searches. Sources for online searches include: ancestry.com, legacy.com, obituaries, newspaper articles, and social media. Lastly, the DCRI Call Center may contact the medical records/release of information (ROI) department at the patient's enrolling hospital or other hospitals the patient has visited to obtain a death/discharge summary; the billing offices at those hospitals to obtain billing records; or request patient charts from their primary care provider or other healthcare providers. Because the Call Center's processes may not identify all patient deaths, the study team is using the National Death Index (NDI) as a secondary information source to improve death event data capture.

3.3. National Death Index Ascertainment

The Centers for Disease Control and Prevention National Center for Health Statistics (NCHS) contracts with state vital statistics offices to receive and compile annual death registries in the NDI, a centralized database of all US deaths. The NCHS only allows use of the NDI for public health and health policy research. Unlike the other death data sources (e.g., Social Security Administration's Death Master File, Medicare Master Beneficiary Summary File, or individual state vital statistics), all US jurisdictions report all deaths to the NCHS, which makes the NDI the most complete death data set available in the US today. The implication is that NDI deaths are actual deaths and the absence of an NDI death means that a patient may be considered alive at the end of the reporting year. This distinction becomes important when determining a study subject's last known status (i.e., dead or alive).

An early release file is made available when approximately 90% of the (previous) year's death records have been received and processed. At present time, this file typically is available in late January or early February and is considered preliminary. The final file reflects "all" of the (previous) year's death records. This file is usually available in late October or early November. The final file is static and is rarely modified. Extensive information regarding user fees, file specifications, and details on the NDI matching methodology are provided in the NDI Users Guide.[6] TRANSFORM-HF plans to conduct annual NDI final file searches in the first two study years and will conduct early release file and final file searches in later years when the total number of death events is greater.

4. Death Event Verification

In TRANSFORM-HF, all deaths must be verified before they are counted as death events for the study. The study team has defined specific procedures for DCRI Call Center, NDI search, and Study Site death verification (see Figures 1 and 2). In order to gain information on the number of mortality events that are yielded from the different methodologies—and a better understanding regarding the timing and agreement between them—the NDI searches will be conducted as a parallel procedure to the DCRI Call Center processes.

4.1. DCRI Call Center Death Verification

The DCRI Call Center triggers the death verification process through four routes: proxy interviews, online searches, medical record searches, and notifications from enrolling Study Sites. Proxy interviews are the primary means by which the DCRI Call Center first learns about a patient death.

The DCRI Call Center will attempt to obtain verification for all triggered events. Acceptable verification includes: an obituary or grave marker, second proxy confirming the patient's death, or medical records documenting the death. An acceptable obituary/grave marker must include a first name, last name, middle initial (when applicable), and date of birth that matches information entered for the patient at enrollment. Age may be substituted when the obituary/grave marker does not include the date of birth, but only when the patient's state of residence matches as an additional criterion. Finally, an NDI search containing the patient's death information may be used

as sole verification of a death event triggered by the Call Center when other verification methods are unsuccessful.

	Verification Status					
Initial Source/Trigger	**Yes**				**No**	**Total**
	Obituary or Grave Marker	**2nd Proxy**	**Medical Record**	**NDI**		
Proxy interview	n	n	n	n	n	n
Online search	n	n	n	n	n	n
Medical record search	NA	NA	n	NA	NA	n
Enrolling site	n	n	n	n	n	n
National Death Index (NDI)	NA	NA	NA	n	NA	n
Total	n	n	n	n	n	n

Figure 2. Death Triggers and Verification Methods.

4.2. National Death Index Death Verification

Researchers submit study records for NDI searches in specific record formats using the NCHS's coding structures. Three combinations of data elements are accepted: (1) Social Security Number (SSN), sex, full date of birth; (2) Last name, first initial, month of birth, year of birth; and (3) Last name, first initial, SSN. Additional data elements may be submitted to increase the likelihood of a true match including the following: middle initial, father's surname, state of birth, state of residence, marital status, and race (using NCHS race categories).

NDI search results are returned to researchers via output files. The NDI process first searches for possible matches using seven criteria. If any criteria are met, the death record is selected as a possible match. Next, each selected record is scored and classified into one of 5 groups to aid researchers in determining whether any selected record is a true match.

The TRANSFORM-HF study team plans to narrow down the possible matches to the best single match and use the NDI suggested algorithm for determining whether the selected record is a true match with an enrolled patient. There may be cases where the NDI information is the only source for the mortality event, and therefore serves as both the trigger source and verification.

4.3. Study Site Death Verification

As stated above, Study Sites are responsible for identifying and verifying deaths occurring during the index hospitalization. These deaths are verified by sending a copy of the patient's death/discharge summary to the DCRI Call Center. Although less frequent, Study Sites may also voluntarily notify the TRANSFORM-HF study team that a patient has died after discharge. In these instances the DCRI Call Center will utilize the procedures described above to verify the death.

4.4. Mortality Review Committee

The TRANSFORM-HF Mortality Review Committee is comprised of clinicians and representatives from the DCRI Call Center and statistical team. This committee's primary purpose is to review cases where there appears to be conflicting data that calls into question the reliability of data from another source (e.g., last known date alive).

5. Limitations

We acknowledge several limitations to our methods. First, we do not adjudicate type of death. Second, the Call Center's procedures depend upon information supplied on patient contact forms. If that information is incomplete or changes, follow-up may become difficult. Third, we do not know the extent to which missing data will impact our NDI search results. Nonetheless, we believe our procedures improve upon current death identification and verification processes used in explanatory and pragmatic trials.

6. Conclusion

As PCTs work to streamline trial data collection and infrastructure and minimize burden on site investigators and patients, robust and accurate means of capturing death events are needed. We propose a hybrid solution that involves Study Sites, a centralized Call Center procedure, and NDI searches. Through this process, we have described what constitutes a death event for the TRANSFORM-HF PCT. Other studies may use different death event definitions. However, it is important to clearly define this endpoint before patients are enrolled. We recommend that PCT sponsors and investigators convene an international study group to determine how mortality will be defined and measured in PCTs.

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Estimating Clinical Trial Bleeding Events Using Electronic Health Record Data

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Abstract. Clinical trials conducted for regulatory approval may include outcomes that are informative but not routinely collected in clinical practice. This situation can be problematic when pragmatic clinical trials (PCT) seek to use electronic health record (EHR) data to test the effectiveness of medical products and services in actual practice settings. We use TIMI bleeding events to illustrate how a complex clinical trial endpoint can be implemented using EHR data. While we were able to demonstrate that our EHR-defined bleeding events were associated with differences in patient clinical outcomes, we are not confident that these measurements could be replicated in other locations with consistent reliability and validity. We believe the development of PCT endpoint definitions is an important issue that should be addressed by medical and informatics professional societies, regulators and the medical products industry.

Keywords. clinical trial, electronic health record, endpoint major bleed

1. Introduction

Pragmatic clinical trials have been proposed as a means for testing the effectiveness of medical products and services in actual practice settings.[1] However, clinical trials conducted for regulatory approval may include outcomes that are informative but not routinely collected in clinical practice. This situation can be problematic when pragmatic clinical trials seek to use electronic health record (EHR) data. This paper uses patient bleeding events to illustrate this issue and the problems it creates.

2. Bleeding Classification

Contemporary treatment for acute coronary syndromes (ACS), myocardial infarction or unstable angina, typically includes anti-thrombotic therapies that reduce the likelihood of a subsequent heart attack or stroke, but increase the risk of bleeding complications. [2] Because blood volume loss is not measured directly, clinical trials rely upon surrogate measures that typically use either laboratory criteria that approximate blood loss volume or clinical criteria that describe blood loss diagnosis and treatment.[3] For example, TIMI bleeding classifications emphasize laboratory criteria; whereas, GUSTO bleeding classifications emphasize clinical criteria.

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Previous research has demonstrated that data phenotypes derived from EHR diagnosis and procedure codes have limited ability to identify serious bleeding events.[4] We took an alternative approach and implemented TIMI bleeding classification definitions using actual EHR data. We then estimated the associations between index hospitalization bleeding event severity and subsequent clinical events at 24 months follow-up. The Duke University Medical Center (DUMC) Institutional Review Board approved this project with a waiver of informed consent (Protocol ID: Pro00016034).

3. Methods

3.1. Study Population

This study's population included consecutive patients with ACS undergoing percutaneous coronary intervention (PCI) procedures at Duke University Medical Center (DUMC) between June 2002 and December 2008. Patients were included if they had an ACS diagnosis (ST segment elevation myocardial infarction [STEMI]; non-ST-segment elevation myocardial infarction [NSTEMI], or unstable angina [UA]) and significant CAD ($\geq$ 75% stenosis in $\geq$ 1 epicardial segment). Patients were excluded if this was not their first PCI during the study periods or they had significant ($\geq$ 75% stenosis) left main CAD, congenital heart disease, or moderate or severe valvular heart disease.

3.2. Data Collection

Index PCI Procedure: The Duke Databank for Cardiovascular Disease (DDCD) was the primary source for baseline demographic, medical history, physical examination, catheterization, and hospitalization administrative data.[5-7] We defined three categories of ACS (STEMI, NSTEMI, and UA) using a hierarchical approach based upon *International Classification of Diseases*, 9th Edition, Clinical Modification (ICD-9-CM) codes collected in the DDCD and its associated administrative databases. DUMC's laboratory reporting database was the source for hemoglobin concentration (g/dl) and hematocrit test (%) results. Blood product usage information (number of transfusions) was obtained from the Duke Blood Bank.

TIMI Bleeding Event: We identified TIMI bleeding events using information obtained during a time window beginning at 30 days before the patient's index PCI admission and ending at that admission's discharge date. Major bleed was defined as: (a) an absolute decrease of $\geq$5g/dl for hemoglobin concentration; or (b) an absolute decrease of $\geq$15 % for hematocrit; or (c) an intracranial hemorrhage (ICD-9 diagnosis code 430-432). Minor bleed was defined as: (a) an absolute decrease of $\geq$3g/dl for hemoglobin concentration or (b) an absolute decrease of $\geq$ 10% for hematocrit. Both bleeding definitions were adjusted to account for transfusions. If a patient received 1 unit of red blood cells during the time window and that unit was before the 2nd laboratory value, we subtracted 3g/dl from hemoglobin concentration and 9% hematocrit from the 2nd value to adjust for the transfusion.

Follow-Up Clinical Events: The DDCD and DUMC administrative systems were sources for follow-up clinical event data.[8] Follow-up clinical events used in this study included: all-cause mortality, all cause readmission, and readmissions for bleeding. Death events were identified through the DDCD follow-up protocol and confirmed by

an independent physician mortality committee. However, readmission information was available only for DUHS. Readmissions were identified through administrative databases using the ICD-9-CM coding to identify bleeding events.

3.3. Statistical Analyses

Reporting of baseline characteristics and index hospitalization resource use is organized by TIMI bleeding event type (major, minor, and no bleeding event) within ACS type (STEMI, NSTEMI, and UA). Values for baseline characteristics and index hospitalization resource use are summarized as mean (standard deviation) for continuous variables and as percentages for categorical variables.

Follow-up period clinical event rates by index hospitalization bleeding event type were estimated using the Kaplan-Meier method. We used Cox proportional hazards models to estimate unadjusted and ACS-type adjusted hazard ratios comparing bleeding event types for all-cause mortality, all-cause readmission and readmission for bleeding.

4. Results

4.1. Study Population

Between June 2002 and December 2008, 3927 patients met our study's inclusion / exclusion criteria. We further excluded 802 patients: 236 with index hospitalization surgical procedures that may require transfusion, 335 with no laboratory data to determine bleeding events and 231 with limited economic data for use in another study (n=231). This resulted in 3125 patients being included in the present study.

Table 1 Patients by Acute Coronary Syndrome Group

TIMI Bleed Group	STEMI (n=1046)			NSTEMI (n=931)			Unstable Angina (n=1148)		
	Major 6%	Minor 15%	No 79%	Major 3%	Minor 8%	No 89%	Major 2%	Minor 4%	No 95%
Patient Characteristic									
Female	56	39	27	58	57	36	39	63	36
Age*	63(15)	62(13)	58(13)	65(14)	68(13)	62(12)	67(12)	68(12)	63(12)
Smoking	33	33	44	45	37	49	67	41	51
Diabetes	17	19	17	36	54	29	33	39	33
Hypertension	61	58	53	82	72	68	94	78	74
Heart Failure	1	8	3	33	26	12	28	17	16
Prior PCI	5	5	6	12	13	9	17	10	17
Prior CABG	3	5	4	15	19	19	11	22	29
Resource Use									
Total LOS*	10(8)	6(7)	4(2)	13(10)	8(6)	4(3)	9(7)	6(4)	3(3)
ICU LOS*	5(6)	3(4)	1(1)	6(7)	3(5)	1(1)	1(2)	1(2)	0(1)
Transfusions*	5(3)	3(1)	2(0)	6(4)	3(1)	2(0)	4(3)	3(1)	2(1)
Pacemaker	15	8	3	1	1	1	6	0	1

*mean(standard deviation), age is in years and LOS is in days.

4.2. Patient Characteristics and Resource Use

The percent of patients with bleeding events (major or minor) nearly doubled from UA (5.1%) to NSTEMI (11.3%) and again from NSTEMI to STEMI (21.0%) with a third of bleeding events being major for each ACS type (Table 1). Most differences in patient characteristics were associated with ACS type rather than bleeding type. Patients with STEMI tended to be younger and had a lower cardiac risk factor profile and fewer CAD procedures. Length of stay (LOS) and transfusion use increased with the severity of bleeding in all ACS types (Table 1).

4.3. Patient Outcomes

Half of this study's patients were readmitted by 24 months follow-up (40.2% at 12 months and 50.2% at 24 months); whereas, death (5.8% at 12 months and 9.2% at 24 months) and bleeding admissions (2.8% at 12 months and 4.1% at 24 months) were less frequent. Having an index hospitalization major or minor bleeding event was associated with worse outcomes through 24 months follow-up and this difference was more severe for patients with major versus minor bleeds.

Table 2 Patients Outcomes by Bleeding Group

	KM % (Events)		Unadjusted		Adjusted	
	12 Months	24 Months	HR (95% CI)	p-value	HR (95% CI)	p-value
Deaths	5.8 (177)	9.2 (283)				
No bleed	5.2 (142)	8.3 (226)	1.00		1.00	
Minor bleed	8.4 (21)	14.5 (36)	1.49 (1.18 – 1.88)	<0.01	1.62 (1.28 – 2.06)	<0.01
Major bleed	13.7(12)	20.6 (21)	1.91 (1.38 – 2.66)		2.02 (1.45 – 2.81)	
Readmit	40.2 (1215)	50.2 (1507)				
No bleed	38.9 (1043)	49.2 (1311)	1.00		1.00	
Minor bleed	45.2 (110)	53.2 (128)	1.13 (0.94 – 1.36)	<0.01	1.28 (1.06 – 1.53)	<0.01
Major bleed	63.1 (62)	69.5 (68)	1.95 (1.530 – 2.49)		2.16 (1.69 – 2.76)	
Bleeding	2.8 (84)	4.1 (122)				
No bleed	2.4 (64)	3.7 (96)	1.00		1.00	
Minor bleed	4.6 (11)	6.9 (16)	1.89 (1.11 – 3.20)	<0.01	1.87 (1.09 – 3.22)	<0.01
Major bleed	9.4 (9)	10.5 (10)	3.02 (1.57 – 5.80)		3.00 (1.55 – 5.79)	

5. Discussion

In this study, we implemented TIMI major and minor bleeding definitions using EHR data from a single health care system. We then demonstrated that these bleeding categories were associated with differences in major clinical events at 12 and 24 months follow-up. These results are what would be expected with a successful bleeding category implementation. However, we also encountered local data management issues related to the presence and timing of laboratory values, and the lack of detailed follow-up data for clinical events occurring at other hospitals. We found that the paired hemoglobin / hematocrit laboratory values required to detect changes and identify TIMI bleeding

events were not always available in our EHR. Some patients had none of these laboratory values during the study period and were excluded from our analyses. Other patients had only one of the laboratory values. We decided to include these patients under the assumption that the baseline laboratory values were obtained at another institution and were not entered into the EHR. We also excluded patients undergoing surgical procedures for which transfusions would be common. Our rationale was that we would not be able to determine whether a patient received a transfusion as a complication of their ACS or because of the surgical procedure. We do not know the extent to which our laboratory value assumptions were valid. Lastly, we used transfusion data to adjust observed changes in hemoglobin / hematocrit laboratory values. Our blood bank database did not contain the date the transfusion was administered. Hence, we assumed the date the transfusion was issued from the blood bank was the date of administration, a reasonable assumption given the short time between removal from controlled temperature storage and administration. Our hospitalization data also had limitations. Our EHR collected complete data on death, myocardial infarction, and revascularizations occurring at DUHS and other hospitals. However, data for other readmission types was only available for DUHS hospitalizations. Hence, our all-cause and bleeding hospitalization estimates should be considered as lower bounds for these events' actual occurrence.

Bleeding complications are important indicators of future clinical events and are relevant outcomes for both explanatory and pragmatic clinical trials. Unfortunately, the recent Bleeding Academic Research Consortium (BARC) bleeding categories recommended for explanatory clinical trials would be more difficult to implement than TIMI bleeding categories using EHR data.[9] Two solutions have been proposed: (1) adopt a common cardiovascular data model that incorporates robust bleeding event definitions or (2) use separate bleeding event definitions for explanatory and pragmatic clinical trials. The HL7 Cardiovascular Domain Analysis Model (CV DAM) has been endorsed by the US Food and Drug Administration and is being use in medical society registries. The widespread adoption of this model would enhance the likelihood that sites were collecting the correct data and would make it easier to pool data across multiple sites. However, it would be difficult to enforce conformance to this model at sites not participating in these registries. Another option would be to use transfusions as a surrogate for bleeding events? Transfusions have been shown to be an important indicator in clinical practice and have been included as a component in previous bleeding definitions. Transfusions could easily be tracked using EHR data and could serve as a marker for minor bleeding events. The issue is capturing the elements that would comprise a major vs. minor or no bleeding event. Clearly, this is an important matter that should not be left to informatics professionals alone to resolve. Whether major bleeding events can be described solely by EHR data or whether additional information from clinical site physicians will be required is a matter for future research.

6. Conclusion

As PCTs work to streamline trial data collection, care must be taken to assure that appropriate endpoint data are captured. While EHRs can be of assistance, we have demonstrated that implementation of a common explanatory trial endpoint becomes a complex process when using EHR data. We believe that the development of PCT

endpoint definitions is an important issue that should be addressed jointly by medical and informatics professional societies, regulators and the medical products industry.

7. Disclosure

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Insight into Health Care Outcomes for Persons Living with Heart Failure Using Health Data Analytics

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Abstract. The Integrated Funding Model (IFM) is designed to measure the impact of a bundled model of health care for patients with Congestive Heart Failure (CHF) for a period of 60 days post discharge. CHF is a primary reason for patient admissions. The goal of this study is to gain insight into the effectiveness of the IFM pathway intervention on health care outcomes for persons living with CHF, using Health data Analytics.

Keywords. Data Analytics, Descriptive Analytics, Business Intelligence, Congestive Heart Failure, CHF, Integrated Funding Model.

1. Introduction

There are 600,000 Canadians living with heart failure and 50,000 Canadians are diagnosed with heart failure each year, with a cost amounting to 2.8 billion dollars a year [1]. In 2013 alone, the cost of hospital admission related to Heart failure in Canada was estimated to be $482 million [2]. The Integrated Funding Model (IFM) is an Ontario funded project designed to measure the impact of a bundled payment and service delivery model of health care for targeted populations of patients for a period of 60 days post discharge from hospital [3].

A medium size hospital in Toronto was selected to lead a 2.5-year project to study a standardized IFM pathway for persons with Congestive Heart Failure (CHF). The pathway begins at admission to hospital and ends 60 days post hospital discharge. In hospital, patients meet a Clinical Care Coordinator who provides a case management service to the patients for 60 days after hospital discharge.

1.1. The Pathway

The 60-day IFM pathway is a community based intervention that encompasses four components: 1) standardized *education modules* provided by one health services agency, 2) an individualized post-discharge Action Plan that guides each CHF patient to titrate their medications in response to early signs of heart failure exacerbation, 3) a hotline to

call a nurse for advice, (4) a Heart Failure Clinic (HFC) follow up within 2 weeks of discharge and urgent access to the HFC as required once the Action Plan has been initiated, and 5) care coordination as provided by a clinical case manager from the time the patient is enrolled in the IFM until they are discharged from the IFM pathway at 60 days post discharge. Besides, at the beginning and end of the 60-day pathway each patient completes a Self-Care of Heart Failure Index (SCHFI) [4-7] that measures patients' perception confidence in managing their chronic disease their and compliance.

The educational modules are six: CHF Zones (daily self-monitoring activities), Action Plan (daily diuretics and dose adjusted diuretics), Diet (low sodium diet), HF (heart failure causes and symptoms, common medications), Activity (activity goals), Advanced Care Planning (ACP) (feelings and emotions). The modules are completed during the 4 first visits to the patient.

1.2. Analytics

Analytics are methods used to analyze structured and unstructured data, the main two types are descriptive and predictive analytics. Descriptive Analytics to analyze existing data to understand what happened in the past, while predictive analytics analyze data to build a model by which we can predict what will (likely) happen in the future [8]. Health data analytics promises particularly performance enhancement [9].

In this paper we will use health descriptive analytics [10], to understand the situation of CHF patients who are following a pathway and gain insight into few of the CHF patients' health care outcomes.

2. Sample

An data warehouse integrates large amount of data from disparate sources across an organization, and is used as a system that drives business intelligence (BI) [11] including reporting and data analysis. Data were retrieved from a mid-size hospital data warehouse in Toronto Canada, and were analyzed to answer the following two questions:
1. Does completion of the educational modules reduce the likelihood of readmission?
2. Is there an improvement in the Self Care of Heart Failure Index measurements at the end of the IFM pathway?

3. Methods

Descriptive Analytics are methods that describe what happened in the past and that can be used by decision makers to improve performance or plan for quality improvement [9]. They rely on retrieving data from a data source (usually a warehouse) and using statistical methods to report about desired indicators. The IFM was implemented on April 1, 2016 and when the project started data were available until September 31, 2017. Since we wanted to compare health care outcomes in the 60-days period prior to admission to the IFM to the 60-days period post-discharge from the IFM, the data were collected for the period between February 1, 2016 and September 31, 2017.This approach allowed us to compare the pre-post periods for all CHF patients discharge from the IFM at or before July 31, 2017.

8 weeks Pathway

Index Event ←——————————————————→ **Discharge Date**

Figure 1. Pathway chart.

3.1. Measures

The Self-Care of Heart Failure Index measures compliance (16 items) and confidence (6 items) using a 4-point Likert type agreement scale.

3.2. Analysis

We conducted descriptive analytics using (1) chi-square test to examine the association between the completion of the IFM educational modules and the likelihood of readmission within the 30 days of discharge and a binary logistic regression to test the association between the number of modules completed and the likelihood of readmission; and (2) a paired-sample t-test to test the change in the pre and post pathway Self-Care Heart Failure Index scores (compliance and confidence).

Age, sex, and LACE score were part of the collected data and were adjusted for in the logistic regression. LACE score is based on the LACE index developed by Walraven et al. [12]; it predicts early death or unplanned readmission after discharge from hospital to the community. The LACE index was named using a simple mnemonic where each letter stands for the first letter of its components, 'length of stay' in the hospital during the current admission, 'acuity of admission', 'comorbidity of patient' and 'emergency department use'. 'Length of stay' refers to patients' length of stay in his/her current admission. 'Acuity of the admission' is defined in a binary manner – the admission being acute if unplanned and not acute otherwise. 'Comorbidity of the patient' is measured using the Charlson comorbidity index score[13].

4. Results

In total, 61 CHF patients were enrolled in the IFM and 645 were non-enrolled. Female patients represented 54.1% of the sample, 11(1.6%) patients were 20 to 48 years of age, 43(6.1%) patients were 49 to 64 years, 90(12.7%) were 65 to 74 years, 178(25.2%) were 75 to 84 years, 303(42.9%) were 85 to 94 years and 81(11.5%) were 95 years and above.

There was no significant relationship between the completion of the two education modules deemed to be the most important modules for helping patients manage their condition (Action Plan Module and HF Zone Module) and the likelihood of patients' readmission within the next 30 days of discharge (chi-square = 1.13, df=1, p=.29 for the Action Plan module and chi-square = 0.68, df=2, p=.71 for the HF Zone module).

However, a binary logistic regression was conducted to test whether the number of completed modules predicted readmission. Results found that a higher number of completed modules was significantly associated with reduction in readmission, Chi-Square (6) =17.19, p<0.05.

Controlling for age, sex, LACE score (i.e. a measure of the risk of readmission) on admission and pathway stream, patients who completed 3 to 4 modules are about 11 times more likely not to be readmitted than the patients who completed 0 to 2 modules. For patients who completed 5 or 6 modules, the likelihood increases to 35 times.

Both Self Care of Heart Failure Index measurements, Compliance and Confidence, showed a significant enhancement between the beginning and end of the IFM pathway (t=-8.99, p<0.001 and t=-4.84, p<0.001 respectively). The average patient confidence increased by 27.4% (from 56.41 to 71.87) and the average compliance increased by 50% (from 54.29 to 81.45).

5. Conclusion

The effectiveness of interventions targeting CHF patients is of paramount importance to deliver high quality care; indeed, effectiveness is one of six indispensable quality of care indicators in healthcare services formulated by the Institute of Medicine (IoM) : safety, patient-centeredness, timeliness, efficiency, effectiveness, and equity[14]. This study examined the use of data analytics methods, particularly descriptive analytics, to gain insight into the effect of the IMF pathway intervention on patients' readmission, compliance and confidence.

The preliminary results show that the IFM pathway significantly enhanced patients' confidence and patients' compliance as measured by the Self Care of Heart Failure Index. The results also show a significant association between the number the modules patients complete and the likelihood of their readmission. Plans are underway to test the impact of the pathway using a larger sample.

Health data analytics encompass important methods that allowed us to have insight into health care outcomes for persons living with mid to late stage heart failure. The first results imply the effectiveness of the IFM. More comprehensive data analyses can further contribute to improve program planning and performance.

6. Disclosure

Conflict of Interest: None.

7. Acknowledgment

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ICT-Based Interventions for Women Experiencing Intimate Partner Violence: Research Needs in Usability and Mental Health

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Abstract. The aim of this systematic review is to summarize studies in different settings that used Information and Communication Technologies (ICT) to address intimate partner violence (IPV). We've conducted a systematic review using PRISMA guidelines using the following databases: PubMed, CINAHL, PsycINFO, and Web of Science. Inclusion criteria were ICT-based interventions addressing IPV, focused on women. 21 studies were identified in which ICT was found to be a suitable low-cost option for screening and disclosure of IPV, as well as for preventing IPV. More research is needed to use ICT for prevention and treatment of IPV, taking consideration new ICT environments such as virtual communities.

Keywords. Women, Intimate Partner Violence (IPV), Information Communication Technology (ICT), Virtual Communities, Public Health

1. Introduction

Violence against women (VAW) has been described a "Global Pandemic" by the United Nations (UN News Center, 2014); it is considered both as a human rights (Human Rights Council, 2006) and public health issue (Garcia-Moreno & Watts, 2011). Informatics tools for IPV promotion and prevention are important to take into consideration and use, especially that Information and Communication Technologies (ICT) are expanding their reach in developed and developing countries. This paper presents an analysis of a systematic review of the available literature on the effectiveness of ICT for IPV interventions.

2. Methods

A standard systematic review was conducted employing a digital search of bibliographic databases including PubMed, the National Center for Biotechnology Information (NCBI), PsycINFO, and Web of Science. The literature was systematically screened by titles, abstracts, and by applying key search terms that included ehealth, violence against

women, mobile health, email, online support, technology, computerized intervention, women, intimate partner violence, online, cellphone, web-based, digital, health, information communication technology, computer-based, electronic screening, and domestic violence. We only searched articles that were written in English. Several quantitative studies that addressed ICT use, level of IPV and/or abuse, changes in safety behaviors, depression scores, and level of IPV disclosure by women with past, current, and/or at risk of experiencing partner violence, were eligible for inclusion in the review. The most current search was completed on May 30, 2018.

3. Results

In total, 171 articles were identified among which 72 articles were duplicates. Out of the 99 unique articles 74 were excluded based on the content of their abstracts. After reading the full text of the remaining 25 articles 4 articles were excluded, and 21 articles were maintained for analysis (Ahmad et al., 2009; Bacchus et al., 2016; Braithwaite & Fincham, 2014; Chang et al., 2012; Constantino et al., 2015; Eden et al., 2015; Fincher et al., 2015; Fiorillo, McLean, Pistorello, Hayes, & Follette, 2017; Gilbert et al., 2016; Glass, Eden, Bloom, & Perrin, 2010; Hassija & Gray, 2011; Humphreys, Tsoh, Kohn, & Gerbert, 2011; Koziol-McLain et al., 2018; MacMillan, 2006; Renker & Tonkin, 2007; Rhodes et al., 2006; Rhodes, Lauderdale, He, Howes, & Levinson, 2002; Scribano, Stevens, Marshall, Gleason, & Kelleher, 2011; Sprecher, Muelleman, & Wadman, 2004; Thomas, Miller, Hartshorn, Speck, & Walker, 2005; Trautman, McCarthy, Miller, Campbell, & Kelen, 2007)

Many common themes were similar across articles. Table 1 presents the common themes of focus across the included studies. These themes depict the objectives of the study interventions. ICT was used in 2 articles and 13 articles used ICT for screening and disclosure, while 5 articles assessed the ICT suitability to address IPV. Some articles targeted many objectives; hence, the total number of themes is 21.

Table 1. Common Themes in the Studies

Common Themes	Article
IPV Prevention	(Braithwaite & Fincham, 2014; Gilbert et al., 2016)
Screening and Disclosure	(Ahmad et al., 2009; Bacchus et al., 2016; Chang et al., 2012; Constantino et al., 2015; Gilbert et al., 2016; Humphreys et al., 2011; MacMillan, 2006; Renker & Tonkin, 2007; Rhodes et al., 2006; Rhodes et al., 2002; Scribano et al., 2011; Sprecher et al., 2004; Trautman et al., 2007)
ICT Suitability	(Ahmad et al., 2009; Bacchus et al., 2016; Chang et al., 2012; Fiorillo et al., 2017; MacMillan, 2006)

3.1. IPV Screening and Disclosure: ICT vs paper or face-to-face

In two studies, IPV screening was found to be equally effective using ICT or usual face-to-face/paper method (Chang et al., 2012; MacMillan, 2006). One study reported high

disclosure of IPV using computers (Chang et al., 2012). One study found that women were less likely to disclose IPV using the computerized intervention, one study included African American women in a Women, Infants, and Children (WIC) services setting (Fincher et al., 2015). A study that used a tablet during perinatal home visitation for disclosure, found the tablet to be perceived as a conduit through which the interpersonal connection between women and home visitors (Bacchus et al., 2016). One study found that women were more likely to disclose IPV using ICT lead to higher rates of screening and disclosure (Trautman et al., 2007).

3.2. ICT Suitability

ICT was found suitable, in terms of confidentially, usefulness, and satisfaction in three studies (Bacchus et al., 2016; Fiorillo et al., 2017; Renker & Tonkin, 2007); however, some participants in one study expressed skepticism about the ability of ICT-based interventions to empathize, retain privacy, provide support, and deliver meaningful feedback (Ahmad et al., 2009). Additionally, three studies reported that women found ICT-intervention suitable for IPV disclosure (Ahmad et al., 2009; MacMillan, 2006; Scribano et al., 2011).

3.3. IPV Prevention and Treatment

Two studies addressed IPV prevention (Braithwaite & Fincham, 2014; Gilbert et al., 2016). One study showed that most participating women were less likely to report experiencing physical IPV at follow-up (12 months); less likely to report IPV with injury; and less likely to report severe sexual IPV (Gilbert et al., 2016). The study by Braithwaite et al. that targeted both male and female reported - less physical aggression committed by females at post-treatment, as well as less physical aggression committed by males and females at 1-year follow up; also, the study showed large reduction in expected counts for female and male perpetrated physical aggression at the 1-year follow-up (Braithwaite & Fincham, 2014).

4. Discussion

4.1. Need of Usability Studies

Our systematic review shows that ICT-based tools were found acceptable and suitable by women experiencing IPV. This is encouraging given the fact that software usability was consistently overlooked in the included studies. Usability research is needed in the field as it can enhance drastically the adoption and effective use of ICT-based tools. Usability is even crucially needed given the mental health and cognitive challenges faced by women experiencing IPV. Indeed, literature in the IPV field suggests that women facing IPV experience intense mental health challenges (Simmons, Lindsey, Delaney, Whalley, & Beck, 2015); this suggests that studying the usability of the ICT tools developed for women experiencing IPV is paramount; however, the articles did not address usability issues. This is a significant oversight given that the lack of usability testing is known to facilitate errors (Fairbanks & Caplan, 2004) and decrease effectiveness (Hashim & Ahmad, 2016), especially in situations of extreme stress.

Moreover, it is well-known that the perceived usability of an eHealth tool influences attitude towards its adoption and use (Lindblom, Gregory, Wilson, Flight, & Zajac, 2012); therefore, overlooking usability constitutes a major oversight in developing ICT solutions for women experiencing IPV.

Three other factors indicate that usability is important in projects addressing IPV: Computer self-efficacy, computer anxiety and mental workload. Computer self-efficacy and computer anxiety were found to be predictors of a user's perception of a software tool (Lindblom et al., 2012) and mental workload is also a factor influencing task performance(Longo, 2018); given that women experiencing IPV are prone to face mental health challenges (Flanagan, Jaquier, Overstreet, Swan, & Sullivan, 2014; Simmons et al., 2017) it becomes imperative to investigate software usability in interventions addressing IPV.

4.2. Need for ICT-based Mental Health components

Our findings indicate that there is lack of IPV studies addressing mental health challenges. Given the prevalence of mental health illnesses including depression (Bhandari et al., 2012; Kastello et al., 2016), anxiety (Karakula Juchnowicz, Lukasik, Morylowska-Topolska, & Krukow, 2017) and stress among women experiencing IPV, there is a definite need for research addressing their mental health challenges. These studies can make use of ICT based mental health interventions. Indeed, many ICT-based approaches to mental health challenges emerged recently, including the use of Apps and web-based platforms (Connolly et al., 2018; El Morr, Maule, Ashfaq, Ritvo, & Ahmad, 2017; Mak et al., 2018) for Cognitive Based Therapy (Acosta et al., 2017; Beatty, Koczwara, & Wade, 2016), Acceptance and Commitment Therapy(Pots, Trompetter, Schreurs, & Bohlmeijer, 2016), and mindfulness (Ahmad, El Morr, & Ritvo, 2018). IPV research can benefit from a research agenda that uses ICT to address mental health challenges for women experiencing IPV.

4.3. IPV prevention

Finally, more research is needed around IPV prevention as most of the work in the field addresses challenges that women face after they have experienced IPV.

4.4. Limitations of the study

An important limitation of this review is the lack of homogeneity between studies considered, as different methods and varying measurement scales were used. Considering this situation, studies could not effectively be compared.

5. Conclusion

ICT-based IPV screening, prevention, awareness, and action tools show promise of reducing decisional conflict, improving knowledge and IPV risk assessment, and motivating women to disclose and discuss IPV. Data suggests that ICT-based screening tools for IPV are best used as a supplement to face-to-face screening allowing for more in depth and tailored advice from healthcare providers(Chang et al., 2012). The use of

ICT-based interventions can be a low-cost option, especially in disseminating awareness and IPV prevention (Hegarty et al., 2015), due to the wide availability of ICTs for most women, especially in more developed countries. However, usability is overlooked in most studies and it is vital to consider usability in ICT-based interventions addressing IPV given the complexity of the situation and the impact usability have on adoption, reduction of errors and effectiveness.

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Guiding Improvements in User Experience: Results of a Mental Health Patient Portal User Interface Assessment

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Abstract. Patient portals provide patients with electronic access to their health records. Since there has been limited use of patient portals in mental health settings, there is a lack of research regarding the usability of the technology amongst this patient population. The purpose of this study was to assess the usability of a mental health patient portal, and to provide the study site with design recommendations. Ten (n=10) participants completed a guided user interface assessment on laptops and tablet devices, along with a structured questionnaire. Findings revealed a number of modifiable aspects of the portal design to improve the usability of the technology for the end user.

Keywords. patient portal, mental health, psychiatry, user interface assessment, health information technology, health informatics

1. Introduction

Patient portals are a technology that provide patients and their family members with online access to their health record [1]. In Canada, patient portals are typically tethered to an organization's electronic health record, however other functions may be present such as appointment scheduling, and communicating with a health professional. Patient portals are relatively new for mental health populations [2], and therefore there has been limited research that has explored their design and usability in this unique context.

2. Purpose

Given the limited research assessing the usability of patient portals in mental health contexts, the purpose of this study was to: 1) conduct a user interface assessment of a mental health patient portal by potential users of the technology; and 2) provide design recommendations to improve patient portal usability at the study site based on the findings of the user interface assessments.

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3. Methods

3.1 Setting, Participants and Recruitment

This study took place at a large mental health teaching hospital located in Toronto, Ontario. The user interface assessments were conducted in meeting rooms within the hospital. Ten (n=10) participants were recruited via email invitations and poster advertisements. Previous usability research informed the sample size for this study [3]. Participants were provided with an honorarium for their participation.

3.2 Materials

The usability testing was conducted using a laptop, or tablet device to access the patient portal (testing environment) depending on the preference of the participants. Hypercam© software was used to capture and record the screen and audio of participants.

3.3 Procedure and Data Sources

Demographic information and self-rated technical skills were collected from participants at the beginning of the session. To avoid potential variations in procedure, each participant was provided with a scripted verbal introduction to the session by a facilitator, and consent was gathered for the video and audio recordings. Next, participants were asked to perform several task scenarios while 'thinking-aloud'. As part of the study, participants were provided with the context of the tasks and were asked to complete thirteen (n=13) task scenarios within the portal. The task scenarios reflected the key functionalities and features of the patient portal that patients may access (e.g. registration, login, finding lab results, messaging, reading clinical notes, finding an appointment, completing self-assessment etc.). Task scenarios provided context so that users could engage and perform representative tasks in the portal. In addition to the facilitator, a member of the research team sat in the corner of the room to take notes during the assessment.

Once participants finished completing the task scenarios, they were asked an open-ended question to allow them to share with the researchers their overall experience using the portal. Participants were then provided with a System Usability Scale (SUS) questionnaire. SUS is a ten-item Likert scale that assesses the overall usability of a system [4]. The SUS examined the general users experience and feedback about the patient portal. Ethical approval was received from the study site to perform the study.

3.4 Data Analysis

The facilitator of the study transcribed the data collected from the audio and screen recordings. The notes taken by both the facilitator and observer were transcribed, and compared with each other as well as with the audio recording. The data transcribed consisted of: 1) observations of the participants' pathway to complete a task; 2) any problems/challenges experienced by participants; and 3) any comments or recommendations made by participants. Descriptive statistics were generated for the questionnaire and SUS data, and a thematic analysis was performed for the qualitative data such as that from the audio recordings, and open-ended question [5].

4. Results

4.1 Participant Demographics

Ten participants (n=10) took part in the study. Nine participants (n=9) performed the full set of assessments and one participant performed a partial assessment. Four participants (n=4) were female, five participants (n=5) were male, and one participant reported being non-binary. The mean age was 41 years old (SD = 12 years). No further demographic information was collected.

4.2 Findings

The mean SUS score was 78.3 (good), with scores ranging from 55 (poor) to 97.5 (excellent). Through the user interface assessment, participants were prompted to vocalize their impressions and provide recommendations on what changes could be made based on the issues identified when completing the task scenarios (see Table 1). Participants found the registration email to be clear with instructions, but reported the email had too much text. During the registration task, six of the ten participants reported that the security questions were limited and hard to relate to. Recommendations for potential security questions included: "what is your first pet's name?", "what is your favourite teacher's name?" and "where did you meet your spouse, or get married?." Participants had difficulty indicating whether a unique username or email was required for logging into the portal. One participant recommended using asterisks (*) for mandatory fields. Another participant suggested the sign up page to indicate if passwords require uppercase letters and/or numbers.

During three different tasks, participants requested an increase in the text size and a change in font colour to improve visibility.

Allergies were listed on the main page of the portal but participants stated that the allergy list on the main page was not 'clickable' for further information. Four participants suggested a direct link to further allergy information from the main page.

In the laboratory results task, participants were easily able to locate the results, and found the calendar filter easier to use than manually entering a date. Participants also reported that it would make sense to have the most recent results at the top, and marking them in a different colour would help them focus on specific results. The messages, discharge summaries, and appointments were found easily by participants. However, participants had difficulty locating the 'print function' and 'print details', due to the small font and font colour.

For the self-assessment task, participants reported that the list of self-assessment questions was too long. One participant said, "It might be triggering, if I have to do more than 10 questions." Participants suggested self-assessments to be between 10-20 questions. Another participant stated that, "ninety questions long! It might not be possible for me." The same participant suggested the ability to save part of the self-assessment and allow participants to return to complete the self- assessment at another time.

Five participants reported that consults should be separated from the admission tab. For the messaging task with health professionals, participants wanted an additional prompt indicating whether a reply was necessary. Six participants had issues locating notifications and were unclear as to the meaning of the notifications.

Table 1. Major issues identified by participants during usability assessments

Issue #	Participants	Task	Issue	Participant recommendations
1	P1, P3, P6, P7, P8, P9	Registration task	Security questions are not relevant and not easy to relate to (i.e your parent's graduation, your parent's high school)	Suggestions for security questions: -What is my mother's middle name? -What is my first pet's name? -What is your favourite teacher's name? -What is your favourite author? -Where did you meet your spouse?
2	P2, P4, P5, P7, P8, P9, P10	Home page task	Self-assessment notification and side menu fades to the background	Provide clear spacing between sections; Decrease size of main page picture; Place notifications in a cloud/distinct shape
3	P2, P5, P6, P7, P8, P10	Allergies task	Allergies were not clickable from the main page of portal	Have a direct link from the allergy list on the main page for further allergy information
4	P2, P4, P7, P9, P10	Lab results task	Difficulty understanding the date range	Have most recent lab results on the top of the list
5	P1, P2, P3, P7, P9, P10	Appointment task	Unable to locate the print function	Change the color and increase font of print button
6	P1, P2, P3, P4, P7, P8, P9, P10	Self-assessment task	Questionnaire is too long and overwhelming	Limit self-assessment questions to 20 questions; Have the "save" and "submit" buttons
7	P6, P8, P10	Self-assessment task	Drop down menu was slow to respond or had no response	N/A
8	P1, P3, P6, P8, P9	Consult task	Consult was hard to find, confusion as to why admission and consult notes were together	Consult and admission should be separated; Consult and progress notes make sense together
9	P3, P6, P7, P8, P9, P10	Change notification settings task	Difficulty locating notifications	Change color of buttons and background; Change the button with 3 dots to "more information" or "more"

5. Recommendations for training/support materials

The findings of the user interface assessment resulted in recommendations for the development of training and support materials at the study site. For example, staff training should include how to register a patient for the patient portal, and how to answer common questions about the portal including who will have access to the portal. In addition, staff should know about some of the common issues patients may face when using the portal including the possibility that registration links could go to their junk mail. Staff should also be trained on providing descriptions of the documents that patients will see when they open their portal, and also know how to navigate and perform tasks in the portal themselves.

In terms of support materials, participants desired to view in a brochure or support document the key features of the portal, how to register for the portal, whether the substitute decision maker automatically has access to the patient's health records, and what to do in emergency situations. Participants wanted clarification on changing the way they interact with the portal, such as how to change date ranges in the laboratory results tab, how to update personal information, as well as how to change notification settings. In addition, participants wanted to know the definition and purpose of key features in the portal, such as self-assessments, consult notes, discharge summaries, and safety and comfort plans. Last, participants wanted to know who to contact if they: 1) had any difficulty registering for the portal, 2) had questions about appointment scheduling; 3) saw abnormal laboratory results displayed.

6. Conclusion

Results of the mental health patient portal interface assessment demonstrate that there are improvements required of the technology if it is to be used optimally by the intended user population at the study site. However, it should be noted that people with mental illness are not homogenous, and thus these findings may not be generalizable to all mental health patients. A number of suggestions for the development of training for staff and support materials were identified to further support the successful use of the portal by the patient population. Overall, this study demonstrates that considering the experience of potential users of a patient portal through a user interface assessment is an important pre-implementation activity to contribute to its successful launch. Future research exploring post-launch user experience would also be of value.

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eSource for Standardized Health Information Exchange in Clinical Research: A Systematic Review

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Abstract. The availability of research and outcomes data is the primary limitation to evidence-based practice. Today, only a fraction of clinical decisions are based upon evidence derived from randomized control trials (RCTs), the gold-standard of knowledge discovery. At the same time, clinical trial complexity has steadily increased as has the effort required at clinical investigational sites. Direct use of electronic health record (EHR) data for clinical trials has the potential to address some of these needs, improving data quality and reducing cost.

Keywords. eSource, electronic health records, secondary data use, clinical research

1. Introduction

Direct use of electronic health record (EHR) data in research has long-been a goal for biomedical researchers because of anticipated increases in data quality and reductions in site burden. Sporadic attempts toward this have been reported over the last decade [1,2]. However, to move beyond single-EHR, single-EDC (electronic data capture), and single-institution implementations, data standards and process re-design are needed as are rigorous evaluation of data quality, site effort, cost and feasibility.

Since 2010, over 20,000 clinical studies have been registered annually in clinicaltrials.gov with a 13% increase in the number of studies reported from 2015 to 2017 [3]. This is occurring at a time when clinical trial complexity continues to rise [4-9] and has resulted in escalating costs, forcing clinical development off-shore [10] and increasing site burden causing first-time clinical investigators to turn away from this work [11]. Reports have consistently articulated challenges and information-related workflow analysis and process redesign at clinical investigational sites are sorely needed [2,5,15,16]. Implementations of web-based EDC systems has not resolved the redundant and manual activities in site-based clinical research that significantly impede clinical trial research and has not reduced the overall costs. The need for advances in information management and use within clinical trials has been consistently articulated [5,6,9,12-16], and has spurred national initiatives such as TranCelerate and the Clinical Trails

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Transformation Initiative (CITTI). Formative work by Kim *et al.* distilled 42 distinct ways (14 use case categories) in which direct use of EHR data might improve clinical trials [17]. However, the clinical trial data collection use case is the most difficult and least demonstrated. Therefore, the objective of this systematic review is to identify and analyze the existing literature and current research efforts that aim to utilize direct, electronic EHR data extraction (eSource) and identify any gaps or limitations present for promoting standardized health information exchange in clinical research.

2.   Methods

A survey of the literature was conducted to identify studies using direct EHR data extraction in clinical research. Several searches were performed in PubMed and Embase using the following key words: *eSource, EHR, direct EHR, EHR extraction, integration,* and *clinical research*. MeSH terms were also leveraged in order to address the various levels of search term specificity. Results were deduplicated prior to the application of inclusion and exclusion criteria (Table 1). Next, titles and abstracts were screened by two independent reviewers to further narrow the search results. The remaining articles were reviewed to identify articles relevant to eSource initiatives in clinical research settings, in which direct use of EHR data might improve clinical research.

Table 1. Inclusion/Exclusion Criteria

Inclusion Criteria	Exclusion Criteria
1. Solutions that utilize eSource to directly exchange data electronically from the EHR-to-EDC	1. Direct electronic EHR data extraction was not the main focus of the manuscript
2. Relevant to a prospective clinical study use case	2. Solutions not applicable to a prospective clinical study use case

3.   Results

An initial search resulted in 2,174 articles. Seventy-four additional records were identified from other sources (i.e., reviewing reference lists and grey literature). After deduplication, a total of 1,747 articles were left for screening. Screening of titles and abstracts left us with 86 articles. A final screening of the remaining articles in full gave us a final total of 14 relevant articles (Figure 1). Most of the articles were excluded because (1) the research was not conducted in in the context of a prospective clinical study, (2) the manuscript was theoretical in nature rather than experimental, providing no true eSource solution for implementation or evaluation, or (3) the mechanism utilized for EHR-to-EDC exchange was not electronic and required significant manual processes.

Four critical dimensions were identified to categorize each study in relation to one another. These dimensions include (1) whether the study was conducted at a single site or was part of a multi-site study, (2) whether the study utilized a single EHR or multiple EHRs, (3) whether or not the study was conducted as part of an ongoing, prospective clinical study, and (4) whether or not relevant standards were used (see Appendix 1 for a complete summary).

Figure 1. PRISMA diagram
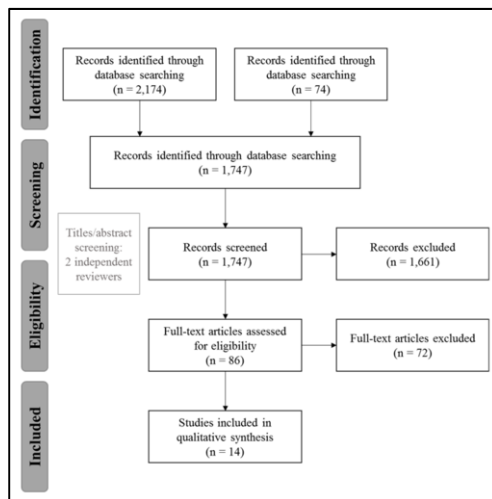
Eight of the fourteen manuscripts (57%) described single-site, single-EHR implementations. Of the six manuscripts describing multi-site studies, four were part of the same pilot study (EHR4CR European Pilot), a collaborative initiative across several European countries. Therefore, while the four manuscripts were each distinct in their interpretations of the study and their evaluative methods, and were included in this review, we would consider this to be a single eSource approach. Therefore, across the 14 manuscripts identified as part of this review, there were a total of 11 distinct eSource interventions evaluated. The majority of the interventions described (7 of 11) were not part of an ongoing, prospective study; and only 1 of the remaining 4 was a multi-site, multi-EHR implementation.

4.   Discussion

Routine clinical documentation has long been used for research. Though the quality of medical records data and their use in research has long been questioned [18-23], the practice of medical record abstraction, by which a person reads all or part of the paper or electronic medical record, chooses desired data, and records the data onto a study-specific data collection form has been the mainstay of data collection in clinical trials [24]. However, medical record abstraction is time intensive, reliant on a human abstractor to sort through the uncertainty and inconsistency in medical records and is associated with high and highly variable discrepancy rates (median 647, average 960 discrepancies per ten thousand fields with a standard deviation of 1,018 from a large pooled analysis) [25]. To decrease and control the high error rate and variability of medical record abstraction, clinical trials have relied clinical trial monitors to verify collected data with the original medical records. However, the substantial cost and error rate from medical record abstraction remains. As part of a concurrent effort to evaluate and synthesize previously reported outcomes, we identified significant weaknesses and offer recommendations for improvement [26].

The use of eSource constrains medical records abstraction subjectivity and the opportunity for error in two very important ways. (1) eSource automates data abstraction and pre-populates the study-specific eCRF(s). This completely eliminates transcription errors and errors in pulling data from the wrong place in the record. This also reduces the time involved in medical record abstraction. (2) Where multiple values are available, they are displayed with the necessary context for the abstractor to select the correct value. As a result, eSource decreases cognitive load associated with medical record abstraction by representing them externally rather than requiring the abstractor to hold the information in working memory [27]. The efficacy of these mechanisms in reducing data error and abstraction time has been demonstrated [28-31]. We are now at the point where information systems leveraging data standards can increase clinical research efficiency and quality [32]. However, these methods need to be tested for effectiveness and acceptance in the context of real multicenter clinical trials. Several early studies using a single source of data for research and patient care appeared over a decade ago [2,33-34]. Since that time, implementations and evaluations have been scarce and almost always confined to single-EHR, single-EDC, single-institution implementations [35].

4.1 Single-Site, Single-EHR Implementations

In the STARBRITE project, Kush *et al*. demonstrated the feasibility of single clinical data capture with subsequent use in patient care and a clinical trial [2]. In the same year, Murphy *et al*. demonstrated custom-built EHR screens that included research data, which were later extracted from the EHR database [33], and Gersing and Krishnan designed a behavioral health EMR that integrated research and care [36]. During the same time, institutions began using warehoused clinical data to pre-populate prospective registries, including building registry data elements into the EHR [37]. Thus, there was early evidence that clinical data can be captured once and subsequently used for patient care and clinical research.

In 2009, Kiechle et al. reported an EHR-to-EDC pilot conducted in collaboration between Siemens and the Frauenklinik of the Technical University of Munich, called "the Munich Pilot" [29]. This study's technical solution consisted of a portal, an integration engine, and an adapted EDC system. This work leveraged HL7 messages in existing healthcare information systems [29]. Following receipt of an HL7 message from an EHR, the integration engine then translated the data into the Clinical Data Interchange Standards Consortium (CDISC) Operational Data Model (ODM, www.CDISC.org) exchange standard and stored the data in a validation buffer from which the data were displayed for human review, confirmation that the data belonged to the indicated patient, and initiation of transfer of the data to the EDC system [29]. The Munich Pilot demonstrated a statistically significant reduction in data collection time. However, there were too few data queries to assess this pilot study's impact on data quality [29].

In 2014, Laird-Maddox *et al*. demonstrated pre-population of diabetes eCRFs in a Cerner EHR extension of the IHE RFD standard [38]. This technical solution was built within the Cerner Millennium EHR and Discovere research data capture system [38]. Discovere is a separate, web-based platform that can be used independently of Millennium and supports traditional electronic case report form data capture [38]. The RFD-based technical solution enabled electronic transmission of relevant data from the Millennium EHR to Discovere [38]. The technical solution leveraged an EHR-generated Continuity of Care Document (CCD) containing the most recently populated values for the study data elements [38]. The pilot reported minimal interruption of the EHR session

and available data flow from the EHR to the study eCRF without manual reentry [38]. The investigators claimed improved data quality and reduced data collection time, but the results were not quantified [38].

In 2015, Lencioni *et al.* reported on EHR-to-Adverse Event Reporting System (AERS) integration [39]. At the University of Arkansas for Medical Sciences (UAMS), AERS was implemented and interfaced with the Epic EHR to leverage routinely collected clinical data and automate detection of detectable adverse events (AEs) [39]. The system integration software was developed to provide systematic surveillance and detection of adverse events knowable from the health record including (1) lab related adverse events that are auto generated based on study participants' lab results and (2) unscheduled visits. The system uses MirthConnect's web service, HL7 messages, and the IHE Retrieve Process for Execution (RPE) integration profile [39]. Implementation of this system was associated with a reduction in sponsor generated AE-related queries, and a staff-estimated 75% increase in lab-based AE reporting. Data quality was not assessed. The system remains in use today at UAMS and has been followed by additional ongoing EHR-to-Research system integration activities. This work demonstrates the direct integration of an EHR with clinical research systems. However, this solution was implemented at a single site and assessed only two endpoints based on staff perceptions.

Nordo *et al*. reported development, installation, and evaluation of standards-based EHR-to-eCRF software in an ongoing single site for an OB/GYN registry [28]. The technical solution was based on the IHE RFD integration profile. The evaluation study compared eSource to non-eSource (usual practice of manual medical record abstraction) data capture. The overall average data capture time was reduced with eSource versus non-eSource methods (difference, 151 sec. per case; eSource, 1603 sec.; non-eSource, 1754 sec.; p= 0.051) [28]. The average data capture time for the demographic data was reduced (difference, 79 sec. per case; eSource, 133 sec.; non-eSource, 213 sec.; p < 0.001) [28]. This represents a 37% time reduction (95% confidence interval 27% to 47%). eSourced data field transcription errors were also reduced (eSource, 0%; non-eSource, 9%) [28]. Though the study promisingly concluded that the use of eSource versus traditional data transcription was associated with a significant reduction in data entry time and data quality errors [28], the results lack generalizability due to implementation at only one site.

4.2 Multi-Site, Multi-EHR Implementations

Several authors report on aspects of the collaborative EHR for Clinical Research (EHR4CR) initiative [31,34,40-43]. Using a different architecture than RFD, the RE-USE (Retrieving EHR Useful data for Secondary Exploitation) project leveraged a semantic mapping process to match EHR data to elements of the electronic case report form for research [31]. In a pilot conducted at George Pompidou hospital in France, they found that 13.4% of the study data elements were present in EHR and available for pre-population of study CRFs [31,34]. In the same pilot precision, positive predictive value, ranged from 62%-84% and sensitivity ranged from 31% - 84% [31]. Beresniak (2017) estimated cost benefit of the EHR4CR platform for the three use cases (trial feasibility assessment at sites, subject recruitment and data collection) including 50k–500k € for EHR4CR platform service provider fees using experts rating hypothetical studies as part of pre-commercialization assessment [41]. The EHR4CR European Pilot went further than a single facility and demonstrated installation of the software in university hospitals

in five European countries. However, the EHR4CR platform has not yet been tested in a randomized clinical trial [42,44].

4.3 Multi-Site, Multi-EHR Implementations as part of Ongoing Clinical Trial

Ethier *et al.* reported results from the European FP7 TRANSFoRm project towards developing an infrastructure for a Learning Health System in European Primary Care (www.transformproject.eu); a major work stream of the project was directed at developing eSource connectivity for randomized controlled trials [30]. FP7 refers to the European Union's Seventh Framework Program for research, technological development and demonstration. Similar to EHR4CR, the TRANSFoRm scope of functionality was broader than the aforementioned attempts at EHR-to-eCRF integration and included automated eligibility screening and support for recruitment, pre-population of study CRFs, study data document archival in the EHR, and mobile-device capture of Patient Reported Outcomes [30]. The technical approach extended CDISC's ODM so as to send the data queries to the EHR and to then prepopulate the CRF with 26 extracted data elements [30,45]. The TRANSFoRm eSource method and tools were implemented as middleware between the EHR and the EDC system. However, the approach required collaboration from each of the five EHR vendors to implement [30]. The study compared TRANSFoRm to standard methods for the outcome of clinical trial recruitment in primary care [30]. Although this study failed to detect a significant difference in overall or weekly recruitment rates, the secondary outcome of data completion rate did show a significant treatment-related difference. Unfortunately, data quality and site effort were not evaluated. Nonetheless, the TRANSFoRm project did demonstrate that implementation of EHR-to-EDC integration can occur within an RCT's start-up timeline.

4.4 Limitations

We acknowledge the inherent limitations of this review. Although we attempted an exhaustive search of the literature using robust biomedical databases, manuscripts meeting our inclusion criteria were difficult to find, and we understand that some relevant manuscripts may have been missed. Further, while we leveraged the efforts of two independent reviewers to screen the titles and abstracts, only a single reviewer screened the full-text articles. We realize that our methods would have been strengthened by having double-review throughout.

4.5 Future Research

As part of an existing effort to expand on the work of Nordo *et al*., we – in collaboration with several academic, industry, and government partners – are currently working to convert existing EHR-to-eCRF software from the RFD standard to the HL7 Fast Healthcare Interoperability Resources (FHIR) standards to support EHR- and EDC-agnostic implementation. This approach would provide a standards-based tool for semi-automated, near-real-time direct EHR data extraction for use in multi-center clinical studies that builds on strengths and overcomes weaknesses prior approaches, specifically targeting generalizability and scalability.

5.   Conclusion

The long-sought, semi-automated extraction and direct use of EHR data in clinical trials is within reach. As described above, solutions have been developed, evaluated and improved. However, generalizability, scalability, and effectiveness towards increasing data quality and efficiency in multicenter studies has not been demonstrated. Therefore, additional studies are needed to address the critical barriers to progress in streamlining clinical trials by probing these unanswered questions, furthering the development of critical methods and tools, and directly testing their impact on data quality, collection cost, collection time, and site recruitment. The answers to these cost, quality, time, and socio-technical implementation issues will inform the true value of EHR-to-EDC eSource data collection towards streamlining clinical studies.

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Appendix

Appendix 1. Summary of the Literature (S = single-institution / -EHR, M = multi-institution / -EHR)

Source	Institution	EHR	Within Ongoing Trial?	Standards	Findings / Limitations
Gersing K, et al. (2003)	S	S	N	N/A	Designed a behavioral health EMR that integrated research and care.
Murphy EC, et al. (2007)	S	S	N	N/A	Demonstrated custom-built screens in an EHR system that included capturing research-related data, which were later extracted from the EHR database.
Kush MG, et al. (2007)	S	S	Y	HL7 CDA, CDISC ODM	STARBRITE Demonstration Project: demonstrated the feasibility of a single capture of clinical data with subsequent use in patient care and a clinical trial. Due to the delayed finalization of clinical documentation at the institution, initial data capture occurred in the study CRF.
Kim D, et al. (2008)	M	M	N	N/A	Distilled 42 distinct ways (14 use case categories) in which direct use of EHR data might improve clinical trials. Five use case categories involved the conduct of prospective clinical studies – the primary interest of this review is the clinical trial data collection use case.
Kiechle M, et al. (2009)	S	S	Y	HL7, CDISC ODM	The Munich Project: Leveraged HL7 messages from the EHR and, upon human review, data was transferred to the EDC system. Demonstrated a statistically significant reduction in time for data collection activities; resulting in an almost five-hour reduction in data collection time.
El Fadly A, et al. (2011)	S	S	N	HL7 CDA, IHE RFD, CDISC ODM	RE-USE Project: leveraged a semantic mapping process to match EHR data to elements of the eCRF for research. The RE-USE approach demonstrated a reduction in redundant data entry and improvement in data quality and processing speed.
Laird-Maddox M, et al. (2014)	S	S	N	HL7 CCD, IHE RFD	Cerner Discovere: demonstrated pre-population of diabetes eCRFs in a Cerner EHR extension of the IHE RFD standard. The investigators claimed improved data quality and reduced data collection time, but the results were not quantified.

Beresniak A, et al. (2014, 2016)	M	M	N	HL7 RIM, EHR4CR	EHR4CR European Pilot: report on aspects of the collaborative EHR4CR initiative. Estimated cost benefit as part of pre-commercialization assessment. The EHR4CR European Pilot went further than a single facility and demonstrated installation of the software in university hospitals in five European countries. However, the EHR4CR platform has not yet been tested in a RCT.
Doods J, et al. (2014)	M	M	N	HL7 RIM, EHR4CR	
De Moor G, et al. (2015)	M	M	N	HL7 RIM, EHR4CR	
Dupont D, et al. (2017)	M	M	N	HL7 RIM, EHR4CR	
Lencioni A, et al. (2015)	S	S	Y	HL7, IHE RFD	AERS: EHR-to-Adverse Event Reporting System integration with the EHR to automate detection of detectable Adverse Events. The system uses MirthConnect's web service, HL7 messages, and the IHE RPE integration profile. Associated with a reduction in sponsor generated AE-related queries, and a staff-estimated 75% increase in lab-based AE reporting. Data quality was not assessed. Implemented at a single site and assessed only two endpoints based on staff perceptions.
Ethier JF, et al. (2017)	M	M	Y	CDISC ODM	European FP7 TRANSFoRm Project: developing eSource connectivity for randomized controlled trials. Formally evaluated using a mixed-methods study of TRANSFoRm as a nested cluster randomized trial embedded fully within an RCT. Failed to detect a significant difference in overall or weekly recruitment rates, but data completion rate did show a significant treatment-related difference. Data quality and site effort were not evaluated. Demonstrated that implementation of EHR-to-EDC integration can occur within an RCT's start-up timeline.
Nordo AH, et al. (2017)	S	S	N	IHE RFD	Development, installation, and evaluation of standards-based EHR-to-eCRF software in an ongoing single site for an OB/GYN registry; based on the IHE RFD integration profile. Compared eSource to non-eSource data capture. The overall average data capture time was reduced (difference, 151 sec. per case; eSource, 1603 sec.; non-eSource, 1754 sec.; p= 0.051). eSourced data field transcription errors were also reduced (eSource, 0%; non-eSource, 9%). Results lack generalizability due to implementation at only one site.

125

Development of Data Validation Rules for Therapeutic Area Standard Data Elements in Four Mental Health Domains to Improve the Quality of FDA Submissions

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Abstract. Data standards are now required for many submissions to the United States Food and Drug Administration (FDA). The required standard for submission of clinical data is the Clinical Data Interchange Standards Consortium (CDISC) Submission Data Tabulation Model (SDTM). Currently, 45 business rules and 115 associated validation rules exist for SDTM data. However, such rules have not yet been developed for therapeutic area data standards developed under the last reauthorization of the Prescription Drug User Fee Act (PDUFA V). The objective of this effort was to develop data validation rules for new therapeutic area data standards in four mental health domains, assess the metadata required to associate such rules with standard data elements, and assess the level of data validation possible for therapeutic area data elements.

Keywords. data standards, therapeutic area standards, validation rules, CDISC SDTM, regulatory submissions

1. Introduction

With acceptance of risk-based approaches in clinical trials, the era of expecting zero-defect data and the correspondingly high expenditures in data cleaning is coming to a close [1-3]. As a result, data cleaning activities in clinical research are becoming more targeted towards data needed for study endpoints [4]. At the same time, advances in data standards for regulatory submission in the United States are aimed at standardizing data sufficiently for use of software to facilitate the regulatory review process.

Data standards are now required for submission of data from clinical and nonclinical studies as of December 17, 2016 [5]. In particular, the Clinical Data Interchange Standards Consortium (CDISC) Study Data Tabulation Model (SDTM) is required for clinical study data. To assist the regulated industry with data submission, the Food and Drug Administration (FDA) has published 45 business rules and 115 validator rules that check that the study data are conformant to the standard and will support regulatory review and analysis [6]. These business and validator rules, however do not yet exist for efficacy data, but could be developed as part of therapeutic area data standards.

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Detection and resolution of data discrepancies (called data cleaning) during a study should be informed by submission data standards. The extent of data cleaning for a study should depend on the scientific and operational needs of a study. In particular, data collection and cleaning scope should be defined by those activities necessary to ensure that the data are capable of supporting study conclusions [7]. This is operationalized through establishing acceptance criteria for data error and designing data collection, processing, and control procedures that consistently produce data meeting the criteria [4].

Thus, while we report methodology for developing data cleaning rules along with standardized data elements, these are of a different sort than FDA business and validator rules. While over time some may prove useful and be desired by reviewers, we currently recommend their use on any particular study only to the extent that they are needed to assure that data are capable of supporting research conclusions. We specifically do not include rules toward pursuit of zero defects or out of concerns from the past that a single defect would call an entire submission into question and delay the review process [7]. Rather, we offer them for use when necessary to meet the scientific aims of a study and based on standards to facilitate efficient sharing and implementation.

It has been shown from first principles that delaying detection and resolution of discrepancies foregoes opportunity to resolve discrepancies in some cases, renders some discrepancies unresolvable, and increases the cost of resolving others [7-9]. Thus, any such rules, especially those to which data must conform for regulatory submission, should be implemented as far upstream in the data collection and management process as possible [4].

2. Background

A rule is a statement of a condition against which data are evaluated. For example, *"lab values from a complete blood count can't be negative"* or *"measured physical quantities captures as percentages must range between zero and one"*. In clinical research data management, such rules are referred to as query rules, edit checks, or discrepancy checks.

The earliest reports of data processing in clinical research included accounts of rules-based data cleaning [10-18]. In the therapeutic development industry, rules-based data cleaning has occurred on most if not all studies [4]. In fact, fear that notice of an errant data value would substantially delay a regulatory submission prompted the practice of developing and running often hundreds of rules for a clinical study. On older studies, the clinical investigational site was contacted in attempts to resolve each discrepancy against the source, often the medical record [7]. The disposition and resolution of each discrepancy was tracked from origination to resolution. The discrepancies often numbered in the thousands for a small study of a few hundred patients. It was not uncommon for 10-30% of the cost of a clinical study to be spent on data cleaning and monitoring [2].

With widespread use of web-based electronic data capture (EDC) software and associated processes, efficiencies have been gained and data discrepancies are usually communicated to sites upon data entry where they can be resolved quickly and where tracking is automated. Using EDC systems, data discrepancies are usually communicated to sites upon data entry where they can be resolved quickly and where tracking is automated. The process continues to rely on development and use of rules. Similar to clinical decision support rules in medical informatics, in the absence of standards data

models and associated controlled terminology or standard data elements, rules could not be widely shared or reused, leaving untapped inefficiency.

With respect to regulatory decision making, the Center for Drug Evaluation and Research (CDER) receives more than 150,000 submissions each year, adding up to millions of data values considered in regulatory decision-making. The FDA has been supportive as the regulated industry organized to develop standards through CDISC. The FDA looked toward further data standardization to facilitate handling such large volumes of data and under the Prescription Drug User Fee Act (PDUFA) to improve the efficiency of the review process required data standardization. In 2010, CDER established the Data Standards Program with the goal of standardizing efficacy data not yet tackled under the CDISC SDTM.

As part of the CDER Data Standards Program, four therapeutic area data standards have been developed in the mental health domain: Schizophrenia, Major Depressive Disorder (MDD), Bipolar Disorder (BPD), and Generalized Anxiety Disorder (GAD). Briefly, candidate data elements were identified from data collection forms from recent marketing applications and NIMH-funded studies. The initial set of data elements was consolidated. Unique data elements were defined and then vetted by clinical experts, regulatory authorities, professional societies, and informatics experts. Each set of data elements was then represented in Unified Modeling Language (UML) use case and activity diagrams and class models. The four therapeutic area standards were balloted through Health Level Seven (www.hl7.org, HL7), an ANSI-accredited standards development organization, and after passing ballot were published as HL7 standards. Once published, the standards were provided to CDISC for use in Therapeutic Area User Guides (TAUGs) to support the evaluation of marketing applications submitted to the FDA for drug development and clinical trials (one TAUG per domain). The TAUGs were developed under the Coalition for Accelerating Standards and Therapies (CFAST) initiative.

At the time of this publication, CDISC had already developed the therapeutic area user guides (TAUGs) for two of the four domains, Schizophrenia and MDD [19-24]. The existing user guides are provisional standards that demonstrate how to represent therapeutic area specific data using the CDISC foundational standards (www.cdisc.org).

Data checking rules have not traditionally been a part of these standards but are desired by the regulators and regulated industry alike. Further, existence of standard data elements and common data models in which they are structured, enables definition and sharing of data checking rules to accompany the new standards and assist in submission and use of data submitted in the standards.

3. Methods

Standard data elements for the four therapeutic areas were mapped to the CDISC SDTM Implementation Guide (SDTMIG) version 3.2 [25] and SDTM version 1.4 [26]. Mapping began with the Schizophrenia and MDD data elements, as the TAUGs had already been developed and were able to be referenced for mapping to SDTM. Independent reviews of the data elements and their subsequent mappings to SDTM were conducted by two study members. Each reviewer manually compared the standard data elements against the respective TAUGs using a simple search, mapping those identified in the user guides. This was done by comparing the definitions to determine if they were semantically related. Data elements that did not directly map to one of the standard SDTM variables

were represented in the Supplemental Qualifiers (SUPPQUAL) domain and associated back to the parent record in one of the general, observational domains. SUPPQUAL is an extension mechanism utilized for representing and relating data values not accommodated in existing domains [25].

While the user guides did offer insight into where to best store the therapeutic area-specific data elements within the CDISC models, not all data elements were covered in the TAUGs and no direct mapping document was provided for Schizophrenia. Supplementary documentation was provided for MDD with mapping examples for several common data elements (shared across the four therapeutic areas) and a number of MDD-specific data elements to the CDASH model, which offered suggestions for mapping to SDTM; but, again, not all data elements were covered. Leveraging the methodology implemented for Schizophrenia and MDD mappings, the BPD and GAD data element mapping followed suit.

Upon completion of the mapping, data validation rules (or edit checks) were written according to the Good Clinical Data Management Practices (GCDMP) against the therapeutic area-specific data elements and the SDTM with the intent of identifying all possible relationships that could be leveraged for data validation. The edit checks aim to detect inconsistencies in the data or potential data errors, which will ultimately improve the quality of the data [4]. The complete list of therapeutic area-specific data elements was reviewed to determine those most necessitating checks. The foundational SDTM model and its existing standards' data elements were also considered when developing the rules. The rules were written using ANSI standard SQL (American National Standards Institute, Structured Query Language), the de facto standard for relational databases.

4. Results

In total, 415 data elements were mapped. Of the 415 total data elements, 215 (51.8%) mapped to general observation classes and 200 (48.2%) mapped to special-purpose domains. A total of 41 data elements were shared across all four models (Figure 1). Several additional data elements, while they may not have been common across all four models, were shared between two or three of the four. For example, among the 85 total Schizophrenia data elements, only 26 were unique to Schizophrenia (Table 1).
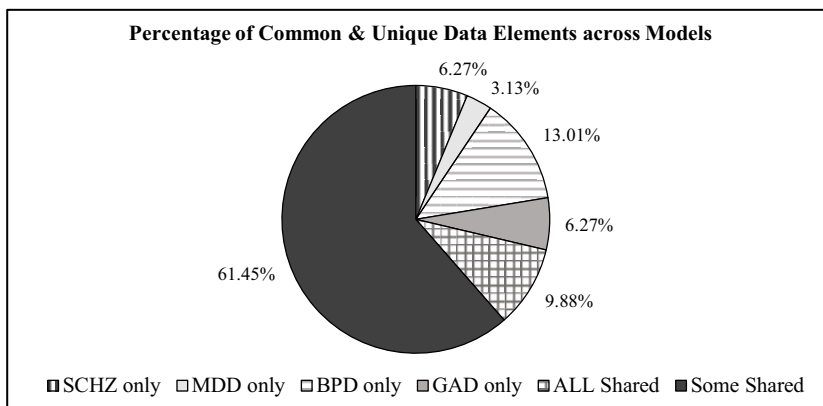
Figure 1. Percentage of common & unique data elements across MH models.

Table 1. Data element counts and percentages per therapeutic area data model

	Schizophrenia (N = 85)		MDD (N = 94)		BPD (N = 144)		GAD (N = 92)	
	n	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Therapeutic Area Specific	26	30.6	13	13.8	54	37.5	26	28.3
Common with *any* Model	59	48.2	81	43.6	90	28.5	66	44.6
Common in *all* Models	41	69.4	41	86.2	41	62.5	41	71

Upon completion of the mapping, a total of 371 rules were developed on 191 individual data elements across the four therapeutic areas. The rules were classified into three categories: range checks (1.1%), logical inconsistencies (56.0%), and missing values (42.9%). Approximately one-third (30.4%) of the checks were written against date fields to verify consistency across other date fields or fields with data dependencies.

On average, 79.1% of the data elements had validation rules that were written against common data elements (those common across the therapeutic areas) versus 20.9% against unique, therapeutic area-specific data elements. For each therapeutic area, rules were written against a total of 49 Schizophrenia data elements, 41 for MDD, 54 for BPD, and 47 for GAD (Table 2). Less than one-third (27.1%) of the Schizophrenia data elements had rules programmed against other SDTM fields external to the Schizophrenia standard data element set. MDD, BPD, and GAD each had similar results: 27.5%, 26.5%, and 15.9%, respectively.

Table 2. Validation rules written against common data elements versus unique data elements per therapeutic area compared to full data element list. (DEs = data elements)

	Schizophrenia (N = 85)		MDD (N = 94)		BPD (N = 144)		GAD (N = 92)	
	n	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Rules against Common DEs	33	67.4	40	97.6	44	81.5	34	72.3
Rules against Unique DEs	16	32.6	1	2.4	10	18.5	13	27.7
Total DEs with Rules	49	25.7	41	21.4	54	28.3	47	24.6

5. Discussion

It was anticipated, and confirmed, that many of the general observations would map to the Medical History (MH) and Disposition (DS) domains, given the nature of the therapeutic area data elements and the typical data collected during clinical trials. This would likely translate across other therapeutic areas, as in many cases, the data points of interest tend to align with those two domains: the MH domain captures historical data relevant to the study endpoints (i.e., prior and concomitant conditions), while the DS domain captures most of the data relevant to the study milestones [26]. It was also predicted that at least one-third would not map directly to an SDTM general observation domain and would require mapping to SUPPQUAL, based on previous experience with data element mappings to the common data models such as SDTM [27]. We predict that this would also be the case in other therapeutic areas, but realize that this could vary based on the complexity of and data points of interest for a particular therapeutic area.

As SDTM does not allow for the creation of new variables, the SUPPQUAL domain is used to capture additional data elements (or "additional Qualifiers for an observation") that do not "fit" within the current set of standard variables within the general observation

classes [26,27]. These variables are then associated back to parent records within a general observation class using a domain identifier.

With the mapping and validation rule development came a series of challenges. As previously mentioned, the Schizophrenia and MDD TAUGs were referenced in order to complete the mappings. However, not all data elements were covered in the TAUGs, nor were there direct SDTM mapping documents for either model. Approximately 20.0% of the Schizophrenia data elements were not explicitly mapped in the Schizophrenia TAUG, whereas close to 60.0% of the MDD elements were not mapped in the MDD TAUG (although some were covered by what had been mapped in Schizophrenia, as these models shared common data elements). On average, 13.8% of the data elements had not been mapped in either TAUG, which required that the SDTM and the SDTMIG be referenced.

Furthermore, a few of the common data elements shared by both Schizophrenia and MDD were not mapped consistently within the TAUGs. As several of these elements were also shared by BPD and GAD, a decision needed to be made as to which SDTM variable to map to so as to allow for consistency across all models (and to allow for standard query rules for common data elements). Challenges were also met when developing the validation rules for data elements that were mapped to the SUPPQUAL domain. Data elements requiring multivariate rules in which two or more data elements were from the SUPPQUAL domain, complicated the structure of the query due to the nature of the table generated for SUPPQUAL elements.

A limitation of this effort is that both the mappings and the validation rules have only been validated internally. However, as the mappings leveraged existing TAUGs and preliminary mappings from CDISC, we are confident in the accuracy of the mappings. Additionally, the validation rules have only been developed and written in the SQL code, but the rules have yet to be programmed and tested/validated. Currently, both the mappings and validation rules have been submitted to CDISC for review and collaboration between both teams continues in an effort to complete validation. This external review may result in changes to the mappings and/or validation rules. However, as nearly 90.0% of the Schizophrenia and MDD data elements had been previously mapped by CDISC in the TAUGs, and since the BPD and GAD elements were either common or similar in structure, it is anticipated that any changes or updates to the mappings would be minimal.

The collaboration with CDISC continues and TAUG development for the BPD and GAD models is underway; the mappings from this effort will be leveraged for their development. Additionally, continued FDA engagement is planned so that the team responsible for implementing the validation rules have also had the opportunity to review the rules and provide feedback. It is critical for all three groups be in sync as the mappings and the TAUG development will greatly affect the validation rules. The final rule set will be turned over to the FDA for implementation and dissemination to industry. It is recommended that a continuous feedback loop be maintained as the rules are implemented and executed for continuous quality improvement.

6. Conclusion

Standardized data elements and validation rules can improve the quality of data that is submitted by sponsors for regulatory decision-making. Validation rules accompanying standard data elements support sponsors in checking data consistency as early as possible

in the data collection process, a clear best practice. Existence of such rules can decrease the cost of data management and increase the quality of data submitted to the FDA.

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Effects of Telenursing Triage and Advice on Healthcare Costs and Resource Use

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Abstract. Telenursing triage and advice services are continuing to expand both nationally and internationally. A primary role of telehealth nursing triage is to channel patients or clients towards appropriate levels of care, thereby reducing healthcare costs and freeing up resources. Purpose: The objective of this research is to: (a) present an overview of the current research, (b) describe the extent to which telenursing services are fulfilling this role, (c) identify gaps in the literature and (d) propose future research directions. Methods: The report consists of a scoping review of current literature based on the framework suggested by Arkseyand O'Malley (2005). Results: Although the available research spans a variety of jurisdictions, which makes comparison difficult, there is some evidence that suggests telenursing services empower clients to access levels of care in keeping with the severity of their symptoms, as well as enabling clients to engage in self-care when appropriate. This in turn leads to cost savings for the broader health care system. Conclusion: More evaluation of telenursing programs is needed to identify consistent savings. Health outcomes should be a part of the research.

Keywords. telehealth, nursing informatics, cost, patient outcomes

1. Introduction

Healthcare costs on an international level are steadily increasing, often at a rate faster than the Gross Domestic Product (GDP). Since the turn of the century, healthcare spending per capita has more than doubled in OECD countries [1]. In 2017, Canada spent CA$6,604 per capita on health care. The largest portion of health care funds goes to hospitals (28%) followed by drug costs (16%) and physicians (15%) [2].In spite of ever increasing expenditures, access to health care and health care facilities in Canada has not changed extensively. According to Statistics Canada, 15.8% of Canadians did not have a regular health care provider in 2016 [3]. Of those Canadians who did, roughly 40% report they are able to get a same day or next day appointment with their primary care physician. 65% of Canadians find it very difficult or somewhat difficult to access care after hours; often the only available facility is the emergency department (ED). In 2014-2015, there were 16 million visits to EDs in Canada, with 90% of visits concluded within 8hours. Only 10% of ED visitors were admitted to hospital, which suggests that at least some of the patients could have been cared for in less urgent health care settings.

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Telenurse call centres have been established in many countries to help citizens seek appropriate levels of care for their symptoms, which may include use of home treatments for minor complaints. This scoping review examines the effects of telenursing services on overall healthcare in terms of cost and resource use by asking the following questions: (1) Is there any evidence that callers will follow the advice and recommendations given by telenurses? (2) Does the fact that they have contacted a telenursing service lead to more appropriate health care decisions? (3) Does the cost of providing call centre services have a positive impact on reducing overall health care costs?

2. Specific Aims

The aim of this scoping review is to identify the current state of the literature regarding the effectiveness of telenurse call centres in supporting citizen callers to make more appropriate health care decisions, and if this is leading to resource and cost savings within the broader healthcare system.

3. Background and Significance

Telenursing is a relatively new branch of nursing. It is defined as the provision of nursing care in a remote fashion, usually over the telephone without face-to-face contact between client and care provider. Stand-alone telenursing services have grown substantially over the past twenty years, often in response to health care provider shortages and the increasing need to use scarce resources wisely. In Canada, 10/13 provinces and territories provide telenursing triage and advice services [4]. Services commonly include symptom triage, recommended levels of care, general health information and education, referrals to other services, and the administration of specialized programs. Many telenurses work in call centre settings, accepting calls from the general public on a multitude of health related concerns.   There are several costs that arise from operating nurse call centres: the initial cost of setting up these services, and ongoing operating costs. It is timely to investigate if tele-triage services have a positive effect on the health care system in general as callers/citizens are seeking more appropriate care e.g. trying home treatment rather than a doctor visit, or a scheduled MD visit rather than a visit to ED.

4.Methodology

This scoping review of the recent literature is based on the framework suggested by Arksey and O'Malley [5]. Step 1 involved developing research questions as stated in section 1 above. For step 2 a search was conducted of the CINAHL and PubMed databases for articles from 2004 onwards, in English language, with the search terms "tele triage"; "telenursing benefit"; "telenursing cost"; "nurse telephone hotline"; "telenursing evaluation"; "telenursing"; "telenursing impact"; "telenursing outcomes" and "telephone triage". Selected articles were required to refer to telenursing triage and advice as the main objective, or at least as a prominent feature of the overall purpose of the study. Studies were required to report data for measures or indicators used to document telenursing triage and advice outcomes. Articles that did not meet the majority

of the inclusion criteria were excluded, together with case studies, systematic reviews, review articles, editorials, opinion letters to the editor, and commentaries. The search generated 1917 articles for abstract review. After removing duplicates there were 1035 remaining articles. Exclusion criteria included articles that were not focusing on teletriage and advice, teletriage and advice services not performed by nurses, and where the call was not initiated by the caller/client. 101 articles were chosen for full text review. At this stage, exclusion criteria were articles that did not address evaluation of teletriage and advice, articles that focused on nursing experience or nursing practice, or where the only measure was caller satisfaction. 23 articles were included in the final review.
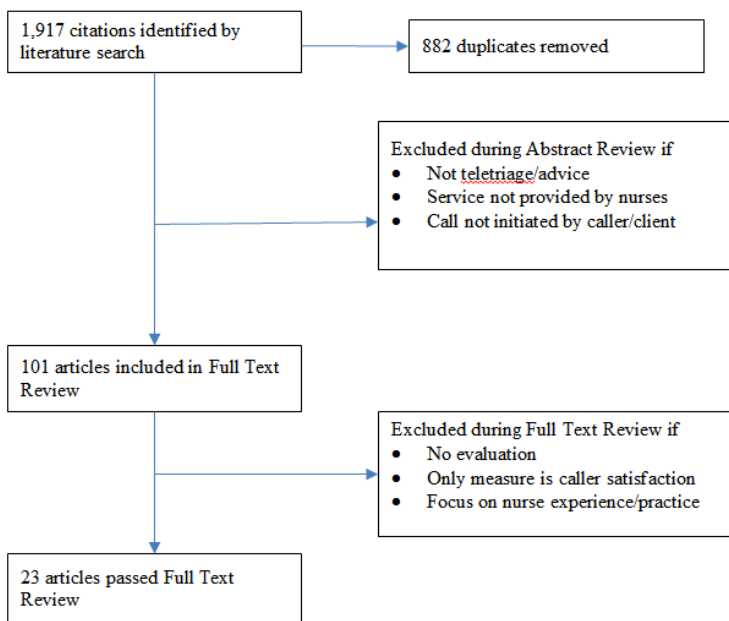
Figure 1. Article Search Diagram.

5. Results

5.1. Evidence of Cost Savings

Most of the articles are using cost analysis, i.e. comparing the cost of the call service with various face-to-face services. In a study at the Denver Health NurseLine, Bogdan et al compared the cost of the caller's original intent for care with the cost of the nurse's recommendation and the cost of the caller's action. During the study period nurse recommendations represented a saving of $26,400, or 28%, over the cost that would have been generated if the callers had not used the teletriage service. The callers' final actions in accessing care still led to savings of $14,568, or 15.5%. Extrapolating this figure to the 30,000 calls the NurseLine receives in a year, the telenursing service could save the healthcare system roughly $1.6 million. The annual cost for the service is less than $650,000 for net savings of roughly $1 million. [6]. Marklund et al found similar results

in a Swedish study with an average cost saving of €22.20/call. With roughly 25,000 calls per year, savings could reach €1 million. The cost of the service is not given, but it is implied that the €22.20 are net savings per call. [7] Both these services are open to the general public and staffed with generalist nurses.

Navratil-Strawn et al calculate the Return on Investment (ROI) at the Nurse HealthLine available to customers of a US insurance company. The service provides triage and advice. The study took place over a 12 month period; the researchers compared each caller's pre-call intention, nurse recommendations and actual services. Claims data were used to measure caller adherence. The cost for the program was calculated at $8.7 million, while savings were calculated at $13.8 million, for an ROI of 1.59 [8].O'Connor evaluated a specialist service for callers with inflammatory bowel disease in the UK over two 12-months periods (April 2008-March 2009/April 2009-March 2010). The author notes that 85%/80% of calls were resolved over the telephone; 14.9%/19% of callers required outpatient appointments, and <0.1%/<1% were admitted to hospital. The cost for the various services is £5.64 per call, £20.00 for a doctor's appointment, £87.00 for hospital follow-up, and £87.00 to 117.00 for an emergency department visit [9]. Evans (2012) and Roberts (2008) calculate cost savings by comparing the cost of the service with the cost of admission to acute care. Evans discusses the Elsie Bertram Diabetes Centre where 50% of patient contact is over the phone. The phone helpline is staffed with Diabetes Specialist Nurses. During the study period of November 01, 2008 to Oct 31,2009, there were 5703 phone consultations. 95% of these calls were dealt with by phone alone. The cost per call is calculated at £23 while the cost of admission for hyper- or hypoglycemic episodes ranges from £846 to £2634 [10].Roberts describes a COPD hotline in Western Australia. Over the two year study period the hotline was used by 118 callers with between 1 and 20 calls each for a total of 675 calls. The annual cost of the hotline is $20,040 while an admission for COPD exacerbation averages $4,000. During the study period, 78 ambulance calls were averted, and the patients' individual action plan was activated 117 times. Roberts speculates these callers might have ended up in hospital without the hotline [11].

Spaulding reports on the Minnesota flu hotline that was established to deal with the high volume of people with symptoms or concerns about the H1N1 pandemic. Spaulding compares the cost of a call with the cost of face-to-face healthcare: $12 per call vs. $192 for a clinic visit, $269 for urgent care, and $876 for an emergency department visit [12].North et al calculate savings at Ask Mayo Clinic by comparing the callers' pre-call intent with the nurses' recommendations for callers who were later diagnosed with appendicitis. Although in these cases the nurses' recommendations were generally for a higher level of care than the caller's pre-call intent, savings were generated by having callers with appendicitis seen in a more timely fashion which prevented potential complications. The total charge for treatment of perforated appendicitis is $40,000 [13].

5.2. Citizens Accessing more Appropriate Levels of Care

3/23 articles discussed clinical appropriateness of the telenurses' advice. Snooks et al found 84% of recommendations to be clinically appropriate [14]; Singh et al: 95-96% [15]; and Marklund et al: 97.5% [7]. Where the advice was thought not to be clinically appropriate, it erred on the side of caution, i.e. the nurse's recommendation for care was considered too high.13/23 studies evaluate caller/client adherence to the nurse's recommendation. Light, De Coster, and Navratil-Strawn use insurance claims to verify if the client followed the nurse's recommendation about the level of care. Light et al look

at parents of febrile children who were given home care recommendations only. 74/110 parents had originally planned on a physician visit. After triage, 53/74 parents followed the nurse's home care advice. 29/110 parents were unsure what to do prior to the call. Following the call, 28/29 parents cared for their child in the home rather than seeking medical attention. 7/110 parents had already decided to care for their febrile child at home and were looking for home care advice from the nurse. In total, 80% of parents adhered to the nurse's home care recommendation [16].De Coster et al breaks down callers by demographic and symptom characteristics and finds that by demographics, uptake of the nurse's recommendation ranges from a low of 34.2% (client under 4 years of age; Health Care Provider [HCP] in 24h) to a high of 65.5% (client 50+ years of age; ED). Adherence by symptoms ranges from 27% (infant care, HCP in 24h) to 63.4% (cardiac; ED). There is little difference based on gender. Uptake for self-care recommendations is generally high and ranges from 74% to 89.2% [17]. Navratil-Strawn identifies similar adherence rates: 55% (2014) [8], and 57% (2014) [18]. Authors who relied on callers' self-reporting of adherence to nurse advice found rates ranging from 70% adherence [6] to 100% [16] – this latter specific to the recommendation of an emergency department visit. In a study of LINK Alberta, Williams et al found 87.5% of callers reported adherence to self-care recommendations [19].20/23 studies address resource use either by comparing pre-call intent and post-call intent, or using objective data such as insurance claims. Generally the authors who have described cost savings identify these savings as a result of callers seeking a lesser level of care than they had originally intended. Three authors that break down resource use into urban, suburban and rural areas, note that there are differences both in pre-call intent, nurse's recommendation, and final caller action: Hogenbirk et al [20], Dunt et al [21], and Navratil-Strawn et al [8]. Typically a range of medical services options is available in metropolitan areas, while in rural areas the local hospital may be the only option for face-to-face care. This may lead to a higher rate of accessing care in the emergency department, both as caller intent and nurse recommendation [21].Bolli et al found that the implementation of a nurse triage and advice line at a Swiss pediatric hospital led to an increase in ED visits, however the fact that parents called the nurseline before visiting the ED allowed for better planning of these outpatient visits and better workflow [22]. Wetta-Hall et al found that calls to a nurse triage and advice line led to decreases in ED visits, and while there was an increase in GP visits there was also an increase in self-care behaviour [23].

Some specialist services find that most caller concerns can be resolved over the phone. Reid and Porter report on a chemotherapy helpline in Northern Ireland, where fewer than half the calls require a face-to-face visit. Without the helpline, patients would have no choice but to visit their doctor for help in dealing with troublesome side effects [24]. Other specialist services with nurse helplines include a service for parents of children with congenital abnormalities (Gischler et al) [25], patients with movement disorders (Roberts-South et al) [26], and palliative patients cared for at home (Phillips et al [27] and Roberts et al [28]). These services have in common that they serve a small population with significant medical and care needs. Nurse helplines provide a first point of contact serve to resolve concerns and streamline access to face-to-face care. Determining if callers adhere to the nurses' recommendations can be difficult. Studies that use objective data i.e. insurance claims show lower adherence than those who rely on self-selected and self-reporting survey participants. Overall, reported adherence is greatest when the nurse's recommendation matches the caller's pre-call intent.

6. Discussion and Conclusion

Telenursing triage and advice services have the potential to save money and resources within the overall healthcare system. Current research that uses objective data such as insurance claims shows cost savings for the overall healthcare system, but there is not much of this type of research. Further research is needed to specifically identify callers' pre-call and post-call intent and actions. Since some callers had intended a lower level of care than was recommended by the nurse, or no care at all, these kinds of calls can lead to higher costs in the short term, but potentially to better clinical outcomes and cost savings in the long term, as described by North, where timely diagnosis of appendicitis allows for prompt treatment that is less costly than treatment of complications [13].The research on appropriateness of advice shows that the advice is clinically appropriate in 85-90% of cases, and where not considered appropriate, the recommendations are for a higher level of care rather than too low. Clinical decision support systems reflect the fact that nurses are unable to see their clients as well as not being able to collect objective health data and may recommend higher levels of care than a clinician would recommend in a face-to-face encounter. This review provides a limited scan on the impact telenursing triage and advice services have on the broader health care system. The focus is on costs and resource use, with lesser emphasis on health outcomes. It is important to recognize that theoretically these services could function as a barrier to accessing medical care, while the thrust should be towards client empowerment by sharing information to assist with appropriate health care choices. The studies that did track callers' pre- and post-intent of seeking care show a marked increase in self-care decisions following the call, but this also includes some callers who had not planned on any care for their symptoms. Lastly, it is difficult to compare cost benefits of telenursing services in different jurisdictions, as the overall health care systems differ substantially. However there is a scarcity of research even in jurisdictions that can be easily compared, e.g. Canadian provinces. In order to justify expansion of telenursing triage and advice services it is imperative to conduct more standardized studies in various jurisdictions, using objective data whenever possible, and comparing health outcomes as well as program costs. In summary studies from various jurisdictions have shown a decrease in ED and GP visits as well as cost savings following the use of a nurse triage and advice line. There is great variety because of variances in healthcare jurisdictions, as well as variances in study parameters and cost calculations. More research in more settings is needed to show consistent benefit from telenurse triage and advice services.

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Use of Agile Project Methodology in Health Care IT Implementations: A Scoping Review

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Abstract. Health care organizations are investing in system solutions that can be leveraged across the continuum of care (i.e. electronic medical records (EMR's); electronic health records (EHR's); health information exchanges (HIE's) and patient portals. The importance of these systems and how they have evolved over the past 30 years has been well researched. The value and benefits of these systems are therefore well known; however, it is estimated that most projects are typically 100% over budget and a year behind schedule [1, p. 2]. In this paper the authors examine what literature is available on agile project management methodologies in health care settings. A scoping review of the literature available specifically on agile methods use in implementing systems within health care was undertaken. Findings revealed there is very little literature available on agile project management methodologies used in health care IT systems implementations. The authors identify there is a strong need for research to look into project management methodologies and identify areas in the project lifecycle, where change is needed to increase clinical systems adoption.

Keywords. agile methods, agile implementations, health systems, implementations, implementation science, project management

1. Introduction

It is critical for research to be conducted in the health care project management field in order to address the number of project failures that drain scarce resources away from the health care system [1]. There is consensus emerging among policy makers and researchers that the problems with health care information technology (IT) projects are due to sociological, cultural and financial issues [2]. According to the literature, IT implementations in health care continue to be a struggle and challenge. As a result, there is a need to better understand project management approaches that are used in health care IT projects, as it is important that implementation practices change along with the ever-changing technologies being implemented.

2. Background

When the PMBOK guidelines were made available in the 1980's the common project management methodology at that time was the traditional "waterfall" approach [3]. The

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premise behind the traditional method is that of a "one size fits all" approach that does not hold true in today's health care industry. New project management approaches are needed. As a response to this, the agile approach was established in the late 1990's and specifically used for software development. A definition provided by Hoda et al., [4] is: "Agile methodologies follow a iterative and incremental style of development and dynamically adjust to changing requirements and that enable better risk management". Agile project management is considered to be an innovative and modern approach of the 21st century [5].

No one-project management methodology is suitable for all projects, regardless of how the Agile Manifesto authors feel about this. Health care IT projects are time and cost sensitive. Following a iterative approach and requiring end users to support continued improvement of a system are not well suited to health care as errors can be very costly from both a budget and risk to patient care perspective. Despite its potential importance, little peer-reviewed literature can be found to support the use of agile methods in health care IT implementations. It is time for a change to occur in IT implementations and this change could involve moving towards the concept of agile.

3. Method

3.1 Evaluation Framework

Arksey and O'Malley's framework [see 6] was used to conduct the scoping review.

Stage	Description
Stage 1:	Identify research question
Stage 2:	Identify relevant studies
Stage 3:	Study selection
Stage 4:	Charting the data
Stage 5:	Collating, summarising and reporting the results

Table 1: Arksey and O'Malley's framework

3.2 Research Questions

The paper answered the following question: "What literature is available on agile project management methodologies in health care settings?" The authors examined the research on health care IT systems' implementation and where in the project lifecycle the agile approach would add the most value.

3.3 Search Strategy

A search strategy was developed to retrieve relevant studies from the databases: MEDLINE, Psychinfo; IEEE Explorer and PubMed database. The databases were searched using two queries that combine terms agile methods, agile implementations, health systems implementations, implementation science and project management. The search was limited to full text, English language material between 01/01/2015 and 01/01/2018. These dates were used to collect more recent articles around agile use in implementation as IT processes and solutions change rapidly.

3.4 Inclusion and Exclusion Criteria

To be included in the review, a peer reviewed publication had to meet the inclusion criteria set out by the researcher. First, the study had to discuss agile methodology used in a health care setting. Secondly, the study was included if it provided a framework or guidance on how agile methodology could be used in health care, and thirdly, focused on any case studies of agile methodology implementations in health care systems. Articles that did not specifically discuss agile methodology application or use in health care settings, were not a full text article, were not in English, did not fall in the date range or could not be downloaded and accessed were all excluded from this study. A single reviewer performed an initial scan on all the results of the search and rejected those that did not meet the criteria based on an initial scan of the titles and abstracts (n = 176). Two researchers reviewed the titles and abstracts of the studies identified in the literature search to determine whether the inclusion criteria have been met. All disagreements between reviewers regarding the selected articles were resolved through discussion and consensus. A single reviewer extracted articles meeting the inclusion criteria for a full review. The selected studies were also examined for redundancy and duplicates were removed.

3.5 Data Extraction

Once a final set of studies was identified, general study characteristics were extracted. Next, the goals of the study were identified and extracted. The project approaches were extracted along with the benefits and barriers experienced and placed in a table. This information was helpful in informing what changes in a project lifecycle were needed for a successful implementation using agile.

4. Findings

4.1 Selected Articles and Characteristics

Overall the search yielded 176 articles for consideration. Many articles were rejected during the initial title and abstract review because they were studies not related to agile projects of health care IT. From the 176 articles that were considered, 95 were not related to agile projects of health care IT, a further 11 could not be extracted, 42 were duplicates, and six articles did not meet the date criteria. After a full review a further 10 papers were excluded, as they were not about agile projects in health care. Therefore, 12 studies were included in the review.

4.2 Synthesis of Findings

There were a variety of study designs employed in the papers that were analysed, these included; hermeneutic systematic reviews, summative evaluations, mix method research design, action design research, qualitative analysis and the most popular was case study research. In the next section of the findings we outline the key themes that emerged. In general there is very little available literature on agile project management methodologies used in healthcare IT systems implementations. There were a few themes

or patterns that emerged during the review from the 12 papers that were analysed that will be described in greater detail below.

4.2.1   Literature Available on Agile Project Management Methodologies Used for Healthcare IT Implementations

Tolf et al. [7] suggested that for agile methods to be adopted in hospitals, project management activities would need to focus on building adaptive capacities instead of being operations based. Lodha [8] suggested that hybrid models must integrate with a quality management system. The authors provided no information about how hospitals would need to change their IT implementation strategies to move towards an agile approach. In Pitkanen et al [9] the summative evaluation was based on using an Agile Instrumental Monitoring (AIM) methodology [9] in order to determine if the user experience could be improved in health IT. The authors identified that there was a need to collect additional evidence and that the AIM methodology could be used to assess if the user experience could be improved.

Greenhagh and colleagues [10] develop a framework for predicting and evaluating the success of technology, to support health and social programs. Although the review did not provide information about where agile methods that have been used to implement health care IT, it did provide a new framework that could be used for evaluating the success of technology. Future use of this framework may provide further insights into how technology affects patient care and safety. As part of this work, several case studies were conducted. The case study papers provided some insights into health IT system implementation projects. However, little information was available on how agile methods are applied in the project lifecycle.

4.2.2   Impact to the Project Lifecycle on Using Agile Methods

Dafydd et al. [11] conducted a useful case study at the National Health System (NHS) in England, UK. The review discussed the usefulness of creating smaller teams of users and developers. The outcome of this project was a simple, effective and popular semiautomated, online information technology (IT) system that was achieved at a low cost. This is a useful observation for adopting agile methods. Health care organizations may consider creating smaller mixed professional, clinical and technical teams to work on projects taking a simpler approach to delivering complex IT solutions.

Although some case studies did reference agile methods, the impact of agile method use on the project lifecycle was not discussed; for example, one case study review [12] concluded that significant commitment and involvement is needed from business areas; however, the authors did not discuss at which points in the project lifecycle does this need to occur. Dafydd et al's [11] case studies did not provide clarity as to how the project lifecycle changed when using agile as opposed to traditional method. Albornoz et al [13] suggested that providing multiple mock-ups and testing was a useful method for ensuring user requirements are met. Tamblyn and colleagues [14] conducted a case study that used agile development cycles and concluded that the success of the project was related to obtaining support from leadership, having clinical champions, and providing an ongoing feedback mechanism from users to the development team. The researchers identified that this led to priority issues being resolved. From these case studies there is some direction provided on how and where the traditional project lifecycle could be changed to adopt the agile method. Lastly, Kushniruk and Borycki

[15] provided insight using qualitative analysis into how new approaches to usability testing are required to support agile processes. The paper discusses the importance of having the ability to rapidly collect data and perform analyses. In summary as, agile methods require testing to be conducted throughout the development cycle, tests need to be flexible and low cost.

5. Conclusion

Stave [5] stated that the authors of the Agile Manifesto had predicted that agile methods would replace traditional methods in the future. The replacement of traditional methods with agile methods in health IT has not been shown to improve the quality of health care IT implementations. Although there is discussion in the literature about the use of agile in health care, little evidence exits of its use in delivering health care IT solutions. There is also little research on how the project lifecycle is impacted and where agile methods could be incorporated Vrhovec [16] stated that agile methods are rarely studied and that additional research is needed where agile methods are used to deliver health care IT. Specifically, it is important to understand how agile methods are being adopted and if agile methods have an impact on the failure rate of health IT projects. Research is needed on all methodologies being applied, whether it is, the traditional approach, agile methods or hybrid methodologies. Lesmana et al [17] identify that combining traditional and agile methods into a hybrid project methodology not only improves the speed of project delivery, but also delivers high quality solutions to end users. This would be very helpful in health care. Delivering projects quicker would enable health care organizations to do more with their funding, which could improve health care service delivery. Delivering solutions that are high quality that meet user requirements would reduce the number of systems that are abandoned and contribute to improving health service delivery.

Health care IT projects would benefit greatly from additional research on how agile methods have been used to deliver health care IT projects, including an understanding of possible project outcomes. By assessing and evaluating agile methods and how they could be adopted for health care IT projects, one could help reduce the high percentage of IT project failures.

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Ghosts in the Machine: Identifying the Digital Health Information Workforce

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Abstract. In descriptions of digital health the role of human agency and the work of managing and governing health information and communication technology is often invisible. This paper reports preliminary results of a scoping review of the literature and a national workforce census, undertaken as part of a research program to shed light on the responsibilities and the contributions of the health information workforce. The global literature is not a good indicator of the actual proportion of health informaticians, health information managers, health librarians or other health professionals who are engaged in health information work in Australia. While the research interest in health information work of all descriptions is increasing, the practice of health information work is neither highly skilled nor easily identifiable in findings of an Australian census. Reforming this workforce may be a key to translating digital health rhetoric into measurable improvements in health system performance.

Keywords Health information, information technology, labour force, occupational status

1. Introduction

Digital health may appear to have a life of its own. Consider the ITCH conference statement "Health information technologies are revolutionizing and streamlining healthcare and their uptake is rising dramatically"- as though these technologies could do all of this without human support or intervention or collaboration. Healthcare in general is notable for its highly trained professional workforce, carefully regulated in the interest of public safety. Yet in descriptions of digital health, the role of human agency and the work of managing and governing health information and communication technology, of ensuring that digital health data are harnessed for health knowledge, is often invisible.

Major investment in digital health initiatives too often proceeds without recognising and implementing the specialised workforce development that is needed to deliver on the promises for healthcare - enhancement, streamlining, transformation, revolution, and so forth. Clinicians, managers and technicians cannot be assumed to have the skills,

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experiences, attitudes or perspectives necessary for this work. Yet these initiatives proceed despite decades of calls for attention to this issue, and reports of lessons learned. For example, in Australia national accreditation standards for documentation and communication of critical information in healthcare do not specify agents [1]; Standards Australia's Digital Hospital Handbook identifies only two key roles - chief clinical information officers and health information systems managers [2].

Health workforce policy and planning in this area is not helped by multifarious claims to the expert high ground. Existing professional associations may be in competition for members at the same time as new and more nuanced professional associations also are emerging (for example, [3], [4]). The aim of this paper is to describe progress, through a literature review and a workforce survey, toward making the case for a distinctive specialised digital health workforce, with a clear professional identity, a definitive body of knowledge, and formal education paths.

2.   Scoping Review Method

A scoping review [5] was used to trace the emergence and evolution of health information work as specialised work, through bibliometric and thematic analysis of the published literature describing an instrumental or professional human role in health information work. Searches were conducted between July 2017 and March 2018 using health, social science and information science databases: Ovid Medline, Embase, CINAHL, Applied Social Sciences Index, and Library and Information Science Abstracts. Relevant items were also identified through citation checking and search of grey literature. In the structured databases, we searched for combinations of the words in Table 1, in title or abstract (example item counts show Medline result numbers at July 2017).

Table 1. Health information work search term sets.

"health information" OR "healthcare information" OR "health care information" = 19,375 items
OR "health knowledge OR healthcare knowledge OR health care knowledge" = 2,417 items
OR "health data OR healthcare data OR health care data" = 5812 items
NO FEWER THAN TWO OF [informatics OR management OR technology OR library OR systems OR digital] = 138,199 items
[work / worker / workers / workforce OR profession / professional / professionals / professions OR role / roles OR staff /staffing OR expert / expertise / experts OR specialist / specialists / specialized /specialised / specialisation /specialization OR leader / leaders / leadership OR champion / champions OR manager /managers OR "change agent"/ change agents"] = 3,767,278 items

Combining all three sets in Medline retrieved 1,782 items; a similar strategy in the additional databases retrieved 1,466 items. The combined results were screened for relevance by applying the inclusion criterion "describes an instrumental or professional human role in health information work" to the abstract of each item. The final group comprised 253 publications; selected examples are included in this paper and a full list is available from the authors. The following details were extracted manually from the

abstract of each item: Position identity, title, or label; Role, responsibilities, functions; Knowledge, skills, attributes.

3.   Scoping Review Results

We found literature on this topic from 1973 onward. The number of items expanded dramatically from 1990s; numbers since 2010 are more than double all of the 1990s. Differing core concepts persist about what 'health information' is, giving rise to a variety of titles for the roles of people doings3pecialized work with health information, e.g. information manager, information specialist, librarian, computer specialist, informatician, knowledge manager, or informationist [6], [7]. We grouped the titles that appeared in the literature into 6 major categories as shown in Figure 1.

Series1, Health Librarian, 63, 25%

Series1, Health Informatician, 77, 30%

Series1, Health information manager, 40, 16%

Series1, Medical-Nursing-Allied Health, 28,

Series1, Other, 22, 9%

Series1, Health IT, 23, 9%
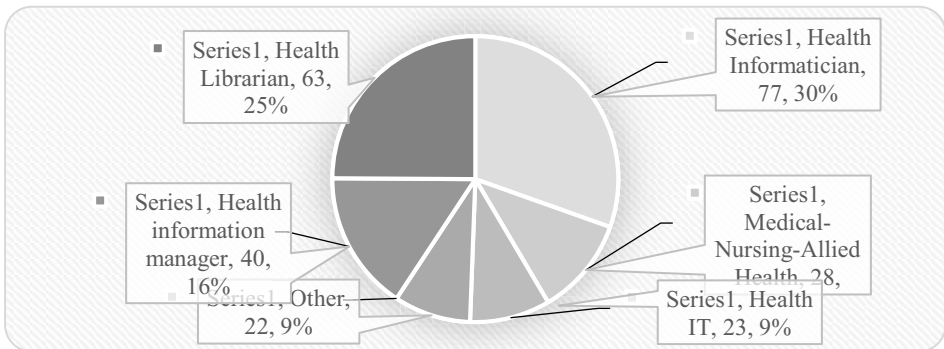
Figure 1. Titles of people who do specialized health information work, in the literature

Not all identities used in earlier decades have continued in mainstream use, and some contemporary terms have gained favour. 'Knowledge manager' was used in the 2000-2009 decade but not much since then. Newer position titles include 'clinical decision support staff', 'patient education specialist', 'health information counsellor', 'information therapist', 'health literacy practitioner', 'information doctor', and 'digital health advisor'. Work described as 'health information systems' and 'health IT' currently has high profile champions [8], [9]. Positions in low- or middle-income countries are more likely to include the term 'community' or 'community-based' implying roles that use the existing health workforce to gather health data or monitor health information activities. (e.g. [10], [11]). Future merging of roles is sometimes predicted or proposed, e.g. health information management interests in common with biomedical informatics [12]; "skills of health informatics, information systems, and data analytics bridging the interests of clinical and nonclinical professionals" (in an education program cited in [13]).   Suggestions to redefine or widen the scope of an existing type of role are common. For health information managers, functions such as data scientists, data stewards, information governance [14], or in health services management and research [15] are proposed. For health information professionals or librarians, potential functions include guiding consumer access to health information [16], or data management in electronic medical record initiatives [17]. Ideas about informaticians' expanding roles are found in titles that include 'informatician' preceded by a range of adjectives – applied, clinical, biomedical, health(care), consumer health, medical, nursing, pathology, population, public health, or research (e.g. [18], [19], [20], [21]).

Assimilation of health information work within the scopes of practice of clinical healthcare professions including nursing, medicine and allied health is also expected (e.g. [22], [23]). Nurses are recognized as routinely using informatics processes and information technology to address patient safety concerns [24]. Allied health professionals such as pharmacists and physiotherapists are also acknowledged as users of health information for clinical decision making and stakeholders in health information systems (e.g. [25], [26]).

There is advocacy of graduate specialist education for health information workers (e.g. [27], [28]); and of continuing education options for updating practitioners' skills ([29], [30]). Competencies are frequently cited, often in terms of a 'minimum' set promulgated by a professional body (e.g. [31], [32]). There is seen to be potential for accreditation of different specialized university degrees by a combined health information authority [33].

4.   Workforce Survey Method

Two universities began a joint program of empirical research into the health information workforce in 2016. This involved establishing a national health information workforce census. A Health Information Workforce Census Management Group, Expert Panel and Consultation Group were formed, with representation from key associations and agencies.

WHO guidelines were used to develop a minimum data set, and a Delphi approach was used from February 2017 to January 2018 to gather expert input and consult widely about the data elements required. Based on the agreed minimum data set an online survey instrument was constructed and pilot tested by members of the Management Group, Expert Panel and Consultation Group in early 2018 [34].

The census was open for one month in May 2018. It was promoted widely through industry, professional and government organisations, to anyone who self-identified as being part of the health information workforce. As a guide, and not exclusively, it encouraged participation by anyone working within the following areas: Clinical coding; Clinical costing; Clinical documentation improvement; Digital health infrastructure; eHealth systems; Health data analytics; Health informatics; Health information governance; Health information management; Health information systems or services; Health information technology; Health librarianship.

5.   Health Information Workforce Census Results

There were 1849 usable responses to the inaugural Health Information Workforce Census. Detailed analysis is under way; rounded descriptive statistics from the summary report [35] are presented here. Respondents were from all Australian States and Territories, and were 78% female and 22% male. The highest educational level of respondents was: 44% Bachelor or Honours degree; 22 % Masters degree; 15% Graduate Certificate or Diploma. 7% had no post-secondary educational qualification in health information.

The main fields of occupation reported were health information management (37%), health informatics (22%), clinical coding and classification (16%), health librarianship (14%), data analytics (9%), and costing (2%). Additionally 12% were registered as healthcare professionals with the Australian Health Practitioner Regulation Agency. The

broad occupational categories with which respondents identified themselves were 51% professional, 34% managerial, and 14% clerical.

Professional associations to which at least 1% of respondents belonged were (in alphabetical order) the Australian College of Health Services Management, Australian Computer Society, Australian Healthcare and Hospitals Association, Australian Information Industry Association, Australian Library and Information Association Health Libraries Australia, Clinical Coders Society of Australia, Health Informatics Society of Australia, Health Information and Management Systems Society, and Health Information Management Association of Australia. However, 45% of respondents said that they did not belong to any professional association related to their health information work.

Respondents were also asked how long they intend to remain in the Australian health information workforce. Over half (56%) said that they plan to leave within 15 years.

6.   Discussion

Taken together, these preliminary findings from our scoping review and workforce census show that the research literature is not a good indicator of the actual proportion of health informaticians, health information managers, health librarians or other health professionals who are engaged in health information work in Australia. Further, while the peer reviewed literature about health information work of all descriptions is increasing, the real-world practice of health information work is neither highly skilled nor easily identifiable in Australia. The arguments in favour of the status quo are not evident; it seems that greater coherence and cohesion in the current health information workforce could have obvious efficiencies (scope and scale) and widespread benefits (accountability and transparency) in the digital health environment.

It is not surprising if healthcare organisations struggle to work out optimal human resource planning to achieve their digital health vision and mission. The health information workforce seems hardly to see itself in terms of this bigger picture of health system change, and a fair proportion will disengage soon. The preliminary results of our research already highlight issues of relevance and sustainability for many health information associations. One possible scenario is that one such group will outcompete others to become the most distinctive and credible organising force for digital health information work. Another is that a broad coalition of such groups will take up the challenge to establish an evidence-based regulated health profession to manage and govern digital health. Workforce restructuring of this kind may be driven by high-level health policymakers, oblivious of the currently invisible expertise and available human resources. By default, health information technology vendors may own the risks and the returns on the investment in digital health, with their executive officers answerable under commercial law for service agreements.

Comparative international analysis of the literature review results is under way to see where there is evidence of health information workforce models that are more (or less) effective in contributing to realise the benefits of digital health. With the census, considerable care was taken to use standard census categories (for education level and occupational group, for example), and to structure data collection so that the census can be customised for use in jurisdictions other than Australia. In November 2018, a New Zealand version of the census, auspiced through a research collaboration between Australian and New Zealand universities, is the next step toward what needs to become a

global research effort. Only this way can the results be translated into workforce reform on the same scale at which digital health operates.

This paper uses the analogy of "the ghost in the machine" [36] to describe the absence of a readily recognisable, professional, specialised health workforce to manage and govern digital health. We believe that there is a serious risk to aspirations for safe and equitable health systems, if the concept of "digital health" is assumed to have inherent scientific and ethical power to inhabit and redirect the human beings in the health workforce into new and better ways of providing healthcare. The question "Why is ehealth it so hard?" [37] continues to resonate with the many and varied professionals who are engaged in digital health work. Our research is exploring answers that have a broad and deep focus on human agency in digital health. Reforming the existing health information workforce, clarifying the roles and responsibilities of those in it, may be a key to translating digital health rhetoric into measurable improvements in health system performance. Our work aims to make health information work visible, as a basis for such improvements.

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The Value of Patient-Peer Support in Improving Hospital Safety

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Abstract. Healthcare systems worldwide have dedicated several years, special attention, and action toward improving safety for their patients. Although many innovative technological solutions have helped providers reduce medical errors, hospitalized patients lack access to these solutions, and face difficulties in having a proactive role in their safety. In this paper, we examine how patient-peer support can be a valuable resource for patients in the context of hospital safety. Through semi-structured interviews with 30 patients and caregivers at a pediatric and an adult hospital, we identify the potential benefits of incorporating patient-peer support into patient-facing technologies. Facilitating such support can provide patients with new avenues for engaging in, and improving, the quality and safety of their hospital care.

Keywords. Patient safety, peer support, human computer interaction; user centered design; consumer health informatics; hospital; medical errors; technology.

1. Introduction

Every day, patients in hospitals around the world are impacted by medical errors and experience avoidable, and often deadly, harm. Ensuring the safety of patients has therefore been a priority for governments and healthcare organizations around the world [1]. To reduce medical errors, hospitals have implemented technological interventions—such as medication barcode scanners and Computer-Physician Order Entry—into their clinical workflows [2]. Although these interventions have demonstrated some degree of success, hospital safety remains an ongoing concern in healthcare systems. More work is needed to understand why these problems persist, and to explore additional opportunities for effective interventions.

In recent years, policy makers, organizational leaders, and researchers have increasingly acknowledged the importance of engaging patients in improving safety [3,4]. Indeed, patients have expressed willingness to be involved in their safety during their hospitalization, and have demonstrated proactive measures they take to protect against avoidable harm (e.g., double-checking medication labels, asking providers about hand sanitation) [5,6]. However, patients still face several systemic barriers when speaking up about concerns, and lack access to sufficient resources to help prevent errors [7].

The support of patient-peers is one potential resource that could help remove the barriers that patients encounter when attempting to engage in their safety. Patients who

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participate in peer support programs experience a number of benefits, including improved health outcomes, self-efficacy, knowledge, and empowerment, all of which can impact their participation in safety [8,9]. Moreover, previous studies have observed and identified opportunities for patients to exchange support addressing quality and safety issues in their care [10–12]. Despite great potential for patient-peer support to improve safety, systems that scaffold this support *within* the hospital are nonexistent. Thus, understanding patients' peer support needs in the context of hospital safety, and exploring ways to facilitate this support, are important next steps towards including patients as equal partners in improving hospital safety.

In this paper, we explore inpatient perspectives on how support from patient-peers could improve their safety during their hospital stay. Our findings from a semi-structured interview study with 30 inpatients and caregivers reveal new opportunities for patient-facing technologies to help patients take on a greater role in their safety.

2. Methods

Our study took place at two hospitals in the Pacific Northwest region of the United States: one children's hospital, and one adult tertiary care hospital. As part of a larger project to investigate the information needs and design requirements of a patient-facing mobile application, we conducted semi-structured interviews with 30 participants (12 pediatric inpatients, 3 parents of pediatric inpatients, and 15 adult inpatients). All participants were approached, consented for the study, and interviewed during their hospital stay. The study was approved by the authors' and study sites' Institutional Review Boards.

To prompt and motivate discussion during interviews, the research team developed a series of paper-based 'feature cards'. Each card represented a hypothetical feature of a futuristic patient-facing technology (e.g., setting reminders for medical events, estimated arrival time of providers coming to the patient's room) and were based on themes relating to the patient's hospital experience (e.g., patient-provider communication, learning more about my health). During the interviews, participants were asked to review and respond to each card. The research team member conducting the interviews asked follow-up questions—such as which cards they valued most, least, and why—as appropriate.

Each interview, lasting approximately 45 minutes, was audio recorded and transcribed for analysis. A research team member did an inductive, qualitative analysis of each participant's transcript to identify themes. These themes underwent discussion and iteration with other members of the research team. Below, we present findings for one particular feature card: "Frequently Asked Questions (FAQ) by patients like me". We focus on this card because it was specifically created to (1) explore design solutions for conveying useful safety information to patients, and (2) understand patient perspectives on peer information about hospital safety.

3. Findings

Twenty-nine out of thirty participants (97%) responded positively to the idea of having access to information from patient-peers on the subject of hospital safety. In the following paragraphs, we describe our how participants envisioned using this information to improve their safety. Each quote from a participant is accompanied by a unique identifier: YP# (Youth Patient), YC# (Youth Caregiver), and AP# (Adult Patient).

YC13, YC14, and AP9 believed that having FAQs from patient-peers would help them think of questions or concerns that they might not have otherwise considered. YP7 spoke to us about his desire to have the FAQ feature, and real-time, up-to-date information about his health, within the same mobile application. He saw FAQs from peers as a resource to think of questions for his care team, verify information that he received from his providers, and fill knowledge gaps that he might have about his care.

Many of our participants thought that the patient-peer FAQs could help patients and caregivers establish a 'baseline' experience to proactively recognize errors and avoid anomalies in their care. A subset of participants mentioned using FAQs to identify side effects, or allergic reactions, to medications that they might receive during their hospital stay. AP5 was undergoing chemotherapy at the time of his interview, and explained how FAQs from patients would reinforce the safety information that his care team had given him earlier during his extensive treatment. AP10, recovering from surgery, expressed interest in learning whether her medications *"make people feel nauseous or have like constipation..."* YC14 was caring for his two-year-old daughter in the hospital. He wanted to read FAQs from other patients who had similar medication allergies as his daughter, as the information would help him decide whether he should be more watchful for side effects, or outright refuse the administration of a potentially harmful medication.

Other participants interpreted this concept more broadly, seeing FAQs from peers as an opportunity to compare or align their own longer-term health experiences with other patients like themselves. YC15 was caring for her daughter with a respiratory infection, and wanted to determine patterns through general trends, such as, *"in the last 15 days or last one month, how many patients like that has been admitted, what is their experience, what kind of medications they got…I will be knowing that I'm not alone…"* AP13 was also interested in FAQs to understand the quality and safety of his long-term health. To manage his diabetes, he wanted to know the average patient's A1C levels, and what constituted a healthy blood count. He went on to say, *"I may want to know what happens if I go hypoglycemic, what happens if I do the opposite, and I'm too high."*

 Related to the idea of long-term quality and safety of care, a few participants discussed the potential for FAQs from peers to be made available before, during, and after their hospital stay. AP12 suggested incorporating peer information as an educational tool into the pre- and post-surgery materials she received from her care team. AP8 mentioned having this information accessible before admission and after discharge, stating, *"I'd use that while I was in here [the hospital] and I'd use it while I was home."*

This information was considered valuable because, as some participants described, finding useful information from peers is burdensome and arduous for patients undergoing treatment from their hospital bed. AP15 was a surgical patient who talked about her unsuccessful attempts to seek out such information: *"I wanted to know how other people did, how [they] went through this [surgery]. Because…I was curious how other people dealt with this, and there's no way really to find that out."* (AP15)

Although most participants reacted positively to having access to FAQs from patient-peers, YP9 was not interested in this feature, and did not expand on her reasoning. AP8 spoke in more detail about the potential drawbacks of including such a feature in a patient-facing mobile application. She believed that keeping the FAQ content relevant, current, and accurate would be difficult. In addition, she thought that having someone available to answer all the questions that patients might have would be a technical and logistical challenge. Despite these concerns, AP8 still responded enthusiastically to the idea of exchanging support with other patients like herself.

4. Discussion and Conclusion

Our findings demonstrate the value our participants saw in FAQs from peers to improve hospital safety. Patients and caregivers thought their peers could help them discover new questions or concerns, verify their understanding about their care, and recognize when they experience a deviation from what is expected in their care. Although some drawbacks emerged from our discussions with participants, the benefits—such as proactively avoiding harm and maintaining long-term safety—were clear.

In previous work, we explored the needs, opportunities, and design recommendations for patient-facing technologies to enable peer support in the hospital [11,12]. The findings in this paper build upon that work by delving into peer support as an upstream patient-centered intervention to improve the quality and safety of hospital care *before* harms occur. Furthermore, patient-peer support is distinct from, and complementary to, the support that patients receive from their providers [13]. Thus, not only does patient-peer support help to underline the safety concerns that providers share with their patients, but it can be effective in ways that past safety campaigns and interventions have not.

Our participants discussed at length how experiential information from other patients could offer a form of emotional support (i.e., not feeling alone in their health journey) to help them feel safer in the hospital. However, patients face many challenges in seeking out this information through existing online health communities and other sources. For example, patients' cognitive and physical functions are negatively impacted by the medications, procedures, and equipment they manage in the hospital. Similar patients might be in rooms that are grouped closely within hospital units, but health privacy laws hinder their chances of meeting and interacting with each other. Patient-facing technologies that incorporate peer support features are uniquely positioned to overcome these challenges, and to make experiential information easily accessible to patients during their hospital stay. These features could accommodate shared experiences of past, present, and future patients, and connect patients across boundaries such as geographic location, diagnosis, and type of treatment.

Peer-support features can also help patients take proactive steps to improve their safety, before a medical error can cause serious harm. Our participants explained how practical advice from peers—including what side effects to watch for, recovery management, and care anomalies to be aware of—could help them avoid errors during their hospital stay. Such support goes far beyond the reactive measures (i.e., error reporting) that are sometimes triggered after emotional and physical harm have already occurred.

Patients have a key role in improving hospital safety, but need greater access to tools and resources that support their involvement in these efforts. Technologies that facilitate patient-peer support is one resource that can help patients identify, prevent, and report errors, while acknowledging them as experts and equal partners in their care.

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An Informatics Framework for Maternal and Child Health (MCH) Monitoring

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Abstract. Most cases of maternal deaths could be avoided with timely access to quality healthcare, but a key challenge in addressing quality of care in maternal health, is the lack of accurate data. We present a review of the difficulties of collecting and analyzing maternal health data. We propose a comprehensive informatics monitoring framework to track progress on the achievement of the international targets and priorities toward ending preventable maternal mortality and improving maternal and child health, that at the same time builds capacity at institutional and country level to collect indicators and to generate actionable and comparable knowledge that facilitates analysis, research, and evidence-based decision making.

Keywords. Health information technology (HIT), maternal, child

1. Introduction

According to a 2016 systematic analysis by the United Nations (UN), approximately 830 women die every day around the world from preventable causes related to pregnancy, and 99% of all maternal deaths occur in low- and middle-income countries (LMICs) [1]. A large and growing body of research suggests that most cases of maternal deaths could be avoided with timely access to quality healthcare [2]. A key challenge in addressing quality of care in maternal health, is the lack of accurate data. For example, in many low-income countries, maternal deaths go uncounted and frequently the cause of death is unknown or not recorded correctly and the maternal care process is equally poorly registered or not registered at all [3]. Many patient registration systems and electronic health records in low resource settings have problems with non-standardized record-keeping techniques which result in missing records, inconsistencies, poor data quality, and inaccuracies and hence undermine evidence-based decision making in healthcare service delivery [4]. This makes it difficult for national health programs to allocate resources where they are needed the most. To achieve this goal is necessary the integration and harmonization of high amounts of heterogeneous medical data that is stored in different health information systems. Such a task is challenging in both developed [5] and developing countries [6]. In this paper, we review some of the challenges in collecting and analyzing this data, and we propose an ontology-based data integration approach to effectively combine data from heterogeneous sources.

2. Current Approaches

Comprehensive database applications for a domain can reduce variation within that domain. There are some proposals such as the Perinatal Information System (SIP) developed by the Pan American Health Organization (PAHO/WHO/CLAP). SIP's aim is for the health team to learn about the characteristics of the health service users, assess the outcomes of the care provided, identify the priority problems and conduct a operational studies [7]. It contains a model of perinatal clinical history with pre-codified and open data, 170 variables entered by clinicians or under their supervision. SIP has been modified several times due to the need to keep their contents updated, as well as to include the priorities - national and international - defined by the Ministries of Health of the region. It also allows automated report production and the transferring of local data across institutions. The tutorial handbook contributes to the record's consistency. In a study [8] in 20 maternity hospitals (5 Countries, 40% Private and 60% Public) 85% had a reliable information system by the third year of use of SIP. 15% of hospitals still had problems at that time that were already clear during the second year. The evaluation of the impact of yearly reports shows that 58% of recommendations were fulfilled, especially those regarding the complete filling-in of clinical records (62%) and to a lesser extent, variables that reflect clinical practices and organization of services (52%).

One of the most comprehensive and proven perinatal datasets is the one implemented at the Medical University of South Carolina (MUSC) Perinatal Information System (PINS). A validated, research-quality perinatal database with multiple edits and audits to ensure accuracy [9], for all women delivering at the MUSC, which is a regional tertiary referral hospital in the southeastern United States. The MUSC PINS database includes detailed information on each mother's medical history, linked to neonatal data (such as medical diagnoses, medications, and laboratory tests) from delivery to hospital discharge. However, even though it is a statewide regional perinatal information system, comprehensive antenatal care information from outside the hospital setting is not available.

The Netherlands established national domain information models to support electronic information exchange based on HL7 RIM, using cases from perinatology as a national pilot, with the aim to support the development, adoption, implementation, and maintenance of the EHR in Dutch healthcare practice [10]. They chose perinatology because there was an existing need for communication improvement with a sufficient consensus and standardization among different professionals represented in a national data set. Their approach was to allow clinicians to understand better where 'their' information is in the Domain Message Information Model (D-MIM) to individually analyze each information item, attribute and value in the domain and map it to existing HL7 RIM classes, attributes, and vocabularies. They found that in some instances, additional agreements are necessary about the preferred vocabulary in the Netherlands, because the professional organizations need to harmonize their materials. Another finding was that the limitations are reached for what should be part of the (national) standard, and what professional organizations should develop and maintain within their realm.

The Global Network Maternal Newborn Health Registry (MNHR) provides prospectively collected, population-based pregnancy outcomes for defined geographic regions within low- and middle-income countries [11]. Its data describes demographic and healthcare characteristics and major outcomes of pregnancy. All definitions used by the MNHR are consistent with the WHO definitions, whenever possible. One of the

limitations of the MNHR is the difficulty in ensuring the inclusion of all pregnancies, and especially those with early pregnancy loss. Some sites encounter challenges in tracking the outcomes of pregnant women who migrate in or out of the study clusters. Other challenges include categorizing critical pregnancy outcomes, determining accurate birth weights of certain groups of infants e.g., stillbirths, infants delivered at home. The MNHR also is a tool for evaluating the effectiveness of strategies of care because, unlike with the use of periodic surveys, data is collected continuously over time within the same population-based cohort. This enables investigators to determine the impact of interventions to improve outcomes, to monitor trends over time, and to evaluate the changing patterns of perinatal care to inform health policy.

3. Current Issues

Regarding the consensus on data indicators, some issues persist. For example, despite the global burden of perinatal deaths, there is currently no single, globally acceptable classification system for perinatal deaths. Instead, multiple, disparate systems are in use worldwide. The World Health Organization (WHO) is developing a globally acceptable classification approach for perinatal deaths [12] but these have not been universally adopted. While the integrated WHO tool is designed to assess quality across the continuum of care, the standards currently included in the tool are not fully representative of all the areas of care that need to be assessed. Antenatal care is not assessed at all and postnatal care in a very limited way. These are typically neglected areas of care that are often not included in quality improvement activities. This is in part because national standards for antenatal and postnatal care are often not in place. Developing such standards and including them in a comprehensive quality of care assessment is a priority.

The inter-country differences in registration systems, also imply biases in recorded mortality rates. The challenge is to distinguish 'real' variations in the value of an indicator from variations due to differences in registration practices and definitions and from random variation [5]. From a practical point of view, a compromise must be struck between useful, important indicators that satisfy many of the formal characteristics and are still accessible. Mortality indicators are particularly sensitive to biases related to the construction of indicators. For example, changes in birth notification and registration practices can cause major biases. In 1994 Germany reduced the lower limit for birth weight for registration of fetal deaths from 1000 to 500 g. Consequently, the perinatal mortality rate jumped suddenly from 5.5 per 1000 to 6.6 per 1000, an increase of 20% [13].

Databases using the International Statistical Classification of Diseases and Related Health Problems (ICD) can facilitate cross-country comparisons, but revisions can alter the results of comparisons. Regarding perinatology, in its 10th revision, chapters ''O'', ''P'' and ''Q'' are relevant to perinatology. An analysis of these codes shows that 163 ICD9 codes are mapped onto 235 ICD10 codes in chapter P, and 180 ICD9 codes for anomalies onto 620 ICD10 codes [14]. Changes in the ICD version used to register causes of death or morbidity will consequently result in systematic shifts in the overall levels reported. The World Health Organization (WHO) and collaborating partners are developing the WHO Application of ICD-10 to perinatal deaths: ICD-Perinatal Mortality (ICD-PM) [12]. Tables comparing causes of death and morbidity across countries should explicitly state the ICD version used for coding.

Some countries have taken steps to homogeneous coding practices on a national level. For instance, the Danish society of gynecology and obstetrics has elaborated a guideline for registration of births which selects a number of codes from ICD10 and the Nordic Classification of Surgical procedures and Treatments that were found to be relevant for registration on a national level, with additional definitions and criteria for use where necessary [15]. In general, the burden on individual providers of collecting data has been well documented [16], as has the lack of use of data collected at such great cost [17], which breaks the feedback mechanism whereby monitoring and review can result in improved provision of interventions.

Another challenge is data aggregation and overlap. For maternal care, clinical data is often generated from various sources (prenatal screenings, primary care providers, midwives) and the health information may exist in both paper-based and computer-based systems at institutions located in different geographical locations. The overlap across systems introduces the potential for data variation through duplication of data entry and differing concept definition or context of use. Studies show that redundant and inconsistent records lead to errors, extra effort, misdirected data, over-reliance on the spoken word, inaccuracies, information loss, limited standardization, miscommunications, decision changes, and limited outcomes evaluations [18]. Also, failure to share patient information across data systems can lead to inefficiency and reduce the quality of care. One study [19] pointed out the deficiency in communication among health professionals and that both lack of communication and lack of clarity of medical records are major causes of medical incidents. Research has shown how coordination and communication among clinicians and across settings resulted in greater efficiency and better clinical outcomes [20]. An Institute of Medicine report [21] explained that a health system must have efficient and accurate ways of capturing, managing, and analyzing clinical data collected at all the different sites where care is provided.

Also, the course of pregnancy, childbirth and child development involves a series of stages referred to as the prenatal, intrapartum and postnatal periods of care, involving several medical disciplines during each stage, using a variety of technical jargon registered in different systems. The ability of communication among EHRs that contain such kind of information, which would allow interoperability, requires that terms in all involved systems share their semantics. However, gathering information from EHRs connected to different information systems is a challenge and involves the adoption of semantic interoperability solutions. To address this, the healthcare sector has developed standards for medical vocabulary (SNOMED-CT) and message information models (FHIR) that carry many of the features present in Semantic Web standards such as the Web Ontology Language (OWL). For example, Implementing FHIR in MCH domain, requires additional structure definitions and rules about which resource elements and terminologies map to particular MCH requirements [22]. Semantic interoperability is then also needed because of the seemingly arbitrary meaning of data across different health sectors, which may result to classification errors when collecting data. The solutions based on formal ontologies can enable the effective semantic interoperability because for systems to interoperate, they have to share the meaning of their terms, which requires a well-defined semantics.

Obstetric and Neonatal Ontology (OntONeo) [23], aims to represent the diversity of data registered in EHRs involved in pregnancy care. Such ontology will be able to join different standards and terminologies adopted by information systems that deal with prenatal EHRs and provides a demanded specialized vocabulary planned to include a

more comprehensive formal representation in comparison with other currently available ontologies and terminological resources. OntoNeo still needs additional validation in different communities of physicians and healthcare professionals.

4. Towards a Comprehensive Framework for Maternal Health Informatics

The still high maternal mortality ratio (MMR) could be explained because gains in coverage do not always result in safe and high-quality obstetric care due to limitations of *training and process improvements*. To achieve sustained improvements, local groups will need not only need outcomes metrics and education on best practices for care but also to develop ways to examine their current care delivery process and identify areas for improvement: 'What gets measured gets managed' [24]. Studies have also shown that medical knowledge, job satisfaction, and self-efficacy do not increase by only using continuing medical education (CME) intervention and that using only one mode of learning fails to stimulate lateral learning i.e. learning from your peers [25]. We are currently developing a comprehensive set of metrics for maternal outcomes and process variables that will be useful for low- and middle-income countries. An Alicanto™ (http://www.alicantocloud.com) social community education site is being established for maternal health centers in Latin America to have access to evidence-based education and best practices to collect outcomes through the continuum of care, keeping standardization of clinical structure and content across all databases; while being technologically and culturally appropriate. Based on our review of other maternal health databases, an initial set of consensus metrics will be used to track outcomes. An online asynchronous discussion forum will be used for communities of practice to share their experiences and discuss challenges in care delivery and data collection with colleagues. Through the community site, we will provide support and tools on how to collect and analyze that data for quality and process improvement, but we believe that a co-creating approach to developing metrics, is more successful, engageable and sustainable. Of particular interest is what process-oriented data can be collected to measure quality of care delivery in low resource settings.

5. Conclusions

There is a global need to end preventable maternal deaths and to improve maternal and child health. Despite multiple approaches, there is no universal consensus on their implementation, causing discrepant data indicators, heterogeneous coding practices, and data overlap. There are also difficulties in technical and semantic interoperability, causing deficiencies in communication among health professionals. As a result, health systems and governments have very limited outcomes evaluations. We propose a comprehensive informatics monitoring framework that will be created based on a consensus community of practice and an ontology-based data integration approach, in which there is not only data collection, but processes variables are included and can be used in a feedback mechanism to improve training and monitoring. This approach will build capacity at institutional and country level to generate actionable and comparable knowledge that facilitates analysis, research, and evidence-based decision making.

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The Use of Head-Worn Augmented Reality Displays in Health Communications

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Abstract. The health industry is always seeking innovative ways to use technology to create or improve the experiences of their professionals. Such improvements are seen in a variety of areas including the analysis of relevant health data and the establishment of new ways of communicating medical education and training. Advancements in head-worn augmented reality displays (HWDs), such as the Microsoft Hololens, present a unique opportunity to leverage technology in the ongoing challenge of creating meaningful and novel educational experiences. This paper will review contemporary HWD technologies, how these technologies are being used to enhance the work-training environment, and how these technologies might enhance the communication of health professionals.

Keywords. augmented reality, health information, information technology, algorithms, survey

1. Introduction

In the past decade, innovations in research and technology have made it possible to combine virtual and real environments. Within the health industry, many academic institutes and medical training hospitals are already using virtual- and augmented-reality technology to train medical students and practitioners. However, with many current simulation technologies [1], the equipment required is not portable and cannot be transported easily. The recent introduction of new, portable head-worn augmented reality technology devices (HWDs) have created numerous exciting new possibilities.

1.1. Purposes

This paper has three primary purposes: 1) to survey the current state of HWDs; 2) to explore how the application of HWDs can contribute to the health industry; and 3) to outline some of the current obstacles for an effective Augmented Reality (AR) experience.

1.2. Background

Augmented reality (AR) systems are defined as systems that enable real-time interactions between virtual and real objects that coexist in the same space [2]. These systems utilize

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many different forms such as head-worn displays, projections, and mobile phones to allow users to view virtual objects in the real world (e.g., Pokémon GO). For decades, researchers have recognized the great potential of AR to enhance activities in diverse fields such as geographic studies [3], data science [4], education, and health.

1.2.1. Potentials in Different Industries

Current AR research generally focus on three topics; 1) outlining AR's potential in different environments, 2) addressing the problems with AR, and/or 3) surveying the state of AR. These topics have been investigated in various industrial environments.

Within the manufacturing industry, Zhong et al. [5] and Boulanger et al. [6] describe how we can use AR to collaborate on training tasks. By sharing the view of the person being trained, wearing a head mounted display, their systems allowed the trainers in a remote site to view and manipulate virtual objects in a variety of training tasks.

In an educational environment, Bower et al. [7] looked into applications of AR and their potential to facilitate students' learning. The researchers highlighted the usage of mobile phones and tablets to overlay media onto the real world, making information available to students when they need it, on the spot. Bower et al. discussed potentially easing cognitive overload by providing students information when needed, in the palm of their hands. While we present only two examples of how AR is affecting manufacturing and education, we would like to acknowledge that there are many other industries that have been utilizing AR such as in museums, where this technology is being used to display information about their exhibits [8]. More importantly, in this paper, we will discuss the use of AR in health.

1.2.2. History of Head-Worn Augmented Reality Displays

Research on head-worn augmented reality displays (HWDs) has been conducted since as early as 1993. Feiner et al. [9] looked into implementing 2D interface windows in a 3D augmented reality (AR). One of the earliest works in AR, these researchers were able to create a system that overlaid images on a see-through display, simulating virtual windows containing useful information such as self written notes in a real-world environment (figure 1a).

Azuma et. Al [2] studied issues such as real-time tracking and portability, while also looking at advancements in and applications of the technology in the years prior to 1998. Their work provided a foundation for researchers interested in the field; many issues outlined by Azuma et al. continue to be addressed in recent years. Although research up until 1997 mostly focused on hardware aspects of AR, we would like to note that the hardware is only one part of the design required to create the smooth augmented experience desired by individuals and industry.

Aside from hardware advances, research on AR interfaces and interactions have led to numerous outcomes such as the presentation of digital objects in the real world. Bell et al. [10] described applying visual size, shape, and location constraints to the virtual objects projected on the user's visual area. They designed an algorithm to aid in managing constraints such as locating related virtual objects or preventing the objects from occluding each other. Although the algorithm yielded comfortable interactions, Bell et al. believed it could be significantly improved.

Newer head-worn systems such as Microsoft's Hololens [11] (figure 1b) or Magic Leap's Magic Leap One [12] are examples of powerful portable AR systems that are available to consumers. Not long ago, this technology was only available in labs and specialized environments. Through HWDs, a digital world becomes part of the environment, allowing users to interact with the objects and interfaces that these systems project.

There are few studies investigating use of these types of devices for health communication. Due to the novelty of these displays and the ongoing development of the software required to create applications for these displays, further investigation is crucial to bring these displays into health communications.

(b) Feiner's window system with an HWD in 1993 [9]. The large black cube and white triangle are transmitters for two 3D tracking systems. Tracker receivers are on the head-mounted display, waist, and wrist.

(a) One of the latest HWDs released: Microsoft's Hololens (2016) [11]. It requires no external component and all sensors are implemented with the device. Inputs are in the form of air gestures.

Figure 1. A Comparison of HWDs

The Hololens is one of the most advanced devices and currently the best candidate for use within the AR research space, due largely in part to the hardware design choices. Kress et al. outlined [13] the carefully thought out architecture of the Hololens and showed the balance of comfort and performance achieved by the first fully untethered mixed reality headset.

1.3. Motivations

AR has found a home within the health field and specifically the medical field where it is used in various medical tasks and procedures. The use of AR for medical training is becoming increasingly common because of the realistic experiences AR can offer. This could be because blending virtual objects with the real world provides students and professionals novel possibilities for learning complex procedures. Barsom et al [1] showed that when compared with traditional training apparatus, HWDs allow for new levels of accessibility at a fraction of the cost.

2. Applications in Health

2.1. Medical Training

Barsom et al. [1] systematically reviewed the effectiveness of AR applications in medical training. These applications are used to blend virtual and digital elements with a physical environment in order to introduce new educational opportunities for medical professionals. The researchers concluded that although these AR applications are generating public as well as scientific interest, there was not sufficient evidence to conclude that the applications were capable of effectively transferring retainable information to the user.

Recent studies have investigated the use of AR to improve surgical navigation. Both Okamoto et al. [14] and Chen et al. [15] developed AR-based simulations with the aim of improving the safety and reliability of surgery. Okamoto et al. [14] developed an application for surgical navigation in the abdominal area; the system leverages a see-through display and a rigid scope that enables the surgeons to obtain a 3D view. Okamoto et al.'s study identified several problems linked to the use of AR, such as viewing organ deformity, the difficulty of evaluating the utility of the device, lacking in portability, and high cost.

Chen et al. leveraged a head-worn display, created an application, and tested it with actual patient data in a real-world scenario; they verified and demonstrated that the accuracy of their application was sufficient to meet clinical requirements (However, only within a simulated environment). Pratt et al. [16] adopted the Hololens in order to bring a new level of precision and planning into reconstructive surgery. Through preliminary studies, Pratt et al. were able to demonstrate that using HWD could help with the precise localization of perforating vessels. In summary, AR has been an asset in medical training and the introduction of HWDs precludes a new level of precision for some procedures.

2.2. Collaboration

The study of collaboration in AR is becoming increasingly popular. HWDs enable a new type of accessible collaboration in the form of group interactions with a single digital object in a real-world environment. Users are now able to collaborate on complex data sets using 3D visualizations, which can be shared between individuals wearing HWDs. Current research on collaboration primarily revolves around having one HWD receiving instructions and a computer or a mobile device sending the instructions. Ryskeldiev et al. [17] looked at using mobile video streaming to create StreamSpace, an application that provides remote collaboration by sharing one user's environment with another. This type of collaboration can be readily applied in the health industry for medical training purposes, understanding health data visualizations, or any other collaborative tasks that might benefit from a remote collaboration. Velamkayala et al. [18] studied the effects of using Hololens in navigation tasks. Velamkayala et al. asked participants to navigate the university library while wearing a HWD and following the instructions given in-situ by an operator who was remotely connected to the navigating user's camera. The researchers found that, compared to other devices such as the iPhone, the Hololens system yielded improved performances. Moreover, the participants using the Hololens felt a lower cognitive workload when navigating the library. However, users had negative feedback pertaining to the comfortability of the device. A more comfortable experience may in turn generate more efficient outcomes.

To the extent of our knowledge, due to the novelty of the devices, using HWDs for collaboration within the health industry has not yet been looked into and show potential as a useful form of communication.

2.3. Information and Data Presentation

Head-worn augmented reality displays (HWDs) offer an immersive way for users to visualize and interact with data. Hoffman et al. [19] introduced a Hololens method for visualizing and interacting with complex molecular structures: the Hololens provides the authors with a 3D structure, allowing for a deeper level of understanding than the commonly used 2D screen is able to provide. Similarly, Hanna et al. [20] have showed that the Hololens has the sufficient power and comfort required to be useful in facilitating autopsies, microscopic examinations, and digital pathology; they tested the Hololens by having Pathology residents perform an autopsy while wearing the device. During the study, instructional screens and diagrams were displayed to successfully guide the user through an autopsy.

In other disciplines such as city planning and physics, users are already taking advantage of AR to discover new ways of visualizing complex, multi-dimensional data. Zhang et al. [4] used the Hololens to visualize Toronto's city data. Strzys et. al [21] leverages the Hololens by combining aspects of AR with a well-known thermal flux experiment. Strzys et al. showed that this combination facilitates students' learning process by allowing them to visualize an otherwise invisible process.

Design frameworks such as The Personal Cockpit [22], (an evaluated design space for effective task switching on HWDs) and Ethereal Planes [23] provide guidelines to assist in the creation of meaningful information layouts and interfaces of superior utility both quantitatively and qualitatively, for use in any field, including health. This research could also be applied to create meaningful layouts for new health applications. Ens et al. also introduced a layout manager [24] that allowed users to find virtual applications quickly in their real-world environment by using a novel algorithm which carefully chooses where windows should be placed, based on the user's surroundings. Future research is needed to generalize these findings in medical procedural and analytical tasks. To our knowledge, there is limited research examining the efficiency of using HWDs such as the Hololens in completing procedural or analytical tasks in the field of health communication.

3. Future Directions

As emphasized in the previous sections, HWDs such as the Microsoft's Hololens are novel, powerful, and portable; hinting at much untapped utility. However, like every technology, there are some limitations which must be considered. Currently, such devices are limited by their field of view (FOV). Still, even with such limitations, the current iteration of the Hololens is sufficiently functional for investigating means to improve overall user experience as it relates to AR and HWDs.

Another limitation features the in-situation awareness of information placement: where do we place information based on the environment around the user of the device? Displaying crucial, supplementary data in AR for use in procedure or training proves difficult for a plethora of technical reasons. A visually busy environment such as a procedure room for neonatal resuscitation training (See Fig. 2), illustrates numerous

potential dilemmas such as: What type of information should be displayed?; How should the information windows adapt when a person or object, enters or leaves the environment? These environments are often not only visually busy, but physically chaotic.

In future work, we plan on exploring the limitations outlined in Ens et al's work on spatial memory [22]. Combined with the mapping of virtual information spaces to a physical environment [23], we hope to create an algorithm that would facilitate the work of the AR users (figure 2). Furthermore, the intuitive way of presenting data and information, as well as the collaborative aspects of the Hololens present opportunities to expand into new research areas within the health industry such as health informatics.
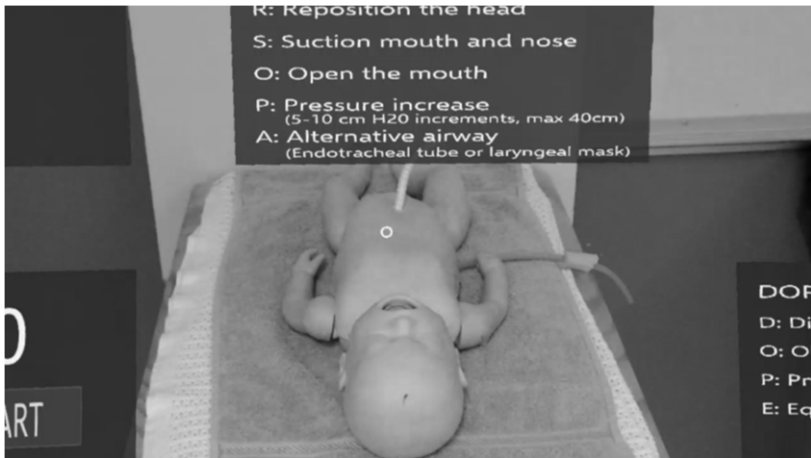
Figure 2. A possible information space for neonatal resuscitation

4. Conclusion

In conclusion, the use of new head-worn augmented reality displays (HWDs) such as the Hololens and MagicLeap One could prove to be quite beneficial within the health industry. Augmented reality (AR) allows us to work with digital objects in a physical environment, while enhancing a variety of tasks such as analyzing complex data, or medical training. Additionally, the improved portability of contemporary HWDs allow users to have an untethered experience while interacting with digital objects. This paper explored the potential use of HWDs for important applications in health communications. We also provide an up-to-date look at the current research going into HWDs. Although there is still some work to be done in order for these HWDs to be more effective, the current state of these devices provides us with a good beginning point for the development and research of portable AR applications within the health industry.

5. Acknowledgements

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Using a Markov Chain Model to Analyze the Relationship Between Avoidable Days and Critical Care Capacity

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Abstract. Hospital capacity strain is ubiquitous, and a significant stressor in critical care. Avoidable days (AD) are frequently used as a metric of capacity. Using a Markov chain model, we studied the relationship between AD and surgical cancellations in a cardiovascular ICU. The model varied the probability of discharging a patient to study this effect over a pool of 10^8 simulated patients with length of stay data reflecting the actual population. The model behaved as expected with decreasing AD with increasing probability of patient discharge. However, there was no effect on the surgical cancellation rate. We conclude that there is no relationship between AD and critical care capacity as measured by surgical cancellation rate.

Keywords. Capacity, critical care, Markov chain model, avoidable days

1.Introduction

Hospital capacity is a universal problem with finite resources and constant demand. Increasing physical capacity is expensive and may not be effective. A focus on system efficiency and throughput is an alternative (1). There are significant risks associated with capacity limits (2). Patients in the intensive care unit (ICU) waiting transfer are exposed to nosocomial infections, unnecessary interventions and tests (3).

Avoidable day (AD) is one way to measure throughput and developed to track causes of transfer delay (4). They are counted from the time a patient is ready for transfer but unable to leave for other reasons, such as needing homecare services. This concept has expanded into ICU where the AD count starts when the patient is ready for transfer but remains due to a lack of capacity on the receiving unit. Lack of capacity directly impacts surgical ICUs because they cause surgical cancellations. Tracking AD is thus used to identify capacity barriers. AD reduction studies focus on quality improvement methods; targeting intervention by opinion (5). Most of these studies are "before/after" with no sustainable improvement. This raises the question whether a relationship really exists between AD and capacity.

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The purpose of this study is to evaluate the relationship between AD and capacity, measured by surgical cancellation rate, in a cardiovascular ICU using a Markov chain model.

2.Methods

The unit in this study is a specialty ICU in Edmonton, Alberta with 24 beds for patients who require cardiac surgery, heart or lung transplant, mechanical circulatory support, and extracorporeal life support. In addition to unplanned admissions, approximately 7 post-cardiac surgery cases are scheduled each weekday. No surgery is planned on the weekend but there are 1 or 2 emergency admissions per day. The unit is funded for 1500 surgeries yearly. A bed management system facilitates throughput, with a bed manager assigned to place patients ready for transfer. Two attending physicians and nurse practitioners are on throughout the day, with a single attending physician in-house overnight. Standardized admission and transfer orders are used.

Data for this study was extracted from a provincial critical care information system (eCritical Alberta) attached to a data warehouse (TRACER). With ethics approval, all patients admitted to the ICU from November 2013 was obtained. The study was limited to patient flow so only the length of stay (days), day of admission, and admission type was collected. The data was used to generate a length of stay histogram and the histogram of the number of admissions for each day of the week. A program was created to model the 24-bed unit. At any given time, a patient could be in one of the following states:

    A. Awaiting admission
    B. Rejected admission due to a lack of an available bed
    C. Admitted to ICU
    D. Admitted to ICU, ready for transfer
    E. Transferred

The simulation assessed occupied beds each simulated day. At the start of the day, the program would loop through all the occupied bed (state C) and decrement their length of stay by one. If the length of stay was zero, then the patient was moved to state D. Dead patients cannot accumulate AD. The model accounted for this by setting a probability of death (pDeath) for each length of stay, based on actual mortality data for each length of stay. Patients moving to state D were automatically moved to state E based on a randomly determined risk of death.

Then a random number was generated and the number of patients to be admitted that day (state A) was set based on the number of admissions for each day of the week histogram. Each simulated patient was assigned a length of stay randomly generated based on the length of stay histogram. The simulation ended after 10^8 patients had been in state. Once the patients had been generated, the program tested for available beds and "admitted" (state C) as many patients as capacity permitted. If there were patients in state A but no available beds, patients who were in state D were transferred (moved to state E), based on a transfer probability (pWaiting) between 0 and 1. State A patients were then moved into any newly empty beds. Any remaining patients in state A at this point were moved to state B and included in the surgical cancellation rate. The simulation

would then cycle through patients in state D and move patients to state E, based on a transfer probability (pNotWaiting) between 0 and 1. Any patients left in state D at the end of the "day" would add to the total AD count, but remain in state D.

Bed manager decision-making is dependent on many unmeasurable factors. In this ICU there are generally two circumstances where a patient is transferred; when there is another patient waiting for the bed and when there is downstream capacity. Patients that are deemed not ready for transfer are never moved. In general, the bed manager is considerable pressure to make a bed available for all critically ill and post-operative patients. This may be impossible if there are no empty ICU beds and no one is ready for transfer or there are no post-ICU beds. pWaiting accounts for the pressure to transfer patients out of the ICU because there is a patient waiting for the bed. When there is no immediate bed demand from a patient, the bed manager must then balance multiple demands when deciding to transfer a patient that is ready to go. Factors include whether a post-ICU ward bed is available and competing demands for that bed by other services. Modelling this is much more complex so pNotWaiting was included to account for this. The Markov chain model is shown in Figure 1.
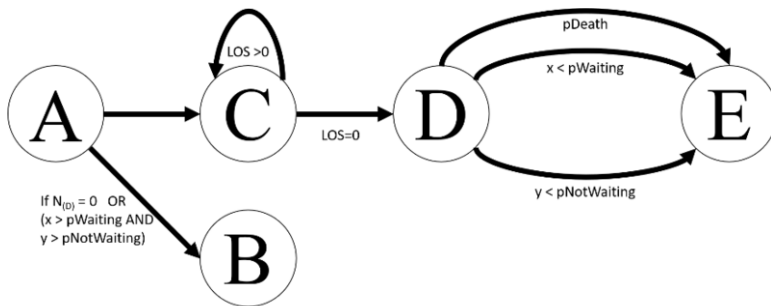
Figure 1. Markov chain model for a simulated cardiovascular intensive care unit. See text for state abbreviations. x and y represent random variables set each cycle. LOS =preset length of stay. N(D) = number of patients in state D.

3.Results

The simulation was run 231times for all combinations of pWaiting|pNotWaiting from 0 to 1 in 0.05 intervals excluding any pairs where pWaiting < pNotWaiting as there would be no circumstances where a patient would be more likely to be transferred when there is nobody waiting to be admitted over being transferred if someone is waiting to be admitted. AD behaved as expected. As pNotWaiting increased, the number of AD decreased for all pWaiting values. As pWaiting decreased, AD also increased. Figure 2 shows AD plotted against pNotWaiting, with examples of pWaiting = 1, 0.75, 0.5, and 0.25. Note that the graph ends when pWaiting < pNotWaiting. The surgical cancellation rate initially behaved as expected. Decreasing pWaiting resulted in an increasing

cancellation rate. However, as pWaiting approached 1, the cancellation rate flattened and tended to cluster around 7.78% (figure 3).
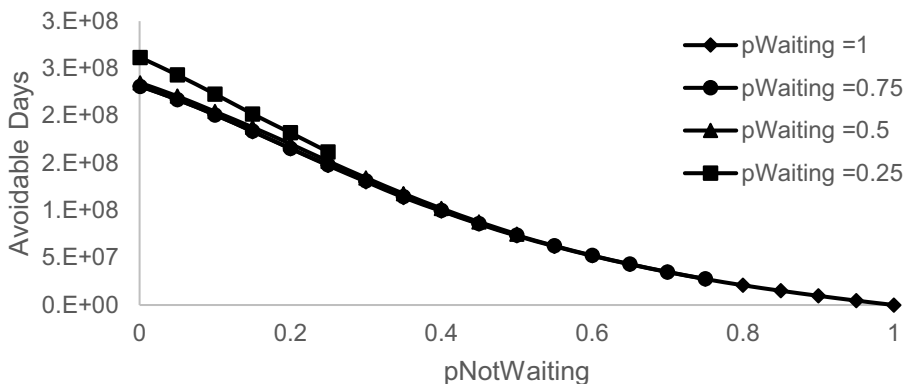
Figure 2 AD plotted against pNotWaiting for various values of pWaiting.
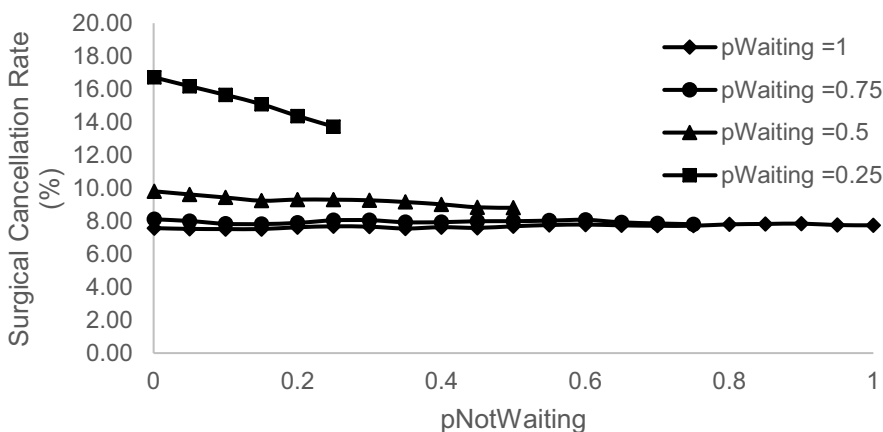
Figure 3. Surgical cancellation rate plotted against pNotWaiting for various values of pWaiting.

The correlation between cancellation rate and AD was calculated for each interval of pWaiting. There was a reasonable correlation when pWaiting was 0.9, 0.95 and 1.0. This fell off rapidly and only recovered when pWaiting was 0.55. However, this likely represented mathematical artifact, given the decreasing number of datapoints.

Validating the model requires comparing with reality. Actual surgical cancellation rates over three years was 6.93% with no change over time. Actual AD was not compared to the model as there have not been 10^8 admissions and the data is inconsistently collected.
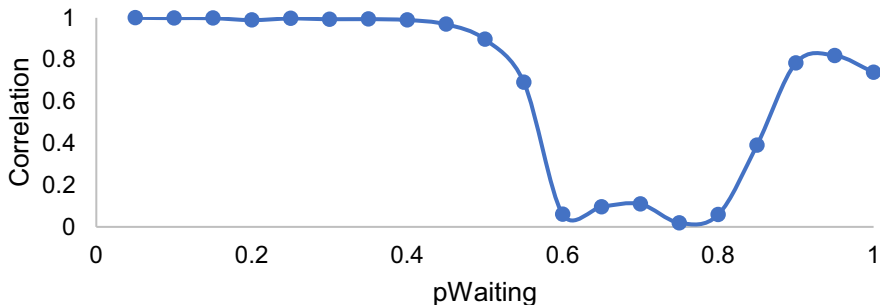
Figure 4. Correlation coefficient between AD and surgical cancellation rate for each 0.05 interval of pWaiting.

4.Discussion

This study demonstrates no meaningful relationship between AD and capacity; measured by surgical cancellations in a large ICU. When pWaiting was above 0.90 (i.e. a patient was transferred > 90% of the time when another patient was waiting), a moderate correlation existed between capacity and AD. However, even at high pWaiting, there was no meaningful change in cancellation rate across all pNotWaiting values. The Markov chain model behaved as expected, with decreasing AD when transfer probabilities increase. The model also generated expected surgical cancellation rates when compared to actual administrative data.

There are several modelling methods that can be used to study throughput in critical care. The simplest is stock and flow which uses continuous simulation modelling (6). When the ICU model was created, the time interval was set as 24 hours so continuous model seemed inappropriate. Discrete event simulation and Markov chain model are similar however, given the number of variables and steps, a discrete event simulation grants increased modelling flexibility without increasing accuracy (7). Thus, a Markov chain model would seem to be just right.

This is the first ICU where this modelling method was used. This unit was chosen as the unit was easier to simulate. There are few non-surgical admissions, and these are never refused. When there is a capacity problem, the only recourse is to cancel surgeries. Thus, all refused admissions in the model reflect surgical cancellations. Surgeries are never cancelled for a lack of operative resources but rarely if the patient dies prior to surgery. As this is a specialty ICU, there are limits to the generalizability of the model. The inputs to the model are clear (i.e. post-surgical admission) and outputs from the ICU are either via death or discharge to a post-surgical ward. The model would need to be adjusted to reflect a different ICU. Another limit was there was no way to detect if the real patients were in state C or D. Some may have been in state D unbeknownst to us. For example, a real patient with a listed length of stay of 4 days could be in state C for 3 days and state D for 1 day. In the simulation, this patient would remain in state C for 4 days and then move to state D and then accumulate AD. Effectively, simulated patients accumulated AD longer than the original length of stay profile. The exceptions would be when length of stay was one day or when the simulated patient died. However, given the

large number of simulated patients, an equal distribution of artificially extended lengths of stay would be a reasonable assumption. This equal distribution, therefore, did not introduce additional bias into the model. Another model limitation was the absence of human bias in transfer decisions. For example, a real patient with an extended stay in the ICU or a problematic family, may be a transfer priority. In the model, all simulated patients who completed their length of stay were equally exposed to transfer probabilities without bias.

The relationship between critical care capacity and AD has largely been assumed. This mathematical model utilizes a Markov chain model and demonstrates poor correlation between capacity and AD. Interventions to address AD in order to increase capacity would seem to be of little value. Future studies should use caution when using AD as a metric. Follow-up work with this model will compare different ICUs and quantify effect of bed number as well as patient population subsets, such as transplants.

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Using Digital Health to Support Best Practices: Impact of MRI Ordering Guidelines Embedded Within an Electronic Referral Solution

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Abstract. *Background:* Between 2003 and 2012, the number of MRIs performed in Canada more than doubled to 1.7 million [1]. According to a 2010 Health Council of Canada report nearly 30% of MRIs were inappropriately ordered [2]. The use of diagnostic imaging referral guidelines has been shown to improve the appropriateness of imaging orders [3, 4].
Objectives: To identify the number of unnecessary pre-consult MRIs ordered for patients with knee pain. As well, the impact that new evidence-based clinical decision support (DS) guidelines embedded within the referral form has had on the number of unnecessary MRIs was investigated.
Methods: This study employed a retrospective design approach. Charts of all knee pain patients over the age of 55 who were referred for consultation to the 5 participating orthopedic surgeons during the study period were reviewed by three medical students.
Results: 270 patient charts were included in this study. MRI was ordered for 60 patients with only 56.7% having had a prior X-ray. Of the 60 ordered MRIs, 50 (84%) were considered inappropriate, while only 10 (16%) were appropriate. Our results were compared to previous results of a quality improvement study implemented at the same clinic. A substantial reduction of 12% in the number of pre-consult MRIs and a 5% increase in the number of ordered X-rays before consultation was demonstrated.
Conclusion: This work highlights the impact of including DS tools within an electronic referral form to support clinical best practices.

Keywords. Electronic referral (eReferral), enabling technology, decision support, diagnostic imaging, clinical value, benefits realization, best practices, digital health

1. Introduction

Between 2003 and 2012, the number of magnetic resonance images (MRI) performed in Canada doubled to 1.4 million per year [1, 5], and will continue to increase as the population ages [6]. According to a Health Council of Canada report, as many as 30% of MRIs were ordered unnecessarily in 2010 [7]. Research suggests that the percentage of

inappropriate imaging referrals ranges extensively from 1% to 88% [4, 8-13], however, there is a lack of research within the Canadian context to fully understand the prevalence locally. An orthopedic surgeon in Kitchener, Ontario, together with some colleagues, recently completed a quality improvement project by conducting a retrospective chart review on patients who were over 55 years of age and presented with knee pain. Many of these patients were referred by their family physician to have a knee MRI prior to seeing the orthopedic surgeon for a consultation. When reviewing the charts for those patients who had a pre-consult MRI prior to the orthopedic consult, the surgeons determined that 78% of the MRIs were unnecessary, and in 73% of the cases a diagnosis would have been possible with only an x-ray (results not published).

Supporting clinical best practices through the implementation of a clinical decision support (DS) tool is sought to reduce the escalating orders of unnecessary diagnostic imaging [14]. The implementation of a DS tool at the point of order has been shown to reduce the total number of MRI and computed tomography (CT) imaging examinations by as much as 36% [3, 15-17]. One study that measured the proportion of inappropriate examinations before and after implementation of the DS by using a chart review found that in addition to a reduction in the total number of MRI and CTs ordered, there was a 50% reduction in the proportion that was deemed inappropriate [13]. This research substantiates the assumption that DS not only impacts the number of imaging orders, but also the level of inappropriate orders.

The System Coordinated Access program (SCA), funded by the Ministry of Health and Long-Term Care and housed at the eHealth Centre of Excellence (eCE) in Waterloo, Ontario, is supporting the development and deployment of an electronic referral (eReferral) solution across five Local Health Integrated Networks (LHINs) in Ontario. Waterloo Wellington LHIN (WWLHIN) was the first to go live with the eReferral solution for orthopedic referrals in August 2017. At the same time, the Joint Department of Medical Imaging (JDMI) at the University Hospital Network in Toronto, Ontario, were pursuing the development of clinically validated guidelines for diagnostic imaging requests. These guidelines are based on the area of injury and provide clear direction on the imaging that should and should not be requested, as well as non-imaging options for care.

The SCA and JDMI teams have worked collaboratively to leverage the eReferral solution as a tool for knowledge translation of the newly developed imaging guidelines. These guidelines have been used to establish appropriate phrasing that is integrated into the eReferral form to support referring physicians with diagnostic imaging decision making (Figure 1). The main objective of this retrospective chart review was to assess the impact of the DS language embedded within the orthopedic form on the number of pre-consult MRIs ordered for knee pain patients 55 years of age and older referred to a local orthopedic clinic, and the proportion of those MRIs that are deemed as clinically unnecessary. Results were also compared to those of the previous QI study conducted through the same Orthopedic Clinic. The results of this study are highly relevant to the provincial efforts to address the problem of unnecessary ordering of MRI that when controlled will impact the wait times for imaging services and reduce costs associated with performing unnecessary tests.

DIAGNOSIS: ☐ Hip Right / Left ☐ Knee Right / Left	REASON FOR REFERRAL:
☐ Osteoarthritis ☐ Inflammatory arthritis ☐ Fracture	☐ Primary Replacement: ☐ Hip ☐ Knee
☐ Post-traumatic arthritis ☐ Failed hip or knee replacement	☐ Opinion on <u>prior</u> replacement: ☐ Hip ☐ Knee
☐ Joint derangement not yet diagnosed	☐ Opinion/management advice: ☐ Hip ☐ Knee
☐ Other:	URGENCY: ☐ Routine ☐ Urgent

X-RAY REPORTS OF THE AFFECTED JOINT MUST ACCOMPANY REFERRAL

If no X-ray report is available from within the last 6 months, we recommend the following views:
Knee: AP weight bearing, lateral of knee flexed at 30°, skyline | **Hip**: AP pelvis, AP and lateral of affected hip
Patients are required to bring their X-Rays to their appointment.
In the setting of osteoarthritis, MRI is not usually further contributory and is not recommended.

Figure 1. eReferral form with embedded DS language for DI ordering at point of referral.

2. Methodology

A convenience sample of 5 orthopedic surgeons was recruited for this study. All orthopedic surgeons were accepting faxed referrals directly from providers, and referrals (electronic and fax) processed through an Orthopedic Central Intake. The surgeons provided a list of all patients who attended an orthopedic consult with them between October 2017 and May 2018. The electronic medical charts for this patient list were reviewed by three medical students, and only those who met the inclusion criteria (>55-year-old patient referred for knee pain) were included in the study. Data was extracted from the referral letters that PCPs sent to specialists as well as from the clinic's electronic medical records database. Data collected included the date of referral, date of consult, age, gender, diagnosis, intensity of pain, duration of adherence to pain management, X-ray ordered, number of MRIs requested pre or post consult, and post-consult disposition. A sample of 10 reviewed charts were assessed prior to the data collection to measure the inter-rater level of agreement among the trained medical students regarding the decision on the appropriateness of the MRI ordered. The trained medical students provided the final decision on the necessity of MRI ordering for patients prior to the consultation under the supervision of the orthopedic resident and with the consultation of one of the participating orthopedic surgeons when needed. The medical students followed a decision algorithm previously developed by the orthopedic specialists involved in the QI study.

3. Analysis

To maintain confidentiality, participants were de-identified and assigned unique numbers. Data was analyzed using the Statistical Package for Social Sciences (SPSS) (SPSS; IBM Corp, Armonk, NY. Version 24; 2018). Descriptive analyses were conducted. Summary statistics including means and standard deviations for continuous variables and frequency distributions for categorical variables, were used to describe the sample. Fleiss Kappa test was used to determine if there was agreement between the reviewers' decision on whether the MRI ordered prior to consultation with orthopedic surgeon was appropriate. Fischer Exact and Chi-square tests were used to examine the association between categorical variables based on MRI ordering and appropriateness. Independent student t-Test was used to determine if a difference exists between the means of two MRI groups (appropriate vs inappropriate and MRI vs. no MRI) on a continuous dependent variable. A p-value <0.05 was considered statistically significant.

4. Results

4.1. Patient Characteristics

Table 1. Patient characteristics. Different letters between groups = Significant difference (P<0.05); same letters between group means =Non-significant difference (P≥0.05). *P-value <0.05 was considered statistically significant

Characteristics of patients	Overall (N=270)	MRI appropriate (N=10)	MRI Inappropriate (N=50)	Total MRI (n=60)	No MRI (n=210)	P value (MRI vs. No MRI)
Age years Mean (SD)	68.4 (± 9.2)	59.7 (±4.4)	64.1 (± 8.0)	63.4 (±7.7)	68.8 (± 9.1)	**P=0.000**[*]
Gender n (%) Females	165 (61.1)	4 (40)	24 (48)	28 (46.7)	137 (65.2)	**P=0.009**[*]
Severity of Pain n (%)						P=0.387
Mild	7 (2.5)	-	1 (2)	1 (1.7)	4 (1.9)	
Moderate	38 (14.1)	2 (20)	6 (12)	8 (13.3)	32 (15.4)	
Severe	32 (11.9)	-	4 (8)	4 (6.7)	28 (13.4)	
N/A	193 (71.5)	8 (80)	39 (78)	47 (78.3)	145 (69.3)	
Duration of adherence to management n (%)						
Acute	6 (2.2)	1(10)	1 (2)	2 (3.3)	4 (1.9)	
None	1 (0.4)	1 (10	-	1 (1.7)	-	
3-6 months	7 (2.6)	-	2 (4)	2 (3.3)	5 (2.4)	
6-12 months	8 (3.0)	1 (10)	2 (4)	3 (5.0)	5 (2.4)	
12+ months	22 (8.1)	-	3 (6)	3 (5.0)	19 (9.0)	
Unknown	23 (8.5)	-	1 (2)	1 (1.7)	22 (10.5)	
N/A	203 (75.2)	7 (70)	41 (82)	48 (80)	155 (73.8)	
X-ray ordered n (%)						
No	22 (8.1)	3 (30.0)	15 (30.0)	18 (30.0)	4 (1.9)	
Yes	204 (75.5)	-	1 (2.0)	1 (1.7)	203 (96.7)	
Yes-prior to MRI	34 (12.6)	6 (60.0)	28 (56.0)	34 (56.6)	-	
Yes- Post MRI						
Yes- At consult	7 (2.6)	1 (10.0)	6 (12.0)	7 (11.7)	-	
Unknown	1 (0.4)	-	-	-	1 (0.5)	
	2 (0.8)	-	-	-	2 (1.0)	
Post-consult disposition						
Conservative treatment	142 (53.0)	6 (60)	35 (70)	41(68.3)	101(48.5)[b]	**P=0.000**[*]
Arthroplasty	118 (44.0)	-	14 (28)	14 (23.3)[a]	104 (50.0)[b]	
Arthroscopy	8 (3.0)	4 (40)	35 (70)	5 (8.3)[a]	3 (1.5)[b]	
Wait time Mean (SD) days	181.9 (±143.5)	251.5 (±143.5)	175.4 (±110.8)	185.61 (±114.5)	181.08 (±151.1)	P=0.852

Charts of 437 patients with knee pain were retrospectively reviewed, and 167 were excluded as they did not meet the inclusion criteria. A total of 270 patient charts were included in the analysis. Table 1 presents the demographic and clinical characteristics of the sample and the appropriateness of MRI ordering. The mean age of patients was 68.5 (± 9.26) years. There were 165 (61.1%) females and 105 (38.9%) males. The severity of

pain was only reported for 77 knee patients in the charts, and of those, patients reported pain severity as follows: 41.6% severe pain, 49.4% moderate pain, and 9% mild pain. The most common diagnosis of the knee pain was osteoarthritis (82.8%). Other diagnoses included tears, injuries, degenerative changes, baker's cyst, fractures, or a combination of these. The post- consult disposition for most patients was conservative treatment (53.0%), followed by arthroplasty (44.0%).

A total of 60 (22%) knee pain patients were ordered a pre-consult MRI. Mean age of patients with ordered MRI was 63.4 (± 7.70) years, while the mean age for those with no ordered MRI was 68.8 (± 9.19) years. A statistical significant difference was detected between both groups (p=0.000). In the pre-consult MRI group, 53.3% were male while in the non-ordered MRI group 34.1% were males. A statistically significant difference related to gender was detected between both groups (p=0.009). Regarding the post consultation disposition, 68.3% of patients who received MRI prior to consultation were considered for conservative treatment (non-surgical), while 50% of patients who were not ordered MRI prior to consultation were considered for arthroplasty (surgical). Significant differences were detected between both groups regarding each post-consult disposition (p<0.001). Of the 270 charts, 140 patients were referred to the orthopedic clinic after the eReferral system went live. Of those, 52 were referred using the new form which included the imaging DS guidelines, either through the electronic referral form or fax.

4.2. Incidence and appropriateness of MRI ordering

Pre-consult MRIs were ordered for 60 of the patients included in this study. Of those, 56.7% had X-ray ordered prior to the MRI, 11.7% had X-ray following the MRI, and 30% did not have any X-ray requested prior to consultation. Fleiss Kappa test results showed a moderate agreement between reviewers on the decision of appropriateness of MRI ordering prior to consultation, K=0.583, (95% CI, 0.225 to 0.941), p=0.001. Of the 60 ordered MRIs, 50 (84%) were considered inappropriate, while only 10 (16%) were appropriate.

4.3. Comparison with quality improvement study

Table 2. Comparison of results of DI study and Quality Control study

	DI appropriateness study (October 2017 -May 2018)	Quality study (Oct 2015-Oct 2016)
	270 charts	650 charts
Demographics **Mean age** **Gender**	68.5 y	67.8 y
Females	61%	57%
Males	39%	43%
Pre-consult MRI	60 (22%)	221 (34%)
X-ray ordered pre-MRI	57%	52%
Inappropriate MRI	84%	77%

This study builds on the QI study conducted by the orthopedic clinic to assess the number and appropriateness of pre-consult MRIs ordered for knee pain patients ≥ 55 years referred to the same clinic during the study period Oct 2015- Oct 2016. Table 2 summarizes the comparison of results between both studies.

5. Discussion

This current study was one of the first to explore the effect of DS embedded within an orthopedic referral form on the number of pre-consult MRI scans ordered for knee pain patients > 55 years of age. It also assessed the proportion of those MRIs that are considered clinically inappropriate. Moreover, this study compared its findings to an earlier QI retrospective chart review study (unpublished data) conducted at the same clinic.

The proportion of cases diagnosed with osteoarthritis in the older patients presented with knee pain in this study (84%) is consistent with the estimated prevalence of OA (60-80%) reported in other studies [18]. Similar to the literature,[19] more than half of patients in our sample (61%) who suffered the burden of knee pain were females.

A pre-consult MRI was ordered for 22% of the patients in this study; of those, the majority were deemed clinically unnecessary (84%). Of the patients who were ordered knee MRI before consultation, only about half of the patients had an x-ray ordered prior to the MRI. This finding is in concurrence with Petron and colleagues who reported that only 44% of patients in their case-control study received a radiograph prior to the pre-consult MRI [12]. This is expected given the shift in the PCPs recent approach of overusing MRI and underusing X-ray when assessing knee pain patients. Evidence shows that PCPs tend to order a high number of MRIs [12]. This is common practice even though MRI findings in older patients with knee pain are more sensitive to detect knee pathology rather than clinical knee lesions [12], which does not necessarily explain the cause of pain [20], and can confound the diagnosis, the surgical decision, and the treatment plan [12, 21]. This low diagnostic efficacy of MRIs ordered for knee pain patients > 55 years of age further emphasizes the importance of embedding the guideline tool within the referral form to assist PCPs with their imaging order decisions. The DS guidelines from the JDMI group and embedded in the orthopedic referral form are reflective of evidence and do not recommend MRIs where degenerative changes are known or suspected. In these patients, radiographs are not required to make a diagnosis.

Interestingly, a significant variation in the post-consult disposition was detected among patients with pre-consult MRI vs. those with no MRI. The proportion of conservative treatment as post- consult disposition was higher among patients with a pre-consult MRI (68%). Conversely, the surgical decision (arthroplasty or arthroscopy) was lower for patients with pre-consult MRI (32%). These findings are mostly consistent with previous research that concluded MRIs ordered by PCPs before consultation were significantly less likely to result in a subsequent surgical decision compared to the MRI ordered by orthopedic surgeon [22]. This variation in the surgical decision even with the presence of the MRI findings could be related to the number of radiographs ordered for patients. In our study population, the lack of radiological evidence of the severity and extent of arthritis in 30% of patients who were ordered MRI prior to the orthopedic consultation may have influenced the surgical decision, consistent with other research that found MRI of degenerative changes of the knee in older patients would do little to influence orthopedic surgeons to modify or change their surgical management decisions [12] compared to the radiographic evidence [23].

This study demonstrated a trend favoring a higher probability that the embedded diagnostic imaging guidelines in the referral form positively impact the ordering of pre-consult MRIs. Overall 25% of patients in our study had been referred for an MRI scan; 4% were deemed necessary, while 21% were considered unnecessary MRI scans performed before their orthopedic consultation, and 30% of these scans were not

preceded by an x-ray. The study didn't demonstrate a statistical significance though between the clinically necessary vs unnecessary MRI scans ordered pre-consultation. However, when compared to the existing QI study results, our findings showed a reduction of 12% in the proportion of overall pre-consult MRIs ordered as well as an increase of approximately 5% of x-rays requested prior to MRIs. The lack of detection of any significance difference regarding the appropriateness of MRI scans in relation to the use of the DS language could partly be due to the moderate exposure of PCPs to the DS language embedded in the referral form. PCPs may require a longer time of exposure to the DS language to become accustomed to applying the guidelines within their daily practice. Approximately half of the sample (52%) were initially referred to the orthopedic surgeons after the electronic system went live and of those only 37% were introduced to the DS language embedded in the referral form. Also, the limited sample of pre-consult MRI might have affected the statistical power and the ability to detect a significant difference related to the appropriateness of the MRI scans. However, this finding highlights the potential benefits of applying the guidelines in practice, especially if circulated at a larger scale.

It is important to note the other factors that might contribute to the unnecessary diagnostic imaging, which could also affect the adoption of the DS tool. For many primary healthcare providers, MRI is considered as the customary path to referring patients for orthopedic consultation [23]. Patients' expectations, long wait-time for an orthopedic consult together with the general perception of diagnostic imaging as a method to rule out diseases are all important indicators [14]. Therefore, it is valuable to consider these factors while assessing the adoption of the DS tools in practice. Further studies are required to thoroughly investigate the impact of these factors on applying DS in practice.

6. Limitations

This study is retrospective in nature; thus, its findings are exploratory and preliminary. Moreover, the study was limited to patients referred to only one orthopedic clinic within southwest Ontario, making it difficult to generalize findings to different settings and contexts. The strengths of this study lie in its relatively large sample of patients within this setting and that the characteristics of the sample was broadly comparable to the literature. Our results demonstrate positive tendencies but failed to show statistically significant differences. The study results are supported by findings of previously published studies.

Pre-consult MRIs were the focus of this study. It would be useful to investigate the level of appropriateness of post-consult MRI scans in relation to the new embedded DI guidelines in future studies. Also, the study did not assess other factors that might affect the integration of the DS language into practice, such as the effect of patients' expectation, and long-wait times. However, our findings can serve as a baseline for future studies that address these points.

7. Conclusion

DS language embedded within the electronic referral form has the potential to reduce the number of unnecessary MRIs ordered for orthopedic patients. We demonstrated that the

number of MRI scans ordered prior to consultation has decreased and the number of x-rays has increased compared to patients referred to the same clinic prior the integration of the DS language in the referral form. This impact could be increased with wider adoption of the guidelines. Larger-scale studies are needed to explore this potential further.

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Effectiveness of e-Learning in a Medical School 2.0 Model: Comparison of Item Analysis for Student-Generated vs. Faculty-Generated Multiple-Choice Questions

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Abstract. Background Early reports in the literature describe using student-generated questions as a method of student learning as well as augmenting question exam banks. Reports on the performance of student-generated questions versus faculty-generated questions, however, remain limited. This study aims to compare the question performance of student-generated versus faculty-generated multiple-choice questions (MCQ). **Objectives** To determine if student-generated questions using mobile audience response systems and online discussion boards have similar item discrimination scores as faculty-generated questions. **Methods** A team-based learning session was used to create 113 student-generated multiple-choice questions (SGQs). A 20 question MCQ quiz was presented to a second year medical school class made of 10 randomly selected SGQs and 10 randomly selected faculty-generated multiple-choice questions (FGQs). Item analysis was performed on the test results. **Results** The data showed no statistical difference in the point-biserial scores between the two groups (average point-biserial 0.31 students vs 0.36 faculty, p=0.14), with 90% of student-generated and 100% of faculty-generated questions meeting a cut-off of point-biserial score >0.2. Interestingly, student-generated questions were statistically more difficult than the faculty-generated questions (Item Difficulty score 0.46 students vs 0.69 faculty, p=0.003). **Conclusions** This study suggests that student-generated compared to faculty-generated MCQs have similar item discrimination scores, but are perhaps more difficult questions.

Keywords. Medical Education, Pre-Clerkship, Medical Student, Test, Examination, Point Biserial, Item Discrimination, Team Based Learning.

1. Introduction

Multiple choice questions (MCQs) remain one of the most common methods of evaluation in medical schools. However there are a several common barriers to this evaluation technique including: (1) creating a large, vetted question bank, and (2)

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creating questions with high point biserial values. By involving medical students in the question creating process we can potentially avoid both these potential barriers. Methods for doing this have been described previously in the literature [1,2,3]. However no studies to date have compared the performance of these student-generated questions against faculty-generated questions in a formal examinational setting.

Team-based learning is a method that has been utilized to teach students, and has been trialed in the medical education context with good results [2,3]. There is one study that did report significant improvement on performance on end-of-module examinations as correlated with involvement in creating multiple choice questions (MCQs) for a peer question bank [4]. This study also showed improved performance with more peer-created MCQs taken in preparation as well as some evidence that students in the lower/intermediate quartile of the class based on pre-module test performance seemed to gain the most benefit. However reports on the performance of student–generated questions (SGQ) vs. faculty–generated questions (FGQ) remain quite limited. A technique to utilize students in creating multiple–choice questions has been described in a previous work upon which this study aims to build [1]. In this study a small group learning process was used in which students wrote individual MCQs, analyzed and evaluated each other's questions, and these vetted questions were then incorporated into a student–generated question bank. Our current study aims to compare the performance of student–generated MCQs vs. faculty–generated MCQs with a qualitative analysis to determine if these student–generated questions can be utilized as a formal evaluation in medical school.

2. Methods

Full methods of the procedure for carrying out a "team-based learning" session for the purpose of constructing multiple choice questions has been described in our previous paper [1], however will be described in brief below. Groups consisting of 7-8 students per group from a first-year medical class (total of 14 groups) were each assigned a different objective from the otolaryngology core curriculum. Each student designed a multiple choice question which they then brought to their small group session. As a group they then provided feedback for each of the questions brought forward to strengthen them, and each question was revised. Online discussion boards were used. After small group review, each group then selected a single question to be presented to the class as a whole. There was then a final whole-class question-vetting period as a final layer of refining the questions, with the use of mobile audience response systems. This method uses a Medical School 2.0 model where, similar to Web 2.0, students do not only retrieve information from their curriculum, but also actively contribute to it.

From this question bank of 113 total student-generated questions (SGQs), 10 were selected at random. An additional 10 questions were selected from the faculty-generated question bank (FGQs) to compile a 20 question multiple choice test. This test was then given to a new class of second year medical students and item analysis was performed on these questions. Point biserial was the primary endpoint used to describe the performance of an individual question. Point biserial is a measure of how the performance on a specific question correlates to performance on the overall exam as rated on a scale from -1 to +1. Within this metric, -1 corresponds with an exact inverse correlation with overall performance and +1 with a perfect correlation with overall performance. We set a target of a point biserial value of >0.2 as defining a question that

was adequate for use in a formal testing setting, as per item analysis guidelines from the Medical Council of Canada. As a secondary endpoint the difficulty rating of individual questions was also compared as defined as the percentage of students answering the question correctly. Comparison of the two groups of questions (SGQ vs. FGQ) was performed using a Welch two-sample t-test for both of these endpoints to determine significance.

3. Results

10 student-generated questions and 10 faculty questions formed a 20 question test that was taken by a second year medical class. Descriptive statistics of the SGQs vs. FGQs are provided in table 1. 9 out of 10 SGQs and all of the FGQs met the target point biserial cutoff of >0.2. There was no significant difference noted in the point biserial values between the two groups. The mean point biserial value for all SGQs was 0.360 and for FGQs was 0.314. This correlated with a p-value of 0.14.

　　Student-generated questions were more difficult than faculty-generated questions at a level of statistical significance, with the mean difficulty for SGQs being 0.46 and for FGQs being 0.6 (p = 0.003). We also assessed the proportion of questions met a "good difficulty" cutoff, indicating that they were neither too easy or too hard. The cutoff we used in this study was between 0.4 – 0.9. 4 out of 10 SGQ's did not meet this difficulty criteria, while all of the FGQs met the criteria. All four questions that did not meet the difficulty criteria were too difficult as opposed to being too easy. Their individual difficulty scores were 0.38, 0.26, 0.33, and 0.32.

Table 1. Descriptive statistics of student-generated vs. faculty-generated multiple-choice questions.

	Difficulty Score	Standard Deviation	Discrimination	Point Biserial	Good Difficulty
Student Generated	0.468 [†]	0.480	0.381	0.360 [††]	0.6
Faculty Generated	0.688 [†]	0.444	0.330	0.314 [††]	1.0

[†] statistical significance (p = 0.003)

[††] no statistical significance (p = 0.14)

4. Discussion

This paper is the first to our knowledge to assess the feasibility of utilizing student-generated multiple-choice questions in a formal examination. We found that the student-generated questions had a similar item discrimination score to faculty-generated questions as measured by point biserial and thus perform similarly in an examination setting. As previously noted, one of the principle barriers in MCQ testing is to create a large, well vetted question bank. By utilizing students in the process of question making, an institution can rapidly expand their bank of questions to use in future years. Further, our study showed that these SGQs perform similarly to FGQs and thus could be used in formal examinations.

　　There was a difference in difficulty score between SGQs and FGQs. In a previous study it was noted that students who performed poorer overall on the exam performed

better on SGQs as opposed to FGQs, indicating that in their study the difficulty score for SGQs was lower than for FGQs [5]. This was not the experience in our study, as SGQs were more difficult than FGQs. It is not known exactly the reason that SGQs were more difficult. Possibilities include that they tested more specific or detailed points of the material as opposed to more pertinent clinical themes as questions created by a clinician would be, or that there could have been a lack of clarity of the phrasing or wording of the questions that misled some students. These errors may be avoided by further vetting of the SGQs by faculty members and allowing for edits of them prior to using them in an examination setting.

Several concerns do arise from having students involved in question making. The first of these is that students would have access to a large portion of the exam bank used to make up their formative examination. There have been previous reports that when an exam question bank is released to students, they will choose to memorize the question bank as a high-yield strategy for mark inflation, rather than engage in studying methods that stimulate deep learning [5]. It has also been observed that when an exam bank is released to students, those that utilize it more for studying purposes do better on final examinations [4]. Whether this has any impact on future clinical acumen is uncertain. It is unclear, however, the ratio of questions in an exam bank vs. the number to be used on an exam where students will not gain an unfair advantage from having access to the questions, and rather will learn course material to a deeper level by studying from the exam questions. Ways to expand the potential question bank to attempt to increase the ratio of unused : used questions on the exam and stimulate deeper learning would include sharing of MCQs between different institutions. This has been described in previous studies to outline the advantages, particularly for smaller institutions [6,7]. This would also result in standardization of exam questions across a region. Another method would be to institute a team-based learning activity to have students create exam questions that can then be used on future years as described in this study. Not only does this help to create a large question bank, but also helps students to learn via peer teaching as well as to prepare them for their future role as educators.

5. Conclusion

This study showed that student-generated questions performed as well as faculty generated questions in an item discrimination analysis. This would allow them to be used in a formal testing setting for evaluation in medical schools. This would also allow a faculty to rapidly expand their multiple-choice question bank with each year's students creating more questions. Further, sharing of questions between institutions would allow for a large, well vetted testing bank to be formed.

There were several limitations to this study. As this was only observed over a single year's medical class, there were only 113 SGQs that were available. As the otolaryngology curriculum in our institution is a small portion of the overall curriculum, a smaller number of questions were assigned in the testing environment, and thus only a total of 20 questions could be compared. This resulted in a low powered study. However the results were positive and shows that it may be feasible for student-generated multiple choice questions to be used in a formal testing setting.

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Factors Affecting Adherence with Telerehabilitation in Patients with Multiple Sclerosis

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Abstract. The goal of this study was to identify predictors of telerehabilitation
adherence in patients with multiple sclerosis (MS). An adherence prediction model
was based on baseline patient characteristics. Such a model may be useful for
identifying patients who require higher levels of engagements in the early stages of
home telerehabilitation programs. The resulting set of predictive features included
education, patient satisfaction with the program, and psychological domain of the
MS Impact Scale. Resulting prediction of high and low adherence had overall 80.0%
accuracy, 81.8% sensitivity, and 77.8% specificity. We concluded that the baseline
patient information may be instrumental in personalizing levels of support and
training necessary for active patient participation in telerehabilitation.

Keywords. exercise adherence, telerehabilitation, multiple sclerosis

Introduction

Home-based physical telerehabilitation has been shown well accepted by patients with
multiple sclerosis (MS) [1]. Telerehabilitation was described as a promising modality in
patients with MS that can reduce mobility impairments and improve quality of life [2].
Sustainable impact of telerehabilitation depends on patient adherence with their exercise
program. Patients with low adherence require higher levels of engagement including
more extensive training, regular feedback and increased overall support. Identifying
these patients early in the telerehabilitation program may help telerehabilitation team
prioritize available resources and focus on patients who require higher levels of attention
to achieve sustainable patient participation in life-long rehabilitation recommended for
MS patients. Limited information is currently available on potential predictors of MS
patient adherence in telerehabilitation programs. The main goal of this study was to
identify adherence predictors for MS patients participating in a telerehabilitation
program based on baseline patient characteristics readily available in the beginning of
the program.

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1. Methods

1.1. Systems

We used the Home Automated Telemanagement (HAT) system to support individualized home-based telerehabilitation in patients with multiple sclerosis (MS) [1]. HAT is based on the chronic care model and provides support for patient individualized exercise plans and self-management, comprehensive patient-provider communication, and multidisciplinary care coordination as previously described [2].

1.2. Study design

Once screened for entry into the study, all study participants received a comprehensive baseline examination conducted by the blinded assessment team. All patients received necessary exercise equipment and were followed by the clinical management team and receive guidance and support to optimize this plan. Patients using MS HAT received computer-mediated support in following their individualized exercise plans at their homes on a daily basis.

For the body function and structure outcomes, the Modified Fatigue Impact Scale (MFIS) was used to measure fatigue [3] and Expanded Disability Status Scale (EDSS) used for rating overall disability in MS [4]. For the participation outcomes, the MS Impact Scale (MSIS physical and MSIS psychological) measured the physical and psychological impact of MS from the patients' perspective [5] and the MS Quality of Life (MSQOL physical and mental domains) measured multidimensional health-related characteristics. Behavioral and psychological outcomes included MS Self-efficacy (MSSE) [6], Center for Epidemiologic Studies Depression Scale (CES-D) [7], Mental Health Inventory (MHI) [8], and Pittsburgh Sleep Quality Index (PSQI) [9]. The patient satisfaction with this program was measured by the Client Satisfaction Questionnaire (CSQ) [10].

The data from daily exercise logs generated by the MS HAT system were used to generate three exercise program adherence metrics. The adherence with overall exercise regimen reflected how frequently the patients attempted to exercise. This adherence indicator was calculated as the ratio of days when a patient attempted to complete at least one exercise and the total number of days the patient was supposed to exercise (Completion ratio (≥1set/day)). Log-in ratio reflected the proportion of days when patients logged in over total patient's participation days (Log-in ratio). The adherence with exercise plan was calculated as a proportion of completed exercises from the total number of exercises to be performed during total participation period. This adherence was calculated as the ratio of days that the patient did more than 75% of prescribed sets for a day (Over 75% ratio).

All statistical analyses were performed using IBM SPSS Statistics 25 for Windows.

2. Results

2.1. Clustering

To determine predictors of participants' adherence, we first binary clustered patients into groups with high adherence and low adherence with 3 exercise program adherence

parameters (Completion ratio (≥1set/day), Over 75% ratio, and Log-in ratio) using K-means clustering method. The standardized values were used for the clustering and the calculated centers were (0.474, 0.726, 0.645) and (-0.579, -0.887, -0.788) respectively. The final distance between groups was 2.4. In case of ratio values, the centers were (0.999, 0.621, 0.710) and (0.786, 0.188, 0.339) (Figure 1). The clear differentiation of two adherence groups was confirmed by one-way ANOVA test as shown in Table 1.

2.2. Baseline questionnaires

Overall twenty patients with MS (15 females and 5 males) participated in this study. Nine baseline questionnaires were used, and eleven parameters were investigated. Time since MS diagnosis (Years with MS) and the education level (Education, yrs) were included in analyses.
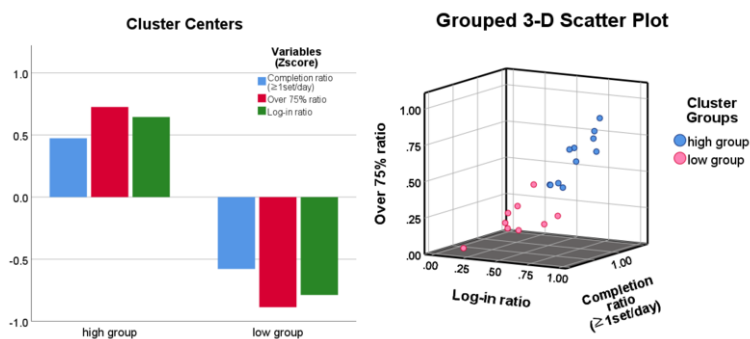
Figure 1. Cluster group centers (Zscore) and three-dimensional scatter plot

Table 1. Comparative descriptive statistics for the cluster groups.

	high group (n=11)		low group (n=9)		ANOVA		Total	
	Mean	SD	Mean	SD	F	p	Mean	SD
Completion ratio (≥1set/day)	0.999	0.156	0.786	0.196	7.303	0.015	0.903	0.202
Over 75% ratio	0.621	0.178	0.188	0.124	37.801	0.000	0.426	0.268
Log-in ratio	0.710	0.149	0.339	0.215	20.715	0.000	0.543	0.259
Years with MS, yrs	23.0	12.59	26.1	14.07	0.273	0.608	24.4	13.01
Education, yrs	15.1	4.21	13.1	2.47	1.547	0.230	14.2	3.59
MHI, 0~100	64.6	14.65	57.5	13.50	1.252	0.278	61.4	14.24
PSQI, 0~21	6.0	3.41	8.0	1.58	2.621	0.123	6.9	2.86
MSSE, 17~85	47.1	13.20	46.2	9.76	0.027	0.872	46.7	11.49
MSIS physical, 0~100	51.5	21.03	64.6	17.28	2.247	0.151	57.4	20.08
MSIS psychological, 0~100	38.9	28.27	47.2	19.14	0.566	0.461	42.6	24.35
MSQOL physical, 0~100	44.7	16.27	39.8	19.46	0.375	0.548	42.5	17.46
MSQOL mental, 0~100	63.8	21.95	57.0	21.28	0.480	0.497	60.8	21.35
CES-D, 0~60	14.1	9.12	20.4	9.06	2.419	0.137	17.0	9.42
Client satisfaction, 8~32	25.7	3.64	21.7	4.21	5.385	0.033	23.9	4.33
MFIS, 0~84	43.1	16.62	49.7	17.34	0.746	0.399	46.1	16.83
MSSS, 0~100	76.3	24.09	75.8	18.72	0.003	0.958	76.0	21.28

high group: cluster group with high adherence, low group: cluster group with low adherence, Completion ratio (≥1set/day): the ratio of days when a patient attempted to complete at least one exercise and the total number of days the patient was supposed to exercise; Over 75% ratio: the ratio of days that the patient did more than 75% of prescribed sets for a day; Log-in ratio: log-in days over total patient's participation days; SD: standard deviation.

No statistically significant differences were found between the high and low adherence groups except the client satisfaction (F = 0.003 to 2.621, p = 0.123 to 0.958). In case of the client satisfaction, there was a statistically significant difference between groups as determined by one-way ANOVA (F = 5.385, p = 0.033). (Table 1)

2.3. Prediction model

All thirteen baseline parameters were investigated to identify features for the binary logistic regression model predicting adherence groups. Correlation matrix was used to exclude features which were highly interdependent. The client satisfaction was selected by the result of one-way ANOVA analysis. The education was selected based previous reports that documented the relationship between patient education and adherence [11]. The MSIS psychological dimension was selected because this parameter was the only parameter that was shown to significantly correlate with the majority of other baseline characteristics (Table 2).

The resulting binary logistic regression model is shown in Table 3. The education, client satisfaction, and MSIS psychological dimension were entered into the model and resulted in the odds ratios of 0.886, 0.622, and 1.039 respectively (Table 3).

From the classification table, we confirmed the model allowed to correctly classify 81.8% of the participants who would exhibit high adherence and 77.8% of the participants with low adherence with the telerehabilitation program. Overall prediction accuracy was 80.0% (Table 4).

Table 2. Correlations, scatter plots and fit lines of patient baseline characteristics.

		Years with MS	Education	MHI	PSQI	MSSE	MSIS physical	MSIS psychological	MSQOL physical	MSQOL mental	CES-D	Client satisfaction	MFIS	MSSS
Years with MS	r	1												
	p													
Education	r	0.030	1											
	p	0.899												
MHI	r	.520*	0.154	1										
	p	0.019	0.517											
PSQI	r	-0.071	0.217	-.574**	1									
	p	0.766	0.358	0.008										
MSSE	r	0.434	0.000	.644**	-0.414	1								
	p	0.056	0.999	0.002	0.070									
MSIS physical	r	-.490*	-0.138	-.665**	0.270	-0.438	1							
	p	0.028	0.561	0.001	0.250	0.054								
MSIS psychological	r	-.466*	-0.178	-.819**	.515*	-.812**	.571**	1						
	p	0.038	0.453	0.000	0.020	0.000	0.009							
MSQOL physical	r	0.313	0.240	.681**	-0.342	.627**	-.526*	-.758**	1					
	p	0.178	0.307	0.001	0.140	0.003	0.017	0.000						
MSQOL mental	r	0.174	0.019	.794**	-.657**	.544*	-.445*	-.693**	.720**	1				
	p	0.463	0.937	0.000	0.002	0.013	0.049	0.001	0.000					
CES-D	r	-0.207	-0.189	-.808**	.649**	-.503*	0.388	.732**	-.524*	-.690**	1			
	p	0.382	0.424	0.000	0.002	0.024	0.091	0.000	0.018	0.001				
Client satisfaction	r	0.119	0.215	0.024	-0.243	-0.091	0.055	0.120	-0.173	-0.027	-0.088	1		
	p	0.616	0.363	0.919	0.302	0.704	0.817	0.614	0.466	0.909	0.712			
MFIS	r	-0.244	-0.050	-.744**	.516*	-.681**	.572**	.805**	-.841**	-.834**	.700**	0.229	1	
	p	0.299	0.835	0.000	0.020	0.001	0.008	0.000	0.000	0.000	0.001	0.331		
MSSS	r	0.290	-0.175	.629**	-.541*	.571**	-0.152	-.611**	.524*	.675**	-.679**	0.103	-.648**	1
	p	0.215	0.461	0.003	0.014	0.008	0.522	0.004	0.018	0.001	0.001	0.665	0.002	

r: Pearson correlation, p: correlation coefficient, *: correlation is significant at the 0.05 level (2-tailed), **: correlation is significant at the 0.01 level (2-tailed).

Table 3. MS patient's exercise demand forecasting model (binary logistic regression model).

	B	S.E.	Wald	df	p	OR
Education, yrs	-0.121	0.174	0.482	1	0.488	0.886
Client satisfaction	-0.475	0.242	3.849	1	0.050	0.622
MSIS psychological	0.038	0.031	1.562	1	0.211	1.039
Constant	11.127	5.864	3.601	1	0.058	

Table 4. Classification table.

		Predicted		Percentage Correct
		Cluster Number of Case		
Observed		high group	low group	
Group Number of Case	high group	9	2	81.8
	low group	2	7	77.8
Overall Percentage				80.0

3. Discussion

Using a logistic regression model, an optimal differentiation of high and low adherence groups was achieved. In spite of the common sense that patients with lower education and a scarce social network need more support and the fact that this pilot study was conducted as a limited number of patients, this pilot analysis revealed that an adherence prediction model should be developed with the patient's satisfaction of program and the psychological impact in the daily lives of MS patients. More careful studies should be conducted to make final decisions on accuracy of factors, but this pilot model using quantitative methods is a demonstration of the spread of further researches. We note that a continuous adherence prediction model with a larger data set should be assessed to further validate the proposed approach. This pilot study supports future work on computer-mediated decision support that would best serve MS patients in the early stages of a telerehabilitation program based on readily accessible baseline information.

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Physicians' Experiences on EHR Usability: A Time Series from 2010, 2014 and 2017

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Abstract. The interest towards monitoring and guiding the development of healthcare information systems on a national level is increasing. In this paper, we report results from the three cross-sectional surveys on physicians' experiences on usability of their electronic health record (EHR) systems in Finland. The research question was: How have physicians' experiences on usability of their EHR systems evolved between 2010 and 2017? The data consists of responses to six usability statements from Finnish physicians working in public healthcare centres and hospitals. Among physicians working in healthcare centres, results between 2010 and 2017 show change for the worse. Among their colleagues in hospitals, results indicate slight improvement only in the domain of ease of use of the systems. In general, contrary to general expectations, the results do not show improvements between the years 2010, 2014 and 2017. In the future, we will continue the monitoring work in Finland on a national level from the viewpoint of physicians and other professional groups.

Keywords. usability, physician, satisfaction, electronic health record, survey

1. Introduction

For several years, usability of electronic health record (EHR) systems has remained a timely topic of research [e.g. 1-5]. Factors of EHR usage, such as technical problems associated with time pressure, separated statistical documentation and difficulties in reading of nursing record, affect physicians' work well-being [2]. Recent surveys have found that physicians experience overall dissatisfaction with their EHRs [1,6]. In addition, literature calls for purposeful and thoughtful design of the systems in order to capitalize on the powerful potential of the EHR systems towards better patient care [7].

In Finnish public healthcare, EHR coverage reached 100% in 2010 [8,9]. Efforts to improve usability of the currently used EHR systems are considered important and are even mentioned in the national Information Strategy for Social and Health Care 2020 [10]. National surveys on e-health implementation and use, EHR usability as well as experienced benefits and challenges from the physicians and nurses viewpoints' have been carried out to monitor and guide the development of healthcare information systems

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[11]. The first survey on physicians' experiences on EHR usability in Finland was conducted in 2010 [12,13]. Next cross-sectional surveys were conducted in 2014 and 2017 [1,14]. In 2017, a similar study with nurses took place [15].

In this paper, we report results from the three cross-sectional surveys for physicians. The research question is: *How have physicians' experiences on usability of their EHR systems evolved between 2010 and 2017?* Six usability statements, which have been identical in all surveys, were selected for the analysis. The focus of the presented analysis is on public healthcare hospitals and healthcare centres. In 2016, there were 20,970 working-age (<65 years) physicians living in Finland; 70% were working in the public sector [16].

2. Related Research

EHR systems with good usability have been reported to decrease the number of errors, help to improve patient safety, support efficient work and thereby allow the clinicians more time with their patients [17]. Typical EHR usability problems related to interface design include violation of natural dialog, control consistency, effective use of language, effective information presentation, customization principles, lack of error prevention, minimization of cognitive load and feedback [18]. Designing EHR user interfaces is particularly challenging because of a wide range of complex information needs in different healthcare contexts, user requirements arising from over 50 physician specialties as well as needs and requirements from other user groups including nurses, pharmacists and therapists [19].

The number of usability studies is increasing. According to a recent review, the most frequent evaluation method is survey; many studies have a summative study objective and are performed late in the EHR system design cycle [20]. Follow-up or long-term monitoring studies on development of EHR systems' usability, however, seem to be scarce [1]. Our earlier study on Finnish physicians' experiences on EHR usability has shown, that between 2014 and 2010 the overall satisfaction [1] had not improved considerably. On a scale 1-7 the average of the ratings varied from 3.2 to 4.4.

3. Materials and Methods

In this study we utilized the usability-focused questionnaire designed in 2010 [12,13] to gather follow-up data and to find out to what extent the situation regarding usability from the physicians' viewpoint has changed between years 2010 and 2017. The procedure of the study was similar in years 2010, 2014 and 2017: The data was gathered from February to March [14] and the invitation to the web-based survey was e-mailed to all working-age physicians in Finland. Table 1 describes the study population.

For the analyses, we selected the respondents from public hospitals and healthcare centres. User responses to the six usability related statements identical in all three surveys were selected for this study. The themes of the statements were related to (1) Technical quality - responsiveness of the system, errors in use and their reflections on patient safety (2) Ease-of-use - success of user interface design and system support for routine tasks and (3) Benefits (Table 2). The five-point Likert scale answers 'Fully agree' and 'Somewhat agree' were combined to form the category 'Agree'. Similarly, the answers 'Fully disagree' and 'Somewhat disagree' were combined to form the category

'Disagree'. The means were calculated from the 5-point Likert-scale answers. Analysis of variance (ANOVA) and Bonferroni's post-hoc tests were used to compare results between 2010, 2014 and 2017. All statistical analyses were carried out with SPSS software version 22.0 (SPSS Inc., Armonk, NY).

Table 1. Study population.

Year	Sample (N)	Sample (n)	of which public hospital (%)	of which healthcare centre (%)	Total response rate (%)
2017	18 326	4 018	49	27	22*
2014	18 257	3 781	46	24	21*
2010	14 411	3929	50	23	27**

*In 2014 and 2017 the sample (N) contains all members of the Finnish Medical Association with valid e-mail address (N). The register did not contain information on who is in clinical work. Though targeted to clinicians, the response was calculated from all physicians, including those not in clinical work.

**In 2010 the sample (N) contained those Finnish Medical Association members, who reported being in clinical work and who had a valid e-mail address. The response rate was calculated from physicians in clinical work.

Table 2. Domains studied and measures used.

Domain	Measure
Technical quality	Q1 = The system responds quickly to inputs.
	Q2 = Faulty system function has caused or has nearly caused a serious adverse event for the patient.
Ease of use	Q3 = The arrangement of the fields and functions is logical on computer screen.
	Q4 = Terminology on the screen is clear and understandable (for example titles and labels).
	Q5 = Routine tasks can be performed in a straightforward manner without the need for extra steps using the systems.
Benefits	Q6 = Information systems help in preventing errors and mistakes associated with medication.

4. Results

The results on physician's experiences on usability of their EHR systems in years 2010, 2014 and 2017 are presented in three parts:

- Summary of 'Agree' responses to six usability statements from physicians working in healthcare centres (Figure 1)
- Summary of 'Agree' responses to six usability statements from physicians working in hospitals (Figure 2)
- Mean opinion scores on a scale from 1 (or 'Fully disagree') or 5 (or 'Fully agree') and comparison of the scores between healthcare centres and hospitals (Table 3).
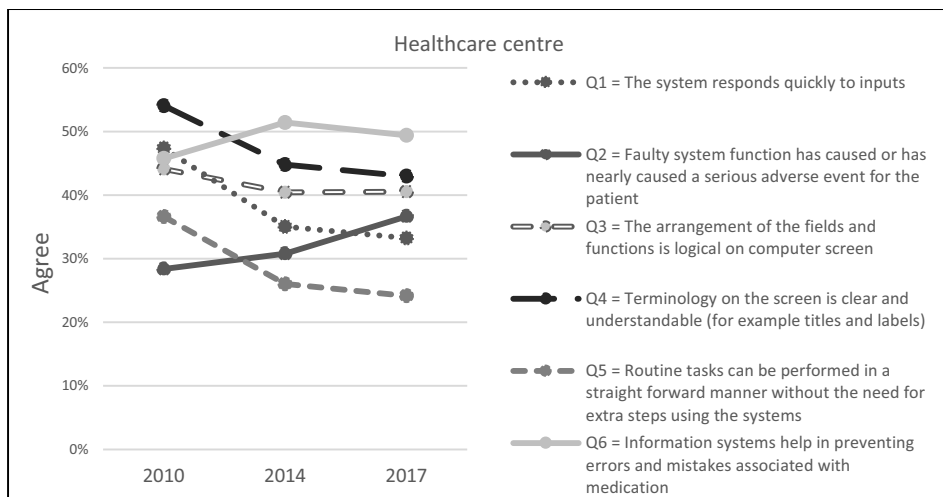
Figure 1. Summary of 'Agree' responses to six usability statements from physicians working in healthcare centres: Changes between 2010, 2014 and 2017.
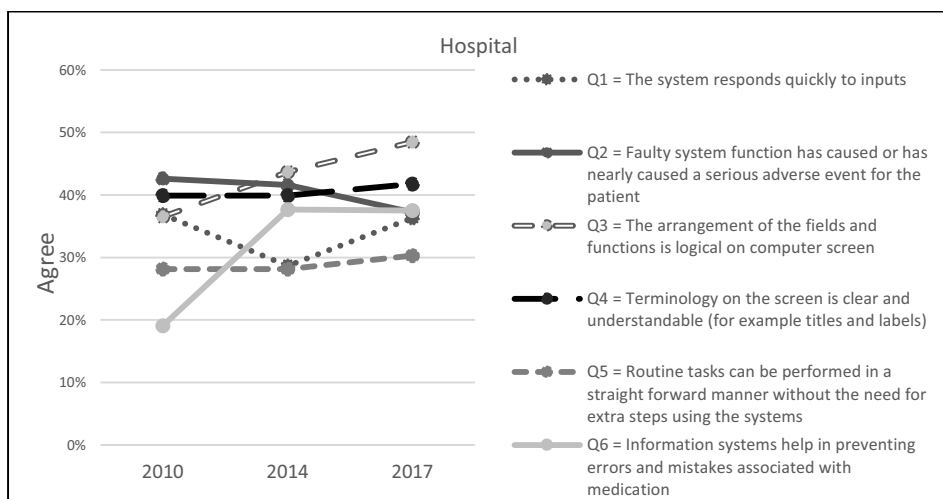
Figure 2. Summary of 'Agree' responses to six usability statements from physicians working in hospitals: Changes between 2010, 2014 and 2017.

Table 3. Comparison of physician's mean opinion scores with scale from 1 (or 'Fully disagree') or 5 (or 'Fully agree') for six usability statements between healthcare centres and hospitals in 2010, 2014 and 2017.

Year	2010	2014	2017	p between 2010 and 2014	p between 2010 and 2017	p between 2014 and 2017
Q1 The system responds quickly to inputs						
Healthcare centre	3.09	2.73	2.66	<0.001	<0.001	0.548
Hospital	2.82	2.58	2.77	<0.001	0.617	<0.001
Q2 Faulty system function has caused or has nearly caused a serious adverse event for the patient						
Healthcare centre	2.82	2.78	2.88	1.000	0.673	0.199
Hospital	3.24	3.07	2.94	<0.001	<0.001	0.006
Q3 The arrangement of the fields and functions is logical on computer screen						
Healthcare centre	3.02	2.84	2.84	0.004	0.005	1.000
Hospital	2.81	2.95	3.07	0.001	<0.001	0.006

Q4 Terminology on the screen is clear and understandable (for example titles and labels)						
Healthcare centre	3.28	3.02	2.96	<0.001	<0.001	0.835
Hospital	2.93	2.90	2.96	0.980	1.000	0.248
Q5 Routine tasks can be performed in a straight forward manner without the need for extra steps using the systems						
Healthcare centre	2.75	2.42	2.29	<0.001	<0.001	0.084
Hospital	2.50	2.47	2.53	1.000	1.000	0.338
Q6 Information systems help in preventing errors and mistakes associated with medication						
Healthcare centre	3.01	3.12	3.03	0.130	1.000	0.276
Hospital	2.32	2.82	2.84	<0.001	<0.001	1.000

5. Discussion and Conclusions

In this paper, we report Finnish physicians' experiences with the usability of currently used EHR systems and changes in their perceptions between 2010 and 2017 based on their responses to six usability statements. Overall, the results indicate that the situation has not improved. Among physicians working in healthcare centres, the mean opinion scores for nearly all statements between 2010 and 2017 showed change for the worse. However, in the responses of physicians working in hospitals ease of use had slightly improved: usability of the use interfaces (Q3 and Q4) concerning the arrangement of the fields and functions on screen as well as terminology, and system support for routine tasks (Q5). In general, the results indicate that the physicians working both in hospitals and in healthcare centres experience that the systems inadequately support their everyday work: both the portion of agree responses and the given mean opinion scores can be considered as low. Contrary to general expectations, the results do not indicate improvements between the years 2010, 2014 and 2017.

Our results suggest that the implementation of National Health Information Services (Kanta) i.e. national centralized patient data repository and electronic prescription since 2014 has not yet met its goals: enhancing continuity of care, patient safety and health care productivity. The six measures on technical quality, ease of use and benefits show no improvement during the follow-up period - in fact, there has been a slight decrease in technical quality and ease-of-use. The Kanta-service integration with the EHR-systems has been a complex technical operation, generating new operating procedures and screens, and also impacted overall speed and benefits of use. Another explanation for the lack of improvements between the years of study may be the EHR system vendors constantly lagging behind in configuring and developing their systems to support the constantly increasing requirements of physicians' daily work.

For the purposes of monitoring of the development of EHR systems and eHealth in a national level, survey is a suitable tool for gathering self-reported data from a large group of participants, benchmarking systems and pinpointing problems and successes. Other usability evaluation methods are needed for detailing usability problems and design improvements [21].

This article is part of a larger research project, which started in 2009 when we developed the first version of the national usability-focused questionnaire for physicians. The project has grown to cover nurses and has become part of eHealth strategy implementation in Finland [10]. Currently, we are developing a similar questionnaire for social care workers. The monitoring of development of healthcare IT systems in Finland from the viewpoint of different professional groups continues, as will international research collaboration to work towards comparable results between countries.

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Development of the Patient Experience Questionnaire for Parents of Pediatric Patients (PEQP)

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Abstract. Patient experience (PX) is an important evaluation criterion for quality in healthcare. Compared to patient satisfaction, however less research has focused on the development of instruments to measure experiences of patients and their families. In the article, we describe the process of developing a PX questionnaire for the parents of pediatric patients in the context of children's hospital and illustrate the questionnaire items for measuring PX. The phases of the development process included retrospective interviews, description of the themes influencing PX and the metrics for measuring PX, as well as iterative development of three versions of questionnaires including data gathering and factor analysis. The final versions of the surveys suggested for implementation at the hospitals include eight PX statements for the outpatient clinic and five statements for the ward. Compared to satisfaction surveys, the developed surveys emphasize the aspects of parent's attitude towards the illness, support for families, and daily arrangements with a child patient.

Keywords. patient experience, children's hospital, pediatric patient, parent, questionnaire, measurement

1. Introduction

There is an increasing interest to apply some elements of business approach in healthcare. This includes a desire to understand how to develop high quality services and offer those to customers to improve their experience of care. For the reason, hospitals have started to collect feedback from their customers – patients. Patient feedback provides opportunities to identify and address problems and gaps in service flow and to monitor the effects of interventions [1]. Furthermore, the experiences of patients are important when evaluating the quality of healthcare services [2,3]. It has been suggested that a compact research instrument would enable monitoring of satisfaction and experiences of patients on a regular basis and thus improving the quality of healthcare services [3].

Some instruments have been developed to measure patient satisfaction [1]. Those are used to evaluate the quality of hospital care from the viewpoint of adult patients. One of the widely known instruments is HCAHPS (Hospital Consumer Assessment of

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Healthcare Providers and Systems satisfaction survey) [4]. Recently, a modified version of the instrument for child patients and their families [5] was introduced. However, it is unclear whether patient satisfaction surveys actually measure satisfaction and whether the hospitals should use the results to support the development activities [4].

Compared to satisfaction, patient experience (PX) is a multidimensional and ambiguous concept [6-8] and thus, it is challenging to define and measure [9,10]. The following themes have been suggested to characterize the concept: PX is more than satisfaction alone, covers the continuum of care, focuses on expectations and individualized care, and aligns with patient-centered care principles [6].

Studies on PX of children, adolescents and their families are scarce [e.g.11]. In Finland, a research project Lapsus [12] was set to investigate the perspectives of pediatric patients and their families on hospital visits, received care and services, and the everyday life with the illness. The project was also to promote that the experiences of the families with pediatric patients to be taken into consideration when planning the services and facilities for new children's hospitals, e.g. the hospital in Helsinki [13]. The project had an approval from the ethical committee of the Helsinki University Hospital. One concrete objective was to develop instruments for measuring and monitoring PX of pediatric patients and their families while receiving hospital care. In this article, we 1) describe the process of developing a PX questionnaire for the parents of pediatric patients in the context of children's hospital, and 2) illustrate the related questionnaire items for measuring PX.

2. Methods

The process of developing Patient Experience Questionnaire for Parents of Pediatric Patients (PEPQ) included several phases and iterations (Figure 1).
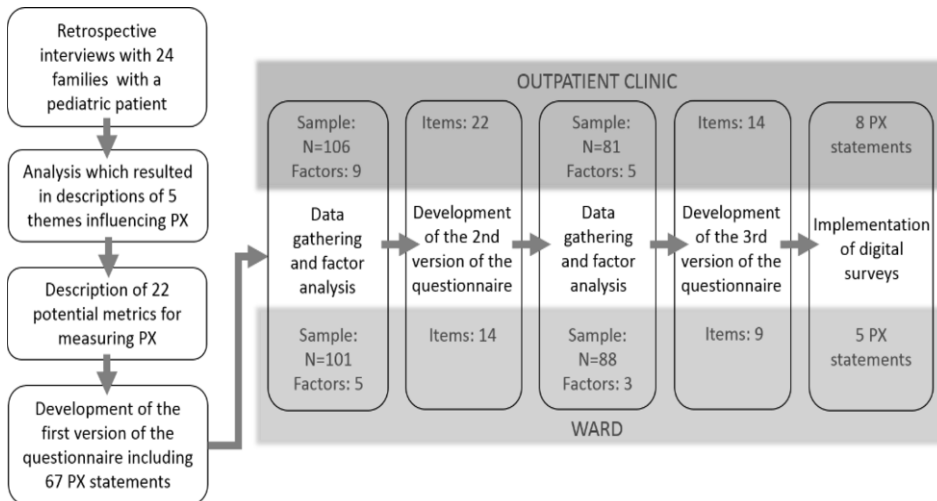
Figure 1. Phases of the process of developing a PX questionnaire for the parents of pediatric patients.

Issues perceived as important and valuable by families served as a basis for developing a questionnaire. In order to map the dimensions and dynamics of PX of

families, we conducted in-depth retrospective interviews with parents having a child with a chronic illness: a cardiac or kidney disease or diabetes, juvenile rheumatoid arthritis or an inflammatory bowel disease [14]. The families were selected by the personnel of the Children's Hospital in Helsinki. The interviews were conducted in winter 2015-2016 and each lasted 1-2 hours. Altogether 24 families participated in the interviews [15].

The analysis of the interview transcriptions yielded in identifying five themes influencing PX of families with a child patient: the success of the treatment, setup of the treatment, the healthcare personnel, coping mechanisms with the illness, support and setup of the everyday life [15,16]. For the purposes of the questionnaire development, we defined 22 preliminary metrics for PX and further created three to four statements within every metric. Thereby, the first version of the questionnaire consisted of 67 statements with a Likert scale ranging from 1 (strongly disagree) to 5 (strongly agree) and 'not applicable' option [16].

The analysis of the interviews and particularly patient journey maps [14] indicated that different aspects of PX emerge in different phases of the patient path. These findings encouraged the development of separate PX questionnaires for hospital ward and outpatient clinic. The first versions of the questionnaires were tested in years 2016-2017 at the Children's Hospital, Helsinki University Hospital, which is responsible to provide care for a number of different kinds of particularly severe pediatric patients from all over Finland [13]. Altogether 144 families participated in the survey study at the outpatient clinic and 119 at inpatient wards, of which 106 and 101 were included in the further analysis of the first round [15]. The data for testing the second version of the questionnaire for outpatient clinic were gathered between 01-02/2017 at the Children's Hospital, Helsinki. In contrast, data for testing the second version for inpatient wards were gathered at the wards of three Children's hospitals in the cities of Helsinki, Oulu and Turku between 12/2017-02/2018. At the outpatient clinic 88 responses and at the wards 93 responses were obtained, of which 81 and 88 were included in the analysis of the second round [15].

As the aim was to develop scientifically valid PX questionnaires for use at the hospitals, we applied exploratory factor analysis (EFA) as the primary method to reduce the number of the questionnaire items in each analysis round. The EFA was employed to identify latent variables underlying the questionnaire statements. In the analysis, we used Kaiser criterion and varimax rotation methods [17]. The sampling adequacy for each iteration was established using the Keiser-Meier-Olkin test (KMO) of sampling adequacy. In each round, statements with low communalities were eliminated before EFA. The key metrics for EFA for separate questionnaires and rounds are presented in Table 1.

Table 1. Summary of the factor analysis: rounds and key metrics for EFA.

	OUTPATIENT CLINIC		WARD	
	Round 1	Round 2	Round 1	Round 2
Original # items	67	22	67	14
Sample (N)	106	81	101	88
Cronbach's α	0.922	0.866	0.91	0.847
Factor analysis				
KMO	0.754	0.696	0.738	0.809
Factors	9	5	5	3
# items	22	14	14	9
Factor loadings	>0.5	>0.75	>0.5	>0.7
AVE (%)	81.48	79.12	79.71	77.67
Cronbach's α	0.888	0.821	0.840	0.884

3. Results

After the analysis, the third versions of the PX questionnaires included 14 and nine items. These items formed the group of suggested PX statements to be measured and monitored at the children's hospitals. However, considering the actual use of the questionnaires at the hospitals for gathering patient feedback and employing the data in improving the services, it was necessary to reduce the number of questionnaire items.

The further analysis of the questionnaire items was done based on the factor loadings and the contents of PX statements. The outpatient clinic questionnaire with 14 items consisted of seven pairs of similar statements, of which the statement with a lower loading value was excluded. In addition, it was reasonable to divide the statement about the busyness of the staff into two items concerning separately nurses and physicians. The analysis of the ward questionnaire with nine items followed the same principles: of the similar statements the one with lower loading was excluded. As the result, the final versions of the digital surveys suggested for implementation included eight PX statements for the outpatient clinic and five PX statements for the ward (Table 2). At the ward, the PX questionnaire is to be implemented as a tablet survey which is distributed to the parents before discharge. The outpatient clinic survey is to be implemented as a mobile survey and the link to the survey will be sent to the parent a day or two after their visit to the clinic.

Table 2. PX questionnaires for parents at outpatient clinic and at ward: PX statements and metrics.

Outpatient Clinic: PX statement *Answers on a five point Likert scale: Agree – Disagree*	Metric
1) The facilities and services at the Children's Hospital are well suited for treating my child's illness	Arrangements of care: Quality of the facilities and care services
2) The information and instructions received from the Children's Hospital staff have been useful	Arrangements of care: Quality of instructions received
3) The doctors have time to answer my questions	Healthcare personnel: Busyness of the staff
4) The nurses have time to answer my questions	Healthcare personnel: Busyness of the staff
5) I am confident that my child will get better or that the treatment will progress in a way that the doctors and nurses have told me	Attitude towards the illness: Confidence in recovery
6) The support and help I have received from my friends and family during my child's illness have been useful	Support and daily arrangements: Experienced quality of help received
7) My child's illness has decreased my own well-being	Support and daily arrangements: Experienced stress or burden due to illness
8) I experience fear and disbelief about my child's illness	Attitude towards the illness: Extreme emotions (anger, fear, sadness, uncertainty)

Ward: PX statement *Answers on a five point Likert scale: Agree – Disagree*	Metric
1) The facilities and services at the Children's Hospital are well suited for treating my child's illness	Arrangements of care: Quality of the facilities and care services
2) The facilities and services at the Children's Hospital are well suited for my family	Arrangements of care: Quality of the facilities and care services
3) I expect that my family's transition back to life at home will go smoothly	Success of care: Fluency of getting back to life at home from the hospital
4) My child's illness has decreased my own well-being	Attitude towards the illness: Experienced stress or burden due to illness
5) I experience fear and disbelief about my child's illness	Attitude towards the illness: Extreme emotions (anger, fear, sadness, uncertainty)

4. Discussion

The use of patient satisfaction surveys have been criticized, since satisfaction cannot solely explain the experiences of patients [8] and surveys fit poorly for investigating the PX [e.g. 18]. In our study, we strived to overcome the applicability issues and reduce the gap between patient satisfaction and PX by developing separate questionnaires for inpatients and outpatients at the children's hospital. This allowed us to focus on the special characteristics and needs of the prevailing sections of the patient paths.

In the developed PX surveys for the ward and outpatient clinic, three statements remained common: statements about the quality of the facilities and care services, the parent's experienced stress or burden due to the illness and extreme emotions. This commonality indicates that the child's illness strongly affects the parents and the whole family. Some of the metrics in the surveys are similar to the themes of the Child HCAHPS [4]: they both involve communication, attention to safety and comfort, and the hospital environment. Compared to the satisfaction survey, our surveys emphasize the aspects of parent's attitude towards the illness and the aspects of support and daily arrangements. Hence, the surveys pay attention to the coping mechanisms of the family. The themes of our survey are aligned with the constructs of PX described by Wolf et al. [6]: patient and family perceptions, partnership and engagement.

So far, collection of PX feedback from the families of children treated in the Helsinki Children's Hospital has been sporadic at best. To this end, with the help of the Lapsus research project, not only understanding of the significance and diverse elements of PX but also the need for systematic collection of PX data have been recognized. User-friendly methods and set outcome measures, produced in the present study, are necessary for utilization of PX results in the development of healthcare processes. In the future, the instruments for collection of PX data have to be validated nationally. Next, through international collaboration it is possible to benchmark PX data between foreign children's hospitals.

The study has some limitations. The focus was on the largest children's hospitals in Finland and families of seriously and chronically ill child patients. For the ethical reasons, the participated families were selected together with the children's hospitals. Further research is needed to study the suitability of the questionnaires for different kinds of healthcare organizations and patient cases. In addition, instruments for measuring experiences of children are also needed.

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Encouraging the Use of eHealth Services: A Survey of Patients' Experiences

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Abstract. To promote eHealth services effectively, it is important to understand what motivates people to use these services and how they can be further supported. Our aim was to explore user experiences with eHealth services from the viewpoint of patients with chronic illnesses. The survey data included responses from 397 patients actively using eHealth services in Finland. Most of them had positive experiences using the services. We found that these positive experiences and the perceived benefits of eHealth services encouraged patients to continue using the services. In order to bolster the use of eHealth services, patients and other potential users must be informed about the new services and how to access them. Healthcare personnel play a key role in introducing eHealth services to patients and instructing them on their use.

Keywords. eHealth service, patient's experience, online questionnaire, user experience

1. Introduction

Patients and the wider public are increasingly using eHealth services that are referring to health services and information delivered or enhanced through the Internet and related technologies [1]. Recent studies of patients' experiences using eHealth services found that patients value getting information, professional responses, and peer support [2,3,4]. Patients also appreciate the possibility to be in touch with healthcare professionals and receive immediate answers [5] as well as to find answers to sensitive topics and difficult questions [3]. Study results show that eHealth services make it easier for patients to feel secure, safe, and in control [3,5,6]. Overall, eHealth services help to process feelings during care and enhance patients' overall satisfaction towards health care personnel [7].

On the other hand, numerous obstacles to eHealth usage have been reported. These include problems with usability [5] and accessibility [3]. In addition, an overload of information has been recognized as a possible risk that may increase patient anxiety [6]. Several studies have also pointed out that while eHealth services or applications are considered a valuable addition (to follow-ups, for example), they should not replace face-to-face encounters with healthcare personnel [6,7].

Currently, eHealth services are not widely used in Finland, even though readiness to utilize the services is considered high [8]. To encourage the use of eHealth services, it is important to understand what motivates people to use the services and how to better support their use.

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This paper reports results from a survey study designed to explore patients' experiences of eHealth services in Finland in 2017. The guiding questions are: *What motivates patients with chronic illnesses to use eHealth services? How can patients be better supported in using these services, particularly by healthcare professionals?*

The target group of the survey was patients with globally common chronic illnesses. This article focuses on the obstacles and challenges that patients encounter when using the services, their pleasant and unpleasant experiences, as well as their desires for future services. The aim of the study was moreover to understand the motivational factors related to eHealth services instead of getting inclusive statistics of the current use.

2. Methods

To explore patients' experiences with current eHealth services in Finland, we developed a web-based questionnaire, which included both multiple choice questions and open-ended questions. The topics of the questionnaire were:

- usefulness of and purposes for using currently available eHealth services (such as patient portals and access to personal health information)
- user acceptance (behavioral intention to use)
- level of support and guidance from health professionals
- barriers in using the existing services
- pleasant and unpleasant experiences
- wishes for future eHealth services.

The questionnaire was in Finnish and some questions were similar to those used in a Finnish national eHealth survey [9]. User acceptance was measured with two questions, adapted from previous surveys [10,11]: "Would you recommend eHealth services to a friend who is interested in them?" and "Are you willing to use eHealth services in the future?"

The questionnaire was validated by a group of three researchers working in the field and the representatives of three target patient organizations (diabetes, heart disease, and cancer). These organizations agreed to participate in the study by contacting their members via e-mail newsletter or through their website. In addition, the reliability of the questionnaire was tested with nine patients and pilot tests were conducted with 28 potential respondents to further validate the questionnaire. The data from the pilot survey was not included in the final results.

The data was gathered between February and April 2017 using a web-based questionnaire tool. As in [12], the target group was early adopters who use computers actively. In addition, we focused on patients with chronic illnesses – diabetes, heart disease or cancer – since these patients are more likely to use the services [13-16] and they could greatly benefit from those. The survey invitation and a link to the web-based survey were sent via email to members of these three patient organizations. The diabetes patient organization sent newsletter emails to all 8,300 of their members and we obtained 89 responses. The heart patient organization sent emails to 16,322 members and 244 responses were received. The cancer organization added the survey link to their webpage and 64 responses were obtained.

Statistical analysis and reliability analyses were conducted using SPSS Statistics 24 software. Cronbach's alpha coefficient was .91 for user acceptance, which indicates

excellent internal consistency [17]. Analysis of open-ended comments were content-analyzed using Atlas.ti software. Open coding was used to identify themes in the data without predefined categories [18]. It was performed in an iterative manner by two researchers (JK, NK).

3. Results

A total of 397 respondents answered the questionnaire. Table 1 shows the demographics of the respondents. The results indicate that the respondents were active users of eHealth services. Out of the respondents, 92% had used at least one eHealth service and the most used was the national My Kanta service, which includes health records and medication recorded by healthcare services.

Table 1. Respondent demographics.

		Total (N=397 / 100%)	Diabetic patients (N=89 / 22%)	Heart patients (N=244 / 62%)	Cancer patients (N=64 / 16%)
Age	Range (y)	23-83	23-80	31-83	31-76
	Mean (y)	64	60	67	57
Gender	Male (%)	36	30	46	5
	Female (%)	64	70	54	95

Almost 90% had used eHealth services to seek information related to their own health or an illness, more than half (53%) had been in contact with care personnel, and 40% had received support from other patients, their family, or a patient organization (Table 2). The respondents had used or tried to use eHealth services mostly on their own initiative (25-74% per patient group). Overall, the initiative to use eHealth services from the personnel's side was quite small (0-10% per patient group).

Table 2. Results concerning the question: "For what purpose have you used or tried to use eHealth services (via computer or mobile phone)?"

	Yes, on my own initiative	Yes, on my own and personnel's initiative	Yes, on personnel's initiative
I have sought information related to my health, illness, or care			
Total %	72	16	1
(Diabetes / Heart / Cancer) %	(74 / 71 / 73)	(19 / 14 / 16)	(1 / 1 / 0)
I have been in contact with healthcare personnel (messages / video contact)			
Total %	28	18	7
(Diabetes / Heart / Cancer) %	(35 / 25 / 31)	(21 / 17 / 15)	(2 / 10 / 4)
I have received support from other patients, their family, or patient organization			
Total %	29	11	0
(Diabetes / Heart / Cancer) %	(26 / 26 / 42)	(5 / 14 / 9)	(0 / 0 / 0)

Over half of all respondents (60%) had pleasant experiences related to eHealth services (Figure 1). In contrast, 23% reported having an unpleasant experience, and this number was particularly high among diabetic patients (42%).
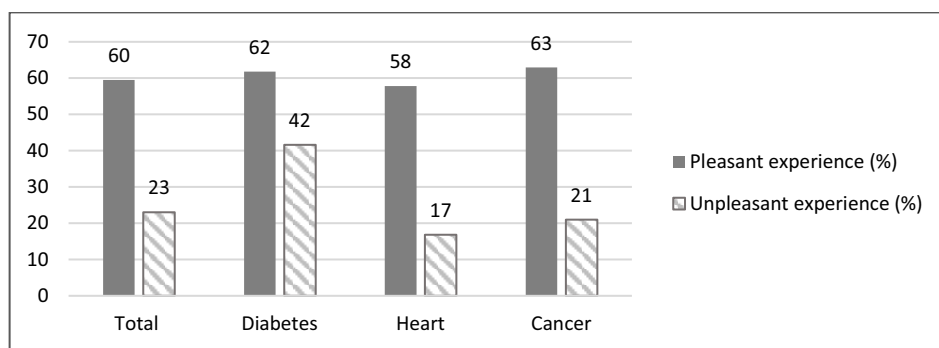
Figure 1. The percentage of respondents reporting pleasant or unpleasant experiences using eHealth services.

The overall user acceptance of eHealth services was high (mean 5.9, STD 1.47, range 1-7 with 7 = strongly agree). There was a significant positive correlation between reporting pleasant user experiences and user acceptance (r_{pb}=.365**, p<.001). Higher age was negatively correlated with user acceptance (r=-.173**, p<.001).

Table 3 presents the results of the qualitative analysis of open-ended answers by describing four of the most common themes within each four questions.

Table 3. Open questions and four of the most common themes of answers.

What obstacles or challenges do you experience in using eHealth services?	(N=284)
Lack of competence in using the services (patients' abilities, skills, and motivation)	(75)
Lack of appropriate computers and mobile devices as well as Internet connection	(47)
Technical issues behind the services, e.g. lack of interoperability between IT systems, lack of a national archive, security, and safety concerns	(38)
Services are not known or are not available	(32)
What kind of support or help would you like to have in using eHealth services?	**(N=232)**
No need for support or help	(63)
Support in finding out what services exist and how to access them	(37)
Guidance and information about services on a general level	(19)
Simple instructions and tutorials on how to use the services	(15)
If you have had a pleasant experience related to eHealth services, describe the experience and the related e-service.	**(N=184)**
Reading and following one's own health information using the national My Kanta service*	(77)
Renewing e-prescriptions via the national Kanta service*	(45)
Electronic appointment booking	(40)
Getting in touch and messaging with healthcare professionals	(29)
If you have had an unpleasant experience related to eHealth services, describe the experience and the related e-service.	**(N=83)**
Lack of up-to-date data at national and regional patient data repository services like Kanta* eHealth services are not easy to use	(22)
Challenges and problems using electronic appointment booking	(13)
Difficulties in starting to use the service (e.g. login, electronic authentication, consent agreement forms)	(11) (14)

*Kanta = The national archive for health information in Finland.

4. Conclusions

The aim of our study was to ascertain *what kind of experiences motivate patients to use eHealth services*. The questionnaire was targeted to patients who had chronic illnesses and access to computers. The results show that the respondents were active users of eHealth services and most of them had positive experiences using eHealth services. Positive experiences seem to encourage them to continue using eHealth services. We also found that increased age appears to be related to lower intention to use eHealth services as in previous studies [19]. The reported positive experiences were related to the perceived benefits of using eHealth services. Most of these experiences concerned basic functions of eHealth such as reading and following one's own health information, renewing e-prescriptions, booking electronic appointments, and communicating with healthcare professionals. These findings concur with earlier studies (e.g. from Finland [8]).

On the question of *how healthcare professionals can better support patients in using eHealth services,* we found that professionals should introduce the services to patients and provide support and guidance on their benefits and use. Currently, the use of eHealth services depends primarily on the patient's own initiative; even active patients need help in finding the services. In their open comments, several respondents mentioned that they need support to find out what services exist and how to access them. In addition, they wanted to obtain basic information and instructions on how to utilize the services. Reported obstacles to use the current eHealth services included technical issues (e.g. lack of interoperability between the systems), services not being easy to use, and a lack of competence in using the services.

Our study had some limitations. The data included responses from about 400 patients with chronic illnesses who were active users of eHealth services, or so-called lead users. The number of respondents can be considered relatively low compared to potential users of eHealth services in Finland and thereby the results cannot be generalized to the whole population. However, for the purposes of the study the number of responses was found adequate since the aim was to increase insights on the motivational and supportive factors of eHealth use. The setup of the study enabled us to identify what motivated lead users to use eHealth services and highlight ways to support their use. These findings are important for planning how to promote the use of eHealth services among potential users. Still, further research could include users that 1) are currently not using eHealth services and 2) are not as comfortable with technology.

To conclude, our main findings are: In order to encourage wider use of eHealth services, it is important to inform patients and other potential users about the new services and how to access them. Informing the patients about the potential benefits will motivate them to start using these services. Healthcare personnel play a key role in introducing the services to patients and instructing patients about how to utilize them properly. For healthcare professionals these changes will include new responsibilities, and they should be supported through additional training and adequate resources.

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Canadian Validation of German Medical Emergency Datasets

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Abstract. Medical Emergency Datasets (MEDs) are brief summarizations of an individual's medical history, providing vital patient information to emergency medical providers. A recent German study [1] evaluated whether MEDs are useful to local emergency physicians and paramedics, and which health data were relevant to their medical management. To validate of the German study internationally, Canadian physicians and paramedics were recruited to provide feedback on the utility of the German MEDs as well as their specific content. Original documents and surveys were translated to English directly, with a goal of collecting quantitative and qualitative feedback. Overall, physicians and paramedics found the MEDs to be useful in their evaluation of hypothetical medical scenarios. Most of the MED content was very useful, with some items appearing extraneous. The findings of this study will be used to inform future development of MEDs as well as to drive future research.

Keywords. Electronic Health Records, Health Information Exchange, Emergency Treatment, Medical Emergency Datasets

1. Introduction

Pre-existing medical information about patients is critical to first responders and physicians in delivering emergency services [2]. Unfortunately, this vital data is often unavailable to providers due to language or geographic barriers, or from patient incapacitation [3]. Even when prior medical records are available, they can be challenging to access in a timely fashion, and may have incomplete, difficult to interpret, or inclusion of extraneous data [3]. Many health regions in Canada and other countries have implemented electronic medical records (EMRs) to improve accessibility of medical records to care providers [4]. Yet, these records are uncommonly organized to provide the most essential information about the patients to be rapidly accessible to health providers in emergencies to guide optimal care.

Over 388,000 German travelers visited Canada in 2017 [5]. Newly enacted legislation in Germany mandates that each German citizen has the right to have a medical emergency dataset (MED) created by their general practitioner which may be accessed electronically by emergency medical providers domestically [4]. Medical emergency datasets included medical information organized in five categories (Table 1). A recent study demonstrated MEDs are very useful to German paramedics and emergency physicians (EPs) treating acute patients in simulated written scenarios [2].

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Table 1. Medical emergency dataset categories & example items within each category

Category	Example Items
Diagnoses	ICD 10 code, diagnosis name
Medication	Drug name, dose, prescriber
Allergies	Substance, reaction
Medical Implants	Date, type
Special Notes	Pregnancy, communication barrier

The study further showed certain items in the MED (i.e. medical diagnoses and medications) are valued greater than others (i.e. allergies and medical devices).

The current technical infrastructure in Germany in which the MED is stored prohibits the digital utilization of these records internationally [1]. Therefore, to aid international acute care providers treating German travelers with medical or traumatic emergencies, the MEDs are currently being adapted by a German research group led by the University Hospital Muensters Office for eHealth to be accessible in mobile devices and in other languages. In collaboration with the University Hospital Muensters Office for eHealth, we sought to test the usability and relevance of MED by surveying Canadian paramedics and EPs to obtain their opinions and feedback. The purpose was to internationally validate the results of the 2015 German study, and to provide constructive feedback on how to best adapt the German MED for Canadian healthcare providers.

2. Methods

The researchers used previously developed German patient MEDs in paper form translated into English in combination with written emergency medical scenarios to obtain quantitative and qualitative feedback from Canadian paramedics and EPs on the usefulness of the medical data to their care of the simulated patients. The feedback forms were also direct translations from the 2015 German study in order to accurately validate their results in a Canadian setting.

2.1. Participants and Recruitment

Paramedics with at least two years of prehospital experience, attending EPs, and senior resident EPs with minimum two years of emergency medicine training were invited to participate in the study. Following ethics approval, recruitment emails were sent to physicians at an academic, tertiary care hospital in Vancouver, BC, as well as to paramedics in British Columbia. Interested individuals contacted the researcher directly if they wished to participate in the study. Electronic communication was used to share study purpose, procedures, MEDs, and other study material. Consent was obtained via email.

2.2. Procedure

Each paramedic and EP was provided with four MEDs and two written emergency medical scenarios. The participant was asked to use an MED corresponding to a hypothetical emergency scenario (i.e. a 70-year-old male on an anticoagulant medication who was in a motor-vehicle collision). Two of the MEDs were applied to the first

scenario, and the remaining two MEDs were applied to the second. Subsequently, the participants were asked to complete five brief surveys (one for each MED, and one for global feedback). The surveys included sections for categorical responses, and additional free text space for written feedback. The study was conducted either in person in an academic office with a study investigator present, or online at the participant's preferred location.

2.3. Analysis

The number of times participants (in the rankings from the survey) rated each category of information (each of the categories and example items listed in Table 1) was summarized as either: "necessary/very useful", "somewhat useful" and "not necessary". For each category the frequency was converted to the percent of times participants considered each of the information categories in terms of being necessary/very useful, somewhat useful or not necessary, and this was tabulated and organized in descending order (from most necessary to least necessary). This analysis was done for both groups – the paramedics and the EPs. In addition to analyzing the ratings obtained from participants regarding information categories, participants' comments were recorded and organized according to the category of information they were referring to (in order to identify recurrent themes about the usefulness of different categories of information).

3. Results

The results discussed in this section focused on the quantitative analysis of the items included in the MEDs, as well as the qualitative themes obtained through free text responses. In total, 25 EPs and 25 paramedics analyzed two MEDs each paired with two medical scenarios. Overall 200 responses (from 50 participants each responding to four total scenarios) were included in the results.

3.1. Quantitative Results

Tables 2 and 3 give the most highly rated information items (organized in descending order, from "necessary" to be included in a MED, down to less necessary). The results are generally consistent across both paramedics and EPs. For example, diagnosis name, date and site were considered the most important aspects of the category "diagnosis", while ICD-10 codes, diagnosis confidence and person who made the diagnosis were not.

Both EPs (74%) and paramedics (81%) found the MEDs to be useful in evaluating the medical scenarios. Specifically, information regarding past diagnoses (EPs = 78%, paramedics = 76%) and medications (EPs = 84%, paramedics = 82%) to be very useful in the MED. Within these categories, some data were considered to include extraneous information (i.e. diagnostic confidence, ICD10 code, who prescribed a medication, and person who made a diagnosis). Similarly, EPs and paramedics described information regarding medical devices and implants (EPs = 32%, paramedics = 52%) as well as special notes like pregnancy and communication barriers (EPs = 28%, paramedics = 27%) to be less useful in their assessments. Only the paramedics considered the allergy section to be useful (EPs = 52%, paramedics = 78%)

3.2. Qualitative Results

Analysis of the qualitative comments also reflected and were consistent with the above rating patterns. For example, one physician noted "I don't need to see diagnostic confidence. Either the patient has a diagnosis or they do not", which was consistent with the low rankings of importance of diagnostic confidence in Tables 2 and 3. Furthermore, another physician stated that "I don't need to know who diagnosed this", also consistent with the lowest ranking for the name of the person making the diagnosis as the category ranked lowest for being necessary in a summary (this also applied for a low ranking for being necessary for the category of who prescribed a medication, which was also found to be not necessary).

The qualitative results for the paramedics mirrored the results from the EPs. For example, one paramedic stated that "Don't care who diagnosed it". Also regarding medication information another paramedic stated that "Don't believe prescriber and form of medication is necessary".

Table 2 – Percentage Rankings of Importance of Information Items for Paramedics

Category	Item	Necessary	Somewhat useful	Not necessary
Diagnosis				
	Diagnosis	**74**	26	0
	Date	40	**49**	10
	Side localization	17	34	**48**
	Dx confidence	10	36	**54**
	ICD10	1	6	**93**
	Person who made Dx	1	11	**87**
	Overall useful	**76**	18	6
Medication				
	Drug name	**60**	30	10
	Agent name	**46**	42	12
	Dose	25	**46**	29
	Taking	12	33	**54**
	Prescriber	2	5	**93**
	Overall useful	**84**	10	6
Allergies				
	Substance	**94**	3	3
	Reaction	**69**	28	3
	Person who made dx	0	3	**97**
	Overall useful	**78**	4	17
Implant				
	Implant	**48**	39	13
	Type	23	**43**	33
	Date of implant	10	40	**50**
	Person who made dx	5	10	**85**
	Overall useful	**52**	28	21
Special notes				
	Communication barrier	**64**	14	21
	Other	28	**59**	14
	Road danger	17	17	**67**
	Pregnancy	8	17	**75**
	Overall useful	27	9	**64**

Table 3 – Percentage Rankings of Importance of Information Items for Emergency Physicians

Category	Item	Necessary	Somewhat useful	Not necessary
Diagnosis				
	Diagnosis	**89**	9	2
	Date	**47**	42	11
	Side localization	25	37	**38**
	ICD10	7	6	**88**
	Dx confidence	6	38	**56**
	Person who made Dx	1	22	**77**
	Overall useful	**78**	14	7
Medication				
	Agent name	**74**	14	13
	Dose	**71**	12	17
	Drug name	**56**	15	29
	Taking	**54**	18	28
	Prescriber	1	22	**77**
	Overall useful	**82**	11	7
Allergies				
	Substance	**85**	6	9
	Reaction	**85**	6	9
	Person who made dx	10	19	**71**
	Overall useful	**51**	9	40
Implant				
	Implant	**77**	15	8
	Type	**50**	42	8
	Date of implant	38	38	23
	Person who made dx	18	0	**82**
	Overall useful	32	26	**41**
Special notes				
	Other	32	18	**50**
	Pregnancy	0	0	**1**
	Road danger	0	0	**1**
	Communication	0	0	**1**
	Overall useful	28	15	**57**

Comments made regarding other categories such as allergies also indicated the importance of some categories, such as the name of the substance causing the allergy, and the reaction to it. However, including the name of the person who made the assessment was considered not necessary by both groups – as one paramedic states "Person who set the diagnosis is not necessary".

Comments regarding the information in the summary overall were also useful and included some interesting recommendations, such as "Should collect more free text on relevant diagnosis" (made by an EP) and "making it more concise with only what is necessary – there was a lot of information that was not useful." Other suggestions concerned the delivery platform, with one paramedic stating that "possibly have is as a smart phone APP".

4. Discussion

Both EPs and paramedics from Vancouver overwhelmingly describe the English-translated German MEDs as very useful in their assessments of unknown patients in simulated acute medical scenarios. These results are similar to those from the previously described German study, and support the hypothesis that MEDs positively impact the emergency care provision in Germany as well as in Canada.

Not every category and item were deemed valuable by medical providers. Of note, both physicians and paramedics identified the same items in the same order of priority for each of the five themes. Emergency medical providers considered medical history and medications to be particularly useful. However, it was noted multiple times that the necessary information (like diagnosis and medication name) were combined with distracting, less useful data (ICD10 code and prescriber). This feedback should be considered when compiling MEDs for tourists who will be visiting Canada.

As German tourism to Canada continues to gain popularity, there will continue to be challenges for Canadian paramedics and physicians treating these visitors to their cities. Language and medical barriers to communicating medical history can be detrimental to emergency care. With English MEDs associated with international visitors, acute care providers will be able to assess and manage their patients with vital clinical information easily accessible. Feedback from Canadian physicians and paramedics will be provided to the German Medical Association so that they may continue to optimize the MED for international, English speaking medical providers.

The participants in this study describe a need for a similar, accessible MED for Canadian citizens as well. Future investigations should look to develop and refine a strategy for allowing Canadians to travel domestically and internationally with a record of their medical history so that they too may receive optimally informed emergency care beyond their provincial borders. The ultimate goal of an integrated electronic medical record for each Canadian citizen will require similar studies to determine what health data is useful for care providers.

Limitations to this study include the small geographical region of the study participants. It is unclear if emergency providers in Vancouver adequately represent the rest of Canadian EPs and paramedics. Additionally, to maintain internal validity, only four patient MEDs were analyzed in this study. The feedback provided is being generalized to guide future MED construction. There will certainly be variation in data included in real patients' MEDs, which we were unable to account for in this study.

Future research is required to further validate the utility of MEDs in a global context. Furthermore, there are larger questions regarding technological implications of MED design and accessibility which were beyond the scope of the present study. Finally, ethical and philosophical implications of MEDs (for example, patient ability be able to modify their data; and addressing discrepancies patient and physician opinions) should be considered in future research.

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Healthcare Data Are Remarkably Vulnerable to Hacking: Connected Healthcare Delivery Increases the Risks

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Abstract. Healthcare data are attractive to cyber-criminals because they contain financial and personal data, can be used for blackmail, and most valuable, are ideal for fraudulent billing. They are also remarkably vulnerable to penetration because of the fluid and always-evolving nature of a patient's medical care and because of the number of clinicians, facilities and transactions required to connect patient care across multiple settings. The addition of mobile healthcare devices and connected healthcare delivery systems (e.g., wearables, monitoring devices, cell phone images) makes healthcare data more attractive but also more vulnerable. Wide variations of digital health use patterns complicates design security solutions for each context or clinician. In this paper we propose a set of connected healthcare patterns, and then discuss security challenges and potential solutions for each of the connected health patterns.

Keywords. Cybersecurity, mobile healthcare, connected healthcare delivery.

1. Introduction

Healthcare data—especially electronic health records—are worth ten to thirty times more on the black market than are credit card numbers. A cyber-thief can buy stolen bulk credit card numbers for anywhere from about $2.50 to $10 a number. In contrast EHR data are approximately worth up to $65.00 each. Why this difference? A credit card can be used once or a few times. But a healthcare record: 1. Has your credit card number anyway and your national insurance ID; 2. Can be used for blackmail; and 3. Most important—is the gift that keeps on giving if used by unscrupulous medical providers. Thus, a physician, or physiotherapist, or pharmacy can bill the government or an insurance company for millions of dollars. In the US, healthcare fraud cost is estimated at over $100 billion/year [1]. And the unscrupulous vendor or provider will know exactly the kind of services, procedures or supplies appropriate for each patient. The fraud is aided by incomprehensible (and intentionally opaque?) medical billing processes and the reality that a lot of sick people are not carefully examining the Byzantine paperwork that accompanies any medical event.

There are several reasons why healthcare data are vulnerable to security breaches. First is that today's medical infrastructure has been adapted from conventional

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computing, and was not designed with the needs of health care. Hence the current generation of micro-processor-based health care equipment is usually better suited to office-like and traditional data processing workflows than to clinical environments. This is especially clear in the use of passwords as an access control mechanism. Second, many of today's medical devices were first designed as stand-alone devices, not as networked components. They lack the basic functionality needed for their new role. Integrating legacy medical devices into the new networked architectures requires a large amount of new software and integration processes creates novel security problems that never existed for the stand-alone design. As an example, a stand-alone insulin pump assumes a single or at most a small number of login accounts for operators. In contrast, when networked, any of the patient's clinicians may need to log into the device, and so the authentication system needs to be re-worked from scratch to integrate into the facility's network-wide authentication framework.

Perhaps the most significant challenge is that modern healthcare delivery is defined by delivery models such as collaborative care delivery where people, processes and technologies need to be connected across multiple providers and settings. A patient may have several health records which must travel across all of these system boundaries to satisfy all of the clinical, scientific, and business objectives involved in that patient's care and billing. While a traditional model of healthcare delivery system has one patient record in one electronic system that is accessible by everyone, we know that is not the reality of healthcare delivery. At a micro level, attempts to manage complex care delivery such as chronic disease management and patient participatory medicine often require the connection of data from multiple systems or devices. At a macro level, there is also a desire to enable system wide analytics and learning, which requires access and analysis of data from multiple systems.

Healthcare IT promises—and often delivers–-faster, better, and more comprehensive medical care. But underlying those promises is the assumption that patient data in the IT systems are secure; and that the safety of the software used to collect, analyze, present and transfer that information is not easily compromised. Still, there are good reasons to doubt the data security of various models of healthcare delivery. Overall, it remains a challenge to define the security requirements for connected health systems, particularly when the ecosystem involves emerging technologies such as mobile devices [2]. While it is impossible to predict all possible patterns of connected health delivery, we can make general inferences about patterns of connectivity that would allow us to better understand security issues with connected healthcare delivery and how to prevent them. This paper addresses the above need and develops three connected healthcare patterns according to the formality and extent of connectivity. We then describe security challenges and potential solutions for each of the three patterns.

2. Modeling Connected Health Patterns

We propose a two-stage model: The first stage reflects the existing and emerging patterns of healthcare delivery that integrates the many different medical facilities and clinicians. We draw on our previous work of different telehealth delivery patterns [5]. The second stage addresses the security needs associated with each pattern. For this, we build on the research on security implications of healthcare devices within smart homes and with the use of mobile healthcare devices. We then seek to integrate the frameworks by analyzing

the set of patterns and security considerations for the varying connected healthcare delivery configurations.

Connected healthcare delivery can be broadly defined as a consumer-centered healthcare delivery model that uses different information and communication technologies (ICT) to connect information sources and processes across the entire health care system [3]. In plain words, this is about how patients and medical systems' EHRs connect. There are substantial variations in the type and number of technologies used to enable that connectivity; and the technologies affect the security needs of each ICT type and complexity. Another consideration is the extent to which a system is formal or informal. A hospital EHR system is always a formal system, while an iPhone app is usually an informal system. Last, we must address the number of ICTs used to allow connectivity. The more ICTs used, the greater the degree of connectivity complexity.

2.1. Connected Health Patterns

Drawing upon the approach described above we develop three connected health patterns according to the number of ICTs and the degree of formality:

One-to-One – This is the most basic pattern. The provider has a formal EHR system and patients can access their records at home via the internet using a dedicated login screen. All patient data are viewed and transacted through the EHR. The One-to-One pattern is the least complicated as the connectivity complexity can be defined *a priori.*

One-to-Many – Patient data are accessed through more than one formal EHR system. This pattern would occur when patient data are exchanged through multiple systems such as a provider EHR and other HIT systems within a hospital or other clinics. One-to-many patterns are moderate in complexity as users may have multiple logins to enable system access or data may need to be integrated across multiple systems to provide a comprehensive picture of a patient's health.

Many-to-Many – Patient data are collected and exchanged through multiple apps and tools, both formal and informal. Patients may use Fitbits, iPhones or other apps to collect, store data, and transmit their healthcare information as well as accessing one or more formal EMR system from their provider(s). Many-to-Many configurations are the most complex because one can seldom predict the degree of connectivity that will occur as new connections may evolve through patient use of social media or other eHealth tools.

3. Results - Security Challenges and Potential Solutions for the Connected Health Patterns

3.1. One-to-One

Despite being the least complex of the connected health patterns, one-to-one connectivity is still prone to security breaches; and challenges can exist at individual and organizational levels. Individual level connectivity involves a patient or family member accessing data. It starts with creating secure passwords that are not shared with other individuals. Individuals also need to be aware of differences in security risks depending on the devices used to access their medical record.

A desktop or laptop computer typically is more secure than a smartphone, as a smartphone is not a single technology but rather many digital components, each which

can be compromised [2]. Smartphone information usually travels through insecure and open communication channels. Patients also need to be aware that all inquiries and transactions about their data need to take place within the formal EHR system. Studies have highlighted how patients are increasingly using social media tools such as Facebook to show data or engage in communication about their health [4], or will use communication channels such as e-mail to communicate with providers. These actions turn formal systems into informal ones and increase security challenges accordingly.

At an organizational level, healthcare settings (e.g., hospitals) need to ensure they have technical safeguards such as data backups, firewalls et cetera for securing system access and transmitting data [6]. Healthcare organizations also need to have administrative security safeguards such as a security plan, protocols for how data can be accessed, and a strategy for how data will be anonymized for research and other purposes.

3.2. One-to-Many

One-to-many connectivity subsumes the security challenges from one-to-one connectivity while also introducing some new ones. Most significant is understanding how data will be integrated across multiple formal systems. Vulnerabilities are amplified when connectivity occurs across multiple systems, vendors, security safeguards and logins/access points. Multi-level connectivity also introduces challenges about what information the many systems convey when collectively combined. For example, some administrators believe that removing key personal identifiers is sufficient to anonymize patient data for system-wide analytics and learning. However, that effort may be defeated when the data from several sources are combined.

3.3. Many-to-Many

The design of human-computer interfaces of health devices focus only on each device's individual cyber security controls. However, critical here, the interaction of many devices linking to the EHR means security should incorporate *collective (network)* cyber security. That is, formal medical devices will interact with informal medical devices (e.g. Fitbits, heart rate monitors, smart phone apps) in *ad hoc* or even in intentional networks to create additional security vulnerabilities. Worse, available security settings seldom enable users to effect more complex security controls in network settings.

To address these issues, security must now address the reality of multiple users of devices (e.g., infusion pump used by many). Moreover, the security settings and controls should reflect use by different categories of users - adults vs. children; patients vs clinicians, as well as different types of connectivity (e.g. formal vs informal).

4. Recommendations

Addressing the above security challenges is an interdisciplinary endeavor. We present recommendations at two levels. At a technical level, medical devices should be designed with the functionality and controls to allow or prohibit the collection and transmission of data from the user or device to the EHR and/or to others (e.g. clinicians, parents).

At an administrative or policy level, we need to improve the often incomprehensible security instructions and explanations for network security both for individual devices and for one and many to many networks that require *collective (network)* cybersecurity.

To that end, instructions and control designs must be tailored to the many different levels of users' understanding needed to appreciate the network-level vulnerabilities. As with the tragedy of the commons, some solutions require policies that incorporate more than one developer and more than one user. That is, the combination of a large number of devices at least multiplies the danger of any vulnerability and potentially leads to new vulnerabilities. A user may be overwhelmed by this combination. Thus, while device developers have the responsibility to provide secure settings for their own devices, they will probably not be aware of the other devices in use, nor are they aware of shortcuts and workarounds which may be motivated by the connectivity of multiple devices. An important mismatch therefore is what the developer might consider adequate for safety thinking about their suite of medical devices. Addressing that mismatch needs a policy-level intervention that governs the integrated picture of medical security.

5. Conclusion

A fundamental system design challenge for connected health is that we often cannot predict requirements ahead of time due to the always evolving nature of connected health systems. This makes security monitoring and governance particularly challenging. Patients are increasingly willing to share their healthcare data assuming that the data will be shared securely, but managing healthcare security must address the growing complexity and connectivity of systems, participants and devices. As healthcare delivery shifts from hospital to community-based care, and patient participatory medicine becomes a driver of healthcare delivery, the number of connected health touchpoints will increase. Another issue is the role of social media involving healthcare and the growing pool of healthcare smartphone apps. All of these increase the number of touchpoints, the cybersecurity attack surface (vulnerabilities), and the potential for security breaches.

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Updated Mapping of Telemedicine Projects in Denmark

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Abstract. Telemedicine is suffering from pilotitis. Only few initiatives manage to scale up to make significant impact. It is challenging to obtain good indicators for dissemination and use, and it is, therefore, difficult to provide evidence that telemedicine projects fulfil the prophecies of reducing cost, improving quality of care and providing equitable access to health care services. The telemedicine mapping project seeks to provide a national contemporary overview of telemedicine initiatives in Denmark. The project is introduced, challenges in keeping the database behind the map updated are presented and attempts to promote rapid update are discussed.

Keywords. Telemedicine, dissemination, benchmarking

1. Introduction

Telemedicine, telehealth, telecare, eHealth and mHealth seem to be used interchangeably in the literature [1]. The technology behind any of these terms has often been referred to as the solution that will reduce the cost of health care, improve quality and provide equitable access to health care services [2]. However, it has proven very difficult to establish evidence that these prophecies really come true. Firstly, the majority of telemedicine projects has not been able to sustain and scale up to a level where real measures could be obtained – something that is often referred to as *pilotitis* [3]. Secondly, it is difficult to obtain valid and reliable outcome measures. It is relatively simple to count how many systems that exist and where they are implemented, but dissemination and availability quantities do not indicate how much it is in use, by whom, and what the outcome of the use is [4]. A recent review study of methodologies used to evaluate telemedicine service initiatives in hospital facilities identified only 137 telemedicine services and found that either telemedicine service implementation is still not a part of mainstream clinical services, or it is not being reported in the peer-reviewed literature. Furthermore, the study stated that the depth and the quality of information was variable across studies, reducing the generalisability [5]. Other review studies support this conclusion [6,7].

Review studies of telemedicine initiatives resemble cross-sectional studies. Although they cover literature published over a period in retrospect, they rarely have a time dimension in their analysis. Telemedicine is a fast-paced technology-driven area where innovative concepts and new application areas are launched frequently. This calls for a longitudinal monitoring of telemedicine projects on a large scale.

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MedCom has since 2013 mapped telemedicine projects in Denmark in a single database. The objective of the database is to annually collect and publish an overview of the diffusion of telemedicine in health care and provide a status for each project as a first step to systematise the wealth of telemedicine experience. For each telemedicine project, the database contains data in the following categories:

- Master data (title, aim, volume, etc.)
- Involved actors (managers, users, etc.)
- Disease area
- Activities (consultation, diagnostics, screening, monitoring, shared care, etc.)
- Relation to specific trajectory programs
- Applied technologies (hardware, software, specific integration to other systems)

The inclusion criteria of the database has been the WHO definition of telemedicine: "The delivery of health care services, where distance is a critical factor, by all health care professionals using information and communication technologies for the exchange of valid information for diagnosis, treatment and prevention of disease and injuries, research and evaluation, and for the continuing education of health care providers, all in the interests of advancing the health of individuals and their communities"[8]. The database contains data on 430 projects (2017), which have been collected among telemedicine initiatives in the 5 regions and the 98 municipalities in Denmark.

The use of mapping data and recording of mapping data are linked together. Data must be *valid, reliable and updated* to be used, and data must be *used* to motivate people to deliver valid, reliable and updated data. As delivering input to the telemedicine database and keeping it updated has been (and still is) voluntary, a lot of effort has been put into the strategy for collecting valid, reliable and updated data to ensure that the data is actually useful. This paper presents the strategy for collecting valid, reliable and updated data about the telemedicine projects' status, aim, volume, disease area, who the users are, what, where and why it is used, etc. The update for 2017 is completed and the 2018 update is in progress. The experiences and lessons learned from these updates will be presented and discussed.

2. Methods and material

The experience is that the combination of a working group (WG) and the use of autogenerated emails contribute to the collection of valid and reliable data to the telemedicine database.

Telemedicine initiatives are often local and only known to the health professionals involved in the projects. Therefore, the WG plays a central role in promoting the database, identifying sources and facilitating the data collection. The advantage of the WG is that it comprises local representatives who i) know what is going on in their respective geographical areas, and ii) have connections to those who do. The WG consists of:

- Representatives from the five regions, which represent the Danish hospitals;
- Representatives from municipalities, which represents homecare;
- Data consultants, i.e. consultants who guide Danish GPs in the use of IT.

Once a year, a coordinated effort between MedCom and the WG is made to collect new data and to update existing data in the database. Until 2016, the procedure has been as

follows: An email template was sent to the WG members. They could either adjust the email to their local context and forward it to contacts at hospitals, municipalities etc., who then entered/updated data directly in the database, or the WG member collected data from their contacts and entered it into the database themselves. Hence, the task of collecting and updating data was decentralised as much as possible to ensure identification of all local telemedicine initiatives. Despite the advantages, the procedure was quite extensive and time consuming for the representatives of the WG, since the task included forwarding the message and/or contacting the contact persons for the initiatives, or the individual who originally recorded the initiative in the database. In addition, contacts might have changed jobs and/or job function causing the procedure to be even more time consuming. To overcome these challenges, a package of autogenerated emails was launched in 2017, including an email to a person behind every initiative once a year to remind them of the database and their task of ensuring the validity of the data recorded. The email is, thus, targeted directly to those qualified to update the initiative and outdated contact info is discovered and corrected, all contributing to a less time-consuming collection of valid data. In the autogenerated email the receiver finds a list of all initiatives to which that person is registered as contact or editor. To ease the access, the list contains direct links to the editor site of the specific initiative. In addition, the email contains 1) a description of the objective of the database and the data elements that might have changed, e.g. project finishing date; 2) link to a guide for recording and updating the initiatives; 3) support info, i.e. contact info and links to the representatives in the WG.

The package of autogenerated emails also includes: i) An email sent to the contact person at the time when he or she is recorded as a contact in an initiative. The email contains guidance on how to register as a user of the database, in case he or she is not already registered, and a direct link to the recorded initiative. Hence the contact can react in case of disagreement on recorded data; and ii) an email that is sent to the editors of an initiative, which is close to the recorded finishing date.

Despite the increased focus on the data collection process, including the autogenerated emails, additional fields to be filled in and efforts to increase correct recording of initiatives, the WG undertakes once a year the specific task of cleaning-up, i.e. to identify duplicates and initiatives with missing information.

3. Results

An interactive map (see Figure 1) has been developed to provide a common overview and, thus, create a basis for disseminating knowledge and collaboration across regional boundaries and sectors. The map provides easy access to knowledge about telemedicine experiences within the Danish health sector. Clicking on one of the dots in one of the municipalities will perform a search for telemedicine initiatives in that municipality and display them in a table. Further search criteria can be added to specify the results.

By October 2017, the telemedicine map contains 430 registered initiatives. The 2018 update is in progress. The number of registered initiatives has increased over the years as shown in Table 1.

Table 1. Registered initiatives from 2013 to 2017

2013	2014	2016	2017	2018
289	345	402	430	Not yet available

It is known that the telemedicine map does not cover the totality of telemedicine initiatives in Denmark. Initiatives may exist in regions and municipalities that have not been registered because of lacking awareness of the existence of the map.

Furthermore, several initiatives are still incomplete, despite an effort to fulfil these initiatives in 2017. This has consequences for data validity.
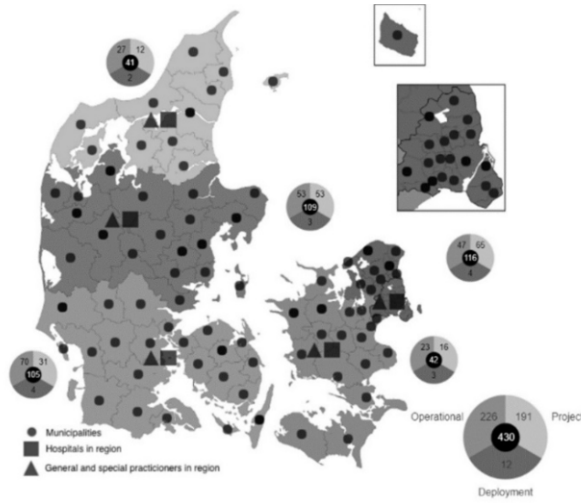
Figure 1. Screen dump of the interactive map of telemedicine initiatives in Denmark (https://telemedicinsk-landkort.dk).

The distribution of the number of pilot projects and initiatives in operation has shifted over time. Figure 2 shows that the number of initiatives in operation exceeds the number of pilot projects in 2016 and 2017.
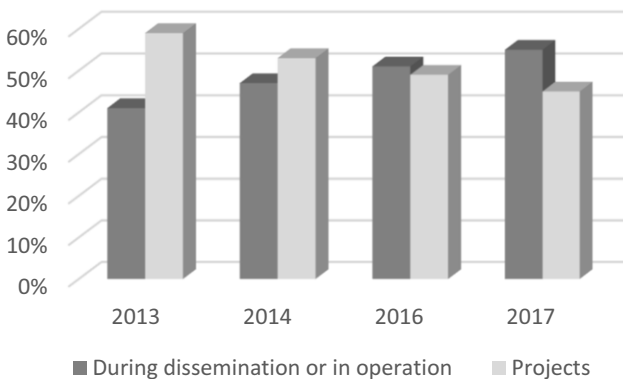
Figure 2. Registered initiatives in operation and in pilot project state.

The telemedicine map is intended for decision-makers, project leaders and clinicians. It is available to the public and everyone can set up a telemedicine initiative on the map. It is accomplished by registering as a user.

It is known that decision makers, project leaders, journalists and students are using the telemedicine map, but no data is available on how much it is used by clinicians.

4. Discussion and conclusion

Even though several strategies have been implemented to ensure the collection of valid and updated data, several challenges remain:

Inclusion criteria for initiative recording are not clear-cut. Different standpoints exist to whether initiatives such as video conferencing and use of telephone qualify as telemedicine. The ambiguity arises because activities – at some point – become standard use and might not be considered as telemedicine. Awareness is given to the fact that the question is up for discussion and might be reflected in diverse recording behavior.

Incompleteness of data remains a challenge. Initiatives may exist in regions, municipalities and general practices that have not been recorded due to either unawareness of the existence of the database or lack of motivation to do so, as recording is voluntary. The latter being strongly related to active use of data. Both factors are highlighting the important role of promoting the database and its usability.

Data is not validated or reviewed by MedCom or any other part before publication. The consequence is that incorrect recording of data is not necessarily discovered and corrected, challenging data validity. However, validation procedures are time-consuming and risk becoming a bottleneck. When an initiative is recorded, an email is sent to the contact of the initiative. This contact person is not necessarily the same as the one who recorded the initiative, and in such a case, it is possible that the contact person reacts to errors or misinformation, which will improve the validity of the data.

To monitor the use of the telemedicine database, Google Analytics tracking has been set up. At this moment, only limited use data has been generated but it will onwards be used to evaluate the use of the telemedicine database in terms of e.g. website traffic. However, even though data can be used to understand several perspectives of telemedicine initiatives, Google Analytics will not reveal *how* data are used. The telemedicine database contains several structured fields and can provide information about e.g. the distribution of the initiatives according to their status (pilot project, being disseminated, in operation, terminated), in which health care sector the initiatives are "located", number of cross-sectoral initiatives, which technologies are used etc., and – if downloaded once a year – comparison over time. This information is valuable for researchers, decision markers, policy makers, and the central administration. All initiatives have a contact person who can provide further information about the initiative by email or phone, and some initiatives link to evaluation reports, enabling knowledge sharing.

Pilotitis is hard to overcome, and the database itself will not achieve this. However, by visualising how many telemedicine activities are ongoing or have been terminated (and *why)*, the database has the potential to bring projects and people together, minimising the number of actors initiating a similar pilot project and/or not taking advantage of experiences already gained elsewhere. Under the assumption that the data is used actively, it could result in less pilotitis and increased focus on scalable initiatives. This will qualify further research of positive, negative and/or unintended consequences of telemedicine. The above underlines the need for continued focus on the usability of the general data retrieval as well as the data entry processes related to the quality of the telemedicine database.

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A Hadoop/MapReduce Based Platform for Supporting Health Big Data Analytics

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Abstract. In this paper, we report our practical experience in designing and implementing a platform with Hadoop/MapReduce framework for supporting health Big Data Analytics. Three billion of emulated health raw data was constructed and cross-referenced with data profiles and metadata based on existing health data at the Island Health Authority, BC, Canada. The patient data was stored over a Hadoop Distributed File System to simulate a presentation of an entire health authority's information system. Then, a High Performance Computing platform called WestGrid was used to benchmark the performance of the platform via several data query tests. The work is important as very few implementation studies existed that tested a BDA platform applied to patient data of a health authority system.

Keywords. healthcare, big data analytics, Hadoop, MapReduce

1. Introduction

Big Data in healthcare is different from other disciplines such as social network or transactional business data in that it includes standardized structured, coded data (e.g. ICD, SNOMED CT), semi-structured data (e.g. HL7 messages), unstructured clinical notes, medical images (e.g. MRI, X-rays), genetic lab data, and other types of data (e.g. public health and mental or behavioral health). Huge volumes of very heterogeneous raw data are generated daily by a variety of hospital systems such as Electronic Health Records, Computerized Physician Order Entry, Picture Archiving and Communication Systems, Clinical Decision Support Systems, and Laboratory Information Systems. These information systems are utilized for functionalities in many healthcare settings such as physician offices and hospitals.

Several published studies have asserted that Big Data managed effeciently can improve care delivery while reducing healthcare costs [1-4]. A McKinsey Global Institute study suggests, "If US healthcare were to use big data creatively and effectively to drive efficiency and quality, the sector could create more than $300 billion in value every year" [5]. A number of published articles also reported using Big Data to improve population health with better policy decision making.

The process of extracting knowledge from sets of Big Data is called Big Data Analytics (BDA) [6]. Kuo et al. [7] and Chrimes et al. [8] further described the potential

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process challenges of achieving full Big Data utilization in five distinct configuration stages: data aggregation, data maintenance, data integration, data analysis, and pattern interpretation. Among the analytic stages, data analysis over vast volumes is key for a successful BDA [9]. However, it is very difficult to efficiently analyze the data using traditional analytic software, such as IBM SPSS, Microsoft Excel or MathWorks MATLAB because Big Data is too large, too distributed, unstructured and heterogeneous. It can take several days, even months, to obtain a result over a very large data set (in terabytes and beyond). Moreover, for complex analyses, the computing time increases exponentially even with small amount of data growth. In the case of Bayesian Network, a popular algorithm for modeling knowledge in computational biology and bioinformatics, the computing time required to find the best network increases exponentially as the number of records rises incrementally. To address the analytical challenges, many recently published studies have suggested that using High Performance Computing (HPC), and parallelization of computing model can efficiently increase analysis performance for the computationally intense problems [10-14].

In this study, we described our practical experience among collaborations with Vancouver Island Health Authority (VIHA) funded research project for health Big Data Analytics. The main objective of this project was to collaborate with establishment of a BDA platform for application. A Hadoop/MapReduce framework formed the platform with noSQL database called HBase representing real hospital-specific metadata and file ingestion. Three billion of emulated patient data were generated and cross-referenced with inpatient profiles based on metadata dictionaries at VIHA.

2. Methods

The basic premise of the implementation of a BDA platform for use in healthcare was to construct the platform capable of compiling heterogeneous clinical data from diverse sources of the hospital system and querying large volumes quickly. Also, the applications must ensure patient data security/privacy. This section describes our approaches.

2.1. The Architecture of the Analytics Platform

The BDA platform harnesses the technical power and advanced programming to produce accessible front-end tools to end users that allow for analysis of large quantities of back-end data in an interactive enriching manner. All this must be accomplished at cost-effective expense for a successful platform to be deployed. Based on the design philosophy, we construct a dynamic platform with interfaced applications (i.e., Apache Phoenix, Spark, and Drill) linked to backend HBase over Hadoop Distributed File System (HDFS). With the Hadoop/MapReduce framework, the platform allowed users to easily analyze and visualize health Big Data [9, 15]. The platform included four components (see Figure 1):

(1). A clinical data warehouse stores healthcare data. Currently at VIHA there are over 1000 tables in its Admission, Discharge and Transfer (ADT) data from hospital system, and annually ca. one million patient encounters add to 50+ years archive (500 million at VIHA and 10 billion Provincially).

(2). High performance Linux clusters (WestGrid University System) were used to install software of big data technologies, build configurations, and run simulation queries (Hadoop ecosystems including Apache Phoenix, Spark and Drill).

(3). HBase noSQL database was used to store data from VIHA clinical data warehouse. HDFS distributes the data to indexed storage across the WestGrid clusters with backup, high availability and redundancy.

(4). A master deployment manager (DM) was used to access the clusters from sponsored accounts over the Portable Batch System (PBS) of the Resource Manager. The access to the DM is controlled by lightweight directory access protocol (LDAP) while accessing to worker nodes was restricted to only the user running the job. This architecture permitted an agile and stabilized access with system administrator that could be launched from any terminal for each PBS job.
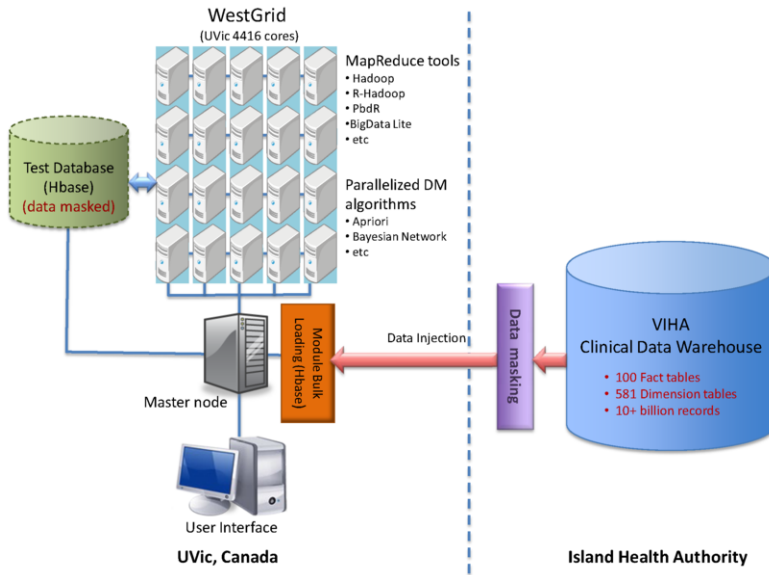
Figure 1. The Big Data Analytics Platform Architecture

2.2. The High Performance Computing Infrastructure

In this study, as described above, we relied on WestGrid's existing architecture as the computing infrastructure. WestGrid is a nationally Canadian funded program started in 2003, mainly used in western Canada while EastGrid and Ontario and Quebec grids are available. WestGrid installation at the University of Victoria (UVic) started in July 2010. The WestGrid computing facilities at UVic have 2 main clusters called Hermes and Nestor. The computing system of these two clusters share infrastructure such as resource management, job scheduling, networked storage, and service and interactive nodes. Hermes is a capacity cluster geared towards serial jobs with 84 nodes having 8 cores each and 120 nodes with 12 cores each, which gives a total of 2112 cores. Nestor is a large cluster consisting of 288 nodes (2304 cores) geared towards large parallel jobs. In this study, we use five dedicated worker nodes and one head node from Hermes cluster.

2.3. Data privacy protection

Ensuring patient data security and privacy was an important requirement in this study. The established platform used the following methods to protect data security and privacy:

(1). Data Masking – Typically this is carried out by database administrators thru rules and regulations set by business/security analysts based on current legislations of BC Ministry of Health. The goal was to generate a comprehensive list of sensitive elements specific to the organization and associated tables, columns, and relationships across the data warehouse and encryption of indexed key stores provided by HBase [8].

(2). Data replication – We worked in conjunction with Business Intelligence and Data warehouse, Clinical reporting, Application Platform Services, Database Administrators, and Physicians/Nurses groups to identify the masking or encryption required and optimal techniques to de-identify and restrict access to patient data. Once the data form distributed HBase data sets across working nodes, it was queried via Apache Phoenix, Spark and Drill only thru PBS held by WestGrid.

(3). Using HBase and WestGrid for Security/Privacy Mechanisms – HBase provided comprehensive security/privacy support thru its qualifiers and key-stores of data ingested. The access control to data stored in HBase was at table level, column family level and column level. HBase supports Kerberos authentication, Remote Procedure Call (RPC) and at-rest privacy protection. Data could not be queried without WestGrid for authentication.

3. Methods

3.1. Data Emulation and Modeling

A BDA platform was benchmarked its performance with clinical data warehouse utilization processes at the hospital level. Currently, huge volumes of health data are continuously generated and added into the archive. Within the archive of data warehouse, two of the largest data sets are the Admission, Discharge, Transfer (ADT) and the Discharge Abstract Database (DAD). ADT has over 1000 tables with 75 columns containing individual patient bed-tracking information, while the DAD is set by a data dictionary of 28 columns contains Canadian Institute for Health Information's (CIHI) diagnostic codes and discharge abstract metadata. These data sets are not system linked to form an all-encompassing database. Therefore, this study showed that these two data sets can be appropriately combined via big data technologies.

In a hospital system, the capacity to record patient data efficiently in the ADT is crucial to timely patient care and quality patient-care deliverables. Thus, the ADT system is often referred to as the source of truth for reporting operations of inpatient to outpatient and discharged [15]. In most Canadian hospitals, discharge records are subject to data standards set by the CIHI and entered into the Canada's national DAD. These two reporting systems, i.e., ADT and DAD, account for the majority of the patient data in hospitals, but they are seldom aggregated and integrated as a whole because of their complexity and large volume. A suitable analysis of ADT and DAD integrated data in this study shows many benefits of using big data technologies to produce high volumes while interactively applying new ways to query the data to find unknown correlations and trends.

Three billion of similated health raw data was constructed and cross-referenced with patient data profiles and metadata based on existing health data sets and elements in standardized data dictionaries. However, there are three main limiting factors in its deployment of using real patient data over application platform. The first reason is any

ethics approval for accessing the entire patient data of the health authority system will be very time consuming. Second, in the proposed analytic setting, the data will have to be migrated off the production database to avoid consuming network resources. This external architecture requires approval based on the VIHA's regulations for public disclosure. Finally, patient data mute be masked/encrypted to standards set to pass privacy impact assements. Therefore, several teams are required to identify the sensitive data then scramble or mask data via optimal techniques to initalize the deployment with end users acceptance of its usability.

Over the span of twelve months in 2014-2015, several interviews were conducted with business intelligence data warehouse, clinical reporting, application platform, and health informatics architecture teams employed at VIHA [9]. During these interviews, an emulated health Big Data was generated from hospital admissions (based on encounter types) and a discharge system (based on diagnoses and procedures). In it, data profiles (including dependencies) and the importance of the metadata for the clinical reporting were confirmed and verified. Furthermore, current reporting limitations of the different combinations of the DAD and ADT data were recorded to form accurate simulation of the existing and future queries. To test the feasibility of the BDA platform and its performance, the emulated patient data had 90 columns that combined DAD and ADT metadata profiles. Thus, it was an accurate representation of the construct of real patient data based on encounter types, location and date/times.

3.2. Data Ingestion and Query Performance Evaluation

The pathway to running ingestions and queries over the BDA platform includes nine pipelined steps [9, 15]: (1) Generating *.csv* flat files, (2) Apache Phoenix Module Load, (3) HDFS Module and Ingestion of HFiles, (4) Bulkloading HFiles to HBase, (5) HBase Compression, (6) Phoenix SQL-like Queries, (7) Apache Spark and Drill Module Loads, (8) Notebook and Python/Pypark Module Loads, (9) Spark and Drill SQL-like Queries.

Thru this sequence, the Phoenix module loaded after Hadoop and HBase SQL code was directed and then iteratively run to ingest three billion rows to the existing HBase. Phoenix can run SQL-like queries against the HBase data. It was utilized to index and place schema over each *.csv* file bulkloaded to ingest using MapReduce. The queries via Apache Phoenix resided as a thin SQL-like layer on HBase. This allowed ingested data to form structured schema-based data in the noSQL database (i.e. HBase). The loads were 50 million each via the index and schema between HBase's RegionServers thru a functional SQL-like code of "salt bucket" that set the number of worker nodes in the cluster to five evenly distributed data. This additional code was deemed necessary as HDFS did not automatically distribute evenly and unbalanced data slowed performance [9]. Performance was measured with three main processes: HDFS ingestions, bulkloads to HBase, and query times. Three flat files (*.csv*) with different number of rows (50 million, 1 and 3 billon) were ingested to HDFS for testing (Table 1).

Table 1. HDFS Data Ingestions

Data Size	Ingestion Time
50 Million records (23GB)	~3-6 min
1 Billion records (451GB)	~60-120 min
3 Billion records (10TB)	~180-360 min

At an optimized iteration, Hadoop Distributed File System (HDFS) ingestion required three seconds but HBase required four to twelve hours to complete the Reducer of MapReduce. HBase bulkloads took a week for one billion and over two months for three billion (see Table 2).

Table 2. HBase Bulkload Durations

Data Size	Bulkloaded Time
50 Million records (0.5TB)	3-12 hrs
1 Billion records (10TB)	60-240 hrs
3 Billion records (30TB)	300-480 hrs

There were 22 test queries for different questions using the ADT and DAD combined data over 50 million, one three billion rows. All queries run on Zeppelin, Jupyter, Spark-terminal and *Pyspark*, as well as Drill took approximately the time of 50-120 seconds to load the data and query all 22 queries could be run at the same time. Spark was configured to run on specialized Yarn-client with 10 executors, four cores with 8 GB of RAM each; therefore, each node had two executors with a total of eight cores and 16 GB memory. However, Drill was faster with its configuration involving inherent ZooKeeper allocations via its *drillbit* components (see [8] for details).

4. Conclusion

In this study, Hadoop/MapReduce framework was proposed to implement the data-intensive distributed computing platform. Srirama et al. [16] indicated that Hadoop is suitable for simple iterative algorithms where they can be expressed as a sequential execution of constant MapReduce models (that could also be configured to be representative of the clinical event model of hospital systems). It is not well suited for complex statistical analysis or iterative problems. To amend the Hadoop's ecosystem weaknesses, we plan to engineer "R" to work over Hadoop (e.g. RHadoop*)*. R provides a wide variety of statistical and graphical techniques, modeling, statistical tests, time-series analysis etc. R and Hadoop complement each other very well in BDA and in data visualizations [17].

This study comprised a constructed Hadoop/MapReduce framework to form a platform for Health Big Data. As indicated in the study [18], there are many analytical challenges to achieve full value of Big Data in Canadian healthcare systems because of information silos, various policies and regulations, and cultural *diversity* in *the healthcare systems*. These hinder patient data in different health care system to be fully integrated. However, our platform did allow for replication of patient data, which reduces architectural resource pressure while integrating data from different data sources to form one patient-encounter-centric database for ongoing analysis. Also, since HBase is linearly scalable and there were no differences in query durations; therefore, it is expected that query time will be a few milliseconds as the number of computing nodes increased to 100+.

Few studies have tested a variety of Big Data tools in Hadoop's ecosystem in healthcare. And even fewer studies have established a simulation of 3 billion patient records. Therefore, this study achieved the top three V's that define Big Data: high performance (or velocity) over its generator of detailed data (or variety) that formed

extremely large quantities (or volume) significantly contributed to ongoing development of Information Management and Information Technologies (IMIT) in healthcare [15].

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Development of a Video Coding Scheme Focused on Socio-Technical Aspects of Human-Computer Interaction in Healthcare

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Abstract. The objective of the work described in this paper was to develop a coding scheme focused on socio-technical issues and considerations for the analysis of video data collected in usability studies of health information systems. The usability and safety of health information systems such as electronic health records, decision support and patient facing applications has become a critical issue. Although a variety of studies and methods have appeared in the literature involving video-based analysis of human factors data from healthcare, few have reported the coding scheme used to analyze the data. In this paper we describe how we have developed and continue to refine a video coding scheme that extends basic usability engineering by considering socio-technical aspects of system use that have become critical to assess in evaluating the effectiveness and efficacy of health information systems in real use.

Keywords. Usability, human-computer interaction, video analysis, health information technology

1. Introduction

A great many different types of health information systems and applications have appeared and continue to be deployed worldwide. However, issues around the usability and safety of systems has come to the fore and there is concern that many systems deployed are difficult to use, potentially unsafe to use and may be frustrating for users (both health professionals and lay people). As a consequence of this, the authors have worked on developing new methods for analyzing the usability and safety of health information systems. This began with work in refining low-cost portable usability engineering approaches to recording and analyzing end users of systems (such as electronic health records) as they interact with the systems to carry out key tasks the system was designed to support [1,4]. Since then, many such usability studies have been reported in the literature, with many involving the video recording of users as they "think aloud" or otherwise interact with the system under study [2,3]. The results of such study have been fed back into redesign and improvements to the usability of the systems. However, there is far less in the literature on how video data (e.g. from computer screen recordings of interactions) from healthcare usability studies can be formally evaluated in

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a principled way. In response, our group has worked on a number of projects where we have developed and refined ways of "looking at" video data from such study that is both replicatable and objective. To do this, we have worked on devising and applying a range of video coding schemes [4]. A video coding scheme consists of coding categories that can be used by those analyzing video recordings of user interactions. The scheme is used to characterize specific user interaction types, problems, issues and suggestions for system improvement that come about from observation and video recording of user interactions in testing or real-world healthcare settings [1]. The authors have previously reported on an initial coding scheme they developed that was grounded in categories and ideas from several sources, including the human computer interaction literature, categories borrowed from seminal work in other areas such as from lists of usability heuristics, usability questionnaires and from prior experience in a number of our projects involving the need to analyze video and identify and classify potential usability problems and issues [4].

Our initial schemes focused on a basic level of human-computer interaction – namely the interaction between a single user of a system and single computer system. The development of the categories (each of which for defined for use by the analyst applying the scheme) used in this initial scheme were very much in line with categories that can be found from different types of human factors research focusing on low-level usability issues, including Nielsen's heuristics, questionnaire scales and guidelines for effective interface design [5]. The categories were mainly useful in identifying surface level usability problems and basic cognitive issues. In this paper we describe new coding scheme categories, focused on socio-technical issues and concepts and describe studies we have conducted that have led to the expansion of the original categories. There was a need to expand our initial categories to include ones related to social aspects, collaboration and the greater use of systems and applications by patients as well as healthcare professionals. In addition, over the past few years the number and range of applications we have tested has grown considerably, from stand-along systems in hospitals to mobile applications for use collaboratively in the community. Our long-term objective is to provide a useful basis for those conducting video-based analyses of a range of health-related systems and information technologies. It is hoped that a new scheme will broaden our previous work (which was focused on identifying and classifying low level usability issues) by extending it with new categories that can be used to identify key issues related to adoption of healthcare IT from a socio-technical perspective.

2. Methodological Approach

The coding scheme described in this paper emerged from collecting data from a variety of sources including the following:

a) Recognition of gaps in the initial coding scheme we developed (which was focused on evaluating surface level usability problems that emerged from our work on usability engineering in healthcare) from conducting numerous empirical studies [6-9]. These gaps were related to key aspects of human-computer interaction that were not defined or described that are related to impact of systems on socio-technical aspects of user interaction.

b)   Extending coding scheme categories to include categories related to users's perceptions about issues such as privacy and consent (which were not focused on in our previous work).

c)   Addition of categories that emerged in considering the communication of health information systems (in relation to usability) that have come to the fore and were identified as major issues.

Our previous core video coding categories focused on aspects of the surface level user interface and the user-system interaction (see Table 1). As described above they were predominantly derived from application of usability categories developed for other purposes (e.g. questionnaire scales, heuristic evaluation research and cognitive theory) and were then modified for use in coding video based usability data using the "coding dictionary" that we have developed and applied in numerous studies to characterize user-system interactions and identify potential problems and issues that could be targeted for being rectified [4] - see Table 1. As can be seen most of the categories deal with surface level usability issues and considerations. These were the categories that formed the basis for the current work in extending them to include additional emerging aspects of human-computer interaction.

The development of new categories described in this paper has evolved over time, with a number of recent studies we have conducted leading to new categories, in particular studies that have involved patients and lay people as end users [e.g. 6-9]. These studies clearly showed the importance to both health professionals and lay end users of considerations like concern about privacy, use of information for legal purposes and other such considerations that would affect adoption, trust and use of new healthcare IT.

This new work has been used to develop a new framework for considering additional aspects of user interaction with healthcare IT has evolved from study and practical considerations in the analysis of a Web-based applications for input of patient information by patients and health professionals. In addition, development of categories for studying near live use of clinical guidelines and studies of health apps on mobile devices [6,7,8]

The new categories described in this paper were refined through an iterative process of review by at least two PhD level researchers in arriving at a stable set of categories over the course of a number of empirical studies. This involved a process akin to development of categories through application of grounded theory approaches, where new categories not defined in the list above, were identified from repeated end user verbal statements and user interactions [4]. Commonly encountered instances of categories of interaction were then grouped together, given a label and definition and given an example that could be used in coding future interactions on new projects (see [1,4] for the overall approach taken to arriving at new categories inductively from verbal data and transcripts).

Table 1. Coding categories for identifying surface level usability issues (adapted from Kushniruk et al., 2015 [4])

VIDEO CODE	WHEN APPLIED
NAVIGATION	Coded when a review of the video data indicates the user has problems moving through a system or user interface
CONSISTENCY	Coded when a review of the video indicates the user has problems due to a lack of consistency in the user interface
MEANING OF ICONS/TERMINOLOGY	Coded when a review of the video data indicates the user does not understand language or labels used in the interface
VISBILITY OF SYSTEM STATUS	Coded when a review of the video data indicates the user does not know what the system is doing
UNDERSTANDING ERROR MESSAGES	Coded when a review of the video data indicates the user does not understand meaning of error messages
UNDERSTANDING INSTRUCTIONS	Coded when a review of the video data indicates the user does not understand user instructions
WORKFLOW ISSUES	Coded when a review of the video data indicates when there are issues with system workflow negatively impacting user interaction
GRAPHICS	Coded when a review of the video data indicates there are issues with graphics
LAYOUT	Coded when a review of the video data indicates there are problems with the layout of screens or information on those screens
SPEED/RESPONSE TIME	Coded when a review of the video data indicates the system is slow or response time is an issue
COLOR	Coded when a review of the video data indicates user does not like color or color schemes used in the interface
FONT	Coded when a review of the video data indicates the font is too small or not readable
OVERALL EASE OF USE	Coded when the user comments on overall usability of the user interface

3. Results

Based on our analysis of both audio recordings of end user interactions, in conjunction with viewing of corresponding video recordings of end user interactions (using an overall approach to category development described in Kushniruk and Patel [1]), a number of coding categories were identified that represent aspects of interaction that go beyond our previous lower level usability considerations. These represent recurrent "patterns" or "themes" that we have identified in a range of recent studies and extend our prior categories, which are listed below in the format of a "coding dictionary" format that can be used in essence as a "manual" by researchers in analyzing video-based usability data. The examples that go along with each category were obtained from a range of studies we have conducted [6-9], and are presented to give a reader an idea of what aspects each code refers to, and to give coders an idea of how to apply the code:

3.1 New Categories Related to Trust, Ethics and Security

TRUST – Coded for when users comment about issues related to trust in using the system. For example, "I don't trust that the information contained in the medication list is accurate or complete, as the patient may be taking other medications prescribed elsewhere which are not in this system"

PRIVACY – Coded for when issues related to the concept of privacy are raised during user interactions with a system. For example, "I am not sure who else is going to see this information I am entering about my past sexual history so I will not fill in all the information – is this information really private?"

CONFIDENTIALITY -   Coded for when issues or concerns related to confidentiality come up. For example, "I hope the information I am entering into my personal health record will be kept confidential and end up in some record in some other system"

LEGALITY – Coded for when legal issues are raised by users. For example, "As a psychiatrist I would recommend use of stress monitoring apps to my patients for monitoring their anxiety, however I am concerned about the legal implications of me doing so if something goes bad with the patient".

CONSENT - Coded for when consent issues are raised in the interaction. For example, "I find the health information exchange less than useful because of the process for consenting them – if patients are not properly consented no data will show up for them".

SECURITY – Coded for when users comment about or have issues with security. For example, if a participant has problems using a system, or cannot even access it due to forgetting passwords – e.g. "I rarely use the system as I forget the password.", or issues about concern about security e.g. "I am worried about how secure the information I enter is, can it be hacked?"

3.2 New Categories Related to Cost and Logistical Issues

COST – Coded for when the issue of cost or expenses comes up. For example: "I would recommend this for my patients but the only problem is most of them can't afford a tablet like an ipad"

UNINTENDED USE/HARM – Coded for when users comment about potential unintended us, access or harm related to the technology being tested. For example, "I am

worried that this system may inadvertently lead to potential harm if the patients are not given enough education or training on its use at home, or misunderstand its limitations”

STRESS – Coded for when the user refers to stress or cognitive overload when using a system under study. For example, “Given all the alerts that appear in this system when I log in, I feel like I am going to have a nervous breakdown - there are too many patient issues listed and once I access one I have to go through all of them and I find that overwhelming”

TRAINING – Coded for when comments are made about training or education (including the need for it). For example, “This is a complex system to learn how to use – I hope I will be getting sufficient training on its use”.

COMMUNICATION/COLLABORATION - Coded for when the user comments about communication or collaboration needs or issues. For example, “The interface is useful but I wish to work collaboratively on genomic problems with researchers at other institutions, and this system is more stand-along without features to support such collaboration”

ORGANIZATIONAL/POLICY ISSUES – Coded for when organizational issues are mentioned by the user. For example, “The application would be of value in this hospital, however management would have to approve of it and tell us that it is consistent with the hospital’s policy for registering patients”

3.3 New Categories Related to Technical Issues

ACCESSIBILITY – Coded for when issues around accessibility of information are raised. For example, need of access by family members on behalf a patient, for example, “This would be a useful application for the elderly at home but would probably be need accessed by the caregiver as well as the patient”.

INTEROPERABILITY – Coded for when the user comments about integration or interoperability issues or concerns. For example, “The problem with this system is that is not connected to the other systems used in this hospital or to the provincial drug database”.

MOBILITY – Coded for when the accessibility or mobility of a healthcare application is commented about. For example, “I would use this system if it were made available on my smart phone as I would use it away from the hospital”.

LOCATIONAL ISSUES – Coded for if issues around the location of use of the system are raised. For example, “We still have spots in the hospital where we cannot use wireless so I think that would be a problem in accessing the system”

CONTEXT – Coded for when technical issues related to the actual context of use (including setting) are mentioned. For example, “I can use the speech recognition interface to the EHR for dictation when I am in a quiet office, but it does not work well in a noisy clinical setting”.

4. Application of the Scheme in Coding Usability Data

The usability studies we have conducted typically result in full video recordings of users as they interact with systems under study. In our current work in applying coding categories we have greatly streamlined the approach. Equipment include screen recording software and a microphone for inputting the user/participant’s verbalizations while using the system under study. User participants are typically asked to “think aloud”

or verbalize their thoughts [1,3]. The process involved in the coding of this audio and video of user interactions with health information systems involves several stages described below:

1. The audio portion of the video is first transcribed in its entirety, creating a log file that will be annotated (with time stamps and video codes)
2. The analyst(s) reviews the video of the interaction (i.e. screens and audio) in its entirety and while doing so considers the video in terms of the codes in the coding scheme (using the coding dictionary to guide them)
3. When a sequence in the video illustrates one or more of the codes in the scheme, the corresponding log file is annotated with the time stamp and the corresponding code
4. The number of codes for each category in the scheme are tabulated, with results fed back to system developers and implementers for ideas on improvement and refinement

Inter-coder reliability scores can then be calculated for studies applying the above codes. This can include having one or more analysts code the same sections of video independently and the calculating either percent agreement, or more formally calculating Kappa coefficient to indicate degree of reliability of the coding. An alternative approach is to have two more coders collaboratively code a section of video and when disagreements in the selection of coding categories (to characterize a section of the recorded video) occur solving them through discussion.

5. Discussion

The authors have been involved in a range of usability studies involving the coding of resultant video data for over twenty years [10]. This has included analysis of a range of technologies including clinical guidelines, web-based portals designed to allow information to health information exchanges and development of apps for use by patients and physicians in negotiating treatments and care. One of the issues in working to provide useful and reliable feedback to system developers and designers is the need to develop effective methods for analyzing video-based data from usability studies. Such data now typically consists of digital video recordings of all user screen interactions, along with a recording of their verbalizations (e.g. using the think-aloud method). Although many such studies have now been conducted, the authors have been asked by many healthcare organizations to provide help and insight into how to analyze such data. In our work we began by focusing on developing coding schemes for the purpose of characterizing basic user interaction with healthcare technologies. Although coding schemes focusing on the interaction between the user and system are needed, a broader range of issues have emerged during the analysis of usability data. As a consequence, categories related to topics such as privacy, consent, communication and collaboration are emerging as areas that need to be included when analyzing video-based usability data. Indeed, the ultimate acceptance or rejection of technology in healthcare often appears to be strongly related to these issues, and hence improved and broadened methods and frameworks for analyzing usability data are needed. We are continuing our work in this area and we are currently working on developing a comprehensive framework for

considering an increasing range of issues/problems in user interaction with systems in healthcare.

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Approaches to Demonstrating the Effectiveness and Impact of Usability Testing of Healthcare Information Technology

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Abstract. In recent years the usability of health information systems has come to the fore as a major issue, with many reported examples of problems with the usability of systems such as electronic health records and other health information technologies (HIT). In response a range of usability engineering methods have emerged to help in the design and evaluation of HIT. Many studies have shown the importance of usability testing methods that include full video recording of user interactions, such as the method known as low-cost rapid usability testing. However, such approaches have been considered by many as being too costly to carry out and some have argued that they may take too long to be used for practical input into improving applications and systems. In this paper we demonstrate several approaches we have taken for proving the cost-effectiveness and benefit of conducting principled usability testing. It is argued that such studies are needed to inform system design and evaluation and for proving to healthcare management the need for properly conducting such studies before releasing HIT.

Keywords. Usability engineering, usability testing, cost-benefit, evaluation, economics, quality improvement

1. Introduction

Worldwide there are increasing reports about the poor usability of health information technology (HIT) being deployed [1,2]. This has included concerns about electronic health record systems (EHRs), decision support systems, mobile applications and other types of HIT applications [3-5]. In response, a range of methods have been applied and refined that can help to pinpoint, classify and rectify usability problems, both for systems being designed and also for deployed implementations of vendor products. In addition, there have been increasing calls for more focus on defining and requiring effective usability for EHRs and related systems [1,6,7]. The question remains as to why usability issues are still a major problem and what can be done about it. Although methods are

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available, such as low-cost rapid usability engineering (involving the analysis of video data of user interactions [8]) the potential issue of their practicality (from a cost and speed perspective) has come up when considering their application in real-world healthcare problems. To address this, in this paper we describe the approach known as rapid low-cost usability testing and present approaches for doing benefits evaluation of its application, along with a discussion of two differing approaches for showing benefits of doing the usability testing.

2. Methods

The authors have been involved in the development and refinement of an approach to usability engineering in healthcare they have termed rapid low-cost usability testing [8]. The approach takes a pragmatic view of usability engineering in HIT and argues that studies can be conducted in-situ, at low cost and rapidly in real clinical settings. The data collection is coupled with application of principled video coding schemes for conducting rapid analyses of the resultant video-based usability data [9]. These methods have been refined through application and feedback from a variety of real-world applications and have led to the development of both analytical and organizational strategies for testing HIT. The approach involves recording the providers' interactions with systems in a real or simulated environment [10]. Screen recordings of all computer interactions are captured and integrated with audio transcripts to facilitate rapid coding of the data using coding schemes that can be adjusted to the application being tested. The resulting protocols are coded to identify and statistically summarize usability issues. Previous studies have shown that the method can be applied rapidly (with results available within a few days of data collection) [8].

In our work we have employed several different methods for estimating the benefits of doing usability analyses, with one approach being application of economic cost-benefit analysis methods and a second approach involving applying quality improvement processes and methods to establish the benefits of conducting rapid usability testing. Two case studies from our work in this area will be used as examples to illustrate the approaches.

2.1 Classic Cost-Benefit Estimation Approach Applied to Usability Engineering

In order to determine the cost-effectiveness of conducting usability studies, classic economic methods can be applied and modified for this purpose. Using this approach, the total costs of applying rapid usability testing are recorded in order to document the costs of applying rapid usability testing [11]. This typically includes: costs of equipment such as cameras and screen recording software, participant remuneration, costs of analysis in terms of time and cost of analysts, and costs of any software required for carrying out analysis of the resultant video. After conducting the actual usability analyses, results from the usability data are tabulated to determine the number and nature of usability problems coded for in the data. Estimates are then made (using tables of software costs post-implementation) to determine the benefits. This is done by estimating the cost of fixing each identified usability problem that would have been propagated through to deployment, had the usability testing not been applied. This estimation is conducted in order to estimate tangible benefits of applying the approach to catch usability problems. The cost-benefit ratio can then be calculated from the actual costs and the estimated benefits.

2.2 Continuous Quality Improvement Approach

In order to assess the benefits of having applied rapid usability engineering approaches in complex organizational settings (once a system has been deployed and released in real world settings) additional methods need to be used. This is because the impact of having conducted usability analyses may be hard to estimate in settings where many variables may have changed over time in the organization. This may make isolating the impact of applying usability engineering alone hard to estimate. For example, measurement of desired outcomes (that are expected to result from applying rapid low-cost usability methods), such as reduced time for a user to complete a healthcare task, user satisfaction, or reduction in errors may be affected by many organizational variables, as well as planned or unexpected events. To deal with this, methods and approaches that have emerged from the quality improvement literature can be applied [12]. This includes the use of control charts and run charts that can be used to map how key performance variable and outcomes change over time, from before a system is introduced to after the system that has undergone usability evaluation [13]. The advantage of this approach is that the time-line developed (for the measured process variables and outcomes) can be mapped against other events in the organization which may have affected the outcome. In order to see if the application of rapid usability testing has had a desired impact over time, there is need to monitor performance data on an ongoing basis after release of the modified system. This may involve baseline monitoring of measures such as time to complete a task, number of user errors per task, user satisfaction with a system (i.e. before the application of rapid low-cost usability methods). After the system or user interface has been modified (using the results from rapid low-cost usability engineering) these measures continue to be monitored. According to principles of continuous quality improvement [13] this will allow for examination of temporal behavior of healthcare processes and a way to establish the time a process changes or improves. The application of the approach for evaluating impact of healthcare IT shows promise in that the approach can also include an indication of external events along the timeline of process monitoring to help explain any unusual circumstances that might affect the value of measures being monitored (e.g. an influx of new staff in a unit might lead to improved efficiency independent of any system modifications or improvements).

3. Results – Examples of the Approaches in Two Studies

From analyses of the results from usability studies where the rapid low-cost usability engineering approach was used and the benefits analyzed, it was found that benefits outweighed costs. In this section two differing case studies illustrating the overall approaches described above will be detailed.

In the first example, in work by Baylis and colleagues in our laboratory, a classic economic cost-benefit approach described above, was conducted in estimating the benefits of doing usability testing using a quantifiable approach [11]. In this study a disease management system had been developed to provide Web-based advice about patients to healthcare providers and part of the system design included application of rapid low-cost usability testing. All the costs of the usability testing (involving 8 health care provider participants) was determined, including cost of all equipment, cost of time

for the study moderator, cost of time for conducting video analysis and cost of paying participants for being in the study. Then the analyst involved in the project conducted video analysis to identify key usability problems. To estimate benefits the number and nature of usability problems detected by the study were arrived at (using tables giving cost for fixing each problem that would have to be fixed). The result in terms of benefits was a % savings ranging from 36.5% to over 200% as a result of doing rapid usability testing. Furthermore, the total cost for conducting the study was well under $10,000 USD. In addition, the methodology also detected errors that would not be considered usability problems, including programming bugs, safety issues and technology-induced errors (that would have otherwise not have been detected prior to widespread implementation). The low-cost rapid usability testing method was found to be useful in detection of both usability problems and technology-induced error (with the cost savings of detecting even one life threatening event due to technology-induced error estimated exceeding several hundred thousand dollars). All estimates of cost-benefit pointed to a positive return on investment for conducting the usability testing.

In the second example, work by Hall and colleagues applied our rapid low-cost usability testing approach in improving the efficiency and effectiveness of a decision support tool used in a 24/7 health call line managed by telehealth nurses [12]. For this study the second approach to evaluating benefits (described above) was applied. Six nurses were audio and video recorded in a rapid usability testing study where they were asked to respond to simulated patient phone calls. All computer screens of the decision support tool used by the nurses were also video recorded and the dialogue with the caller audio recorded. The video and audio recordings were then analyzed to identify usability problems and these were summarized and presented to the organizations health professionals to modify the decision support tool accordingly. The evaluation of beneficial impact involved creating run and control charts that depicted average call times (time to complete call processing) over time as the newly modified system both before and after the system was released to the tele-triage nurses in the real setting. The results indicated reduced call handle times that were on average 11.0 minutes pre-usability analysis, which were reduced to 10.4 minutes over a 3-month post usability analysis release). Superimposed in this time chart were information about organizational events and data points were the date. Time stamps of the tele-triage activities summarizing activities and time to complete tasks. Using this approach, it was found there was a significant decrease in call time after conducting the usability testing, followed by a round of system refinements and modifications that could be attributed to the changes in the system resulting from rapid usability testing (and rectifying the usability problems identified that slowed down the triage process and made the call processing cumbersome). Furthermore, this decrease in call time was on average of 30 seconds per call, which a 5.5% of time saved per call. This decrease in time to complete the main task of tele-triage demonstrated an increase in organizational efficiency given the huge number of calls received per year. The approach allowed for estimates of benefits in a complex real-world dynamically changing environment.

4. Discussion

Poor usability has become recognized as being one of the greatest barriers to effective implementation of healthcare IT today. We have developed an integrated approach to detect serious usability problems that has begun to be applied more widely and can serve

as a safety net for catching problems (i.e. what we have termed low-cost rapid usability testing). In order to provide evidence that the method is actually cost-effective we conducted analyses of several studies to determine the benefits of the approach. The approach has ranged from conducting classic cost-benefit analyses (applied to usability testing) to application of methods from continuous quality improvement. Future work will include plans for knowledge translation and wider dissemination of the method through educational initiatives and design of training programs for universities, colleges, health authorities, vendors as well as governmental agencies [14].

Poor usability has become recognized as being one of the greatest barriers to effective implementation of healthcare IT today. In order to provide evidence that the method is cost-effective we conducted analyses of several studies to determine the benefits of the approach. Future work will include plans for knowledge translation and wider dissemination of the method through educational initiatives and design of training programs for universities, colleges, health authorities, vendors as well as governmental agencies [14].

There have been few documented studies designed to show the cost-effectiveness of methods such as rapid usability engineering in real-world contexts such as healthcare [11-12]. In our work we have applied some approaches that show promise in demonstrating benefits that can be added to usability analyses without requiring much extra cost or effort. Such evaluations will ultimately have the benefit of showing management of healthcare IT projects the value of conducting analyses that improve the use and usability of systems they develop and deploy. Future work will involve development of a strategic framework for guiding in the selection of approaches to evaluating benefits involved in applying usability engineering methods in healthcare.

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Digital Process Innovation for Patient Centred Cancer Symptom Management

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Abstract. Digital process innovation in healthcare enables us to enhance functionality beyond what is enabled in physical process execution. However, the movement from paper artifacts and manual processes to the use of information and communication technologies (ICTs) to support healthcare delivery is challenging because system design requirements for digital processes can be much less structured and more difficult to define than for physical processes. This paper addresses the above issue and presents on our research in converting paper-based cancer symptom management practice guides to digital format for use by patients. We provide an overall architecture and three system design considerations for digital process innovation to support patient centered cancer symptom management.

Keywords. Digitization, process innovation, symptom management, patient centered

Introduction

Digitization, broadly defined as the conversion of analog information and physical processes into digital format [7], is foundational to digital healthcare delivery. On one hand, digitization of processes enables us to enhance functionality beyond what is enabled in physical process execution. Digital process innovation in healthcare such as alerts and reminders, communication channels, patient portals, and decision support and data visualization tools have allowed us to connect and manage patient care across providers and settings. Digital solutions can also be beneficial in supporting continuity of care as they can allow us to remotely monitor symptom severity over time. However, because we cannot fully articulate how digitization will impact processes, work routines and other management issues, it can also lead to hazards and other unintended consequences, as well as inequity in care delivery [1; 6].

The underpinning of digitization is the movement from paper artifacts and manual processes to the use of information and communication technologies (ICTs) to support healthcare delivery. However, this movement is challenging because system design requirements for digital processes can be much less structured and more difficult to define than for physical processes [3]. To date, healthcare lacks frameworks for understanding how to design for digital healthcare delivery [2]. Such a framework would help understand the possibilities that digital process innovation can offer, but also the challenges to achieving such innovation. There is a particular need to understand digital process innovation in specific contexts such as community care delivery. This paper

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addresses the above issue and presents on our research in converting a paper cancer symptom management practice guides to digital format for use by patients. We provide an overall architecture of the digitization process and three system design considerations for digital process innovation to support patient centered cancer symptom management.

1. Materials and Methods

1.1. COSTaRS Symptom Management Practice Guides

This research is part of the Pan-Canadian Oncology Symptom Triage and Remote Support (COSTaRS) project. The COSTaRS team including oncology nurses with representatives from eight Canadian provinces developed practice guides for 15 common cancer treatment-related symptoms [4]. While COSTaRS practice guides were originally developed in paper-based format, a workshop was held in October 2017 which identified research directions for COSTaRS, two of which were design a mobile COSTaRS solution and expand integration into clinical practice by creating a version for patients. This paper describes preliminary work on that task by describing our efforts to develop a digital COSTaRS app that would be used by patients.

1.2. Digitalization of COSTaRS Symptom Management Practice Guides

Fatigue and sleep problems were chosen as the first two symptoms to prototype in the COSTaRS mobile app. We chose these symptoms for two reasons. First, fatigue is the number one symptom experienced during treatment by patients with cancer, with 75.1% of patients with cancer reporting fatigue and 34.4% reporting moderate-to-high levels [5]. Second, fatigue and sleep problems are not common signs for oncologic emergencies nor are they commonly managed using pharmaceuticals, which allows us to provide symptom management guidance without serious safety risks.

2. Results

Fig.1 shows our technical architecture for digital process innovation. Operationalizing the framework begins with defining three system design requirements. The first requirement is identifying where and how data needs to be stored. Our initial plan was to develop a digital COSTaRS app for nurses but we ran into complications with confidentiality and other privacy issues related to the storage of patient data. A patient app avoided that issue as patients can choose whether or not to use the app and with whom they want to share their information.
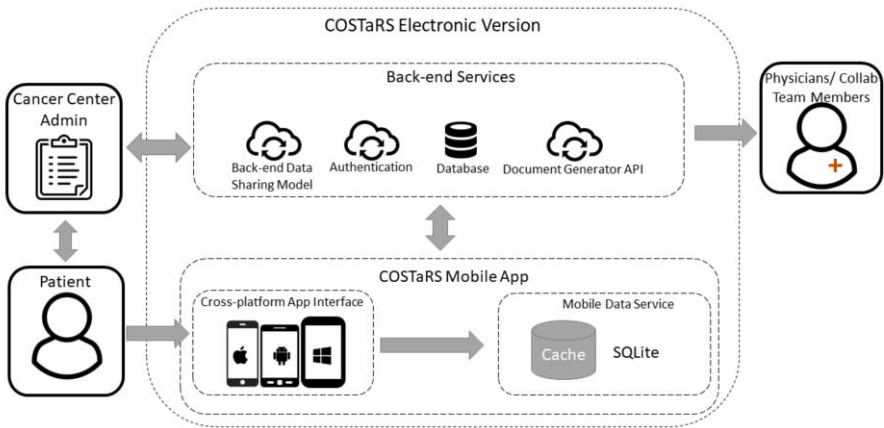
Figure 1. Technical architecture for digital process innovation for patient centered cancer symptom management

Once we defined patients as our target users, the second requirement was how to coordinate all the access points across all system users (e.g. patients, healthcare professionals, administrators). In our framework, a patient's profile is created by the cancer center administration and access to the mobile application (i.e. username and password for authentication) will be created for the patient. As the patient starts interacting with the interface to enter symptom assessment scores and other data they generate self-assessment reports that can be viewed by the patient and are also monitored by the cancer clinic administrators. In addition, the symptom reports can be sent at the patient's request to the patient's physicians or other healthcare professionals collaborating in the patient's care.

The third requirement was determining the platform and types of mobile devices that will be used. One challenge in designing the architecture is that some data entry may take place in an asynchronous manner as patients may not always have online access when documenting symptoms. The mobile data service we used in our architecture works across mobile device platforms (e.g. Apple, Windows, Android) and enables a patient to enter data and have it stored offline in the mobile device. When the patient gets online connectivity, the data will then sync with the central COSTaRS backend database.

2.1. System Design and Digital Process Innovation

As we began to brainstorm the conversion of the COSTaRS protocols from paper to electronic format we identified several opportunities and challenges for digital process innovation. We classified the innovation opportunities and challenges at three levels: patient, collaborative and health system.

2.2. Patient Level Innovation

Paper forms can make it challenging to follow-up beyond the initial assessment. Digitization of symptom assessment can add innovations such as tailoring

recommendations to a patient's specific needs and contexts. Examples of digital innovations include coordination and communication tools. We are planning to link the suggested recommendations for self-care to location functions and tools such as Google Maps or Open Street Maps that can direct a patient to available resources within their geographical area. If a patient has a question related to their care, the app can provide the number of their local cancer center so they can contact their care provider. Symptoms need to be assessed in certain timed intervals and the app will use a calendar and alert system to inform patients when the next assessment is due. Patients will also have the ability to review their historical symptoms logged to allow them to review patterns in symptom occurrence and severity and to judge the effectiveness of interventions

One key challenge to patient level innovation is that the paper based COSTaRS practice guides were designed to be used in cooperation with nurses' judgement. Nurses would assess the patient and use clinical judgement to determine whether the patient's symptom should be classified as mild, moderate or severe. In the patient app, the guides need to be converted to protocols with explicit direction regarding classification of symptoms and how to manage them accordingly. Another patient level challenge is the protection of patient data, particularly if third party tools such as Google Maps are used.

2.3. Collaborative Level Innovation

An advantage of separating the symptom information from the paper based medium in which it currently exists is that we can get innovative with tools to support collaboration. One example is we are able to use information for multiple purposes such as day-to-day symptom management and collaborative care delivery over time. As shown in fig. 1, patient symptom data can be monitored remotely by the Cancer Centre or by the patient's physician and collaborative care team to enable the tracking of symptoms over time.

Challenges to collaborative level innovation include the need to establish protocols for how collaborative care delivery will be supported. This includes protocols on how/when patient data will be pushed to different collaborative team members and who will be responsible for reviewing and following-up with the patient.

2.4. Health System Level Innovation

While the app is primarily being designed to support in-the-moment cancer patient symptom management it can also support health system level innovations. For example, aside from the symptom data we plan to collect other socioeconomic data such as whether the patient lives alone, level of education, and other contextual data. This additional data would allow us to identify different patterns of patient reported symptoms and how they may vary across regions and locations. Our plan in collecting this additional data is to develop a symptom management database to enable ongoing system analysis and learning. This analysis could help with resource planning to better enable us to monitor symptom prevalence and to develop policy, service delivery, and human resource strategies for symptom management in different contexts of care delivery.

Challenges exist to health system level innovations including the need for patients and healthcare providers to trust the data that is collected and shared. We also need to develop algorithms to translate the data into evidence to support the development of services and resources   to support ongoing refinement of the patient centered cancer symptom management system.

3. Discussion

This paper presented an architecture for digital process innovation for cancer symptom management. We describe our conversion of the COSTaRS Symptom Management Practice Guides to a digital app to support patient empowerment. We also described innovation opportunities and challenges at patient, collaborative and health system levels. The biggest benefit of digitization is that it separates information from its physical medium. This enables us to use information for different purposes such as real time patient symptom management and collaborative care delivery as well as health system level innovations such as developing a learning health system for cancer symptom management. It also enables us to improve equity to services by developing innovations to facilitate access to symptom management resources across different settings and contexts. The biggest challenge across all three innovation levels is that digital process innovation introduces new means of connectivity, which brings with it uncertainty around system design requirements such as privacy, system access and collaborative protocols. Another key challenge is the transition from nursing to patient protocols and how to account for uncertainty and judgement. The architecture and three levels of innovation described in this paper help to address these issues by providing system design considerations for digital process innovation to support patient centered care delivery.

Limitations of our research is that it is based on one set of cancer symptom practice guides and we have not fully implemented our system. Next steps in our research is to finish system development of the mobile app and then conduct usability testing with a patient cohort.

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Tools for Engaging Patients on Patient Platforms: A Classification Framework

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Abstract. This paper outlines a framework for identifying and classifying different types of patient engagement tools, available on online patient platforms, according to the flow of information and patient engagement concepts. We demonstrate the application of the framework using data collected from a purposive sample of eleven patient platforms, stratified by various attributes (for-profit/not-for-profit, single/multiple conditions, different conditions). This framework can help health care organizations in better understanding the processes supported by various tools, and thereby determining better ways to engage patients using web-based Platforms.

Keywords. Social media platforms, Patient engagement, Patient tools, Qualitative research

1. Introduction

A vast number of health-specific social media platforms, referred to as patient platforms, are now freely available on the Internet to engage users in their own health related processes. We conceptualize patient platforms as websites that offer means for engaging patients (and their informal caregivers) in their own health care journey (e.g., self-care tools, symptom tracking tools, and discussion forums) with peer networks to support their learning. Patient platforms offer means for patients to actively engage in their health care processes to varying degrees, ranging from seeking and receiving information on specific health conditions, through actively learning about new research findings as quickly, if not quicker, than their healthcare providers, to connecting users with one another for social companionship and emotional support [1,2]. This self-directed approach to find information and support using platform tools instead of, or in addition to, going to traditional health care providers, has been referred to as "apomediation" [3]. Platform tools, including those provided via mobile applications, allow users to manage health issues virtually anywhere, anytime, depending on needs and context. Since these tools provide users with various types of health information, which can have significant implications on the health of individuals and the health care system, it is important to understand what tools are provided by patient platforms and how they may support various forms of patient engagement. In this article we describe the classification of

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platform tools according to the flow of information and a patient engagement framework to illustrate the different types of information provided to users and how they may support users in their health care journey.

1.1. Analytical framework

With no established frameworks or tools to study patient platforms, the analytical framework used in this study builds on the US National eHealth Collaborative (NeHC) framework [4] and concepts relating to patients' role in treatment decisions.

1.1.1. Patient engagement framework

The NeHC framework aligns with various stages of the Meaningful Use incentive program [4]. Although it is intended to be applied to information systems within health care organizations (e.g., patient portals), it offers five patient engagement categories (or levels) which can be used to explore how platform tools engage their users, namely:

1. *Inform me,* which includes information and way-finding tools such as service and provider directories, e-tools such as health encyclopedias, printable forms, and patient education tools such as care plans and tests;
2. *Engage me,* which includes more interactive tools such as mobile apps for finding nearby services, symptom checkers and trackers, interactive online forms, and patient access to view their electronic health records;
3. *Empower me*, which also includes patient-generated data such as surveys, self-management diaries, and health history, as well as interoperable records;
4. *Partner with me*, which includes additional tools such as tools to support shared decision making, home monitoring, and collaboration among health care providers along the continuum of care; and
5. *Support my eCommunity*, which adds support for online communities and forums for patients, health care providers, informal caregivers, and others involved in the patient's social circle (e.g., family and friends)

1.1.2. Patients' role in treatment decisions

Given that the NeHC framework does not account for the different roles that patients may play in their treatment decisions, and that it is primarily intended for health care institutions, concepts from Deber et al. [5] and O'Grady & Jadad [6] were also used to supplement our analytical approach. Specifically, Deber et al. [5] identified two dimensions involved in making treatment decisions: problem-solving and decision-making tasks. *Problem-solving tasks* involve only factual knowledge about diagnosis and treatment options and are preference-independent. *Decision-making tasks* require knowledge, but also "involve weighing the relative importance of potential outcomes" [5]. From these two dimensions, three possible patient preferred roles emerge. *Passive* patients wish to hand over both problem-solving and decision-making tasks to their health care provider(s). Patients who prefer a *shared* role wish to be involved in decision-making tasks and may either hand over or share responsibility for problem-solving tasks with their health care provider(s). Finally, *autonomous* patients wish to keep responsibility for both problem-solving and decision-making tasks. Related to the shared role, O'Grady and Jadad [6] offer an additional *collaborative decision-making* category, in which patients play a proactive role which might involve both clinical and non-clinical issues, and both patients and health care providers engage in a joint learning process.

2. Methods

Framework Analysis [7] was used to analyze platform tools, as well as visual data and textual information relating to them. Data were collected from a purposive sample of eleven (mainly US based) patient platforms to capture: 1) for-profit and not-for-profit platforms; 2) platforms supporting single and multiple conditions; 3) platforms supporting different conditions. Preliminary analysis revealed that platforms provided tools in the public domain, as well as tools for registered users only. Site registration was available without charge but required users to provide their personal information (e.g., email address) and consent to platform policies (e.g., terms of use and privacy policies). Therefore, the analysis of tools provided to registered users relied only on descriptions of these tools, which were posted in the public domain. Ethics approval for the study was obtained from the Research Ethics Board of the University of Toronto. Data were systematically tracked and analyzed according to the preliminary framework described in the previous section. Open coding [8] was also used to identify emerging concepts. This iterative process resulted in the discovery of new findings that are grounded in both the data and the literature.

3. Results

The study revealed three types of tools provided by patient platforms to engage their users, which were classified according to how they flowed information (Table 1) i.e., 1) One-way tools to disseminate information from the platform to users; 2) Two-way tools to provide information based on data and information collected from individual users; and 3) Multi-way tools to post information shared by many users.

   With respect to the patient engagement framework, tools in the Inform Patients category support a patient engagement process whereby information is disseminated from the platform to users, who passively receive information as determined by platform owners without engaging them in making treatment decisions. Tools in this category often featured on the platform homepage or other main web pages. Second, tools in the Involve Patients category support platform users with decision-making tasks, but do not engage them to take on problem-solving tasks. For example, platforms offered one-way tools that allow users to actively select the information they wish to receive (e.g., common side effects to medication); however, the information provided was insufficient for engaging platform users to take on problem-solving tasks. Tools in the Empower Patients category can support users with both decision-making and problem-solving tasks. For example, tools in this category can engage some users to assess the risks and benefits of their own treatment options, actively track their own symptoms, or maintain their own health record. These tools can empower some patients to gain control over their own health issues, and make their own treatment decisions, without necessarily relying on their health care providers to do so for them. The Partner with Patients category refers to a patient engagement process whereby patients are connected with their health care providers to support shared and collaborative decision-making processes. Only two-way tools were found in this category and include, for example, personal health records or health charts.

Finally, tools in the Support Patient eCommunities category allow platform users to connect with one another for information and support and included both two-way and multi-way tools. Table 2 below provides examples of the three types of tools according to the patient engagement process the tools support.

Table 1. Summary and examples of tools provided to engage users in health and information exchange processes

Tools	Flow	Users	Information	Examples
1-way	Disseminates information from platform to users	Typically post information in public domain	Mainly science-based	Health articles, patient information, medical references
2-way	Provides information collected from individual users	Typically collect information from registered users only	Based on data and information collected from individual users over time	Journals, personal health records, self-tracking tools
Multi-way	Posts information shared by many users	Typically allow registered users to share information with many others	Can be science-based, based on individuals experiences or based on information collectively posted by many users	Discussion forums, or other sharing tools

Table 2. Examples of one-way, two-way, and multi-way tools supporting various patient engagement processes

Tool type	Patient engagement process				
	Inform patient	Involve patient	Empower patient	Support patient eCommunity	Partner with patient
1-way	Featured articles, news, trends	Patient information	Medical references, symptom checkers		
2-way	Excerpts from most recent user profiles	User journals, diaries	Self-tracking tools, PHR tools to maintain health records	User blogs, tools for sharing health charts with others	Tools for sharing health charts or records with health care providers
Multiway	Excerpts from most recent forum postings	Forums for sharing experiences	Forums for consulting on treatment or diagnosis	Forums for debating drug therapy	

4.Discussion

In this study, a patient engagement framework was used to identify and classify various tools provided by patient platforms. Our analysis demonstrates that although all of the tools provide health information to engage users, they vary in the types of patient engagement processes supported, and enable users to access different types of information. For example, one-way tools mainly disseminated science-based information, which was typically posted in the public domain to inform patients. However, some platforms offered one-way tools, which allow users to access and interpret medical information that traditionally supports the work of health care professionals (e.g., symptom-checkers). While some patients might use these tools to better prepare for medical appointments [9], others might use them as a proxy for self-diagnosis or care instead of visiting their doctor [10]. In contrast, two-way tools provided information based on user information or personal experiences collected from individual users over time. Thus, they can enable users to learn from personal experiences shared online by other patients with similar disease (or drug use) experiences, thereby supporting patients in ways which differ from the expertise of health care providers(s) [11]. Interestingly, two-way tools were the only type of tools noted for supporting partnering with patients. Lastly, multi-way tools (such as discussion forums) can enable users to consult a community of other users, to seek their advice, and to co-create knowledge that can extend beyond what might be documented in the literature [12,13].

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Applying the Effective Technology Use Model to Implementation of Electronic Consult Management Software

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Abstract. Theoretical models of technology acceptance are critical to scope projects, select interventions, and measure adoption. We describe use of the Effective Technology Use (ETU) model in the design and deployment of software supporting electronic consult management. We applied the model to four project phases: (1) needs assessment; (2) software design; (3) deployment; and (4) uptake assessment. In this paper, we describe how we used the ETU to plan stakeholder meetings, conduct usability simulations, and organize findings from a qualitative analysis to identify implementation facilitators and barriers.

Keywords. Usability engineering, implementation science, electronic health records, technology adoption, clinical informatics, quality improvement., electronic consults

1. Introduction

Health information technology (HIT) is most impactful when coupled with an evidence-based implementation plan. Theoretical frameworks and models can improve the durability of implementations by providing heuristics to plan interventions and measurement strategies [1]. The authors developed the Effective Technology Use (ETU) model to inform implementation plans and explain user uptake patterns (**Figure 1**) [2].
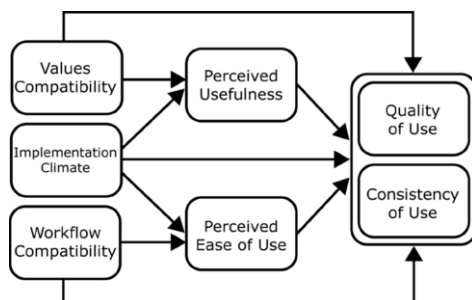
Figure 1. The Effective Technology Use (ETU) model [2].

Based upon Davis' Technology Acceptance Model (TAM), ETU is an 'added-variables' TAM that codifies the extrinsic forces mediating user perceptions of technology [3]. Our model describes three variables shown to influence user perceptions of new technology: (1) compatibility with individual values; (2) compatibility with existing workflow; and (3) climate of implementation (i.e., the extent that organizational culture and leadership expects, supports, and rewards use of a technology).

2. Problem Statement and Purpose

Electronic consults (e-consults) are a common feature in electronic health records (EHR) and are used by clinical teams to coordinate care across a healthcare ecosystem. However, the asynchronous nature of e-consults can create new challenges with patient tracking and interdisciplinary communication. These challenges are compounded by EHR configurations that reinforce single-patient transactions over population management. For example, it can be difficult or impossible for staff to quickly retrieve, track, and process all pending consults for a subspecialty. To manage e-consults safely, users need tools that promote situational awareness and track tasks automatically.

Lacking specialty-specific management tools, administrative and nursing staff at our facility struggled with an increasing e-consult workload. They relied on an array of ad-hoc processes, including handwritten notes, to track consult activity. Hospital leadership, expressing concerns over potential scheduling delays, lost referrals, and staff burnout, charged our informatics department with developing consult management software. The software needed to interface with the EHR and retrieve, aggregate, and sort consults by clinical department. Staff also needed the capability to track workload, including patient contacting efforts.

We describe herein how the ETU model informed multiple phases of our development and implementation campaign. We begin with a description of our needs assessment, organized around the independent variables thought to influence user estimations of technology (i.e., user values, workflow, climate). We then describe two complementary usability evaluations intended to gather formative and summative data. We conclude with a report of usability findings, categorized by ETU constructs.

3. Methods

We divided the program lifecycle into four discrete phases: (1) needs assessment; (2) rapid iterative software design; (3) product deployment; and (4) implementation evaluation. During the needs assessment, we used the workflow and climate dimensions to scope work and plan meeting agendas. Through a series of guided workshops, we engaged clinical champions to identify workflow pain points (i.e., workflow compatibility), gain consensus on project goals (i.e., climate for implementation), and define the ideal user experience (i.e., values compatibility). We then interviewed scheduling staff to document current-state activities and produce a future-state workflow.

During the software design phase, we quickly generated high-fidelity prototype using Agile scrums and conducted simulations to evaluate the usability and usefulness of each feature. Our simulation use-cases explored seven features critical to future-state workflow. During the simulations, we asked participants to share their experiences using a Think-Aloud protocol [4]. Simulation proctors identified design flaws and scored

completion rates for each feature using a 3-point scale (i.e., not completed; completed with difficulty; completed without difficulty). The scores were then added to generate a composite difficulty score for each function. After each simulation, the proctor asked the participants to complete two questionnaires commonly used to score technology usability and usefulness: the UMUX LITE [5] and the System Usability Scale (SUS) [6].

The product owners – a mix of executive sponsors, front-line managers, and clinical champions – agreed to deploy using a "big-bang" implementation. Over the course of four weeks, managers demonstrated the software in several staff meetings. They reviewed consult scheduling policies and explained how the software could improve scheduling efficiency. Following these demonstrations, clinical champions met with target end-users to demonstrate the product and answer questions.

After the roll-in phase, the informatics team completed semi-structured interviews with end-users to identify facilitators and barriers to implementation. We used a standardized script with questions and probes that mapped to each ETU construct. For example, to explore workflow compatibility, we asked: "Do you use Consult Tracker? If so, describe how you use it during a typical workday." To explore implementation climate, we asked: "What training or education did you receive about the Consult Tracker?" All responses were transcribed and coded using the ETU dimensions. The team met daily to review findings, reach consensus, and organize findings into themes.

4. Results

The needs assessment produced requirements for our tracking software (**Figure 2**). The software consisted of a user-interface that retrieved patient information from the EHR and displayed all consults organized by specialty. Consult requests could be sorted by date or pending actions. Staff could denote completed tasks using interface controls.

Figure 2. Screen capture of the Consult Tracker software.

Simulations enabled the informatics team to test prototypes and focus design resources on the most problematic usability findings (**Table 1**). In general, users could complete most tasks without prior training. Usability issues identified with three features (i.e., sorting by date, identifying patients with two prior scheduling attempts, and marking consults reviewed that day) provided key design insights and enabled the development team to prioritize the backlog. UMUX Lite scores suggested participants believed the software was easy to use (mean: 5.63 on a 7-point Likert scale; SD=1.69) and met their needs (mean: 5.75 on a 7-point Likert scale; SD=1.58). The mean SUS score was 82.8 on a 100-point scale – equivalent to an "A" usability rating [6].

Table 1. Findings from usability simulations (n = 8 users). Task performance scores reflect the proportion of actions that were successfully completed by users without difficulty.

Construct	Task or Question	Performance Score
Ease of use	Identify total number of consults	0.95
	Identify pending consults requiring action	1.00
	Sort consults by date of request	0.69
	Identify consults requiring first scheduling attempt	0.80
	Identify consults requiring second scheduling attempt	0.85
	Identify consults with more than two scheduling attempts	0.63
	Determine which consults have been reviewed today	0.38

We completed and transcribed semi-structured interviews with 24 of the 25 users. Twenty-one users reported using the software at least some of the time to manage e-consults. Twenty-two users, however, reported using additional tools to manage e-consult workload including paper lists, personal organizers, and other clinical software.

We organized staff comments about the implementation into four facilitators and eight barriers (**Table 2**). Primary facilitators included favorable usability ratings and the availability of clinical champions to demonstrate the software. Primary barriers included the lack of a formal training program and the need for software features to record personal notes and set task reminders.

5. Discussion and Future Work

The ETU model was instrumental throughout the product lifecycle to guide needs assessment, organize usability evaluations, and measure technology acceptance. By focusing initial meeting discussions around user values, current workflow, and leadership expectations, we successfully delivered a minimally viable product with the first prototype. Our task simulations and usability surveys helped identify important usability issues and potential design solutions – crucial ingredients for Agile scrums. We were also prepared to brief product owners and leadership on our progress by comparing our software usability scores with industry benchmarks. Finally, using ETU constructs to organize qualitative data permitted us to analyze findings at the pace of clinical operations and focus implementation efforts on actionable determinants of technology acceptance. For example, based on participant feedback, we worked with clinical managers to develop a standardized training program.

Table 2. Findings from semi-structured interviews (n = 24 interviews) mapped to ETU model constructs.

Construct	Facilitator (F) or barrier (B)	Representative quote
Implementation climate	F1: interaction with the clinical champion increased probability of use	"[The clinical champion] was friendly and engaging."
	B1: many users indicated they did not recall receiving instruction on use	"It was just a meeting. I wouldn't call that formerly trained"
Usability	F2: users could easily learn to use the software without much, if any, training	"It was pretty self-explanatory."
Usefulness	F3: the work effort tracking affordance was useful to the schedulers	"It's an easy way to identify how many contacts we've made."
	F4: integrated display of first and second contacts improved situational awareness	"It organizes who needs to be contacted and what needs action."
	B2: it can be difficult to sort patients by recently completed staff actions	"I use it for [low volume specialty 1]; in [high volume specialty 2], it's not that useful
	B3: the interface would be more helpful if it could store user comments and notes	"…needs a comment box so I know this patient needs a call back or I need imaging before scheduling."
Workflow compatibility	B4: most users use several software tools to manage all tasks associated with scheduling	"I use three tools interchangeably."
	B5: some users adopt specialty-specific workflows	"We do not use Consult Tracker in [this specialty]; appointments are made before they leave clinic."
	B6: most users prefer real-time data updates	"It is very trustworthy; it just doesn't give real-time information."
	B7: some users expressed concerns that the consult information is incomplete	"I trust it when it updates…like 80-90%."
	B8: users expressed concerns based upon experiences with prior software versions	"Every new program built on top of an older program has glitches."

In summary, integrating a theoretical framework of technology acceptance into both Agile activities and boardroom discussions enabled us to organize assets, improve implementation success, and develop strategic plans for future phases. Nevertheless, there are opportunities to refine our framework of technology acceptance. Specifically, we need to conduct objective studies of program impact (e.g., time-motion studies of staff efficiency or discrete event simulations of patient scheduling) to correlate the influence of each model dimension with eventual technology acceptance. In this way, it may be possible to further deconstruct model dimensions, such as climate, to understand the differential effect of leadership messaging, resource availability, and practice facilitation on user behavior.

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Patient and Family Member Readiness, Needs, and Perceptions of a Mental Health Patient Portal: A Mixed Methods Study

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Abstract. Patient portals are a form of technology that supports patients in accessing their health information, and other functions like scheduling appointments. The presence and utilization of patient portals in mental health contexts is relatively new. Despite research existing in the mental health literature that indicates that there may be benefits when patients have access to their mental health notes, there is limited information as to how best to implement portals, and support adoption among patients and their family members. Given this gap in literature, this study aimed to identify patient and family readiness, needs, and perceptions of a mental health patient portal. Surveys were administered to patients (n = 103) and family members (n = 7) either in-person or over the phone by a Peer Support Worker. The sample of participants consisted of patients and family members affiliated with Canada's largest mental health hospital located in Toronto, Ontario. Study results indicated that patients had the highest interest in the following portal functions: scheduling appointments, checking appointment times, and accessing their health record. Both patients and family members expressed their concerns about cybersecurity and potential privacy breaches. The results of this study, as well as the approach, can inform future patient portal planning and implementation activities at other healthcare organizations.

Keywords. Patient portal, mental health, psychiatry, electronic health records, health information technology, informatics

1. Introduction

Patient portals ("portals") provide patients with access to their health information with the goal that patients will feel empowered to take more control over their health. This technology allows for patients and their family members to have electronic access to their health records and additional functions such as scheduling appointments and health professional-patient communication. Portals have been adopted for many years in acute settings, but portal adoption in mental health settings is relatively new [1]. Research on portals suggests that there may be benefits when patients have access to their mental health notes specifically. A study conducted at a Canadian mental health hospital

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revealed that patients who enrolled in the portal improved their scores on the Mental Health Recovery Scale [2].

2. Purpose

Currently, information is lacking on how best to implement and support the adoption of mental health patient portals among patients and their family members. There is limited information as to why patients may be interested in accessing a portal, what functions are of most interest, and what concerns patients and their family members may have about using the technology. Therefore, the purpose of this study was to identify patient and family readiness, needs, and perceptions of a mental health portal.

3. Methods

3.1. Study sample and setting

The study sample consisted of patients and family member participants affiliated with the Centre for Addiction and Mental Health (CAMH), a mental health teaching hospital located in Toronto, Canada. Patient data was collected from eight inpatient units, and six outpatient clinics. These units were representative of the age (youth to the elderly) and diagnoses (e.g. mood disorders, psychotic disorders, concurrent disorders, addictions etc.). A total of 103 patients and 7 family members participated in the study.

3.2. Study design and recruitment

The study consisted of a cross-sectional survey (with both closed and open-ended questions) administered either in-person or over the phone by a Peer Support Worker. Previous research has indicated that patients may feel more comfortable answering question questions when asked by a peer, and may provide more honest responses to questions [3]. Recruitment of patients took place in-person by the Peer Support Worker at the various inpatient and outpatient locations. This strategy was an effective way of eliciting patient feedback in a previously conducted study at the study site [4]. Family members affiliated with the Office of Family Engagement at CAMH were recruited through email and phone calls. A brief notice asking family representatives to participate in the survey was also included in a family member newsletter.

3.3. Data collection

A unique survey version was developed for each type of participant (one for patient participants, and one for family members). The patient survey was administered by a Peer Support Worker to participants in-person. The family member survey was administered to family members via a Peer Support Worker over the phone. Patients and family members were asked questions regarding access to technology, access to the internet and connectivity, access to the portal via current technology used in their everyday lives, and level of interest in portal functions. Participants were also asked open-ended questions to identify any concerns regarding portal access, or concerns with

family members having access to the portal. Following these questions, demographic information was collected.

3.4. Data analysis

Quantitative survey data was analyzed using SPSS®. Descriptive statistics were generated such as means, percentages and frequencies. A thematic analysis was performed for the qualitative survey data using a thematic approach developed by Braun and Clarke [5]. Two members of the research team coded the data independently and compared codes to improve the rigour and trustworthiness of the findings [6, 7].

3.5. Ethical considerations

This study received ethical approval. Patient and family member identifiers were not collected by the Peer Support Worker when administering the surveys.

4. Results

4.1. Demographic characteristics

The survey was completed by 103 patients (n=54 participants from inpatient units, and n=49 from outpatient clinics), and seven (n=7) family members of mental health patients. Of all patients, forty (n=40) identified as female, fifty-three (n=53) identified as male, one (n=1) identified as both, and one (n=1) identified as cis. Eight (n=8) patients preferred not to say. Of the seven family members, five (n=5) participants identified as female and two (n=2) identified as male. Thirteen (n=13) patients did not have access to a computer with internet. All seven family members had computer access. The distribution of patients among the units and clinics can be found in Table 1.

Table 1. Number of patients who completed the survey in each unit and clinic at CAMH.

Unit	Absolute Frequency	Relative Frequency (%)
Inpatient Unit 1	6	5.8
Inpatient Unit 2	11	10.7
Inpatient Unit 3	1	1.0
Inpatient Unit 4	2	1.9
Inpatient Unit 5	6	5.8
Inpatient Unit 6	16	15.5
Inpatient Unit 7	4	3.9
Inpatient Unit 8	8	7.8
Outpatient Clinic 1	2	1.9
Outpatient Clinic 2	10	9.7
Outpatient Clinic 3	19	18.4
Outpatient Clinic 4	7	6.8
Outpatient Clinic 5	10	9.7
Outpatient Clinic 6	1	1.0
Total	103	100.0

4.2. Patient's readiness and needs

Findings of this study revealed that half (50%) of the patient participants were aware that they had the right to access their health record. One participant revealed that it was "a

little surprising to hear" indicating that they were unaware that they had the right. Patient participants were interested in accessing the portal for reasons related to convenience, availability, and to check the accuracy of information in their record. One participant stated, "when you come to [the hospital], there's a lot to take in and it can be overwhelming, so the portal can help". Two other participants agreed that the portal could provide "easier ways to view programs and appointments" and keep patients aware of "[their] diagnosis, [their] treatment, how [they're] doing, what's going on" etc. A participant had a similar opinion that the portal can be used "to make sure I'm on the same page as my doctor; it's more self-supporting, self-sustaining", and another participant mentioned "[the portal] seems like a good idea especially with medication renewal and appointments. Medication renewal can be a life safer".

The portal functions that were of highest interest to patients were: accessing health records (78% positive, 12% negative), checking appointment times (78% positive, 14% negative), and scheduling appointments (75% positive, 13% negative). Functions of the lowest interest for patients were renewing medication (70% positive, 22% negative), messaging health care providers (64% positive interest, 23% negative), and completing self-assessments (59% positive, 19% negative). Participants in outpatient settings had a higher level of interest in portal functions than inpatient participants (see Table 2). Participants from inpatient settings had a similar level of interest in medication renewals, and a higher level of interest in educational materials.

Table 2. Level of interest in portal functions by inpatient and outpatient settings.

Type of setting	Interest	Portal Functions						
		Messages to Provider	Health Record Access	Appointment Schedules	Appointment Times	Medication Renewals	Educational Materials	Self-Assessments
Outpatient	Negative	19%	9%	12%	13%	21%	17%	16%
	Neutral	10%	13%	10%	6%	9%	17%	20%
	Positive	71%	79%	78%	81%	70%	67%	63%
Inpatient	Negative	27%	14%	16%	16%	22%	10%	21%
	Neutral	16%	8%	12%	8%	8%	17%	25%
	Positive	57%	78%	71%	76%	70%	73%	54%

4.3. Family member's readiness and needs

Family members stated that the portal would be helpful and convenient to facilitate their support of a family member with mental illness. All seven family members (n=7) expressed interest in accessing health records, messaging providers, and receiving educational materials via a portal. Six (n=6) family members reported an interest in appointment times and self-assessments, and five (n=5) were interested in scheduling appointments and renewing medications.

4.4. Patient perceptions of the portal

There were mixed responses from patients about providing portal access to a family member. Less than half (44%) were interested in giving portal access to a family member. One participant said: "I'd prefer to keep my affairs private, but if absolutely necessary I would consent to family access". Another stated: "I like to keep my mom informed because she's a very good support". When asked about concerns with accessing the portal, one participant mentioned their fear of finding "negative comments written

about me by healthcare professionals". Thirty-four (n=34) participants expressed concerns with cybersecurity, and privacy breaches.

4.5. Family member perceptions of the portal

Family members were concerned about cybersecurity and commented on the importance of privacy. One participant mentioned that there should be limited access for family members as the patient's "privacy is important; [I] only want to know about risks, treatment plan, and diagnosis". Family members mentioned that patients should be able to schedule their own appointments, and that family members may just need to know the time. Family representatives reported that they did not want to take on the responsibility of medication renewals and stated that it should be done at appointments.

5. Discussion

Patients and family members shared that a portal is a convenient way of accessing information, and that staying informed may translate into improved mental health. Overall, patients and family members have shown interest in the technology and certain functions such as accessing health records and receiving educational materials. The implementation of these portal functions may improve the adoption and usage of the technology by all user groups. In addition, issues of privacy and cybersecurity need to be considered when implementing a portal in a mental health setting. Limitations of this study include an unbalanced sample size. A balanced sample of patient and family members was anticipated. Due to the variation in recruitment strategies, a balanced sample was not achieved. Alternative recruitment methods can be considered to obtain a balanced study sample.

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Improving Access to Healthcare with On-Line Medical Appointment System

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Abstract. Access to medical care is in many countries an obstacle to timely health care and new technological options for improving the access are not fully utilized. In this project Business Process Modelling and Notation (BPMN) is applied to obtain an efficient, flexible and low cost medical appointment system for a medium size medical centre.

Keywords. Appointment scheduling, Business process reengineering, healthcare access.

1. Introduction

The use of healthcare services is significantly impacted by access to the services, and a multitude of issues influence the behavior of the individual. Ronald Anderson et al. provided a conceptual framework for analyzing access and equity in health care [1] stressing that improving access to care is best accomplished by focusing on contextual as well as individual determinants. Contextual determinants are measured on an aggregate level and encompass community characteristics, health organization and provider related factors in recognition of the importance of community, the structure and process of providing care [2]. Individual determinants consist of biological imperatives (sex, age, genetics) influencing the need for health services, and social factors determining the status of a person, along with the ability to cope with presenting the problem and dispose of resources to deal with the problem (education, occupation, ethnicity) [1].

A key enabling factor to access health care services is in the contextual determinant health organization when establishing the contact. Traditionally medical appointments have been made over the telephone or by showing up in person at a clinic. Schedulers or secretaries have answered calls and by verbal communication this method has allowed for maximum flexibility in dealing with complicated cases. As these methods depend on schedulers the ability to make an appointment is limited not only by the available time slots, but also by the number of phone lines and schedulers. However, web-based appointment systems have been popular, and several studies have conducted satisfaction surveys [3].

Health institutions often acquire Web-based medical appointment systems as software as a service (SaaS), but proprietary scheduling systems are also seen as integrated

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into patient portals on provider's web sites. Implementation processes of standard software solutions are often challenged by integration problems of technical as well as organizational and cultural nature. Business process reengineering can be an approach to to identify possibilities for improving the design of medical appointment systems: from "as is" to "to be." The aims of this process redesign are to improve the process of making medical appointments for small or medium size medical clinics or centers – a critical aspect to increase healthcare quality, efficiency, flexibility and decrease cost.

2. Material, theories and methods

Business Process Management (BPM) is a method that demonstrates ability to deliver improvements in organizational performance, service quality and regulatory compliance. When a business process is coordinated and logically sequenced, which is the case in most health care systems, it will produce value to a client or customer. Hence it is the hypothesis that the health care systems can benefit from applying BPM approaches.

An advantage is that BPM provides a shared language to Information Technology (IT) specialists and business stakeholders communicating with each other. BPM puts more emphasis on the use of information technology as a tool to improve business processes. Two often quoted rules from Bill Gates says: "The first rule in any technology used in a business is that automation applied to an efficient operation will magnify the efficiency. The second is that automation applied to an inefficient operation will magnify the inefficiency". His focus on contextual issues indicates that learning how to design and improve processes is important, not only building an IT system [4]. This contextual focus can be obtained by utilizing Business Process Modelling and Notation (BPMN) as it supports both technical users and business users to manage healthcare processes by providing a notation that business users and technical users understand. The BPMN specification provides a mapping between the graphics of the notation and the underlying constructs of execution languages, particularly Business Process Execution Language (BPEL) [5].

The purpose of process redesign is to identify possibilities for improving the design of a process: from "as is" to "to be". Each process redesign generally improves one side of the devil's quadrangle [4], and detriments of others along the dimensions of cost, flexibility, time, and quality, which are the basic measurements for assessing business activities. Companies compete in the marketplace by one or more of the measurements. The devil's quadrangle can help the healthcare industry to be aware of particular problems in term of time, quality, cost, and flexibility as performance indicators.

The proposed medical appointment system is designed for small or medium size medical centers (clinics) with a reception assisting the user to administer data sets. Make or modify appointment is the chosen target process for this project. The design process is improved by using the Business Process Modelling and Notation (BPMN) method. The strengths and weaknesses was analyzed using several heuristic design principles and the devil's quadrangle model from Dumas [4].

3. Results

The medical appointment process has been improved by introducing an online medical appointment system. It has a highly efficient set of management tools to synchronize, computerize and systematically record data assisted by the use of Internet websites.
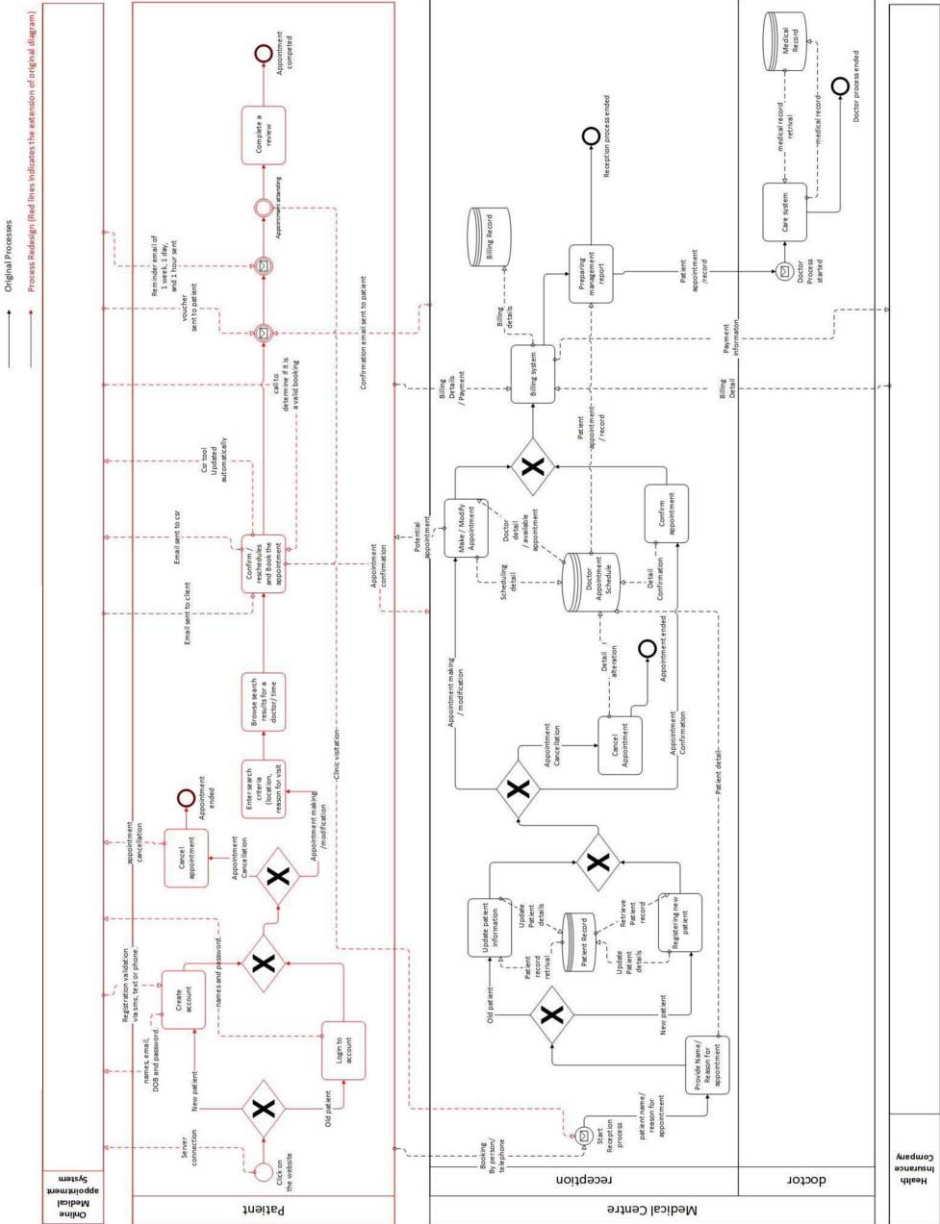
Figure 1. Medical Appointment System (BPMN workflow diagram)

Figure 1 shows the diagram of a medical appointment system of a medium size medical centre with the reception assisting user to administer a huge amount of data

The medical appointment system based on BPMN describes the process of patients making medical appointments using both traditional method and online system.

Online appointment features allow patients to make the appointment through internet, and doctors can manage their schedule online. The online schedules show information such as the doctor's working hours, specialty, available and unavailable appointment times etc. The patient uses the online system to request an appointment. Emails from doctor and the online appointment system will be sent to patient to confirm the appointment. Continuous reminders are sent until the patient meets the doctor.

The process redesign is a combination of incremental improvement and extension of the existing process. The online medical system will dramatically improve measures of performance, such as service, cost, speed, and quality. But it doesn't disregard the existing procedures and structures. Therefore, radical redesign is not the method of reinventing business processes. It is an extension of the existing process, because all processes are kept as shown in Medical appointment system (BPMN). There is an addition of a pool in BPMN namely "online medical appointment". And patients will be the primary person in managing their appointment booking with health practitioners. This process extension requires continuous incremental improvement, as doctor, staff and patient need to learn and adapt to the new system.

There are at least eight principles identified in this target process redesign: Control relocation, Outsourcing, Integration, Parallelism, Activity automation, Integral technology, Interfacing, Centralization, Empowerment. Four of these are particularly relevant to the medical appointment system, and are selected for further analysis and evaluation. The results are summarized in Table 1

Control relocation – Patients take control over which doctor and the time for the appointment. It improves flexibility for the patient as they can make an appointment online without restricting to business hours. It also improved patient satisfaction. However, there's a high probability of patient misusing the system.

Parallelism - Activities can be carried out in parallel especially when greater speed is required during the busy business hour. Overall, parallelism leads to improved performance, reduction of waiting times, reduce throughput time and better use of capacity.

Activity automation/ Integral technology - Online medical appointment technology is deployed to alleviate physical constraints in a business process. It reduces the time that the receptionist spends on electronic work. The online system provides a better quality of service. Activities can be executed faster, increase communication speed, increase information availability, reduce duplicated data entry, reduce human error and offer a more predictable result. However, the cost of implementation, training, and maintenance efforts related to technology can be high. Workers' reluctancy to adopt new technology may decrease the quality of the business process. Another risk is that the Internet can be unresponsive, resulting in a failure to make an appointment. Furthermore, as a patient-focused organization, Healthcare institutions may need to personalize their systems and provide special attention to those who are vulnerable and less technically advanced to ensure fair distribution of resources and care.

Table 1. Characteristics of the business process operation heuristics

	Time	Cost	Quality	Flexibility
Control relocation	Neutral	Negative	Positive	Positive
Parallelism	Positive	Negative	Neutral	Negative
Activity automation	Positive	Negative	Positive	Negative
Integral technology	Positive	Negative	Positive	Positive

The three redesign principles on each of the four performance dimensions of Devil's Quadrangle were further analysed and evaluated. The dimension of time, quality and flexibility will improve dramatically. The biggest drawback of introducing parallelism, control relocation and Activity automation/Integral technology is increasing in cost. However, if utilising other redesign principles identified in this medical appointment systems, further improving the Devil's Quadrangle and reducing the cost may be possble.
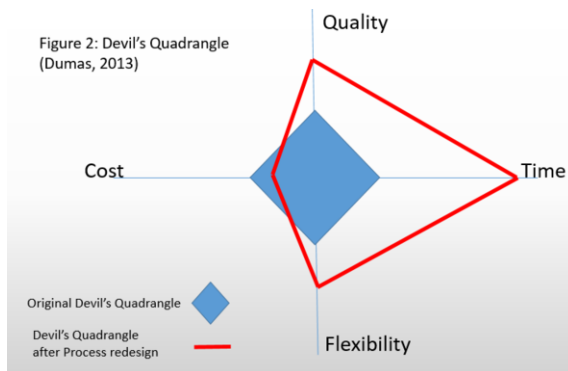
Figure 2. Devil's Quadrangle analysis of achievements of process redesign

4. Discussion and conclusion

This study addresses the use of BPM to deliver improvements in medical appointment systems. It also suggests that medical appointment process will be improved by introducing an online medical appointment system as a result of analyzing the process using BPMN. After evaluating the three redesign principles on each of the four performance dimensions of Devil's Quadrangle, we have discovered that the dimension of time, quality and flexibility will be improved significantly. Nevertheless, the biggest issue of introducing parallelism, control relocation and activity automation/integral technology is cost.

There's a need to further identify issues on the way and resolve them incrementally. Healthcare organizations should analyse the trade-off by using "as is" and "to be" process model. Whether building the system in-house or purchase commercial software, it is highly recommended to tailor the medical appointment systems process ultilising BPMN and other redesign principles identified in this study. There is a good possibility of further improving the Devil's Quadrangle may occur. Using redesign heuristics continuously is necessary in a highly complex and dynamic healthcare system.

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System Dynamics in Remote Monitoring Service for Cardiovascular Implantable Electronic Devices

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Abstract. This methodological paper describes how system dynamics was applied in evaluating the effect of remote monitoring (RM) of cardiovascular implantable electronic device (CIED) workload on clinical resource utilization. The development of a causal loop diagram and a stock and flow diagram and the construction of the simulation model for comparison of an in-person clinic group and RM clinic group are described.

Keywords. clinical resource assessment, system dynamics, causal loop diagram, simulation model, remote monitoring, cardiovascular implantable electronic devices

1. Introduction

A cardiovascular implantable electronic device (CIED) is a medical device implanted in the chest of a patient diagnosed with irregular heartbeat or cardiac arrhythmias. It is an electrical intervention for the monitoring, diagnosis, and treatment of bradycardia, tachycardia and heart failure [1]. With the maturity and wide availability of the telecommunication technology, the remote monitoring (RM) of a CIED has become an increasingly common and reliable form of telecardiology. The RM technology becomes a crucial data collection engine of the cardiology information system when the patient is physically outside of the clinical care setting. A remote monitoring follow-up service model integrating for remote cardiac disease management has received considerable attention as an acceptable method of care delivery in the past decade [2]. The effectiveness of the RM follow-up service model remains contextual based on health care setting integration.

This study used system dynamics modelling to depict the effect of a RM service on clinical workload. System dynamics is a methodological approach to structure and understand a complex, dynamic problem in an environment which is "characterized by interdependence, mutual interaction, information feedback, and circular causality." [3] This type of modelling does not produce precise numerical forecasts, but is an investigative tool allowing comparison of the relative benefits, and potential consequences of various changing options [4].

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Dynamic analysis of healthcare service delivery is needed because of the criticality of supplying the right clinical service to the right patient demand at the right time [5]. From the perspective of a device follow-up clinic (DFC) within a health delivery organization, understanding how RM service affects variation of the service demand is important for decision making to sustain the quality of patient service. This paper describes the methods for applying systems dynamics to this problem.

2. Research Purpose and Objectives

The research purpose was to evaluate the effect RM service on the clinical workload of a DFC. Two clinical protocol groups (in-clinic and RM) were compared. The RM clinical protocols included a combination of both remote and in-clinic visits. The research objectives were:
1. Identify the workload of each clinical protocol;
2. Depict the relationship and interaction of the clinical resource consumption in a conceptual model; and
3. Project and compare the clinical resources needed to serve the implanted patients at one-year and three-years using a conceptual model.

3. Study Design

3.1. Clinical Protocols

This paper describes an example of how the system dynamics modelling can be applied. It was a single-site, single-vendor time-to-event study on the operation of the cardiac clinic at Royal Columbian Hospital (RCH) as the DFC in serving implanted patients with on the regular follow-up service. This prospective, observational, post-test only study design consists of two groups. The in-clinic (IC) group included patients with the implantable cardioverter defibrillator or cardiac resynchronization therapy with defibrillator who attended all follow-up services in person at the RCH cardiac clinic.

The remote monitoring (RM) group included implanted patients who enrolled in the remote follow-up service using the RM services to send transmissions to the clinic. These patients had alternating in-clinic follow-up visits and RM follow-up. In the evaluation, the IC group acted as the baseline in demonstrating the workload difference between the two follow-up clinical protocols.

3.2. System Dynamics: Methodology

The system dynamics modelling was chosen as the study methodology because clinical service demand was naturally complex and involved many interdependent resources and parameters. The RCH cardiac clinic team verified relevant parameters were appropriately captured in the developed model. A visual model to depict non-linear, intermingled relationships was instrumental in assessing the differences between IC and RM groups for workload and clinical resource consumption.

This application of the system dynamics in the research is broken down into three major steps, with each step produces a deliverable, one for the IC group and the RM group.

3.2.1. Step 1 – Causal Loop Diagram

In the first step, a causal loop diagram was developed as a qualitative tool to depict the relationship between the parameters of the clinical resource utilization of the RCH cardiac clinic in service. In the scope of the patient care for the implanted patients, the relevant workload parameters were identified and verified by the RCH cardiac clinic team based on the touchpoints between the patient's service demand and the clinic's resource supply. To process the workload data for system dynamics, each patient encounter in the data collection was analyzed and categorized with the RCH cardiac clinic team for each group. Each service category became a parameter of the clinical resource consumption at RCH cardiac clinic in the causal loop diagram. As an example, a service category of the RM group was the remote service enrollment and start-up. This service was all the support that a cardiac technologist provided to patient enrollment to the RM service. The diagram incorporated the service categories and other parameters that were crucial in serving the implanted patients and devices. The parameters of clinical resource utilization in serving the implanted patients were identified and verified by the RCH cardiac clinic team. Figure 1 is an example of a causal loop diagram which depicts the workload of the in-clinic group in the research.
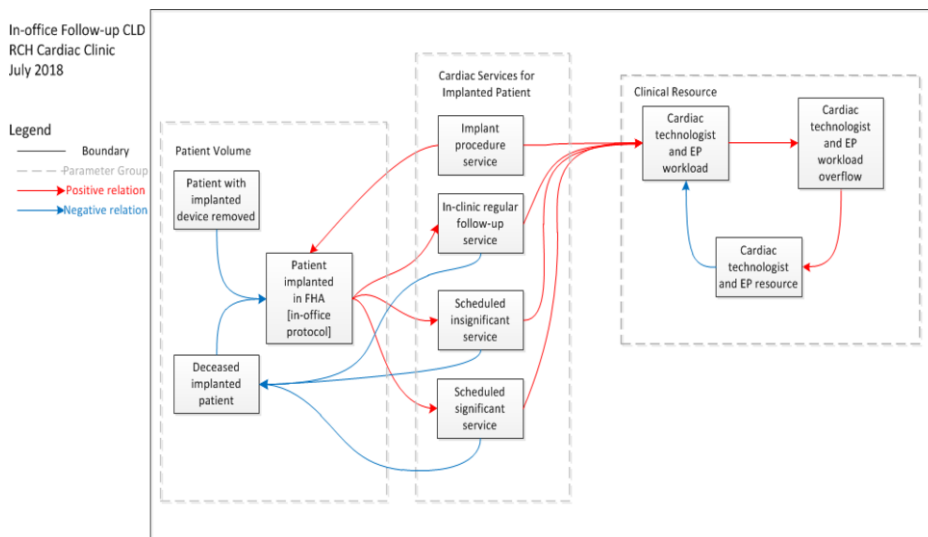
Figure 1. Example of Causal Loop Diagram.

3.2.2. Step 2 – Stock and Flow Diagram

In the second step, the casual loop diagram was translated into a stock and flow diagram for quantitative analysis on workload. Based on the statistical analysis, each parameter was converted to either a stock, or a flow entity. Choosing a stock or a flow entity would depend if a parameter accumulating a balance over the simulation period would be

significant to the research purpose. Stock entities were used to observe dynamic behavior over time; whereas flow entities were used to record the behavior within a time period. In the research, a stock entity was chosen to represent the patient volume, for the clinic's workload of the patient care would cover the lifetime of the implanted device typically for five to ten years. A flow entity was a natural choice for each service category because the provision and the consumption of a service would occur shortly if not simultaneous between the clinic and the patient. The relationships between parameters was established with algebraic expressions. The stock and flow diagram depicted the relationship and interaction of the clinical resource consumption and workload.

After the service categorization was complete for all patient encounters, the total workload of the clinic was summed by time in minutes and by each service category within each study group. The workload included the cardiac technologist's time and the cardiac electrophysiologist's time in each patient encounter. The total frequency of the service demand and the number of patients by each service category were counted. Then three numbers were calculated and assigned to each service category in the stock and flow diagram – 1. the average service demand in the patient group (total number of patients with service by total number of patients); 2. the average service demand per patient (total frequency of the service by total number of patients with service); and 3. the average clinical workload per each service category (total workload by total frequency of the service). Other parameters in the stock and flow diagram were also assigned with a numerical value, such as the implant rate and the mortality rate, so that the diagram could be utilized to run as a simulation model for one-year and three-year projection period. Figure 2 is an example of a stock and flow which depicts the workload of the in-clinic group in the research.

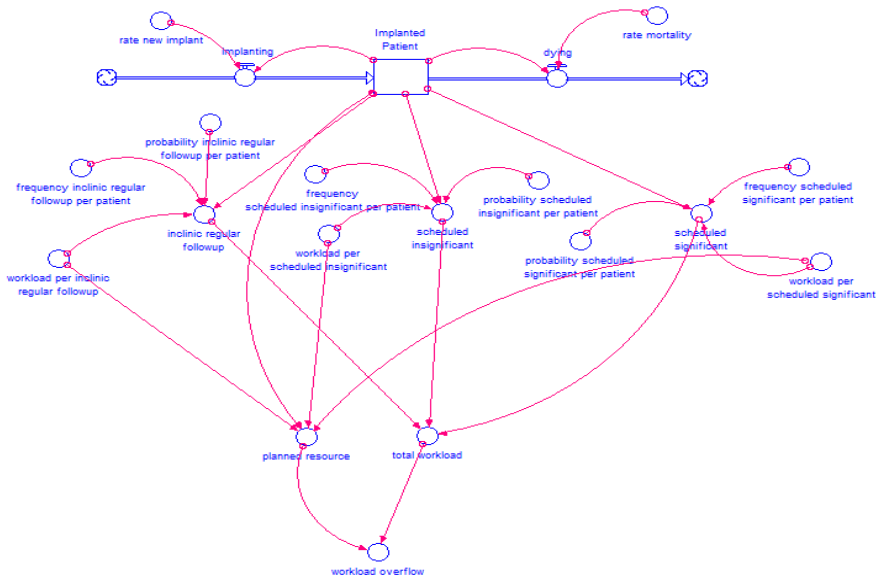**Figure 2.** Example of Stock and Flow Diagram.

3.2.3. Step 3 – Simulation Model

In the final step, the stock and flow diagram was then used to simulate the clinical resource utilization by projecting the service volume of the cardiac patients at one-year and at three-years of time after the study horizon for both groups. In the research, the study horizon was the length of the workload data collection at the RCH cardiac clinic (one year).

4. Strengths and Limitations

This research applied the system dynamics to assess the clinical resource utilization of a device follow-up clinic for the RM follow-up service. Both the causal loop diagram and the stock and flow diagram for the simulation model were instrumental to focus the research on the effect of the RM service while strategically narrowing down to the boundary of the research scope, and leaving out the other less relevant factors.

The causal loop diagram created a backbone of a basic service supply-and-demand model that can be generalized to the other device clinic follow-up without including specific environmental factors for the clinic such as the type of RM technology, the device type, the clinical protocol, clinical workflow, the type of clinical resources of the clinic, and the local health care system. For example, the diagram showed the specific challenges that the RCH cardiac clinic could face based on projected service demands of a growing volume of patients.

The simulation model acted as the platform of the impact analysis of the clinic's capacity in the management of the service supply by the various factors, such as the annual implant rate and the planned resources as presented in the research. The simulation model could be tailored for a specific research.

One limitation of the simulation model is the assumption that the same dynamics behavior of the service demand by the sample patients in each group would repeat in every simulation run. The reality is that the dynamics behavior of the service demand can be random by the patient's cardiac health and device status. In addition, in three years of time the clinic could implement program and workflow change that could improve the overall clinical resource management in the follow-up service delivery. Cautious interpretation of the three-year projection in the workload simulation hence should be made. On the other hand, the simulation model can be reused for sensitivity analysis when the change of a parameter is under investigation.

The data processing in service categorization was beneficial to prepare the data for the specific research setting. For example, at the RCH cardiac clinic, the service categorization broke down the variety of workload to the IC and RM groups. The data processing was performed with a cardiac technologist validating the workload data. The service types of the IC group became a referential baseline in amplifying a perspective of the more variety of the service types of the RM group to demonstrate the different services provided for each clinical protocol of the follow-up service. Although some of the services may be common for all device follow-up clinics, the outcome of the service types was contextual to the RCH cardiac clinic, particularly the staffing structure as a clinical resource in service delivery.

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283

Smart Homes for Healthcare

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Abstract. Smart Homes may improve the care received by the elderly and those with disabilities that prevent them from conveniently accessing care from providers. This paper examines the structures and mechanisms of Smart Homes, explores the advantages and disadvantages for patients receiving care from the comfort of their own homes and describes a model that can be used to view the needs of patients involving Smart Home technologies.

Keywords. Smart homes, home health monitoring, telehealth, mobile health

Introduction

The design, development and implementation of Smart Homes has emerged as an important international trend. In as much as smart phones have become a necessity for everyday living, the trend towards establishing smart homes as the dominant technology has also led to the rise of a global societal phenomenon. Aspects of Smart Homes may already exist in many homes in our community, such as Bluetooth powered light bulbs, security cameras, wireless doorbells, smart TVs, and Amazon Alexa, which is a cloud-based voice service that offers customers the capability to build natural voices for a more intuitive way to interact with their technology [5]. The ideal state between human and computer interaction is to achieve mutual understanding using the provided medium of communication. It is not sufficient to have technology available, but rather, to have technology that can easily interact with people to achieve a desired outcome. When Smart Homes are considered within the context of providing healthcare, researchers and health informatics professionals must consider the number of intricate and complex connections of such devices so their potential can be fully realized, in helping to monitor a citizen's health issues and to help patients manage their illnesses within the comfort of their own home. The objectives of this paper are to: 1. Define a smart home, 2. Describe a model that can be used to consider technologies used to equip Smart Homes for the purpose of providing health care services, and 3. Discuss the benefits and challenges of making homes "smart". According to Ambersheil and colleagues [1, p.1], "a Smart Home (SH) is typically equipped with a series of inter-related software and hardware components that work together to monitor the living space of the resident and understand their activities." As the population ages, there is a greater need for personal care and safer transitions from hospital to home care. Smart homes may reduce the number of patient trips to and from hospitals, especially if they are elderly patients, dementia patients or disabled patients that may not have caregivers available to accompany them. Smart Homes can potentially support these patients in living more independently. The

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following paper will examine the structure and mechanisms that operate within Smart Homes using a model based approach. The benefits and future of Smart Homes, as well as the challenges faced with the idea of Smart Homes will also be discussed. In the model we describe, we outline the four layers in the architecture of Smart Homes, and these will be described in greater detail below.

1. Structure and Mechanisms of Smart Homes

There are four Smart Home architecture layers, the physical layer, the communication layer, the data processing layer, and the interface layer [1]. The physical layer is responsible for sensors in the environment and physiologic sensors. The communication layer is responsible for wireless and wired sensor networks. The data processing layer is responsible for data storage and machine learning, and the interface layer is responsible presenting information and data to the residents and their care providers (see Section 1.1 below) [1].

1.1. The Model of Smart Homes
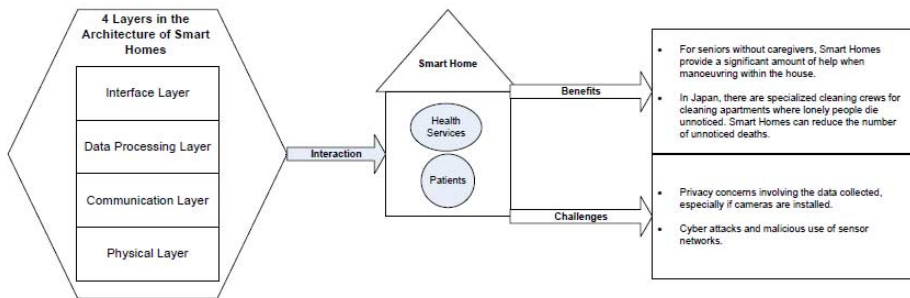
Figure 1. Smart Home interaction with patient

1.2. The Physical Layer

In the physical layer, Smart Home sensors collect the data and transmit it through the communication layer to the processing layer for activity analysis. The output of the analysis could be in the form of alerts or specific information that is delivered through the interface layer to the stakeholders [1]. Within the physical layer, there are two important categories of sensors, discrete state sensors and continuous state sensors. Discrete state sensors have a binary output for representing the state of objects or residents [1]. Examples can include door opening or closing, and lights turning on and off. Within this category of sensors, commonly used state sensors are Contact Switch Sensors (CSS) used for detecting the state of objects. Compared to discrete state sensors, continuous state sensors can be in simple or complex forms, such as numbers, images or sounds [1]. Commonly seen sensors in this category are environmental sensors that capture temperature, humidity, pressure, noise and light data; for example, AlarmNet

supports assisted living and monitoring, and operates using body area networks to obtain physiological data from patients [1].

1.3. The Communication Layer

The purpose of the communication layer is to connect all of the components together. Low-powered wireless networks allow power sensitive devices, such as sensors, to consume the minimum amount of energy possible in collecting data [1]. ZigBee is the most used standard, and is commonly used throughout U-Health or ubiquitous health [1]. U-Health is designed to take into account 12 different types of wireless sensors that record heartbeat, body temperature, blood pressure, motion, location, blood sugar, SpO2, dehydration, cholesterol, humidity, smoke and temperature [1]. Another type of communication is power line communication. These technologies allow Smart Homes to gain access to "universally available electrical communication terminals as the communication infrastructure" [1]. For example, KNX is one of the most successful heterogeneous protocols used in Smart Homes. Various types of media, such as radio frequency, power line and twisted pairs, and IP protocols are used by sensor designers [1]. Lastly, there are personal computer networking protocols and mobile telecommunication systems. The work in this area has included the use of Wi-Fi access points and the transmission of text, digitized voice, and other types of data.

1.4. The Data Processing Layer

Many Smart Homes apply fuzzy logic in the building and monitoring of systems. A fuzzy rule would take the form of the following: "*IF Resident_stay_in_bed for Long and bedroom_TV=OFF then Class_Risky*" [1]. Aside from fuzzy logic, there are also Artificial Neural Networks. These are made up of "highly interconnected processing elements, which process information by their dynamic state response to external inputs" [1]. With these capabilities, artificial neutral networks are able to classify activities, predict activities and control appliances.

1.5. The Interface Layer

According to Amiribesheli, [1], there are four different groups of users for a typical Smart Home; residents (dementia patients, disabled people, elderly people…etc.), informal caregivers (family members), social caregivers (care homes, professional caregivers), and formal caregivers (doctors, nurses…etc.). With these users in mind, an emerging theme is that elderly individuals may have limited short-term memory. Therefore, the design of user interfaces must support natural user interfaces, such as gesture recognition and speech recognition [1]. An example would be the Sweet-Home project, which proposed a voice interface for residents that helps to control the features of the home, such as window blinds, lights and kitchen appliances [1].

2. Benefits of Smart Homes

For seniors who are without caregivers, Smart Homes can provide a significant amount of help when maneuvering within the house or for monitoring one's own health status. TELUS has a Home Health Monitoring platform that interfaces with patients who have chronic diseases so patients can monitor their blood pressure and other health issues by transmitting vital sign and other health information to their healthcare providers [2]. TELUS suggests that "Patients with chronic conditions such as congestive heart failure (CHF), chronic obstructive pulmonary disease (COPD), diabetes, asthma, hypertension and some other health conditions can benefit from an home health monitoring (HHM) programs leveraging remote patient monitoring technology that typically last from three to six months" [2]. This HHM platform consists of a patient station and a clinical station. The patient station consists of a simple interface that includes vital signs entry, question and answer information, and educational material, while the clinical station consists of a clinical editor, monitoring plans and protocols, patient data and records as well as analysis and reporting screens [2]. If a Smart Home is an iceberg, then the TELUS HHM technology is only the tip of an iceberg, because the functions of Smart Homes represent an expansion of the capabilities supported in the HHM solution. With a Smart Home, the future of health care may change significantly.

2.1. The Future of Healthcare

The future of health care may include sensors and algorithms implemented as devices in a Smart Home [3]. Suggested sleep tracker mattresses can analyze sleep quality, microchips in a toilet could detect changes in urine, smart scales may measure changes in weight, and digital mirrors will detect facial skin cancers and changes in facial movement. If any of these markers exceed the normal level of the resident, a report will automatically be sent to the resident's physician or nurse. The physician will then contact the patient to book an appointment for a check-up or a nurse will contact the patient to assess their health status. The ideas proposed are not insurmountable, as with big data analytics such as IBM Watson, this information can easily be analyzed to assist in early diagnosis, treatment, or prevention of diseases. According to the Medical Futurist [3], "in Japan, an estimated 6.24 million people aged 65 or older were living alone in 2015…there are already clean-up crews specializing in cleaning apartments where lonely people died unnoticed" [3]. Smart Homes can lead to the recognition of health conditions and prevent senior deaths. Smart homes will allow for constant monitoring of individuals in their home for potential health issues. To illustrate this, Healthsense currently monitors 20,000 residents in assisted living communities, and has conducted a pilot project to expand this monitoring to private homes. A cohort of 34 older adults participated, and the results indicated a 50% decrease in emergency room visits compared to those who did not have the sensors [2].

3. Skepticism of Smart Homes

Researchers have identified a number of issues associated with Smart Home technologies. A major concern is privacy, especially if there are video cameras in the room. If sensors are placed in homes, there can be issues of "sensor compromise, eavesdropping, privacy

of data, denial of service attacks, and malicious use of sensor networks" [1]. Ethical studies will also need to be conducted in order to determine whether the use of sensors in the home is ethically correct, even if they are for legitimate health care purposes. Residents will also need to be informed thoroughly of how and what data will be collected about them. Smart Home implementers will need to ensure that patient data will be appropriately used and prevent hackers from stealing and selling the information to third parties. Lastly, the usability, workflow and safety of Smart Home technologies will need to be studied [4].

4. Conclusion

As technology advances and data collection methods mature, it is inevitable that the current healthcare system will undergo a paradigm shift to keep up with the changing needs of the population. There are both benefits and challenges in the use of Smart Homes, with the main benefit being an increased awareness of one's health status, and the main challenge being privacy issues. As mentioned earlier, the biggest groups that benefit from Smart Homes are seniors, disabled patients and dementia patients who are not able to be accompanied by caregivers on a daily basis. Smart Homes can assist them to live more independently and comfortably by reducing the amount of travel to see physician offices. However, the residents must be aware of where the sensors are located and which information will be collected about them so that the issue of privacy can be fully addressed as well as understand their interactions with these technologies. In addition, future studies should research into Application Programming Interfaces API) in order to standardize the integration of monitoring devices into the Smart Home. APIs act as an architect's blueprints for building Smart Homes, hence it determines the how the technology will be oriented to create the ideal user experience. The future of Smart Homes looks promising, but in order to have it safely implemented, more pilot studies will need to be done, and the technology will need to be continuously improved throughout each study.

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Data Migration from Operating EMRs to OpenEMR with Mirth Connect

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Abstract. Electronic medical records (EMR) are integral to the functionality of day to day operations in a clinic. EMRs perform functions like scheduling or hosting medical records used by physicians and other staff [1]. A certain time comes when it is necessary to upgrade or change EMRs to maintain efficiency in a clinic. The most arduous part of changing a clinic's EMR is migrating the clinical data from the old EMR to the new. This paper explores the feasibility of data migration between two Electronic Medical Records using open source technologies. This enables smaller clinics to change EMRs when the need arises without incurring huge costs. Using Mirth Connect as a data integration engine and OpenEMR as the new EMR we successfully migrated data from our old EMR to OpenEMR.

Keywords. EMR, data migration, Mirth Connect, OpenEMR

1. Introduction

For decades, physicians have primarily relied on their own judgement when making treatment decisions. Over the years the transition to clinical decision support systems has been aided by the development of various electronic medical records. Usage of electronic medical records has been rising with the 2014 National Physician Online Survey reporting that 75% of Canadian physicians are using electronic medical records [2]. A clinic's requirements can change over time and the EMR used will need to evolve to those changing needs. As new electronic medical records are being developed with more novel technologies, doctors have the opportunity to take advantage of these new systems. However, upgrading or switching EMRs provides a challenge. Migrating all the clinical data from an old EMR to a new EMR can prove very costly.

We wanted to know if there was an alternative to large commercial EMRs for small clinics and if there was a way to migrate data from the old EMR to the new one using easily available technologies. We can take advantage of open source software to construct a solution that will enable a clinic to migrate all of their data should they need to change EMRs.

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2. Methods and Materials

2.1. Data Communication Standards

In order to successfully to connect two EMRs, the messages between the two must be standardized. A combination of Health Level 7 Version 2.x (HL7v2) and custom XML allows for a flexible structure in which data is shared.

HL7v2 is an international communication standard that enables the sharing of electronic health information [3]. It dictates both the semantic standards of clinical data in a message as well as the packaging of said message.

Custom XML formats allow for alternative data points that don't otherwise fall within the HL7v2 standards to be transmitted.

2.2. Communication Server

Mirth Connect Version 3.x is a cross platform health care integration engine [4]. It utilizes a channel based architecture to connect systems and allows messages to be filtered, routed or transformed based on user defined rules.

A Mirth Connect channel consists of four parts: the source connector, filter, transformer, and destination connector [5]. The source connector is responsible for receiving raw messages from the source system and transmitting encoded messages to the destination system, which the destination connector receives. The filter is used to determine whether a message will proceed to through the channel while the transformer can then modify the message. Message modification can range from changing certain fields to changing data types or even the structure of the inbound message. Figure 1 shows the message-processing flow of a Mirth Connect channel.

The message-processing flow is divided into a series of steps between the source connector and the destination connector [6]. First, the raw messages flow into a source connector and are converted to XML through a pre-processor script. Then the data can be filtered or transformed, however the implementation of a filter and transformer is optional. Finally, the message needs to be encoded and sent to a destination connector.
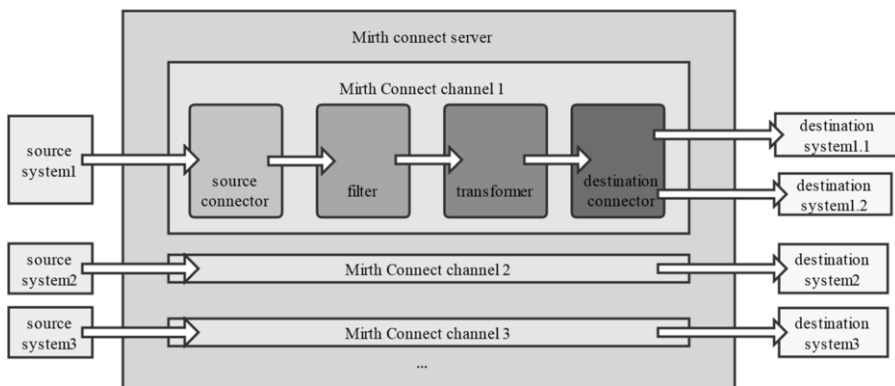
Figure 1. Messaging-process flow.

There can be multiple destination connectors and data can be filtered and transformed again before moving on to the destination system.

3. Case Study

Our clinic uses a custom EMR, the Vistacan Health System (VHS), that is integrated with the Veterans Health Information Systems and Technology Architecture (VistA). Clinicians can make appointments, view patient demographics and submit billing claims through Teleplan with VHS, but the system is fragmented. Clinical data exists both on a MySQL database for VHS and on VistA, with some fields not being shared. Billing options are also limited when third party insurance or cash is used. The EMR also served two separate locations, with limited features to support this. Additional maintenance and development costs to improve the system initiated the process to switch to an alternate EMR.

The most apparent problem with switching our EMR after several years of use was how to migrate the data between the old and new EMR. After exploring several options, it was apparent that most data migration services were going to be costly. We also had to consider which EMR would be most suitable for our clinic and the destination of said data. OpenEMR is a free open source electronic health record and medical practice management application [7]. Certain features like its Patient Portal, the web client, and support of file uploads were appealing (Figure 2). However, it was chosen primarily because of its open source nature and active development community [8]. This would allow us to customize the software to implement custom solutions.

We were in a unique situation where we had access to the source code and databases of the destination and source EMRs. The open source nature gave us the option to develop a data migration solution between the old and new EMR instead of using a third party. We decided to use Mirth Connect, which is also open source, as the primary

	VHS	OpenEMR
Open Source	YES	YES
Free	YES	YES
patient portal	YES	YES
Scheduling	YES	YES
File Upload	NO	YES
Web Client	NO	YES
development community	NO	YES

Figure 2. Features of VistA and OpenEMR.
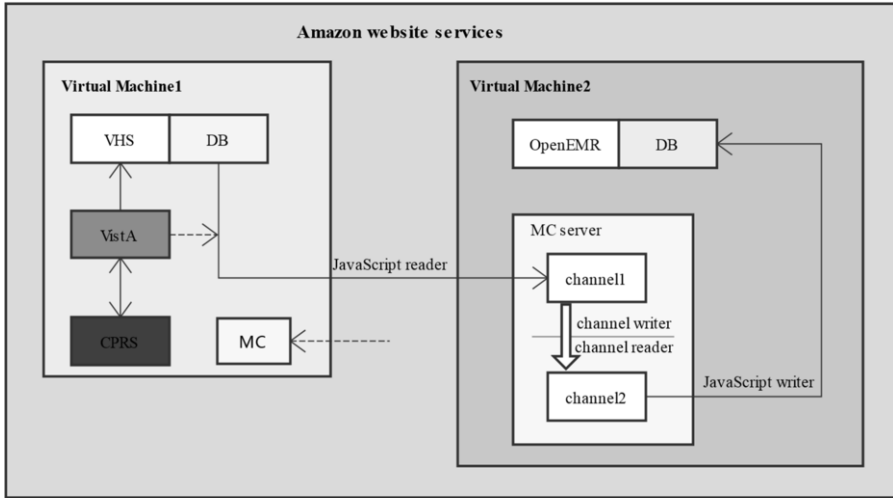
Figure 3. Data migration from VHS to OpenEMR.

method of data transfer. The most challenging part for our data migration was mapping the data points. Finding the proper source and destination of the data and the validation was also the most time consuming. Once the source and destination locations for the data was determined, all that was left was configuring the channels.

As shown in Figure 3, there are three channels deployed on the Mirth Connect server to migrate data from VHS to OpenEMR. The source system and destination system of channel1 is the database of VHS on VM1 and channel2 on VM2. The data extracted from VHS database is converted to XML through a pre-processor script and then is transformed to HL7 through a transformer. In this channel, the source connector type and destination connector type are JavaScript reader and channel writer. Channel2 connects channel1 and the database of channel2 so the processing steps were different in this transformer. In this transformer, the HL7 data from channel1 is written into the OpenEMR database rather than converted to another data type. Entering the data was as simple as writing a SQL command. The channels are deployed if data is updated or new data is added in VHS, allowing OpenEMR to have the most up to date information.

4. Conclusion

Changing EMRs can be a daunting task that requires the transfer of a lot of clinical data in order to make the switch. Sometimes clinics have no choice but to go with an EMR that offers data migration or use a third party service. However, there is an alternate solution for clinics that are small enough in scope that such an upgrade would be too costly. Choosing an open source EMR and using Mirth Connect as a data migration tool allows users to be in full control of the process. Mirth Connects' extensible architecture allows users to create their own plugins, connectors and extensions ensures that it can conform to the user's unique needs. Access to the database and schema of both the source and destination EMR is necessary but once this criteria is met the most challenging part

will be mapping the data between EMRs. After the initial data migration and successful move to the new EMR the channels were disabled but we believe Mirth Connect will be useful in future projects that require integration with other health information systems.

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A Preliminary Conceptual Framework in Knowledge Translation and Health Information Technology for Transparency in Policy-Making (The KhITT Framework)

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Abstract. A preliminary conceptual framework on knowledge translation and health information technology is proposed for transparency in policy-making process. Three domains and ten recommendations/dimensions are briefly described.

Keywords. knowledge translation, evidence-based health policy, health information technology, transparency, conceptual framework

1. Introduction

We live in an era of rapid and continuous change. Globalization has raised the expectations for individual and collective growth and well-being. We must align our focus and efforts toward stronger collaborations and innovative and effective products and solutions. Understanding the priorities and processes that influence health policies and their implications for health outcomes is fundamental. Today more than ever, policy-makers (PMs) need evidence taking into consideration better use of scarce resources. Recently, we have witnessed instead a movement toward policy-based evidence that was depicted in a clever cartoon in the *New Yorker* newspaper: a policy-maker handed a paper to an advisor saying, "Here is my policy; go find some evidence based on it" [1].

2. What Is It…?

In the literature, there is an ongoing debate between KPs and PMs about evidence-based health policy (EBHP), mainly because of a misunderstanding or lack of common definition of evidence [3, 4]. Brief definitions of the main concepts used in this paper are described next.

Knowledge – has been categorized as *propositional* (i.e., formal, explicit, derived from research that can be generalizable) and *non-propositional* (i.e., informal, implicit, derived primarily through practice such as tacit knowledge of professionals or personal knowledge from experience, cognitive resources, and beliefs) [5]. Knowledge in health is generated from different types of *evidence* [6]: research

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findings, clinical experience and expertise, patient values and preferences, and local context and environment [5]. By combining both propositional and non-propositional knowledge we bring together the external (scientific) and internal (intuitive) approaches to knowledge [7].

Knowledge Translation (KT) – Is "a dynamic and iterative process that includes synthesis, dissemination, exchange and ethically-sound application of knowledge to improve the health of Canadians, provide effective health services and products and strengthen the healthcare system" (http://www.cihr-irsc.gc.ca/e/29418.html#2). This process takes place within a complex system of interactions between KPs and knowledge users (including PMs), which may vary in intensity, complexity and level of engagement depending on the nature of knowledge [7].

Policy-making – Is a messy, iterative process with various opportunities to incorporate evidence and strengthen decisions [8].

Evidence-based health policy – Paraphrasing Sackett and associates' [9] definition of evidence-based practice (including policy-making), EBHP is the integration of individual professional (i.e., PM) expertise, through experience and practice, with the best available research findings in the context of specific preferences and values.

Health Information Technology (HIT) – Is technology applied to the health sector that supports information management across computerized systems and improves all aspects of healthcare (e.g., safety, effectiveness, timeliness, equity, efficiency). Open access sources of information embodies radical change, makes HIT broadly available, and provides a forum for sharing information and knowledge toward democratic action. This model of open communication could become a model for political discourse among KPs and PMs.

Transparency – Means openness, accountability, obligation, and honesty to share information/knowledge with the public.

3. Framework For EBHP

In this environment, a vision is described next for an ideal health system where everything will be digitalized, open source, evidence-based, and transparent. That health system will lead in fewer adverse events; better patient, provider and system outcomes; and less corruption by focusing on three main principles: a) *Collaboration* between researchers/knowledge producers (KPs) and PMs for sharing understanding of an issue, and accepting each other's cultural manifestations; b) *Development* of a robust mechanism at organizational level for synthesizing existing knowledge on a topic; and c) *Communication* of synthesized evidence in friendly to policy-makers forms [2].

To actualize this vision, a conceptual framework (Figure 1) is proposed that builds upon the strong commitment of KPs and PMs to effective solutions. These communities with distinct professional cultures that keep them working separately in isolated silos need to connect, communicate, understand each other, and collaborate by using technology. Their collaboration would enhance efforts to set and realize high-reaching goals. This framework aims to ***support*** strong relationships between KPs and PMs; and ***inspire*** individuals and the public to commit to excellence in engaging communities and stakeholders toward transparent, system-based knowledge
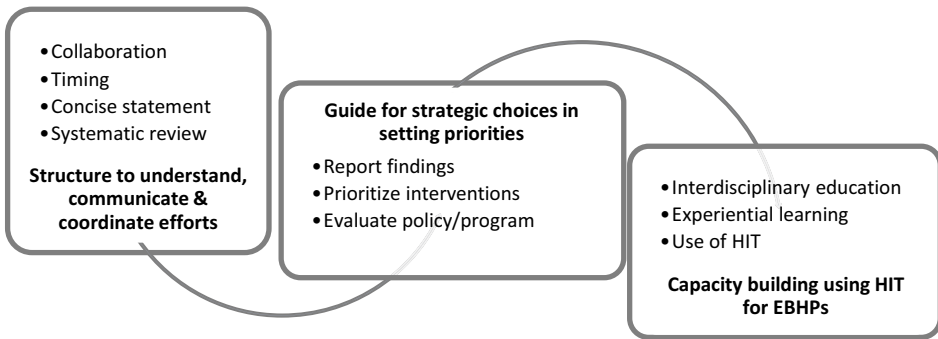
Figure 1. Conceptual Framework for Evidence-Based Health Policy (EBHP).

dissemination and EBHPs. The framework suggests use of technology that supports the development of innovative health policies. It is comprised of ten recommendations organized within three domains:

1. To provide a structure for understanding each other's perspective, improving communication, and strengthening coordinate efforts for effective solutions.
2. To serve as a reference and guide for strategic choices and setting priorities and strategies in incorporating evidence into health policy innovation.
3. To nurture (capacity building) existing and emerging KPs and PMs interested in promoting EBHPs by exploring ways to use health information technology.

This framework emphasizes the important contribution of HIT as a useful tool to increase knowledge translation and transfer via communication among KPs and PMs that may result in transparent use of evidence and network in developing EBHPs [10]. Sharing knowledge is a complex process that also incorporates sharing of cultural aspects, which in turn may reduce KPs and PMs cultural differences and increase use of common language [10].

3.1. Domain 1: Structure To Better Understand, Communicate, and Coordinate Efforts

<u>Recommendation 1</u>: *Collaboration*. Innovative rules and laws need to be developed to reinforce PMs and KPs on a certain topic to work together for developing a health policy. Health ministries and academia need to closely collaborate in several ways. For example, PMs to participate in supervisory committees of graduate students, while KPs to sit with PMs for early discussion on a topic.

<u>Recommendation 2</u>: *Timing*. Immediately upon an issue come in PMs' attention, they need to invite KPs for collaboration. PMs usually need time to understand an issue or problem, collect opinions and different stakeholders' perspectives, and to study relevant to the issue documents before drafting a policy. Since a knowledge synthesis study takes time (6-12 months), timing is one of the most important factors for PMs and KPs to achieve collaborative goals for EBHPs and transparency.

<u>Recommendation 3</u>: *Concise statement*. In collaboration, PMs and KPs develop a clear politically and scientifically acceptable statement of the issue under consideration as early as possible for enhancing the possibility of a systematic and focused priority-setting approach [11]. The statement includes

- Complete description of the problem/issue
- Potential solutions being considered; each scenario demonstrates a different set of reasons, circumstances, ways of thinking, and approaches
- Community (or needs) assessment based on different primary or secondary types of data and sources (e.g., epidemiologic/quantitative, qualitative)
- Funds that may be available toward the development of the new policy
- Timeline about the shortest period of time for response related to the issue
- Relevant stakeholders who may involve in the policy-making process
- Potential health-related outcomes that the development of the new policy might influence (e.g., prevention of a disease, treatment of a chronic health situation).

Recommendation 4: *Performance of a systematic literature review*. After developing the statement, KPs and PMs together need to plan a systematic (or rapid) review focusing on the issue. Both groups of professionals are members of the research team [12].

3.2. Domain 2: Guide For Strategic Choices In Setting Priorities

Recommendation 5: *Briefly report research findings in a friendly to PMs form*. The findings of a systematic literature review need to be in a form friendly to policy-makers.
Recommendation 6: *Prioritize innovative and creative interventions*. For every problem, there is a solution. Developing an action plan and implementation of interventions is one of the initial steps toward the development of a policy.
Recommendation 7: *Evaluate the suggested policy & advance evidence-based policy*. When an EBHP is prioritized, evaluation is an integrative component of the process. Evaluation includes various aspects of the implementation (e.g., satisfaction of the public) and periodical measures of engagement between KPs and PMs [13].

3.3. Domain 3: Capacity Building Using HIT For Promoting EBHPs

Recommendation 8: *Interdisciplinary education for EBHP*. Interdisciplinary training of healthcare practitioners and PMs for EBHPs is fundamental [11], in order to focus attention, resources, and collaborative work on intentional and mission-driven efforts [14]. Their common education might be essential to enhance competencies, improve performance and impact, achieve a supportive culture of collaboration and for innovation [13], and implement evidence-based policies.
Recommendation 9: *Experiential learning for both KPs and PMs*. Training and mentoring graduate students, faculty and policy-makers in research, and knowledge translation activities using workshops and seminars is a promising way for systematically building capacity [13]. Also, developing strategies and mechanisms (e.g., placements for PMs/graduate students/faculty in-residence) may nurture trusted relationships, engagement and networks between KPs & PMs [13].
Recommendation 10: *Use of information technology for communication, sharing experiences, collaboration*. HIT is an effective mechanism that significantly contributes to enhance transparency and quality in health services [15] and knowledge translation [10, 16]. PMs and KPs need to use HIT for analyzing reliable large datasets, better communication and sharing knowledge to co-develop EBHPs.

4. Conclusions

The development of information and communications technologies has dramatically changed the context and way we accumulate evidence and make policies. Access to evidence, including academic and grey literature, used to depend on consultants or other persons who had access to libraries and knew how to navigate scholar journals. Attempts to develop searchable online databases changed the way policy-makers access evidence. However, we need more efforts to enhance collaboration between knowledge producers (researchers) and knowledge users (e.g., policy-makers) to develop evidence-based health policies. The proposed framework for EBHP is focusing on ten recommendations within three main domains based on three principles: Collaboration between researchers and policy-makers; development of a robust organizational mechanism for knowledge syntheses activities based on policy-makers' interestingtopics; and communication and sharing the synthesized research findings in a policy-maker friendly form.

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Modeling Keyword Search Strategy: Analysis of Pharmacovigilance Specialists' Search of MeDDRA Terms

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Abstract. In the information retrieval task, searching and choosing keywords to form the query is crucial. The present study analyzes and describes the keywords' search strategy into a thesaurus in the field of pharmacovigilance. Two ergonomics experts shadowed 22 pharmacovigilance specialists during their daily work. They focus on the strategies for searching and choosing MeDDRA terms to build pharmacovigilance queries. Interviews of four pharmacovigilance specialists completed the observations. Results highlight that, for unusual or complex searches, pharmacovigilance specialists proceed iteratively in three main phases: (i) preparation of a list of terms and of evaluation criteria, (ii) exploration of the MeDDRA hierarchy and choice of a term, and (iii) evaluation of the results against the criteria. Overall, the search and the choice of keywords within a thesaurus shares similarity with the information retrieval task and is closely interwoven with the query building process. Based on the results, the paper proposes design specifications for new interfaces supporting the identification of MeDDRA terms so that pharmacovigilance reports searches achieve a good level of expressiveness.

Keywords. Cognitive work analysis; pharmacovigilance; MeDDRA; Information retrieval; Modelling;

1. Introduction

Information retrieval (IR) from a database is a complex cognitive work that has been the object of different kinds of modelling [1]: some models describe the IR behavior [2] while other, explicative models, represent the cognitive activities underpinning this behavior [3]. Despite their differing perspectives, both kinds share common features [1]. First, they all consider that the IR work comprises three main steps: (i) identifying the research question, (ii) expressing and performing the query, and (iii) analyzing, synthesizing and evaluating the results compared to the research question. Second, IR is an iterative process with loops between the above-mentioned steps.

For instance, Sutcliffe and Ennis [4] (Figure 1) highlight how the initial search question is turn into needs, then into a query entered in an IR system that provides in turn

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results that are evaluated by the users against their expectancies. This model considers various kinds of iterations: unsatisfactory results lead to reformulate the query or to rephrase the needs, while a failed search leads to changing the initial question. Iterations will stop as soon as the results are satisfactory. Two kinds of knowledge may impact the search strategy. User's knowledge of the problem domain deeply influences the way the initial problem is turn into needs, along with the way the query will be formulated, and the results evaluated. User's knowledge of the technology supporting the search impacts the formulation and the execution of the query in the IR system.
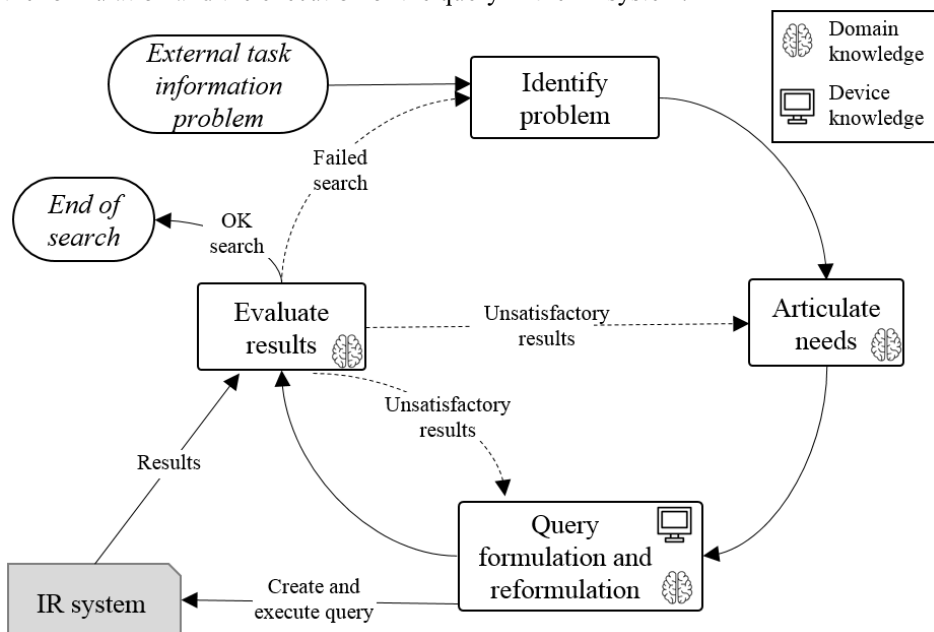
Figure 1. Model of information searching activities and knowledge sources adapted from Sutcliffe and Ennis [4]. Icons represent the type of knowledge that impact the steps of the process.

A crucial element in the IR strategy is the choice of the keywords forming the query. It has been shown that different users with the same background may use different keywords to formulate a query in response to a unique question [5]. This heterogeneity in the keywords chosen may questions the relevance and the expressiveness of the results. Yet, despite the importance of this step, as far as we know, no study explains how users search and choose keywords from a terminology to formulate a query. This study aims to describe the keywords' search strategy into a thesaurus in the field of pharmacovigilance.

2. Background: the PEGASE project

Pharmacovigilance is "the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem" [6]. In France, pharmacovigilance specialists (PVS) of regional pharmacovigilance centers are in charge of analyzing and reporting the adverse drug reactions (ADR) noticed by healthcare professionals and patients to healthcare authorities. For this purpose, they enter the reports into a national online database and codify the ADR using one or several

terms that closely capture the original verbatim. They also search in the database to answer either clinicians' questions about side effects of a medication, or authorities' questions about unexpected drug safety problems (signal detection task). For this, they search existing reports in the database with the keywords used to code the ADR in conjunction with the name of the drug incriminated. In this context, a standardized medical terminology thesaurus, MedDRA® (Medical Dictionary for Drug Regulatory Activities), is useful to unify the codification of the ADR in the reports.

Yet, depending on the PVS' background (e.g. physician or pharmacist) and experience, and on the initial description of the ADR (symptoms of the patient, level of precision, wording), different MedDRA terms may be used for coding this ADR. Then, when PVS need to identify all reports related to a given type of ADR, they first need to identify all MedDRA terms that may have been used to code it. Those terms may be scattered all over the MedDRA hierarchy which makes difficult to find them all and achieve a good expressiveness of the results. The PEGASE national project aims to develop usable tools that help PVS to find all relevant MedDRA terms and to ensure searches achieve a good expressiveness. The present paper reports on the first part of this project: analyzing and modelling PVS' strategies to search and choose MedDRA terms that will form a query.

3. Method

In 4 French regional pharmacovigilance centers partners of the project, 2 ergonomics experts (LD & RM) independently shadowed PVS during their daily work focusing on their strategies for searching and choosing MedDRA terms while searching reports. PVS were asked to think-aloud while performing their searches. Their interaction with the online report database, their behavior and their verbalizations were transcribed for analysis.

Besides, during complementary individual interviews, 4 PVS (one per center) were asked to explain how they would have chosen MedDRA terms in 3 realistic pharmacovigilance scenarios designed by a pharmacist expert in pharmacovigilance (CB): 2 searches to answer clinicians' questions (one "easy", the MedDRA term is mentioned in the question, and one "complex", the case includes multiple symptoms and no MedDRA term is mentioned), and one search in the context of signal detection. Participants were asked to justify each step of their decision-making process. Their decisions and explanations were recorded and transcribed for analysis.

Finally, all data were analyzed to identify the invariant strategies implemented for searching and choosing MedDRA terms along with the variations and their causes. The strategies were modelled through the analytical description method (MAD [7]).

4. Results

A total of 22 PVS were observed (36h10). The complementary interviews lasted 4h. The strategies for searching MedDRA terms for detecting a signal and for answering a clinical question differ from each other on the need for results' exhaustivity. In the context of the signal detection, PVS select the MedDRA terms so that they are sure the query identifies all relevant reports. When answering a clinician's question, PVS may be content with a sample of relevant reports as soon as they enable them to answer the question asked and

give insights on how to fix or manage the ADR. Apart from this difference, the search strategy is roughly the same.

When searching reports of common ADR, PVS know the MedDRA terms and do not have to search them. On the contrary, for unusual or complex searches, PVS do not know the relevant MedDRA terms and must proceed iteratively to find the right one(s). They proceed in 3 main phases (Figure 2):

- *Preparation of a list of terms and of query evaluation criteria.* Based on the verbatim of the ADR notification, on their experience and on their expertise, PVS think to a term or several terms that may represent the ADR. They also mentally estimate the number of reports they expect to find in the database (e.g. dozen or thousands) based on the characteristics of the drug incriminated (date of marketing authorization, class of drug) and of the ADR (known frequency of the effect, amount of documentation about the pair drug-effect).

- *Exploration of the MedDRA hierarchy and choice of a term.* PVS enter successively each MedDRA term they have in mind into the online report database and explore the MedDRA hierarchy around this term by checking its filiation and relatedness[2]. From the term initially entered, they move up and down the hierarchy and, at each level, they explore the terms above and beneath it until they find a MedDRA term that includes all terms that seem relevant to describe the ADR, but not too many irrelevant ones. In the context of signal detection, PVS do not consider the number of irrelevant terms: they prefer to get irrelevant terms and therefore irrelevant reports than missing a relevant one.

- *Evaluation of the results against the evaluation criteria.* The term chosen is combined with the name of the drug incriminated into a query in the online report database. Several (combinations of) MedDRA terms may be tested till the number of reports identified with the query meets PVS' expectation or till all possible terms have been exhausted. That way, choosing a MedDRA term is closely intertwined with the query building.
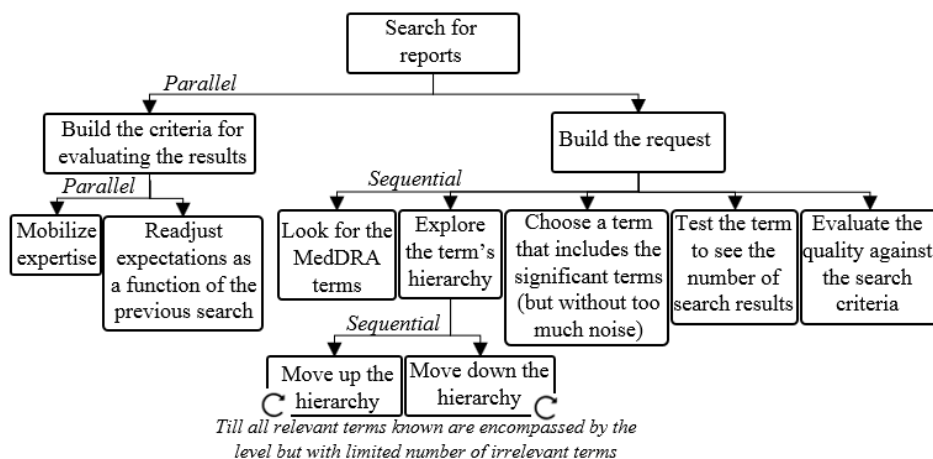
Figure 2. Simplified PVS' MedDRA terms search strategy for answering a clinician's question modelled with the analytical description method.

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[2] The section of the French online report database in which the MedDRA term is entered enables to explore the levels of the MedDRA hierarchy.

5. Discussion

As far as we know, this study is the first to explore how PVS choose MedDRA terms to perform a query in an online report database. To a larger extent, as far as we know, it is the first attempt to model how users of an IR system search and choose standardized terms from a thesaurus to perform a query. Results show that, in the contexts of PVS' answer to clinicians' questions and of signal detection, the search and the choice of keywords within a thesaurus shares similarity with the IR activity as it is usually modelled (e.g. [4]): it is an iterative process based on an informed trial and error approach. Besides, this process is closely interwoven with the query building process and cannot be pulled apart from it. The keyword search and choice strategy could be considered as a subprocess of the IR process and described by Sutcliff and Ennis [4]. For now, the model elaborated from the results of this study applies only to the field of French pharmacovigilance. Similar analyses in other contexts will help generalize it to other pharmacovigilance contexts and finally to any kind of search strategies into a thesaurus.

In the frame of the PEGASE project, this model was used to develop design specifications for new interfaces supporting the identification of MedDRA terms so that reports' searches achieve a good level of expressiveness. For instance, to help the PVS choose the best MedDRA term(s) amongst several, the search interface should present each MedDRA term at its place within the hierarchy with its filiation(s) and relatedness to enable PVS to compare them. Moreover, after having entered the drug name into the online database, as soon as PVS click on a MedDRA term, the interface should display the number of reports that are indexed with this term. It will inform them directly about the relevance of the term in comparison to the defined evaluation criteria. A total of 22 recommendations have been given to designers. Three different interfaces are under development and will undergo user testing.

Acknowledgment

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Uncovering the Mysteries of Electronic Medication Reconciliation

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Abstract. Island Health Authority ordering providers and staff continue to experience challenges related to electronic medication reconciliation. A *Think Tank* was created to seek a deeper understanding of the reasons why end users were experiencing challenges with documenting home medications, managing conversion failures, and writing prescriptions. Strategies to improve configuration, education, and process are underway.

Keywords. electronic medication reconciliation, end user experience, synonyms, conversion failures, medication order sentences

1. Introduction

Electronic medication reconciliation (eMedRec) is a complex process. For some, medication reconciliation is a new concept; for many, the first implementation of eMedRec within Island Health Authority's Nanaimo Regional Hospital (NRGH) may have had unintended consequences on ordering practices, end user experiences, and the delivery of patient care. An Island Health Authority interdisciplinary *Think Tank* was formed to closely examine eMedRec.

Think Tank participants consisted of clinical informaticists, providers, pharmacists, pharmacy informaticists, medication safety and professional practice consultants, and educators. Workflow analysis and detailed testing were conducted over a series of four workshops. Simulating best possible medication history (BPMH) processes, included reviewing content on prescriptions, physician home medication lists, and interviewing a patient as well as provider reconciliation workflows, participants observed the flow of data and how it 'behaved' differently when using different medication synonym orders. Through didactic conversation, open dialogue, and interprofessional discourse, knowledge from multiple perspectives was shared. This supported a deeper understanding of *why* the data behaved differently; some of the mystery and unknowns were uncovered. This paper describes eMedRec definitions and processes, highlights end user experiences, and provides recommendations.

2. eMedRec Definition and Processes

Medication reconciliation (MedRec) is defined as a systematic process in which healthcare providers collaborate with patients, families, and other care team members to

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ensure that comprehensive and accurate medication information is communicated across transitions of care [1]. It is a term that is used to describe *both* (1) an over-arching process that includes multiple disciplines as the patient is admitted, transferred, and discharged across care venues and (2) a discrete task of ordering providers deciding which medications to stop, start, and continue, and resolve discrepancies[2]. Traditionally, MedRec has been conducted on paper; integration of an electronic health record (EHR) supports electronic medication reconciliation (eMedRec).

eMedRec begins with a BPMH. Multiple sources of medication information are reviewed; an electronic home medication list is documented and available for all current and future encounters. During admission reconciliation, the provider reviews the home medication list, resolves discrepancies, and places electronic inpatient orders. As the patient transitions into the next level of care, transfer reconciliation is performed. When the patient is ready to be discharged, the home medications and inpatient orders are reviewed, discrepancies are resolved and, when required, prescriptions are created. A discharge medication list automatically populates into a discharge document. Finally, through either a printed handout or electronic distribution, changes or additions to home medications are communicated to the patient and those providing support.

While the intent and processes of medication reconciliation may seem clear, end users continue to express concerns. As eMedRec adoption and compliance are low, patients continue to be discharged without a clear understanding of their home medication regimen.

3. Background

Island Health Authority (IHA) utilizes *Cerner Millennium* (CM), a proprietary electronic health record (EHR). Electronic medication orders and medication documentation are among many of the integrated processes. Historically, IHA's medication order catalogue supported primary care providers; custom order sentences were built in the outpatient venue for both home medication documentation and prescriptions. While this custom build supported primary care medication management, it did not support robust eMedRec processes.

In early 2014 IHA initiated IHealth; an organizational transformative change supporting the vision of *"One Person, One Record, One Plan for Health and Care"*[2]. Medication orders and medication reconciliation processes were included in system, integration, and end user testing events leading up to implementation. Workflow testing included nurses or pharmacy technicians reviewing multiple sources of information and interviewing the patient and/or family to complete electronic home medication documentation. Home medications were available for ordering providers to electronically reconcile. Inpatient orders were managed using admission and transfer reconciliation interfaces; at time of discharge both reconciled and non-reconciled home medications were available to prescribe, stop, or continue. Ordering providers printed the prescription; the discharge medication list automatically populated discharge documentation. IHA staff and ordering providers tested workflows using the historical medication catalogue; order conversions at time of reconciliation appeared appropriate; order sentences appeared to support workflow. Based on all testing cycle feedback,

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[2]MedRec refers to the over-arching process of medication reconciliation; discrete acts of provider ordering will be written as "admission reconciliation", "discharge reconciliation", and "transfer reconciliation".

IHealth leadership supported implementation with a back-up plan to revert to paper reconciliation processes and hand written prescriptions. As of March 2016 eMedRec went live in congruence of a fully integrated EHR including inpatient ordering and electronic documentation at IHA's NRGH. Unfortunately, a decision to integrate *PharmaNet* negatively affected end user experience.

PharmaNet is British Columbia's provincial pharmacy dispensing database. Pharmacists working in community pharmacies record the medications dispensed when patients fill prescriptions. The database provides medication information such as the product name (e.g. 'morphine extended release'), the number of units provided for the dose (e.g. '1') and the drug form (e.g. '1 tablet'). By selecting '*External Rx History*' in CM clinicians are provided with a side-by-side view of dispensed medications from *PharmaNet* as well as previously documented home medications. The ability to review recently dispensed medications while updating a home medication list supports best possible medication history processes. Unfortunately, the decision to integrate *PharmaNet* was made shortly prior to implementation. As it required a different order sentence strategy, one that aligned with CM standard order sentences rather than historical custom sentences, the hybrid medication catalogue had not been robustly tested with end users. End users expressed challenges shortly after implementation, adoption of eMedRec was impacted.

Many ordering providers reverted back to a hybrid medication reconciliation process. A printed home medication list from *PharmaNet* was used to electronically add home medications to inpatient orders; providers returned to handwritten prescriptions and manual documentation of home medications in discharge notes. With poor adoption of eMedRec, a decision to remove the automated discharge medication list from patient handouts was made. Indeed, medication reconciliation processes remain an accreditation concern for both hybrid and electronic processes.

4. End User eMedRec Experiences

Within NRGH, Specialty and Primary Care Providers provide care for approximately 200 admitted patients. On average, eMedRec is being completed for 40% of admissions and 37% of discharges from inpatient care. Of all admitted patients, 23% are receiving a full eMedRec. These rates have been declining [3]. Frustration, confusion, and loss of trust in the system are a few of the emotions that have been expressed. While some providers have persevered, others no longer utilize eMedRec tools. Indeed throughout the workshops, the *Think Tank* also experienced data behaving in a seemingly mysterious or unpredictable fashion. Through a lens of curiosity and focused effort, members of the *Think Tank* identified three of the most challenging components to navigate:

1. Search struggles with result returns when searching for medication orders,
2. Conversion confusion regarding auto conversion and failure resolution, and
3. Prescription paralysis related to difficulty with prescribing

4.1. Search Struggles

End users search for medications when documenting BPMH and/or creating prescriptions. Complaints center on ubiquitous search returns. Ultimately, the root cause is a design decision to use a system setting that employs a proprietary search algorithm intended for ease of use. The unintended consequence on the end user is the cognitive

overload sorting through a large number of search returns. Teams who are responsible to meet the needs of end users are challenged in finding the optimal number of order sentences to be returned by searches. While search tips, such as entering the medication name, drug form, and dose will refine the number of returns, end users are reluctant to modify search practices.

4.2. Conversion Confusion

Within CM there are two separate venues: (1) outpatient which involves home medications and prescriptions, and (2) inpatient which involves inpatient medications and order sets. These two venues are architected to exist as distinctly different lists within the patient's health record. As such there is a necessity for *conversion* of medication orders from one venue to another at different stages within the eMedRec process. For example, home medications and prescriptions are converted to inpatient medication upon admission and vice versa upon discharge. Generally, this transformation happens automatically within the system. Complex conversion logic directs the behavior of a medication order at points of conversion such as a home medication converting to an inpatient order and an inpatient order converting to a prescription.

Conversion logic is based on order synonym types; order synonyms are not physical products but, rather, *refer* to medication orders that will ultimately result in a dispensed product. Synonyms range from general such as generic (Primary) and brand name (Brand Name) to specific products such as product level synonyms (PLS). PLS will include either the generic or brand name in the description displayed to the end user; they also include specific details such as strength and drug form. Different types of synonyms may be used for the different venues of care delivery.

Table 1. Synonym Types and Examples in Inpatient and Outpatient Venues[3]

Synonym Type	Orderable Example	Inpatient/Outpatient Venue
Primary	Metoprolol	Both
Brand Name	Betaloc	Both
C-Dispensable	Metoprolol inj	Both
M-Generic	*Not currently built*	Inpatient
N-Trade	*Not currently built*	Inpatient
Y-Generic	Metoprolol 100 mg oral tablet	Outpatient
Z-Trade	Apo Metoprolol 100 mg oral tablet	Outpatient

As BPMH is the first step of the eMedRec process, what synonyms are used to document home medications will affect auto conversion. Each synonym type follows its own conversion, or hierarchy path, to determine an appropriate match (Table 2). For example, a primary synonym will only convert to a primary synonym. A brand synonym will convert to a brand synonym, if a brand synonym is not available it will look for an 'N' synonym, if an 'N' is not available, it will look for a 'C' synonym, if a 'C' synonym is not available it will look for a 'primary' synonym. If there is no primary synonym, the end user will experience a conversion failure.

Table 2. Synonym Conversions from Home Medications to Inpatient Medications[4]

From Synonym Type	To Synonym Type for Matches
Primary	Primary
Brand	Brand>N>C>Primary
C-Dispensable	C>M>Primary
M-Generic	M>C>Primary>M other
N-Trade	N>Brand>N other > C> Primary
Y-Generic	M>C>Primary>M other
Z-Trade	N>Brand>N other>C>Primary

Auto conversion failures can happen due to multiple reasons such as lack of a therapeutic substitution build, vendor limitations with respect to PLS auto conversion, and differences between medications available in the community versus hospital/provincial formulary. Troubleshooting auto conversion failures by pharmacy informatics is complex and often completed retrospectively.

The end user experiences conversion failures by a window that disrupts their ordering process. While the content in the window is intended to support clinical decision-making about alternative medications, there are several concerns from an end user perspective:

- Auto conversion failures display too often and for commonly ordered medications.
- End users remain unsure which alternative to select as they may be unfamiliar with the alternative medications listed.
- Prior to implementation, substitution to alternate medications would have been completed by pharmacists.

Another layer of complexity is experienced during reconciliation. Because of the conversion logic, the appearance of orders may automatically change. PLS are commonly used in the outpatient venue and are expressed using a volume dose due to the strength and form being a part of the synonym (e.g. *metoprolol (metoprolol tartrate 100 mg oral tablet)*. Upon conversion to the inpatient venue, non-PLS (e.g. *metoprolol*) are often used and will express the dose as a strength (e.g. *100 mg).*A further confounding issue is the use of a simplified clinical display line (CDL) in eMedRec which does not display all order sentence details. For example the order *morphine (Sandoz SR 60 mg/8hr oral tablet, extended release) 1 tab,* converts to primary *morphine 60* mg with details of the extended release formulation captured within drug form. As the drug form is not displayed as part of the simplified CDL, some end users have mistakenly inferred that their order converted to an immediate release formulation. The concern expressed is that there could be potential harm to the patient. As those end users would not realize that their order is still the same medicinal product, this creates incongruence in their experience.

One final challenge remains with conversion: synonyms that are PLS will convert smoothly at time of prescribing. To the ordering provider, this means that when a home medication that had been originally documented using an order sentence representing a 'C dispensable' synonym at time of admission, dispensing quantity may not automatically complete at time of creating a prescription. Further, in CM current build, only PLS will successfully support e-prescription processes. While IHA continues to print prescriptions, there is keen interest to support future functionality such as the ability to electronically send a prescription to a patient's community pharmacy.

4.3. Prescription Paralysis

There are many nuances to navigate when creating a prescription during discharge reconciliation. While some aspects of the user interface simply require familiarity gained through practice, others seem to remain ongoing challenges for users to make sense of even with repeated exposure. For example, navigating dispense quantity is a significant undertaking. Due to regulatory requirements for prescriptions, dispense quantity is a required field; the prescriber is unable to sign the prescription without entering how many/how much medication should be dispensed. End users report the dispense quantity field for order entry behaves erratically. The *Think Tank* identified the following:

- Prescriptions 'behave' according to how the home medications were originally documented during BPMH. Prescriptions inherit properties from medication synonyms through conversion during medication reconciliation. Depending on the synonym used, the dispense quantity may or may not auto calculate. Unfortunately for end users, synonyms are indistinguishable in appearance, giving rise to an experience of inconsistent or unpredictable behavior of the "dispensequantity" field.
- In some cases, system settings can affect calculation of dispense quantity.
- By design, as-needed ("PRN") medications will not auto populate a dispense quantity.
- How the dose is documented can affect whether dispense quantity can be calculated

Challenges are not isolated to the nuances of the dispense field. Incorrect printer mapping, especially as an ordering provider moves throughout a facility, leads to frustration.

5. Discussion and Recommendations

Prior to the *Think Tank* sessions, understanding of synonyms and conversion logic was only understood by Pharmacy Informatics; appreciation for the deep loss of trust in the system was understood by providers and educators as they are closer to the front-line. As participants shared stories and knowledge, risks were tracked and analyzed, education and practice gaps were uncovered, and mitigation strategies unfolded. It was through the common and vested interest of the *Think Tank* interdisciplinary working group that the dependencies on synonym, order sentence, and conversion strategies for both outpatient (home medications & prescriptions) and inpatient (inpatient orders) venues on end user experiences became readily apparent. Recommendations include but are not limited to:
- Review vendor's assessment of CM system parameters and recommendations to improve auto conversion rates and ordering practices:
  o Move toward vendor-supplied synonyms using CM's medication database *Multum*)
  o Inactivate many of the custom C-dispensable synonyms
  o Review order sentences of custom synonyms and apply them to new *Multum* supplied synonyms
  o Inactivate or hide some of the brand primary synonyms to reduce clutter

- o Decide which synonyms to use for which inpatient orders (e.g. some may be best represented by brand/primary; others by product level such as M, N, Y, Z)
- Review *Think Tank* recommendations with Executive Steering to determine which will be actioned
- Develop a plan for implementation of *Think Tank* recommendations
- Host change management events
- Provide education to fill current state gaps
- Establish a governance structure that will clearly outline roles, responsibility, monitoring, and accountability
- Implement and support front line users with changes
- Create a permanent Working Group to continue to enhance eMedRec process
- Build provincial networks to share ideas related to eMedRec

While eMedRec continues to be a complex process, it is vital to remain curious and unrelenting in uncovering remaining challenges. A *Think Tank* or small working group can provide further insight through interprofessional discussion and discourse, testing of system enhancements, and providing end users with the ability to provide ongoing feedback. Patients' care remains at the heart of why healthcare exists; unsolved challenges of eMedRec should not result in a discharge medication list that is a 'mystery' to providers or patients. Patients deserve to have a clear understanding of which medications they should be taking following discharge in order to stay safe.

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Electronic Physician Profiles: Developing an Interactive Web-Based Report for Physicians at Island Health

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Abstract. Evidence based measurement is accepted as an important aspect of quality improvement. Making this data available to physicians to support them in quality improvement and to inform their practice presents a broad range of challenges. Addressing these challenges requires a solution that allows physicians to leverage the data repositories in the Enterprise Data Warehouse to develop and use evidence based clinical measures using an interactive, user-friendly, and secure infrastructure. In this talk, we discuss key aspects of the development of an interactive web-based report for physicians at Island Health, and present the final product. Given the privacy and security issues surrounding this type of data, a mock profile will be presented, rather than true results for actual physicians. Here, we have developed an initial prototype of a physician level report delivered via Microsoft Power BI as a possible dynamic tool to share these important data.

Keywords. Physician, electronic health record, data integration, evidence-based measurement, quality improvement

1. Introduction

Evidence based measurement is accepted as an important aspect of resource stewardship and quality improvement. Making this data available to physicians to support them in quality improvement and to inform their practice presents a broad range of challenges. Addressing these challenges requires a solution that allows physicians to leverage the diverse data repositories in the Enterprise Data Warehouse (EDW) to develop and use evidence based clinical measures using an interactive, user-friendly, and secure infrastructure. Here, we have developed an initial prototype of a physician level report delivered via Microsoft Power BI as a dynamic, customized tool to share these important data.

2. The Enterprise Data Warehouse

Data warehouses are centralized electronic repositories of information optimized for reporting and analytical functions. Island Health employs an EDW as it includes multiple integrated subject areas allowing for a comprehensive collection of both patient-level and system-wide information. Recent advances in the electronic health record have enhanced availability of physician-relevant data available in the EDW.

Data in the EDW are organized in a star schema, a hierarchical database configuration that contains a primary key table containing measures linked to other descriptive tables. This architecture supports efficiency when querying data. By using iterative and repetitive processes, the EDW allows for easy access to volumes of historical data that are consistently updated on a daily basis. Furthermore, the data are in a "read-only" format to ensure accurate and consistent information is delivered to all users.

The EDW is designed to provide detailed and lightly summarized information to enable authorized users to perform a variety of applications in a secure and efficient capacity. A major feature of the EDW is the assurance of data quality, a data quality engine is used to audit and measure data for ensuring appropriate operations, completeness, and accuracy. A large variety of different data sources are integrated into the EDW, ranging from financial records to detailed patient information. This consolidated wealth of information serves as an integral resource for several current and future clinical applications.

3. Evidence Based Clinical Measures

The Physician Profiles are intended to present providers with information about their patient population, and measures related to the dimensions of quality.

Patient-level summary information is available to each physician, which includes a profile of each physician's patient population, summarizing key patient characteristics (such as age, gender and comorbidities) and providing an overview of the most common kinds of patient groups seen by the physician.

Clinical Measures are developed in alignment with the BC Health Quality Matrix, which assesses quality from individual patient/client, population and system-wide perspectives. The BC Health Quality Matrix was developed in collaboration with the members of the Health Quality Network which included BC's Health Authorities, Ministry of Health Services, academic institutions and provincial quality improvement groups and organizations [1].

The BC Health Quality Matrix includes seven dimensions of quality. Five of these dimensions - Safety, Appropriateness, Accessibility, Effectiveness, and Acceptability - are aimed at quantifying the patient's experience from an individual's perspective as well as at the population level. Clinical quality measures are developed for each of the five dimensions of quality focused on the patient/client experience from both an individual as well as a population perspective. The majority of measures are selected through an iterative consultation process with physicians and departments, though select measures are driven by corporate priorities. At a high level, these measures focus on:

1. Best practice, to help standardize clinical practice and reduce variation to improve patient outcomes and safety
2. Potentially unnecessary care, to help reduce ordering of unnecessary diagnostic tests and treatments through integration with programs such as Choosing Wisely Canada

A small number of measures form a core set that can be compared across all physicians; for example, risk-adjusted ratios for mortality and hospital harm. Risk adjustment for health indicators presented by the Canadian Institute for Health Information can be achieved based on National population statistical coefficients [2],

although measures developed within Island Health can only be risk adjusted based on our patient population data.

The majority of measures, however, are specific to care provided only by a given department (e.g., ED or OBGYN) or are relevant to a subset of departments treating specific population groups (e.g., chronic heart failure).

Two additional dimensions of quality, Equity and Efficiency, are geared towards measuring the system's performance in how care is delivered. Measures to assess the two dimensions of quality focused on the performance of the system in which health care services are delivered are also included, such as length of stay.

4. Secure Infrastructure

Each physician will be able to see their own measures, as well as compare their performance to other groups, where appropriate. Only physicians will be able to see individual physician level results, and each physician will only be able to see their own individual level results.

Data presented by this tool must be kept secure as the content is classified as confidential, meaning the information is protected by Provincial or Canadian legislation or regulations, Island Health policies or legal contracts. An integrated governance system that leverages existing infrastructures within Island Health will be applied. Physicians will only have access to their own patient population data and will not have authorization to view their colleague's information; however, summary measures from all of the respective provider's service will be made available for comparative purposes.

5. An Interactive Web-Based Report for Physicians

The physician profile will be delivered using Microsoft Power BI, an interactive data visualization platform. The reports will be made available on a biannual basis, continually presenting one year's worth of data. By updating the report every 6-months, we will ensure users are viewing current information as well as data that may reflect recently implemented changes in clinical practice.

In addition to providing patient information at the individual physician level, the profiles include overall metrics of the corresponding service or department as well as relevant data from the entire health authority, where applicable. These department and health authority-wide measures act as a reference for physicians to compare their individual metrics to those of their peers. This is an important aspect as peer-based comparisons have been reported as an effective approach to encouraging behavioural change amongst physicians [2, 3, 4, 5]. Furthermore, the local reference comparisons are highly relevant based on the expected similarities in patient profiles and practice patterns.

An important aspect of this report is that it allows for the option to drill-down or interact with the data, enabling users to gain detailed information specific to their patient population. For example, providing safety metrics, such as hospital harm rates, enables a physician to observe the rate within their patient population compared to the population of their department, as well as the overall rate across all applicable services. From this, physicians have the option to view trending data over time, as well as link to individual patient records to view specific details regarding the harm incidents of their patients. This allows physicians to engage with their own data and have access to the most

granular level of information possible. The development and maintenance of the measures, and the report itself, will be done by Island Health staff. This approach was adopted to ensure customizability and flexibility, and enable physicians to access the most useful information possible with the data available.

Resource stewardship is a key role faced by medical staff. Ensuring that the correct data is available to medical staff is a priority for quality improvement work. The goal of this work allows physicians to leverage the data repositories in the EDW to support them in quality improvement and to inform their practice. An understanding of the specific improvement project is required to identify the associated outcome, process and balancing measures. This iterative process of defining the project and obtaining the appropriate measures is accomplished by collaboration between medical staff and data analytics staff. Providing ongoing feedback and appropriate comparisons will support physicians with new information to support excellent health and care for everyone, everywhere, every time.

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Putting Guidelines in the Hands of Patients: A Heuristic Evaluation of a Consumer Mobile Application

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Abstract. Preventive clinical practice guidelines are valuable. However, they are often difficult for primary care providers to implement in the time sensitive primary care setting and alternate approaches warrant exploration. An app called CANBeWell was developed in an effort to allow consumers to identify appropriate guidelines for themselves. Two investigators conducted a heuristic evaluation to identify potential eHealth literacy and usability issues. Several recommendations were made to make CANBeWell easier for consumers to use and understand. CANBeWell is a promising app for deploying preventive guidelines directly to health consumers. Usability testing is planned for the next iteration to ensure that this app meets the needs and capabilities of health consumers.

Keywords. Guidelines, eHealth literacy, health literacy, mobile application

1. Introduction

The Canadian Task Force on Preventive Health Care (CTFPHC) aims to "develop clinical practice guidelines that support primary care providers in delivering preventive health care" [1]. CTFPHC guidelines are based on "systematic analysis of scientific evidence". Thus, CTFPHC guidelines aim to facilitate Canadian primary care providers [PCPs] providing leading practice, evidence-based preventive care for their patients.

Previous research highlighted that PCPs face challenges finding and using guidelines as well as ensuring their currency [2]. Thus, the authors supplemented the CTFPHC with guidelines with those of the United States Preventive Services Task Force (USPSTF) [3] and other literature, for a more comprehensive set of primary care preventive guidelines [2].

Despite the good intentions and potential value of these guidelines in preventive medicine, they are underutilized at present. To increase their adoption, it is imperative to consider alternative methods of deploying preventive guidelines so that they can be efficiently included in clinical practice. A table of the comprehensive set of guidelines is available for PCPs to readily identify which guidelines were appropriate for a patient based on age and sex [2]. However, another approach to implementing guidelines would

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be to allow consumers to find guidelines that are appropriate for themselves. Although the CTFPHC publishes guidelines targeted towards the general public [4] (i.e., health consumers), the content appears to be identical to the information for clinicians and policy-makers. Given that approximately six of ten Canadians do not have adequate health literacy skills [5], many consumers would have challenges finding and understanding which guidelines are appropriate for them. Thus, as currently deployed, the guidelines have limited utility for both clinicians and consumers.

In an attempt to increase the adoption of preventive care guidelines in primary care, one author (CM) guided the development of CANBeWell: a mobile application (app) that conveys the integrated set of CTFPHC and other relevant guidelines for use by both Canadian PCPs and consumers. To increase the likelihood that the CANBeWell app is used in primary care practice, it is important to overcome the current shortcomings of the available guidelines. Namely, the CANBeWell app must a) be usable so that users can quickly identify appropriate guidelines and b) be understandable for health consumers.

Two authors (HM, JG) conducted a heuristic evaluation to assess whether the CANBeWell prototype was meeting these two core objectives. Heuristic evaluation is an inspection method whereby usability specialists compare the system with a defined set of criteria or design guidelines. Heuristic evaluation is quick, inexpensive, and helps identify common issues before usability testing with target users [5].

2. Methods

Two non-clinician investigators (HM, JG) with consumer health informatics backgrounds, who were not involved in the development of CANBeWell, conducted a heuristic evaluation on a preliminary prototype. The investigators assessed usability and demands on eHealth literacy (i.e., how difficult the content may be for consumers to find, understand, and use) using a set of evidence-based heuristics, developed for assessing consumer health systems [5]. Specifically, the nine heuristics (eight general and one optional) used to assess the CANBeWell were:

1. Immediately Inform Users of Purpose and Engage Users, Avoid Registration
2. Use Complementary Interaction Methods
3. Leverage Interactivity
4. Provide Accurate, Colloquial, Comprehensive, Succinct Content
5. Provide Tailored, Flexible, Layered Content
6. Use Visuals to Complement Text, But Avoid Tables
7. Simplistic, Consistent Navigation
8. Simplistic, Consistent Displays
*11. Considerations for Mobile Devices (optional) [5]

One of the investigators interacted with the CANBeWell using a Galaxy Note Edge 6 (Android Version 6.0.1), while the other recorded their findings. CANBeWell allows users to tailor the guidelines shown based on role (i.e., patient vs. provider), sex (i.e., male, female, other), and age. To ensure results were comprehensive, the app was tested using different combinations of user characteristics (e.g., male patient, transgendered patient, female provider) to identify as many opportunities for improvement as possible.

3. Results

CANBeWell demonstrated several strengths. For example, the app did not require users to register or login. The app was aesthetically pleasing and generally easy to navigate. The body figures (see Figure 1b) offered a unique way of navigating to the guidelines. The buttons and font were generously sized and easy to read on a mobile device. On some pages, CANBeWell offered concise information with links to reliable resources.

| (a) | (b) | (c) |
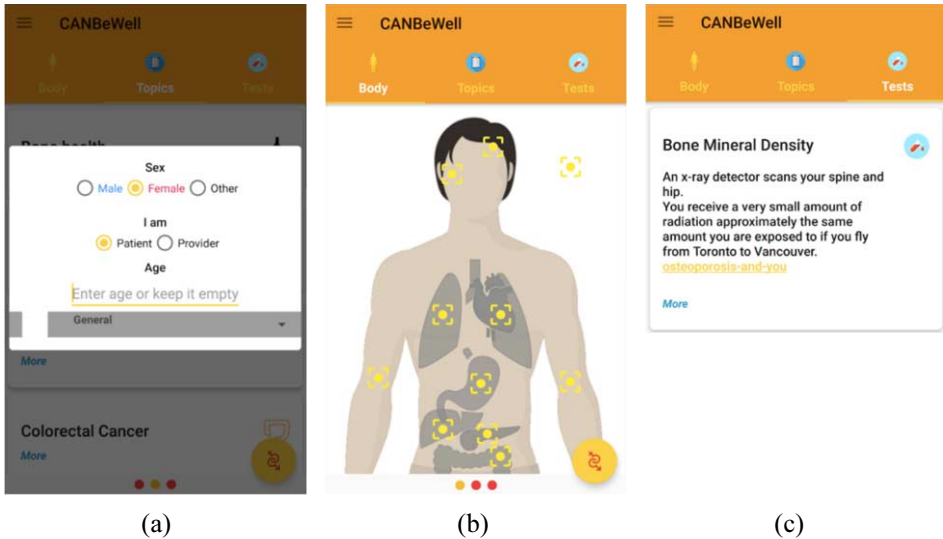
Figure 1. Example Screenshots from CANBeWell a) Tailoring criteria, b) Targets to select guidelines, c) Explanation of Bone Mineral Density.
Produced with permission from Cleo Mavriplis

Despite its strengths, numerous heuristic violations were observed (see Figure 2). These issues represent opportunities to improve CANBeWell to lower demands on eHealth literacy and enhance usability. As such, the investigators made recommendations to improve CANBeWell in its next iteration. For brevity, only select recommendations, with an emphasis on those specifically for health consumers, will be discussed.

The majority of recommendations sought to improve the written content of CANBeWell for consumers and satisfy the heuristic to provide accurate, succinct, colloquial, and comprehensive content. Thus, although as previously discussed some of the pages offered concise information, many other pages had shortcomings from the content perspective. For example, acronyms should be expanded for first use (e.g., AAA, STI) and medical terminology should be explained in the users' vernacular (e.g., high myopia, hypertension). Further, some topics needed more information or explanation to be valuable and other topics had the potential to cause confusion. Additionally, minor typographical issues were observed such as inconsistent capitalization and the use of bullet points.

Importantly, the differences between the provider and consumer information were limited. That is, the content for both the consumer and provider versions of the app were nearly identical. This is concerning because it is doubtful that health consumers will have the knowledge and insight necessary to parse through the clinical terminology and

content oriented towards clinicians. The investigators recommended developing independent apps for consumers and providers to simplify interaction (i.e., users would not have to indicate whether they were providers or consumers) and ensure content was appropriate for consumers.
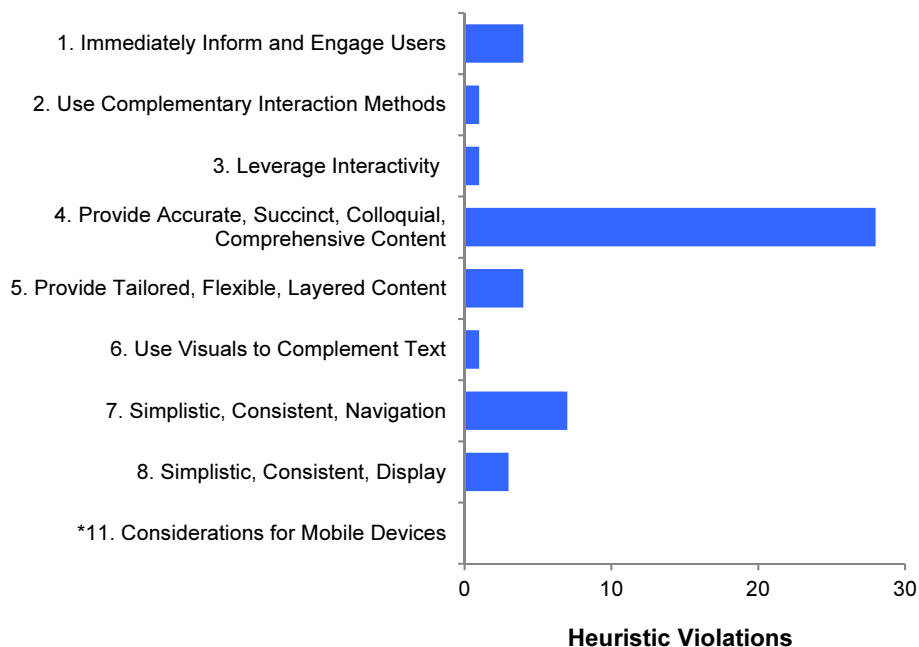
Figure 2. Frequency of Violations as a Function of Heuristic
Denotes optional heuristics from [5] relevant for this evaluation.

To address one high priority issue with the simplistic, consistent, navigation heuristic, a summary of the user entered information (i.e., sex, role, age) should always be displayed to keep the users oriented. It was unclear whether the selections held as the user navigated to different tabs. Further, the active tab should be more visible. Additionally, intuitive names for links should be used and ambiguous names (e.g., link1, ultrasound for AAA, Pros_Cons of tests) should be renamed to explicitly convey where they would redirect users.

Finally, although CANBeWell did provide some tailoring, extensive options were still displayed and could overwhelm consumers. Thus, fewer results should be shown and their appropriateness should be ranked for consumers. With slightly more tailoring (i.e., fewer, ranked guidelines), CANBeWell could support consumers engaging in discussions with their providers.

4. Discussion

This app has the potential to be a very valuable tool for helping consumers increase their awareness of how to prevent disease. However, this investigation revealed several opportunities to lower the demands on eHealth literacy (e.g., improve the content, reduce the number of guidelines displayed) and increase the usability of CANBeWell (e.g.,

show users a summary of their selections). Resolving the issues identified will bolster the usability and usefulness of CANBeWell and therefore increase the likelihood that it will be used. Findings from this study were used to inform the next iteration of the app, which is currently in development. The next iteration of CANBeWell will be subject to another heuristic evaluation followed by usability testing with health consumers to identify other issues with both the content and the usability of the app before it is deployed.

Despite generating valuable feedback for the next iteration of CANBeWell, this study had its limitations. Although the heuristics are evidence-based, they have yet to be empirically validated. Additionally, the prototype was only tested on one device and the investigators had to do a paired evaluation whereby one used the prototype whilst the other recorded their findings. This approach may have influenced each other's findings and limited the number of issues identified. That is, it is possible that additional issues would have been identified, had the investigators conducted their evaluations separately. Unfortunately, the availability of hardware and software that could run the prototype precluded independent investigations. Finally, although the investigators were not clinicians, at the time of this evaluation they were doctoral students in health informatics and therefore may not be representative of typical health consumers who will use CANBeWell. However, their usability and health literacy expertise and familiarity with relevant literature made them well-suited to conducting this heuristic evaluation.

Preventive guidelines provide valuable, evidence-based recommendations that help consumers make healthy decisions and avoid health problems or detect illnesses in the earliest stages for the best prognosis. In contrast to most guideline approaches, CANBeWell empowers health consumers by allowing them to determine which preventive guidelines may be appropriate for them. This approach may be especially valuable given the shortage of PCPs in Canada because it does not rely on either the physician or the electronic medical record. This app may also help shift consumers' and PCPs' focus from treating illness to preventing it.

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"Real-World" De-Identification of High-Dimensional Transactional Health Datasets

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Abstract. This paper presents a framework for addressing data access challenges associated with secondary use of high-dimensional transactional datasets that have been extracted from electronic health/medical records (EHRs). These datasets are subject to the data de-identification "curse of dimensionality" [1] which manifests as substantial challenges to preserving analytical integrity of data contents when high-dimensional datasets must be de-identified and deemed free of Personal Information (PI) prior to disclosure. A large array of methods can achieve this objective– for low dimensional datasets. However, these methods have not been scaled up to the types of high-dimensional data that must be sourced from the transactional EHR if the objective is specifically to generate products that can inform point-of-care clinical decision-making. The Applied Clinical Research Unit (ACRU) in Island Health is implementing a process that addresses key privacy challenges inherent in disclosures of high-dimensional transactional health data. This paper presents a schematic and abbreviated rendering of key principles and processes on which the ACRU approach is based.

Keywords. Privacy, data de-identification, curse of dimensionality, simulated data

1. Background- why the need for high-dimensional transactional health data?

Data required to generate clinically actionable products - evidence-based treatments are built on a foundation of information relating risk factors and interventions to outcomes for identifiable cohorts. For studies working from EHR data extracts, evaluation of treatment outcomes for acute conditions, and analytics supporting management of chronic and commonly co-emergent diseases will call for datasets containing a diverse array of cross-continuum clinical data contents that reflect treatment response or disease progression [2]. In the EHR, these contents (attributes of patients/clients; interventions) are layered onto a transactional data substrate depicting potentially large numbers of patient encounters with a broad array of programs that constitute a health service system, e.g., 1700+ programs in Island Health[3]. Given the multifactorial nature of clinical determinants and interventions, and the variably-spaced distribution of outcome-relevant information across an array of service encounters, efforts to generate clinically-useful and clinically targeted products from EHR extracts will translate routinely into requirements for large volumes of sparse high-dimensional data. Narayanan & Shmatikov [4] suggest this type of request is the rule, not the exception when working with "real world" transactional datasets.

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Privacy challenges associated with high-dimensional datasets - even when direct identifiers (e.g., Name) have been removed from the EHR extracts, the highly granular, multivariate depictions of patient "journeys" embodied in the transactional service encounter data pose substantial challenges to privacy. The reason is that every patient trajectory within a sparse high-dimensional space is likely to be ***distinguishabl*** *e* at some level from all others. This translates into a privacy issue if the variables that distinguish cases in the dataset are available to the public in an identifiable form. When that is true, distinguishable cases in the dataset can be re-identified. Because distinguishability increases multiplicatively with the addition of new linked variables to a dataset, the privacy challenges associated with disclosure becomes very problematic in contexts that require datasets to be deemed free of Personal Information (PI).

Clusters of variables within a dataset that do not function as direct identifiers but nevertheless enable cases to be distinguished and re-identified are known as "indirect identifiers" or "quasi-identifiers – QIDs [5]. Risk for re-identification can be mitigated by rendering people "the same" with regard to distinguishing QIDs. If QIDs are rendered non-distinguishing by coarsening values (e.g. grouping diagnoses into superordinate categories) then this may not compromise analytical integrity of the data. But when re-identifiability issues are addressed by altering values on distinguishing variables in such a way that essential clinical "truth" is altered (e.g., if diagnoses are altered randomly for a subset of cases), then analytical integrity of the data is affected. Legacy de-identification methodologies have not provided a solution for high-dimensional transactional data that do not entail such perturbative alterations of data contents [6], which fundamentally compromise the utility of the data for point-of-service applications.

Legacy approaches to data de-identification - the challenge for a data de-identification methodology is to reduce risk for re-identification of nominally de-identified data while preserving analytical integrity of the data. Most methods that work from quantitative estimates of re-identification risk build from measures of distinguishability, and trace their roots back to a demonstration re-identification attack carried out by Sweeney [7]. Working with a small set of variables (full date of birth, full zipcode and gender) she showed that 87% of the records in the public registries she accessed were uniquely distinguishable. Her work provided substantial guidance for data de-identification methods sanctioned by the US Privacy Rule [8]. If those approved methods are applied to datasets composed of any of 18 classes of QIDs (and no other QIDs), then the risk for re-identification falls into the range .01% to .25% [9].

Any de-identification methodology that entails quantitative estimates of risk for re-identification of distinguishable cases will invoke some variation of Sweeney's approach at some stages in the de-identification process. However, various optimizations of her method (see Aldeen [6] for a thorough review) have not yielded an approach that preserves enough of the essential truth status of data, and derivative statistical properties, to warrant application of analytical results to the care of real patients.

The Applied Clinical Research Unit (ACRU) within Island Health, in partnership with various research groups at the University of Victoria, has taken on a program of research that is "forcing the issue" around developing a more complete set of tools that will enable researcher access to relatively pristine high-dimensional datasets, while meeting privacy obligations. A scenario-based method has been employed to generate a set of principles and procedures which provide a framework for the ACRU's contextualized approach to data access and data de-identification. What follows is a representative scenario, and an excerpt from the set of principles and procedures that are keyed to the privacy protection requirements associated with the data required to carry

out the full suite of current ACRU research projects. The model is intended to support access on the part of the researchers located outside of Canada, so of necessity it targets the objective of rendering the data statistically and logistically/contextually free of PI.

2. A "real world" use case in the area of Mental Health & Substance Use (MHSU)

Clinical problem/research questions – what longitudinal trajectories are associated with excess morbidity and mortality in the MHSU population. What are the causes of this morbidity/mortality–all causes, including but not restricted to overdoses?

Information Products: rates of various outcomes and distal/proximal determinants; severity-stratified trajectories reflecting patterns of patient/client interaction with secondary and tertiary services (provided by the Health Authority); change-points in trajectories associated with service access and/or patient characteristics.

Data required: age, gender; transactions consisting of encounters plus dates with 1700 programs; acute care diagnoses, procedures(14,000 ICD9 categories); Emergency Department (ED) presenting complaints (165 values); ED Clinical Discharge Diagnoses; Minimum Reporting Requirements (Ministry of Health) for MHSU346 variables, ≥1record per MHSU program registration, Pharmacy data; Vital Stats (deaths).

3. Data de-identification principles for "real world" data disclosure and use.

Principle #1–work from a model of the data disclosure and use context. Stated in slightly different terms: create a *target information architecture* that identifies data sources, describes data movement, catalogues analytical approaches and intended products, and locates envisioned data product users/uses.This architecture points to processes where "source of truth" status is invested in the data. Specification of intended data users/uses provides a basis for setting utility constraints [10] on parameters around permitted/proscribed alterations to the data. In effect, the architecture provides an analytical "conscience" for de-identification activities that entail alterations of the data.

Principle #2 –Privacy Model: Distinguishability≠ Re-identifiability ≠ Risk for Re-Identification. "Privacy risk" can be unpacked into three entities: a) distinguishability, based purely on configurations of scores on QIDs within the dataset; (b) re-identifiability, which reflects a mapping of distinguishing pieces of data onto publicly available bodies of information; and (c) *risk* for re-identification. This last entity is a judgment that may be regarded conceptually as a multiplicative function of re-identifiability and a third component – a consideration of what data disclosure activities/scenarios can be regarded as "reasonable" or "reasonably likely" on the part of the data user[11,12]. In attributing "risk" to a candidate data disclosure, it is essential to distinguish these three entities and to be clear about which of these three are being referenced.

Principle #3 – Risk-based access adjudication decisions or policies should be anchored in plausible scenarios. If publicized re-identification attacks are going to be invoked as a justification for data access policies or procedures, or if they are going to be discounted, then involved parties can presumably detail the relevance/comparability of those scenarios to the requested data disclosure. As well, they should be able to delineate a chain of reasonably likely activities that would result in re-identification. Barth Jones [13] and Cavoukian & El Emam [14] provide models for such analyses.

Principle #4 – Cost-benefit analysis. Quantitative estimates of risk based on distinguishability is not the only method for quantifying risk. Wan et al. [15] propose a more fully context-aware approach that employs game-theory and cost-benefit analysis, where the key question is whether there are any reasonably envisioned scenarios in which benefits outweigh risks. If there are no such scenarios, then there is zero risk – from a cost-benefit perspective. Data access adjudicators will need to consider whether such an analysis will carry weight over more 'classic' estimates of risk based on distinguishability of cases. These 'classic' methods may appear to be more objective than cost-benefit approaches, but they introduce quantities (e.g., "adversary power") reflecting assumptions about the external context and data user knowledge that may not be regarded as correct or reasonable by knowledgeable parties [16].

4. De-identifying processes for high dimensional transactional data.

Process#1 – Examine the data at a univariate (single variable) level. Focus on distribution of values on variables in order to locate statistical outliers, where statistical risk may be "concentrated". As well, the data should be viewed qualitatively through data classification scheme "lenses" that are attuned to considerations such as differential sensitivity of data contents.

Process #2 – Data ecology – scan the environment. The objective is to identify publicly available datasets that would enable contents in the requested datasets to function as QIDs. This will substantially reduce the dimensionality of the dataset from a purely quantitative privacy risk perspective.

Process #3 – Secure the data disclosure environment and implement audit controls. Technical controls to prevent unauthorized access or import/export of raw person-level data protects against both current and difficult-to-envision future risks. Depending on what activities are tracked, the audit trail may shed light on at least a portion of the range of re-identification-relevant activities performed by data users.

Process #5a –**If Processes #1-3 yield a small set of QIDs, and no issues around analytical integrity have been flagged: de-identify the data,** *then* **hand-off to researchers for analysis**.

Process #5b – If approaches suitable for low-dimensional datasets put the analytical integrity of the data at risk - carry out the program of research analytics, *then* **de-identify – or execute as an integrated process**. The researchers are the parties that fit the data to statistical models and craft the data products. They are the parties that discover whether and where there are significant and useful contents in the data. As such, when analytical products are crafted from high dimensional data, it is reasonable to expect that workable utility constraints on changes to the dataset can only be determined *after* the researcher has worked with the data.

Process #6 – Generate simulated datasets, recruiting data de-identifiers, researchers, data scientists and domain experts. Such a team would collectively hold the knowledge and skill required to specify the minimum set of semantic and statistical properties that should be preserved in a simulated dataset, e.g., distributions at a univariate and multivariate level; treatment/exposure characteristics and designs to support real-world clinical trials; survival rates; clustering of variables; and a potentially broad array of other covariance relationships among variables [16].

Process #7 – Open/public release – and looping back to the original source data. Process #6, delivers a simulated version of a high-dimensional dataset that preserves

some essential statistical properties and carries no privacy risk. Statistical models can be evaluated against these simulated data, and promising models can then be evaluated (under suitably controlled conditions) against the real data. What results will be validation/refinement of the models, as well as refinement of the simulated datasets.

5. Discussion

This paper proposes a methodology that entails a thorough examination and evaluation of the context of an envisioned data disclosure in service of ecologically informed decisions around privacy protection of the data. The methodology recruits the researcher as an early and "equal" partner in the process of setting utility constraints on data-altering activities employed to bring risk for re-identification down to a level deemed acceptable by data access adjudicators. The full model anticipates the use of emerging tools, e.g., Bayesian model discovery tools applied to multivariate databases [17] to generate simulated datasets that preserve more of the essential covariance and other properties of complexly structured data entities – and to support the open data agenda. These processes are not simple, but they are feasible. They hold out promise for breaking the curse of dimensionality – and enabling more thorough extraction of clinically useful content from the very large body of clinically pertinent information accumulating in real time in every location where an electronic medical/health record has been implemented.

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Challenges in Displaying Health Data on Small Smartwatch Screens

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Abstract. Using smartwatches for self-tracking purposes has become increasingly common. This tracking is possible as a result of the many sensors embedded in modern smartwatches including GPS, heart rate monitor, accelerometer, and gyroscope. The ability to obtain personal health-related data is one of the most compelling reason to purchase such devices. However, form factor limitations create numerous challenges for users hoping to access and interpret the data available. Typically, users rely on a secondary device, such as a smartphone to view health data. The aim of our research is to identify methods to improve user consumption of health-related data directly on a smartwatch. To study and apply novel visualization approaches, several key challenges need to be addressed. We present these here along with their corollary methods of circumvention.

Keywords. Smartwatch, health data collection, data visualization, health tracking

1. Introduction

Wearable devices such as smartwatches and fitness bands are becoming increasingly popular across demographic groups, from kids [1–3] to older adults [4,5]. Reasons for this significant uptake include fitness tracking [6,7] and health monitoring [8–13] capabilities, two of the most widely available features on a smartwatch. Other health-related capabilites of smartwatches such as detecting mental/physical disorders and supporting people with difficulties [14–16] can also improve user health significantly. Many of these applications are based on data captured by sensors on smartwatches (e.g., heart rate monitor, GPS, accelerometer, gyroscope) [12,17]. For example, even the very first programmable smartwatch, the *Chronos* [18], made specifically for athletes, contained multiple sensors for the measurement of such variables as acceleration, air pressure, and a temperature. Being lightweight, accessible, and having various sensors and a wide range of novel interaction techniques [19–21] make smartwatches unique and ubiquitous as a data-tracking device.

While tracking data is possible, consuming or viewing their data is significantly challenged by a number of factors. For example, merely displaying raw data or time-stamped series of measurements may be not be sufficiently informative to users. Instead, users of such devices are seeking answers to many questions that cannot be currently accessible. Researchers have identified common questions that arise during users' fitness activities, such as "have I reached my daily goal?", "how am I doing so far?", "how am I doing compared to my friend, Jane?", [22] which require further analysis of the raw data produced. Providing clear answers to these questions should lead users to improved

interactions with their devices. Thus, using tools and techniques for data visualization and personal visual analytics, which can provide insights, is key in improving user health [23]. For instance, the raw data gathered by smartwatches can be visualized and analyzed in such a way that users can extract useful information about their daily activities, such as steps taken, average/rest heart rate, intake/burnt calories [24]. This data can also be leveraged to motivate habitual changes for health purposes, such as the cessation of smoking [25]. When the data is presented and interpreted properly, it can also help professional athletes to improve their performances [26].

Meyer et al. [27] have shown how visualizing health data can be a challenging and complex task. In fact, collecting inaccurate health data or misinterpreting such data can lead to undesirable side effects. Due to the various limitations of smartwatches, the process of collecting, visualizing, and analyzing health data can add even more complexity. Thus, we present an overview of the challenges regarding collecting, presenting, and analyzing health data to improve our reliance on smartwatches.

2. Data Collection, Representation, and Analysis Challenges on Smartwatches

2.1. Data Visualization and Interaction

One of the main limitations of smartwatches is their small screen size[27–30]. Visualizing health data, which are mostly highly dense, continuous time-series data is often challenged by these small screen sizes. Researchers [31] have recently shown how different visualization factors such as size, frequency, and colour of the visual displays on a smartwatch can impact the reaction time of users. Depending on the data type, there are various data visualization methods which can represent the underlying data. For example, Amini et al. [32] have shown that bar graphs, line charts, and pie charts, in addition to maps and pictographs are the most frequent data visualization techniques in data storytelling and data videos. However, there is no guideline to solve the issues faced in the representation of complex health data on the small screens of smartwatches.

Various specific interaction techniques have been designed for different visualization methods [33–37]. Interactive data visualizations are necessary to provide users with tools to explore the data to gain additional insights. Due to the small smartwatch screen size, when using touch as input, there is a higher chance of content occlusion and errors as a result of the "*Fat Finger Effect*" [38]. New interaction techniques are needed to improve user performance when data visualization techniques are utilized.

2.2. Storage

Continuously collected data creates various tasks. Millions of data points, sampled at very fine time intervals, without visualization and analysis can be difficult for users to interpret. Researchers in areas such as big data, data mining, machine learning, and deep learning are developing techniques related to analyzing massive data sets in a reasonable time. However, due to their lack of memory [39], smartwatches have data-storage limitations.

This is compounded by the fact that embedded sensors are being deployed with higher sampling rates for maintaining the accuracy of the incoming data. Increased

storage capacity may compete with other concerns such as connectivity and battery power. This could be particularly problematic in emergency situations when for example, the user needs to send their ECG to the doctor.

2.3. Processor

Processing and analyzing massive data sets is one of the main challenges data scientists face today in medical science [40,41] and can be extremely difficult, even on computers with high-performance CPUs. Processing of such data sets, such as heart rate data for two years with a high sampling rate, with existing weak processors on smartwatches, is almost impossible. To overcome this, users need to transfer the data to the cloud or other platforms such as PCs, and then review the data. However, analyzing the data in-situ and on smartwatches is essential in many cases [24].

2.4. Batteries

Smartwatch batteries are one of the most influential factors that can prevent users from continuous use of their device [42]. There is a direct, positive correlation between the number of sensors and their sample rates with battery consumption. This is one of the downsides of integrating many sensors with the high sampling rate (number of data points can be captured by a sensor, in a specific period of time) into a smartwatch design. This correlation has motivated designers and engineers to explore solutions which decrease the battery consumption of smartwatches. For example, in the Samsung Galaxy gear S3 smartwatch and Fitbit Charge HR 2, there is a way that users can decrease the sample rate of the heart rate sensor, which increases the battery life. However, an increase in sampling rate and data points is known to produce improved accuracy and insight from the raw data. Manufacturers have also developed operational modes, such as power mode (in many smartwatches, such as Samsung Smartwatches and Apple watches), which can decrease the power of the CPU and kill unnecessary applications to make the battery last longer. Many smartwatches stop recording and storing data using sensors in this mode.

3. Health Data Types

Personal data, especially when related to user health, can be linked to more serious outcomes than simply fitness and exercise. For example, heart rate data can play a significant role in preventing cardiovascular diseases. Analyzing and presenting such data is critical to user self-awareness. Considering the smartwatch limitations, such as the small screen size and limited input methods, we need exclusive visualization techniques when compared to other platforms such as smartphones. In this section, we will describe the most common health data that can be captured and visualized with smartwatches.

3.1. Heart Rate Data

Heart-rate data is one of the most important categories of personal data that can be used to anticipate cardiovascular anomalies [43]. To collect heart rate data, many advanced sensors are available on smartwatches and wristbands [44]. Hernandez et al. [45]

introduced new ways of collecting heart rate data from wrist-motion sensing. It has been shown that analyzing data collected by these sensors could help physicians detect cardiovascular disease symptoms [46].

Various data visualization techniques exist to represent such data, including line graphs and bar charts (Figure 1, a). It is also possible to show heart rate data using pictographs and animation. Text or number are some of the simplest ways to show this information, and since they usually occupy a small screen space, they are used commonly. However, in-situ (e.g. while they are jogging/running) visualization techniques should be considered when visualizing heart-rate data [24]. In-situ visualization techniques help users to get the most information in very short periodof time, in the context of their activity. Innovative techniques [47,48] also need to be considered for consuming such data.

3.2. Sleep Data

Sleep quality is another essential category of personal health-related data. Good quality sleep can eliminate stress levels [49,50] and decrease the risk for cardiovascular disease [51]. Using sensors such as an accelerometer and gyroscope in smartwatches, it is possible to detect different sleep stages based on sleeper's movements [52]. Data captured by various smartwatch sensors can be analyzed by algorithms to recognize different activities [53].

Visual displays, such as line graphs and bar charts are the most common visualization methods on smartwatches used to represent such data (Figure 1, b). However, texts and numbers can be used to add more information such as basic statistical reports (e.g. average sleep duration).

3.3. Fitness Activities Data

With embedded sensors, devices can collect and interpret wrist movements for the recognition of different activities [18,54]. Usually, fitness-activity data is visualized using a collection and combination of multiple data sets. For example, for a jogger, the distance travelled, variations in elevation, and calories burnt are all important. Visualizing a combination of multiple data categories, using different visualization methods, makes the visualization a complex process on small screens of smartwatches.

Another critical factor when representing fitness-activity data stems from the nature of smartwatches as *glanceable devices* [55]. In-situ data visualization is a technique that provides users with enough information in a way that they can get necessary information based on the different situations and conditions in a short period time (Figure 1, c). This can prevent excessive cognitive load while interpreting the visualization. Previous work has shown that smartwatch users find in-situ data visualization a beneficial technique which can be used to deliver the right amount of information in a short time period [24].

Figure 1. a) Heart rate data, b) sleep data, and c) fitness activities data representation on smartwatches

4. Visualizing Health Data on Smartwatches

Techniques such as the compression of existing visualization methods (e.g., line and bar graphs) can help designers represent more information on the small screens of smartwatches (Figure 2, a, c). For instance, Sparklines [56] are compressed line graphs on the y-axis, which are designed to be embedded in texts, images, and tables (Figure 2, b). Using visualization techniques such as sparklines can provide users with meaningful information in a tiny segment the smartwatch screen and the remaining segments can be used to represent more health data and related information. For example, representing heart rate data, sleep quality, and body temperature simultaneously (Figure 2, c), can help users to understand their stress level to prevent future side effects.

Figure 2. a) Compressed horizon and bar graphs to present fitness activities data, b) Sparklines in texts, c) compressed line graphs to represent heart rate data and sleep quality

5. Future Directions

Many researchers are currently working to eliminate hardware issues with wearable devices and especially smartwatches, which include a lack of memory, limited processing power, and limited battery life, by either software or hardware solutions. Solving these issues stands to make a significant, difference as smartwatches might provides users with more accurate and robust data which. This data can be crucial issue

in health science, since the decision-making process of the user is often based on the collected data. In the future, we expect to see more people using smartwatches as the reliability of the data collected collected improves.

Given the limited output and input modalities of smartwatches, new interaction and visualization techniques are required to enhance user interaction and engagement. Novel visualization techniques are necessary to represent thousands of records of health data. New interaction methods to interact with massive datasets on the small screen of smartwatches are also required. Facilitating the use of smartwatches by providing novel interaction and data visualization techniques, as well as improving the reliability of the collected data would be the next step of future research on smartwatches, which stand to make them a truly ubiquitous wearable device.

6. Conclusion

This paper describes some of the most significant challenges regarding data presentation of the most common health data (e.g., data related to heart rate, sleep quality, and fitness activities) on smartwatches. Hardware challenges such as limited storage, processing power, and battery life can affect the processing, representation, and analysis of data. We also show that representation of complex health data on small screen of smartwatches requires further investigation and the development of novel techniques.

7. Acknowledgment

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Evaluative Outcomes in Direct Extraction and Use of EHR Data in Clinical Trials

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Abstract. Use of electronic health record (EHR) data in clinical trials has long been a goal for researchers. However, few demonstrations and fewer evaluative studies have been published. The variability in outcome choice and measurement hinders synthesis of the extant literature. In collaboration with a contemporaneous systematic review of EHR data use in clinical trial data collection, we analyze reported outcomes and recommend a standardized measure set for the evaluation of human safety, data quality, operational efficiency and cost of eSource solutions.

Keywords. Electronic health records, data collection, eSource, data standards, quality metrics, data quality.

1. Introduction

Health information systems have been used for research since the beginning of clinical computing [1]. Today electronic health record (EHR) use is nearly ubiquitous (96% in US hospitals and 87% in clinics) [2] making data from routine care potentially available for secondary uses such as research.

Researchers [3-5], regulators [6], and the National Institutes of Health [7] are calling for and exploring responsible use of routine care data in clinical research [8]. Kim et al. articulate 42 distinct ways in which direct use of EHR data might improve clinical trials [9]. Such improvements are needed. Clinical trial complexity continues to rise [10-16], high numbers of clinical trial investigators decline involvement in a second trial [17]. The need for advances in information management and use within clinical trials has been well articulated [12, 15, 16, 18, 19]. However, it has taken over four decades for viable and generalizable solutions toward direct use of EHR data in clinical trials to emerge.

Industry and academia alike are hesitant to invest in or adopt new technology and methods unless proof exists that an innovation (1) maintains or decreases risk to human safety and data integrity and (2) is financially advantageous[20]. Evaluative data regarding the benefit of direct extraction and use of EHR data in clinical trials, hereafter called EHR-to-eCRF (electronic case research form used as a data collection tool for clinical research) direct data collection, are needed. A contemporaneous review has identified few demonstration projects and even fewer evaluative studies reported in the peer reviewed literature [21]. Rigorous evaluation is needed and we hope to facilitate

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such progress through the inventory and analysis of process and outcome measures use to date in evaluation of EHR-to-eCRF direct data collection.

2. Methods

Fourteen studies and reports of direct extraction of EHR data for use in prospective clinical research were identified in a contemporaneous systematic literature review [21]. Two of the authors (MZ and AN) independently reviewed the studies and agreed on the categorizations. All outcome and process measures reported in each study were identified and categorized. Challenges and limitations of reported measures were cataloged and are described here. We report a set of evaluative measures along human safety, data quality, operational efficiency and cost dimensions for use in evaluation of EHR-to-eCRF data collection.

3. Results

Sixteen measures were identified from eight of the fourteen included studies. The sixteen measures (Table 1) fell into three categories: Human safety, Operational efficiency, and Data quality. One measure, timeliness of data, operationally defined as the difference between the data origination date and the date and time of availability in the eCRF, fell into all three of the aforementioned categories. The two most frequently assessed measures were time savings (reported four times across three studies) and data availability in the EHR (reported in three studies). Few studies operationalized the measures in comparable ways. Thus, measure magnitudes should not be compared across studies. Two studies reported no measures, and one study reported cost benefit obtained through simulation rather than actual measurements. The latter study used expert opinion to estimate cost savings. Cost was not assessed elsewhere.

3.1 Safety Measures

Two measures were categorized as safety measures. The integration described by Lencioni et al. (2015) was designed to detect and facilitate reporting of lab-based adverse events (AEs) in clinical studies. Lencioni et al. use staff estimates of difference in number of lab-based AEs reported following implementation of the system as an outcome measure. The evaluation design was observational in nature and did not include random allocation to the intervention (the AERS system) or comparison to a control group. Operationalization of the measure, staff reporting, is further limited by recall bias and lack of blinding. Studies assessing impact on event detection would be strengthened by use of random allocation and control in study design and measuring event detection through comparison to a gold standard that would support sensitivity, specificity, positive and negative predictive value, and area under the Receiver Operating Characteristic (ROC) curve.

   While timeliness of data arriving in the eCRF is also a commonly assessed dimension of data quality and an indication of operational efficiency, we also consider timeliness of data to be a process measure relevant to safety. The sooner data are

available to a study team, the sooner adverse events can be detected and clinically addressed. The Munich Pilot was the only study to report a timeliness measure. In the Munich Pilot, timeliness was operationally defined as data being available in the eCRF within twenty-four hours of data origination. We recommend reporting timeliness assessment as the lag time distribution for each data element, where lag time is operationally defined as time of data availability in the eCRF minus the time of data origination. Distributional detail supports decision-making regarding use of data in decision support within a study.

3.2 Data Quality Measures

Four types of data quality measures were reported in the included studies: data accuracy, data completeness, representational differences, and data timeliness. The latter, discussed in section 3.1 will not be repeated here. Measurement of actual data accuracy requires knowledge of the truth. Since truth is usually not known, lesser comparisons are used as surrogate accuracy measures [22]. The Munich Pilot and the Lencioni et al. adverse event detection report both use rule-based identification of data discrepancies as a surrogate for data accuracy. Where the approach to rule-based discrepancy identification, i.e., the number and logic of the rules, has been standardized, as often occurs within an organization, the results provide a relative gauge of data quality across studies. However, due to their dependence on the number and types of rules and the strictness of the rules, rule-based measures are not an absolute measure of data accuracy and are of limited value in comparing data quality between implementations in different organizations. Thus, while easy to measure, we do not recommend use of rule-identified data discrepancies as an indicator of data quality.

Nordo et al. operationalized data accuracy as absence of transcription errors between the source, i.e., the EHR, and the eCRF. Comparison to an upstream source of data has the advantage of being an absolute measure and the disadvantage of only measuring data errors that occur between the two assessment points. While measurement of error or discrepancy rates between two process points may be useful for process control, it is a partial measure of the total error or discrepancy rate (from all causes) that may exist in the data. Because data processing methods can vary significantly between studies, rates measured between process points have additional limitations in comparing data quality across studies. The measure should only be used to compare data quality across studies or implementations when the choice of evaluation points is comparable.

Data completeness was assessed in the European TRANSFoRm evaluation [23] in a controlled experiment before and after system implementation. Completeness was operationalized as the percent of subjects with a first clinical outcome measure for which there was also a second. This assessment is limited to completeness of the assessed outcome, and is appropriate if the outcome of interest is the one assessed. However, outside of a cluster-randomized study like that conducted by Ethier et al., the measure may be confounded over time by lost to follow-up. We suggest instead, a four-part completeness assessment as described in Weiskopf et al. [24] and where measured outside the context of a randomized controlled study, correcting for patient attrition.

Representational differences, an oft-assessed dimension of data quality, were reported qualitatively and by only one study. Representational differences were operationally defined as differences in data format or detail level between the study and the EHR that did not change the data meaning. Reported differences included units of measure, synonym use, aggregation such as individual dose versus daily dose, and detail

level at which data were reported. While representational differences do not adversely impact the semantics, such differences can complicate or all together preclude automated data processing such as detection of errors or other signals. Such differences could be categorized according to type or information content [25] differences and counted.

Table 1. Outcomes Reported in Relevant Studies

Study & Standards	Measure: Operational Definition	Result
STARBRITE Kush et al. 2007	1. **Data availability**: Percent of study data elements available in EHR.	75%
	2. **Representational differences**: differences data representation between the study and the EHR e.g., units, synonyms, individual dose versus daily dose, and detail level	Qualitative description
	3. **Workflow**: Qualitative description of workflow steps and sequence	Qualitative description
	4. **Time**: Time required of the site study coordinator during start-up period	20%
Munich Pilot Kiechle et al. 2009	1. **Data availability**: Percent of study data elements available in EHR.	48 – 69 %
	2. **Time**: Reduction in screening visit data collection time (minutes per visit)	53.1
	3. **Time**: Reduction in chemotherapy visit data collection time (minutes per visit)	15.5
	4. **Data quality**: Number of data discrepancies, i.e., queries, identified through programmed data checking rules	Too few queries to assess
	5. **Timeliness**: Time between data availability in EDC system and data origination	≤ 24 hrs
Florida Hospital Laird-Maddox et al. 2014	No quantitative outcome measures reported	
UAMS Automated AE detection Lencioni et al. 2015	1. **Detection rate**: Staff estimated number of lab-related Adverse Events (AEs) detected	75% increase
	2. **Data quality**: Number of rule-based data discrepancies detected in AEs	42% decrease
	3. **Time**: Statement of saved staff time	Qualitative description
REUSE El Fadly et al. 2011	1. **Data availability**: Percent of study data elements available in EHR.	13.4%
TRANSFoRm, Ethier et al. 2017	1. **Recruitment rate**: number of study participants recruited per time period	10%-point difference
	2. **Completeness**: Percent of subjects with a first clinical outcome measure for which there was also a second	14%-point difference
RADaptor Pilot Nordo et al. 2017	1. **Time**: Data capture time measured by automated keystroke and click tracking	37% reduction
	2. **Data quality**: Transcription error rate	9% difference
Japan SS-MIX Kimura et al. 2011	No quantitative outcome measures reported	

3.3 Operational Efficiency Measures

All studies reporting outcome measures assessed some aspect of operational efficiency. Measures included site time, data availability, workflow, data timeliness (described in section 3.1), and recruitment. Site staff or investigator time savings were quantified by

three of the included studies and asserted but not measured by a fourth. Reduction in data collection time was measured by two studies. Nordo et al. directly measured data collection time through screen capture software, while the Munich Pilot reported staff-logged time for two different study forms. The STARBRITE study reported site study coordinator time required for study start-up at the site. Time on task measures for data collection are promising process measures because of the direct nature of the measure and the relevance to decreasing site burden. In a single site evaluation such as the RADaptor pilot, screen capture software, ideal as a direct measure, is feasible. However, in multicenter evaluations, site institutional approval for installation of software that records patient identifiers is time consuming if not challenging to obtain. However, screen capture could be used in a pilot to calibrate and validate time and motion observation or observation-driven keystroke-level modeling. Once validated, the latter could be used in a multicenter study. Such objective, systematic and direct measures are preferred to staff logged time and statements of effort. Further, we recommend these as a basis for workflow assessment. Workflow-based operational efficiency measures must cover all tasks, both physical such as typing, system navigation, and obtaining data time as well as mental tasks such as searching, reading, mapping and choosing.

Data availability is categorized as a measure of operational efficiency because where data availability is low, direct extraction of EHR data for a clinical study may not save enough data capture time to outweigh software set-up and operations costs. Data availability was measured in three studies and ranged from 13.4% in the REUSE pilot [26] to 75% in the STARBRITE study [27]. We expect data availability to vary widely from study to study. For example, we expect higher availability of study data elements for late phase and pragmatic clinical trials; these studies are in part designed to leverage data collected and used in routine care. Likewise, we expect lower EHR availability of data elements for early phase and mechanistic studies that seek data not necessarily generated or used in routine care. However, at least two of the included studies represent two very different operational definitions: (1) presence of data with the same semantic content versus, (2) data directly mapable without algorithmic manipulation. The latter operational definition was used in the REUSE study. Both are informative measures and should be used. In addition, we recommend measuring the percentage of data found in structured *versus* text fields as well as the percentage of study administrative data such as date of subject randomization and research questionnaire data. Both study administrative data and research questionnaires would not be expected in routine care data and their inclusion in data availability assessments can skew results.

Recruitment, operationalized as the number of study participants recruited per unit time, was used as an outcome measure in the European TRANSFoRm study. That study failed to show significance on this measure. It was likely selected because the study's technology also aided identification and screening of eligible patients. Although data collection time savings may allow site staff to spend more time recruiting, we do not recommend recruitment as an outcome measure because other factors can impact staff time allocations and recruitment rates.

3.4 Measures of Cost

One included study assessed cost [28]. However, the assessment was the result of simulation based on expert estimates and not grounded in measures on actual studies.

3.5 Measures of Potential Confounders

Space here does not permit full discussion of phenomena that may confound assessment of outcomes in evaluative studies of EHR-to-eCRF data collection. However, we wish to point out that site characteristics such as organizational change readiness and technological readiness may impact results and should be systematically identified and assessed in evaluative studies.

4. Recommended Outcome Metrics

The synthesis and assessment of outcome measures and metrics used in the included studies yields a more comprehensive set (Table 2) of measures across three domains: human safety, operational efficiency, and data quality. We recommend the following set of measures for use in evaluation of EHR-to-eCRF direct data collection.

Table 2. Recommended Outcomes Metrics

Outcome Measurements / Metrics	Phase of Implementation
Data Availability CRF-to-EHR: Percentage of study data elements available in the EHR/s and the participating site/s.	Pilot and Production
Data Availability CRF-to-FHIR: Percentage of study data elements available in the FHIR resources supported by the EHR/s at the participating site/s.	Pilot and Production
Representational Differences: Number, extent and character of differences in data representation between the study data collection form and the EHR/s at the participating site/s.	Pilot
Data Completeness: Four part completeness assessment as defined in Weiskopf et al.[24]	Production
Workflow Differences: Number, extent and character of differences in process steps and their sequence as assessed by direct observation.	Pilot and Production
Data Collection Time: time on task for manual abstraction and entry, electronic extraction and verification, and hybrid processes for acquiring study data as measured by automated keystroke and click tracking methods such as screen and click capture software.	Pilot and Production
Data Collection Time: time on task for manual abstraction and entry, electronic extraction and verification and hybrid processes for acquiring study data as obtained by direct observation and KLM.	Pilot and Production
Study Start-up Time: Elapsed time from a study initiation milestone to first patient enrolled at the participating site/s.	Production
Data Timeliness: Average time from patient enrolled or visit/s to data availability in the study database.	Production
Data Accuracy: Number of data values that fail to reflect the true state of the patient at the time of interest as measured by performance on standardized cases.	Pilot
Inter/intra-rater Reliability: Surrogate measure for data accuracy measured by the number of discrepant data values between a first and	Pilot and Production

subsequent abstraction by the same (intra-) or different (inter-) abstractor or extraction followed by manual abstraction.

Site Perceptions, Facilitators and Barriers: Qualitative reports of experience with the new technology as reported by clinical study site investigators and staff.   Pilot and Production

Cost: Total cost of data collection using the new technology.   Pilot and Production

FHIR: Fast Healthcare Interoperability Resources; a Health Level Seven standard. KLM: Keystroke Level Modeling

5. Conclusion

Results from existing studies evaluating EHR-to-eCRF direct data collection cannot be compared due to variability in choice and operational definition of evaluative measures. Taken together, the existing studies suggest that outcomes of patient safety, data quality and operational efficiency as well as cost are important to stakeholders. In this analysis, we identified weaknesses in previously measured outcomes and their operational definitions and suggest improved measures for future studies. Further collection of outcome measures and metrics using the measurement plan recommendation will facilitate comparative analysis.

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Designing Health Information for Mutual Empowerment in the Joint Journey of Patients and Healthcare Professionals

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Abstract. The practice of patient-centric empowerment with health information delivered through various channels is widespread and often effective. While empowering patients improves the sharing of power between patients and healthcare professionals, it can also inadvertently disempowers healthcare professionals. This paper proposes an approach to the design of health information with the aim of mutually empowering patients and healthcare professionals. The approach consists of mapping a joint journey, identifying the intersecting information points serving both patients and healthcare professionals, and designing the information in a shareable and mutually empowering fashion.

Keywords. informed patients, empowerment, power balance, patient journey, information design

1. Informing, Engaging, and Empowering Patients

Patients go through a journey in pursuit of healing and recovery. In their journey, patients are informed by healthcare professional, magazines, newspapers, television, printed publications for health information, and various digital 'health decision aids'. There is a massive amount of information available, particularly due to a rise in internet-based devices and other sources such as websites, online support groups, emails, and chat rooms [1].

Being informed is associated with activation, engagement, and involvement [2] [3] [4]. Informed patients make better use of healthcare professional time, show improvements in knowledge, self-efficacy, and in self-management behaviors. Thus, being informed is being empowered [6] [7]. Empowerment is based on awareness, freedom of choice, and responsibility. Being empowered means being able to define and achieve one's goals by identifying the values, needs, and resources one needs in order to solve problems and achieve the goals using knowledge, skills and a heightened self-awareness while having autonomy and responsibility to one's own decision. Overall, empowerment is associated with potentially better care outcomes [8].

In order for patients to become empowered by having health information, they must understand and perceive it as reliable, new, and relevant to their own health situation [9]. However, informing channels, particularly online channels, have limitations and could

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introduce challenges. Information may not be up-to-date, may be misunderstood, overloading, or not trustworthy. Thus, wrong information could mislead patients to make inappropriate requests or decisions regarding wrong interventions, compromise treatment outcomes, and impact the patient's psychological well-being [10].

In order to actively involve patients in their healthcare and empower them, there is a need to design and deliver information that is accurate, updated, reliable, and easily understood by patients and their families. In other words, design of health information for patient empowerment should be patient-centric.

## 2. The Potential Problem with Patient-Centric Empowerment

Historically, there was always an inherent power imbalance between patients and healthcare professionals[11] [12]. With the increased trend of informing, engaging, and empowering patients, they gain more power by becoming partners in decision making and are often responsible for managing their illness and treatment. Consequently, there is inevitably a change in the distribution of power in the relationships between patients and healthcare professionals. Whereas empowering patients has positive outcomes, it may also have inadvertent negative influences on the function of the healthcare professional and the care process itself.

Challenges to the power relationship can come from various sources. In following the inform-engage-empower constructs, the focus here is on the information patients seek, receive, and utilize. When informing only patients, the possible negative influences could result from information conflicting with what the care-provider knows, or may not have. In other words, having patients informed and empowered, may disempower the healthcare professional due to unavailable information, which may lead to negative clinical outcomes [13] [14] [15] [16] [17] [18].

The change in the power relationship between patients and healthcare professionals and the possible negative results suggest that alongside the empowerment of patients, there is also a need to introduce changes in the empowerment of healthcare professionals. Such changes can be applied to education and training, ethics, policy, practice, communication, and information technology. This paper focuses on the design of health-related information that can engage and empower patients, on the one hand, yet be fully shared with healthcare professionals to preserve and boost their empowerment, on the other hand.

3. Designing for Mutual Empowerment of Patients and Healthcare Professionals

Patients and healthcare professionals have a joint journey which should be the foundation for the health information design. The following is a methodological approach to identifying and designing the shared information between patients and healthcare professionals to ensure mutual empowerment. Figure 1 presents a generalized example of the joint journey of patients and healthcare professionals, along with the important joint informing points. The journey map includes three key channels: Patient, Information, and Physician (representing the Healthcare Professional, HCP).
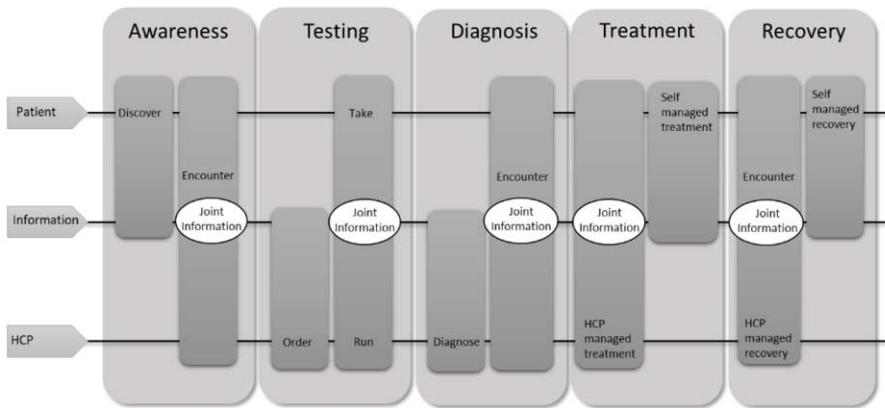
Figure 1. An example of a joint patient – healthcare professional (HCP) journey along with the joint information points (depicted by the white ellipses) that are critical for the mutual empowerment.

3.1. Delineate the Main Journey Phases

The first step is to identify the main journey phases following published practices [19]. Figure 1 illustrates an example of five phases in a generic journey, indicated by the large light grey background areas. The journey takes the patient and the healthcare professional from becoming aware of a medical condition, through testing, diagnosis, treatment, culminating in recovery.

3.2. Map the Joint Activities in the Journey

The second step is to map the joint activities, the touch points, of patients and healthcare professionals. These are indicated in Figure 1 by the dark grey rectangular areas, embedded within the main journey phases that connect between the Patient, the Information, and the Healthcare Professional (HCP) channels. In the example, some activities are not done jointly (i.e., the patient or HCP do it independently).

The important activity in this step is the identification of the joint activities. These are the dark-grey rectangles in Figure 1 that extend between the patient and healthcare professional channels. A patient-healthcare professional encounter is part of the Awareness, Diagnosis, and Recovery phases. In addition, some of the Testing and Treatment activities are done jointly.

3.3. Identify Patient-Only and Joint Information Points

The underlying assumption is that patients can and very often become informed before and throughout any of the activities in their journey. Potential use of information sources is identified in the third step of the methodology. All information sources are generalized in Figure 1 as a single channel of Information, but in a more detailed analysis, all information sources should be identified and delineated separately. Patients may use information sources as part of their discovery of the medical condition in the Awareness phase, as part of the self-managed treatment in the Treatment phase, and as part of their self-managed recovery in the Recovery phase.

The healthcare professionals cannot be aware nor familiar with every information source used by patients on their own. However, much of the information used to inform and engage patients should not only be familiar to healthcare professionals but provided by them, or at least shared with them. Thus, the important activity in this third step of the methodology is the identification of the joint information points; that is, the touch points and the information sources that can be shared by the patient and the healthcare professional. These joint information points can serve as the basis for the mutual empowerment.

The joint information points in the example in Figure 1 are depicted by the white ellipses along the information channel and in the joint activities of the journey. For example, the first joint information point is in the encounter joint activity in the Awareness, Diagnosis, and Recovery phases, where the healthcare professional can provide and share information sources with the patient, and be themselves an information source.

3.4. Define Joint Information Content and Architecture

The fourth step in the methodology is to define the information content and architecture for the joint information points. Specifically, the content relevant for each phase in the journey and for each joint activity should be identified primarily by healthcare professionals in consideration of the information that is available to patients through other publicly available channels. This is critical since the healthcare professional should, on the one hand, be aware of the sources informing patient, and on the other hand, moderate and mediate that and additional information so as to maintain the mutual empowerment.

3.5. Design the Information and Interaction

The fifth step of the methodology should follow collaborative design practices. In other words, given certain information channels such as websites or mobile applications, the conceptual and detailed design of the information should be achieved through collaborative design activities of patients and healthcare professionals.

3.6. Include Communication Channels

An important part of the joint information design is the inclusion of communication channels between patients and healthcare professionals. The communication channels are a natural continuation of informing and empowering patients in that those can facilitate additional information seeking, which on its own may reflect empowered behavior. Moreover, the communication channels serve to keep the healthcare professionals in closed-loop communication with patients, and as such they support further mutual empowerment.

4. Summary of Key Points

This paper introduces two main points: 1. Healthcare professionals share the journey with patients, and in focusing only on patient empowerment we may disempower the

healthcare professional; 2. One of the ways to mitigate this is to design the information used to inform and empower patients, through a joint journey map focusing on the intersecting information points for all participants of the journey.

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A Qualitative Evidence Synthesis of Adverse Event Detection Methodologies

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Abstract. The detection of adverse events (AE) and their relationship to data quality issues through processes or medical error is not currently understood. In order to study the relationship between adverse events and data quality it is necessary to capture as many AE as possible and computational methods will be necessary to handle the large volumes of patient data. The need for adverse event detection methodology has been repeatedly noted but standard AE detection methods are not in place in the US. At present, there are several widely enforced strategies for AE detection but none are both highly successful and computational. In order to maximize AE detection, we have conducted a qualitative evidence synthesis of these approaches. The categorization of the circumstances of the event as well as the resulting patient safety problem and the method of detection provide a means to synthesize AE detection solutions. This has resulted in a set of 130 AE detection algorithms in 9 circumstances categories and 41 patient safety problem categories. This work begins the effort of consolidation of current safety metrics in an effort to produce a common set of safety measures.

Keywords. Data Quality, Adverse Event, Patient Safety

1. Introduction

The detection of adverse events (AE) and their direct relationship to data quality issues as well as their indirect relationship through medical error is not currently understood. Although it appears straightforward that incorrect information could lead to negative outcomes, this relationship has not been demonstrated through a systematic study of EHR data. There is support for the idea that good decisions in healthcare depend on quality data. [11; 14; 16; 18; 21; 23] There are also studies that reveal data quality problems within healthcare information. [13; 19] As a first step in understanding these relationships the challenge of computationally detecting adverse events that occur during patient care must be tackled. At present, there are several approaches to AE detection but none are both highly successful and computational. Some of these are completely computational and detect roughly half of AE [8; 22] and some rely on a process of medical record review (MRR) which severely limits the number of cases evaluated due to task complexity. This study delivers a review and synthesis of the most successful strategies employed by hospitals and required by regulatory and accreditation organizations in the US.

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2. Background

A data Error is any "Instances of inaccuracy, any deviation from accuracy no matter what the cause." [24] Studies on the perception of data quality by physicians have reported that healthcare data was not dependable, and that data in EHRs were often incomplete, inaccessible, inaccurate and unreliable. [9; 10; 12; 17; 25] The potential for adverse events clearly exists.

Medical errors that happen during healthcare encounters have a significant impact on patient wellbeing and occur at a staggering rate. There are approximately 1 billion outpatient visits and 35 million hospitalizations in the US each year. Out these 1 of every 10 hospitalized patients develops a healthcare acquired condition (HAC). [1] If there is a relationship between data error and medical error, we need to understand and make directed efforts to correct records specifically where the likelihood of harm is increased. This is important for both patients and institutions.

AEs are "… an undesirable clinical outcome resulted from some aspect of diagnosis or therapy, not an underlying disease process. Preventable adverse events are the subset that are caused by error" [1] AEs can be categorized as 1) unavoidable (part of the patient's condition), 2) potential (near miss) 3) preventable (harm or pAE) and can come from active medical errors at the point of care or from latent causes present within care settings. AEs happen both in the presence and absence of medical errors. Examples of AEs include adverse drug events, falls, and healthcare acquired infection, surgical and procedural complications.
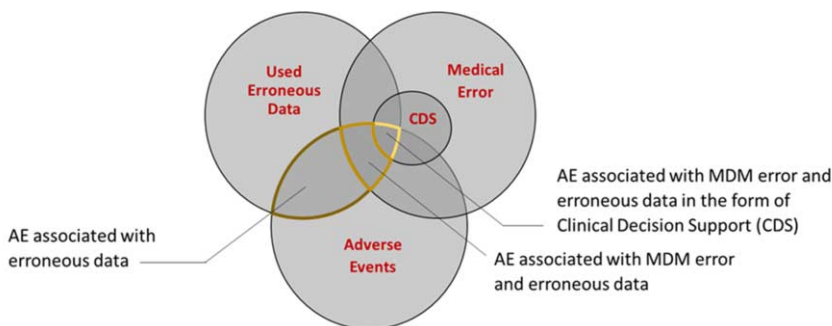

Figure 1. The area where data errors intersect AE and in some cases medical error.

2.1. Common Safety Metrics

There is a need for a common set of safety metrics which reflect meaningful outcomes. In the United States however there is currently no central authority or national strategy for building common safety metrics resulting in duplication of efforts and no clear singular source for patient advocacy or ultimate accountability.[1] Patient safety organizations (PSO) collect data and do analysis and reporting on patient safety concerns. They are regulated by the US Agency for Healthcare Research and Quality (AHRQ). Multiple PSO have designed approaches to address this problem using retrospective surveillance with administrative coded data, observation and voluntary reporting as well as MRR. Each of these miss adverse events and some are excessively expensive so cannot be conducted at scale. [15; 20; 22] Further, methods that are currently used at large scale are not sensitive enough to show improvement over time. [1]

3.   Methods

It is clear that detection methodologies used today identify a low percentage of all safety events.[1] In order to gain an understanding of the challenges faced in detecting patient safety events we need to tease out the components of methods which are widely used and accepted. This includes exploring barriers to the implementation of safety event detection. Through comparison and categorization of detection methods we hope to gain insights into the problem and open the path for quantitative research into methodological improvements.

This qualitative evidence synthesis of the current literature on adverse event detection has resulted in categorization and synthesis of detection methodologies. The body of literature reviewed includes governmental, patient safety organizational efforts as well as academic work and has employed purposeful sampling of the literature relating to most widely used detection methods. The literature was limited to detection methodologies which were considered typical in order to provide an assessment of patient safety event detection for the largest number of instances and to provide a base of expected and mandated methodologies for future study.

The inclusion criteria for the review was for the focus system to describe a method currently in place in hospitals for regulatory or financial purposes. Literature was excluded if it was focused on methods not currently in use in hospitals and not mandated by any PSO. Each source was reviewed and compared for similarities and patterns that could be categorized and synthesized (e.g. data source used for detection or type of safety event). The literature was also examined for themes and conceptual models. For example, the mechanism of patient data review is in some cases computational, using administrative data, alternatively it can be detailed medical record review (MRR) and in other cases a hybrid methodology is used.

In order to maintain high confidence in the findings, the four levels of Confidence in the Evidence from Reviews of Qualitative Research (CERQual) [5] were followed: 1) the sources included were all carefully designed and evaluated, 2) the concepts and methods were coherent among the sources, 3) adverse events and their detection methodologies were consistently described in all sources, 4) the sources all referred to patient safety and delivery of care primarily for inpatients.

4.   Results

The results of this synthesis describe an overall approach to patient safety event detection which is retrospective and relies heavily on administrative data. ICD codes are consumed alone or in combination with medical record review to search for poor care quality. Based on this it is clear that detection methodologies currently in use may be impacted by data quality further mudding our understanding of patient safety.

The literature provided detailed descriptions of methodologies from five primary governmental and PSO organizations. Included in the final analysis for this review were methods used by the Centers for Medicare and Medicaid Services (CMS, hospital acquired conditions) [2], Institute for Healthcare Improvement (IHI, Global Trigger Tool) [7], the Agency for Healthcare Research and Quality (AHRQ, Patient Safety Indicators (PSI)) [3], The Joint Commission (TJC, Sentinel Event definitions) [4], and the National Quality Forum (NQF, serious reportable event (SRE) definitions)[6]. Each organization uses a set of definitions for patient safety or adverse events which we

grouped according to categories of circumstance, patient safety problem and adverse event detection method used.

Table 1. AE detection algorithms by source and event circumstance.

	Source				
Circumstance	**AHRQ**	**CMS**	**IHI**	**NQF**	**TJC**
Care Management	3	7	16	9	4
Criminal issue				4	3
Environmental				3	1
General					4
Medication			15		
Patient protection			1	4	3
Product or Device				3	
Radiologic			1	1	1
Surgical or invasive procedure events	15	7	18	5	2

When taken together there are 130 potential adverse event detection algorithms resulting from these different organizations in 9 circumstance categories (table 1). It is clear that there is alignment of focus on major areas of concern (39 algorithms in the care management category and 47 in the surgical category). This relationship is not surprising since events in these categories are clearly definable safety issues which are captured in coded administrative data, the most computational mechanism of patient data review. For the detection of the less obvious safety issues MMR was used alone or in combination with computational methods. Underlying the care circumstance categories are 41 granular patient safety problems (e.g. lost patient, blood irregularity, falls, pressure ulcers) which represent opportunities for algorithmic implementation along with data quality checks.

The synthesis reflects that the conceptual frameworks behind these different approaches share many commonalities in circumstance and problem focus but variability in detection approaches. Thirty-two used only administrative data, forty-seven used observational and MMR data only and 51 used a hybrid approach. This suggests that safety events are well covered by these categories and that they can be used for future study of barriers to the implementation of safety event detection and as a base for quantitative research into methodological improvements.

5. Discussion

The patient safety metrics included here have come from governmental agencies, patient safety organizations and regulatory bodies. Some of their definitions overlap but their implementation varies. Because there is no central US authority for patient safety metrics a gap exists. The work here describes currently used and accepted measures and categorizes them according to the circumstance of the adverse event being measured, the problem and method of detection. From this work it is clear that there are some circumstance and problem categories that are the subject of more focus. Further study is needed to determine if this is due to their severity or detectability. Reconciling the adverse event detection methodologies in a computational format is viable especially in the categories with heavy overlap. Our confidence in these findings is high because the underlying research used by these organizations has been well designed and conducted, the resulting focus areas and methodologies are similar, the approach to correction of

these problems is consistent and the context of the literature is primarily inpatient patient safety.

6.   Conclusion

Medical error is a significant problem in healthcare today.[1] The large-scale adoption of the EHR suggest that data quality will become a serious problem in the future if it is not already. Data errors occur with certainty in every EHR at unknown frequencies or care areas. Adverse events occur at every hospital, as a result of process and as a result of medical error. Some AEs may actually result directly from data errors. To ferret out this connection we must be able to consistently define and collect adverse events which occur during patient care. We have seen a consistency in AE detection circumstance, resulting patient safety problem in detection methodologies. We've also identified a focus in the areas of surgery and care management. With the understanding of adverse events and their detection provided by this synthesis the important work of building a foundation for comparative testing and quantitative analysis of patient safety event detection can be undertaken allowing for the eventual development of detection methods which can be implemented completely computationally.

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A Usability Evaluation of the InfoSAGE App for Family-Based Medication Management

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Abstract. The design of a mobile medication manager within a broader family and elder-centric collaboration platform faces challenges of usability and wide applicability. To inform the development and use cases of eldercare apps, we present the preliminary results of a usability study of an iOS and Android app intended for both family members and aging adults for the mobile management of medication lists. Seven participants were recorded during the performance of eight typical use-case scenarios of the medication portion of the InfoSAGE app. Audio and video recordings were analyzed for themes and events. The aim of this paper is to help inform future design choices for eldercare mobile apps.

Keywords. health information technology (HIT), elderly, smartphone, usability

1. Introduction

There is a rising life expectancy of populations in both developed and developing countries. The number of people aged 60 years and over has tripled since 1950 and is projected to reach 2.1 billion by 2050 [1]. Many informal caregivers of frail elders have high levels of stress that can lead to physical, mental and financial problems [2]. Technology enabled support systems may help improve the care coordination between patient and family members [3-4] but acceptance of technology and sustained usage for elder care application remains a challenge [5-11], particularly for mobile applications [5,6,11]. We present the preliminary results of a usability evaluation of the InfoSAGE [3] family-based care coordination mobile app, and propose recommendations for the development of future mobile applications for medication management for elders.

2. InfoSAGE

InfoSAGE (https://www.infosagehealth.org) is a communication and collaboration platform for family caregivers and elders navigating the aging process developed by the

Division of Clinical Informatics at the Harvard Medical Faculty Physicians at Beth Israel Deaconess Medical Center (BIDMC) in conjunction with aging researchers at the Institute for Aging Research at Hebrew Senior Life [3]. It consists of a web-app and mobile-app for the sharing of tasks, calendars, contacts, medication lists, and associated care discussions. InfoSAGE is primarily intended as a family-centric tool coordinating care around a single elder, called a keystone, but is frequently utilized by single users for the management of medication lists. InfoSAGE is open to the public and free to use. To date, 321 users have signed up across 180 family networks.

Currently, the primary focus of the research surrounding the InfoSAGE platform is in the observation of changing medication lists, the discrepancies between family maintained lists and medications recorded in health records, and medication safety. A novel, family-curated medication manager was developed for InfoSAGE, leveraging online National Library of Medicine databases, and versatile recording methods to capture name, type, dose, strength, route, indication, schedules, and administration directions in a readily accessible and shareable format. Owing to the diversity of age within our target user population, InfoSAGE was developed to be approachable and usable by both aging older adults, their baby-boomer children, and younger users. Despite increasing smartphone use in those 75 or older, achieving the desired usability across this age range can be challenging and benefits from iterative, systematic design.

3. Methods

A convenience sample of subjects was recruited from the Boston area using advertisements and referrals from collaborating facilities at Hebrew Senior Life, and through a grass-roots campaign focused on BIDMC. Online local message boards were also utilized to increase the reach and diversity of the sample. Persons age 18 or older who are involved in the care of an elder aged 75 or older, or the elder themselves were invited to participate in the study. This study was conducted under the review and oversight of the Beth Israel Deaconess Medical Center institutional review board (#2014P000296) using observational usability methods [13-14]. All study visits took place at BIDMC facilities, using the iOS InfoSAGE app (version 2.8) on a provided Apple iPad Pro. Participants' interactions with the screen were recorded by a camera as well as screen capture software. During the testing process, participants were asked to 'think-aloud' as they completed the study scenarios, in order to capture any reasoning behind their specific actions. Spoken comments were recorded and transcribed.

Eight scenarios of varying level of complexity were employed to capture common use cases for the medication manager feature of the InfoSAGE app. Participants were asked to add multiple medications with varying strengths, doses, and schedules. Both generic and name brand medications were included. Participants were also asked to utilize other primary features of the app such as drug-drug interaction notifications. No specific instruction was given from study staff about the study scenarios, nor were any participants shown how to use any feature of the app. If a scenario could not be completed due to difficulty, participants were given guidance on how to proceed. Participants used standardized instructions and scenarios, and did not enter any of their own, or elder's, personal health information.

Demographic and subject-reported comfort with the Internet was collected prior to beginning the study scenarios and an after-study survey was collected to evaluate the system and process. Participants were asked to rate on a Likert-type scale, with one

corresponding to 'Strongly Agree' and seven to 'Strongly Disagree', the ease of use, satisfaction with entry speed, the usefulness of in-app help, the difficulty of completion, and how useful the app would be as part of their informal caregiving. Semi-structured interviews were used to obtain further feedback from participants.

4. Results

All audio recordings were transcribed and thematically coded using an iterative process by a study staff member in consultation with the rest of the team. Codes and themes were categorized into five groups: Software response, user actions, user feelings, usability process, and task completion. Video recordings were analyzed using the Behavioral Observation Research Interactive Software (BORIS, v. 7.0.8), coded for events and themes and correlated to associated audio events. Time to complete each scenario was recorded, along with metadata such as the number of taps, use of in-app help, and frequency of mistaken 'clicks.' Observations were captured from seven participants involved in the care of an elder. Median age was 50 (2.5 IQR), and 71% were female. Demographics and self-reported skills are shown in table 1.

Table 1: Demographics, Survey Responses, Time to Complete (n=7)	
Age (Median, IQR)	50 (2.5)
Female (%)	5 (71%)
Ethnicity	
Hispanic or Latino	1 (14%)
Not Hispanic or Latino	6 (86%)
Race	
Black or African American	1 (14%)
White	6 (86%)
Level of education	
4-year college graduate	5 (71%)
Masters or doctoral degree	2 (29%)
What is your comfort level with using the Internet?	
Very comfortable	6 (86%)
Comfortable	1 (14%)
Do you currently care for an elderly family member? Yes	7 (100%)
On average, I access InfoSAGE: Never	7 (100%)
I would personally rate my skills with online websites as	
Intermediate	3 (43%)
Expert	4 (57%)
I would personally rate my skills with mobile apps as	
Beginner	1 (14%)
Intermediate	4 (57%)
Expert	2 (29%)
Questions (1=Strongly Agree, 7=Strongly Disagree)	**Mean (SD)**
Overall, I am satisfied with the ease of completing these tasks	1.3 (0.5)
Overall, I am satisfied with the amount of time it took me to complete these tasks	1.3 (0.5)
Overall, I am satisfied with the usefulness of the help for completing these tasks	1.8 (1.6)
How would you rate the difficulty of completing the task scenarios	1.7 (0.5)
Overall, after completing these tasks, I feel that this could potentially be used on a regular basis as part of my patient care/loved one's patient care and communicating my current list of medications with my care provider/loved one's care provider	1.2 (0.4)
Time to complete	14m04s

All participants were naïve users, having never used either the InfoSAGE website or mobile applications. Except for one participant, all self-rated their skills with mobile apps as intermediate or expert. All were familiar with the general use of the iPad. Each participant successfully completed all eight scenarios, with an average time to completion of 14 minutes 04 seconds. Familiarity and comfort with the app increased for each subsequent scenario after the first despite increasing complexity, and the average time to complete scenario two, the addition of warfarin (5mg tablet, by mouth, once daily) to the medication list, decreased by 37% when compared to scenario one, the addition of lisinopril (5mg tablet, once daily).

Audio and video coding uncovered confusion in the entering of medication details surrounding doses and strengths, and was the most consistent theme observed in all participants. Two participants suggested that the current method of entering medication (figure 1) "feels redundant." The app currently employs several fields that seem repetitive (use of dose and schedule, naming conventions) but allow for maximum flexibility in the recording of a wide range of medications, prescribing practices, and delivery methods (aerosol, injection, by mouth).
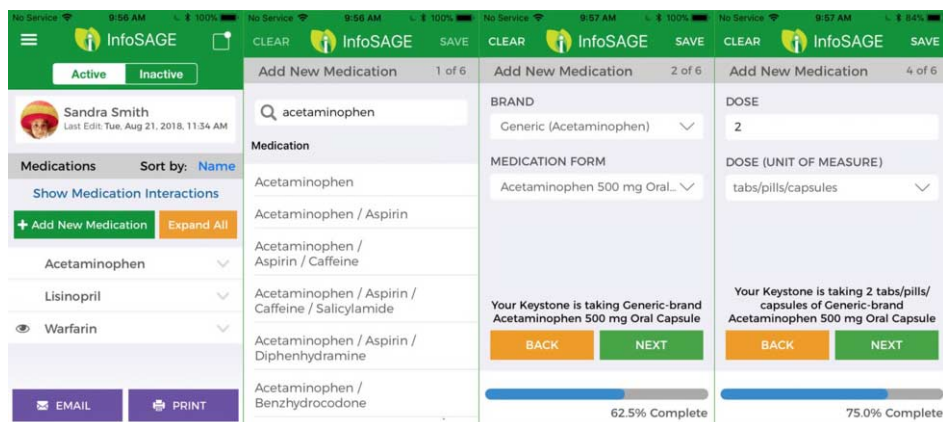

Figure 1. Adding a medication to the InfoSAGE mobile app, process flow

Terminology was a consistent source of questions, ambiguity, and hesitation throughout the scenarios. Two participants confused medication side effects with drug-drug interactions, and all but one participant had difficulty discovering where medication side effects were listed. The difference between generic and name-brand medications, and how they are listed through the app, also proved to be challenging for participants. Medications are loaded by searching the National Library of Medicine's RXNorm database, which also contains information about dose and strength. These strings are shown to the user for selection of the appropriate medication, but often contain details, including generic names, that must be confirmed on further screens. Lastly, the difference between deactivating and deleting a medication was a consistent point of clarification. Deactivating is used when a user stops taking a medication but wants to keep it on record, and deleting removes it. Despite these difficulties, participants also remarked on the ease of use of the app, and several expressed that the utility may be useful in their own informal caregiving. To the question 'Do you think that this system could possibly improve your mother's care', one participant stated:

"Yes, but not my mother's care. It would improve my sister and I -- our sanity. I think it would be more useful for us than for her, which in essence would benefit her. More for everybody to figure out what is going on."

Another participant indicated that the thoroughness of the medication entry process made her feel secure. As the user enters additional details, the app automatically constructs a summary sentence for that medication. Others requested additional features, or changes to existing features, another commonly observed theme:

"I'd like to see a planner, or daily schedule, or something. That would be useful, so what we've just done is only useful to the extent that it feeds into that. But you have to take nothing for granted."

Overall, participants were satisfied with the ease of completing the scenarios (1.3, SD: 0.5), the amount of time each task took (1.3, SD: 0.5), difficulty of each task (1.7, SD: 0.5), and the utility in their own caregiving (1.2, SD: 0.4).

5. Discussion

Our findings indicate that while users were able to use the app, there were difficulties in understanding both the content and the wide range of options to enter medications. The comments regarding the ability of users to understand the terminology, side effects and drug interactions suggest that more improvements are needed to respond to health literacy issues [15]. The drug information for elders and their caregivers will need to be further developed at a language level that more users can understand [16].

Design may help users distinguish differences between side effects and drug-interaction, such possibly using different colors and labels. Some users also expressed confusion on the various options for entering medications. By adding more functionality to the app we can support more possible scenarios of medication schedules, but we may be increasing the difficulty of the app for users that have simpler medication regimens. We will need to balance feature rich but usability poor tradeoffs. We may consider in future having a simpler entry form for rapid entry and a link to more advanced fields.

A few users also had some issues recognizing which items were buttons. This is in part due to the flat graphical style of the most recent release of the mobile operating system. Frequent changes by mobile computer makers to user interface layouts will cause problems for users with less computer experience and may be particularly problematic for older users that may have vision problems.

While there are some evaluations of mobile apps with elders [17-19], however the existing guidelines for user interfaces used by elder populations from international organizations such as The World Wide Web Consortium [20-21], The European Commission [22], and the US Government [23-24] have focused on web-based interfaces. Future research could strive towards a consensus recommendation on user interface guidelines for mobile apps for elder health applications with insights from academic groups, industry groups, elders and their families.

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Realizing Quality & Experience Benefits Through EHR Adoption & Use: A Conceptual Model

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Abstract. A conceptual model of EHR adoption and use is presented, which details the components necessary to realize both quality and experience benefits. The model was developed based on a review of the conceptual and theoretical frameworks related to technology adoption/use and quality in health care. It includes 42 constructs, six key constructs, three antecedents, four moderator variables, and two key benefit areas (i.e., quality and experience) at the micro, meso, and macro levels. The model has been operationalized through identification of over 130 metrics for measuring the constructs. The model may be used to inform planning, decision-making, and evaluation of EHR implementations and benefits realization. It is recommended that the EAU model be further tested.

Keywords. Electronic Health Records, Benefits Realization, Conceptual Model.

1. Introduction

The adoption and use of electronic health records (EHR) has been proposed to improve quality in health care [1,2]. However, there is currently limited evidence on the positive effects of EHRs on quality [3]. Further, although "quality" is widely referred to as an organizational goal in health care, it is unclear what "improve quality" actually means, especially related to use of the EHR [4]. For health care organizations such as Island Health that have adopted an EHR to facilitate the realization of purported quality benefits, the lack of a standardized definition for quality and corresponding dimensions and metrics to evaluate quality is a significant barrier to achieving and measuring quality benefits. Additionally, with the release of the Institute for Healthcare Improvement's new Quadruple Aim Framework [5], the "experience" of patients and providers is an emerging area and outcome of interest for health care organizations. Patient experience is defined as "the sum of all interactions, shaped by an organization's culture, that influence patient perceptions across the continuum of care" [6]. Similarly, *clinician experience* refers to the "work life of health care providers, clinicians and staff" [7]. Given burgeoning research on provider burnout resulting from EHRs [9], the role of EHRs in improving patient and provider experience needs to be further explored.

In order for organizations to fully realize EHR benefits in quality and experience, there is a need to identify: (1) the dimensions of quality and experience, (2) metrics to measure quality and experience, and (3) the prerequisite components of EHR adoption.

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This paper proposes an evidence-based conceptual model of EHR adoption and use (EAU) to support health care organizations in understanding the "big picture" of EHR adoption, use, and quality/experience benefits realization. By identifying metrics for measuring the constructs, the EAU model has also been operationalized for measurement to support formative evaluation of EHR adoption/use and benefits realization at Island Health and other health care organizations.

2. Background

To explore the relationship between EAU and quality benefits realization, the EAU model (Figure 1) was developed at Island Health from June 2017 to January 2018 following a review of frameworks and literature related to technology adoption/use and health care quality. In general, quality and EHR adoption frameworks developed in Canada were selected. The EAU model was developed as a conceptual model, as conceptual models depict conceptual frameworks, organize constructs and relationships [20], and are very helpful in complex or rapidly emerging fields [20].
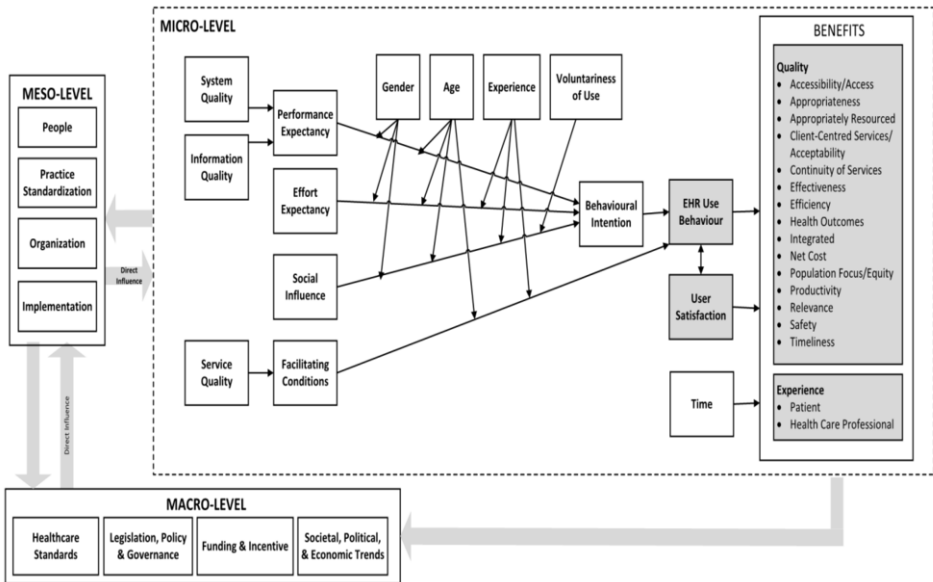

Figure 1. EHR Adoption & Use (EAU) Model

The EAU Model is based on ten technology adoption/use and quality frameworks used at the local, provincial, national, and international levels: (1) the Unified Theory of Acceptance and Use of Technology (UTAUT) [10]; (2) Canada Health Infoway's Benefits Evaluation (BE) Framework [11]; (3) the eHealth Observatory's Clinical Adoption Framework (CAF) [12]; (4) Island Health's Quality Framework [13]; (5) the BC Health Quality Matrix [14]; (6) The Clinical Systems Transformation (CST) Benefits Framework [15]; (7) the Agency for Healthcare Research and Quality (AHRQ) Domains of Health Care Quality [16]; (8) Health Quality Ontario's Quality Attributes [17]; (9) Accreditation Canada's Dimensions of Quality Care [18], and (10) the Clinical Adoption

Meta-Model [19]. As such, the EAU model combines 42 evidence-based constructs/components of technology adoption/use with universal quality benefits that can be measured for EHR benefits realization at three levels: micro (individual level), meso (organizational level), and macro (national/international level). In total, the model includes six key constructs, three antecedents, four moderator variables, and two key benefit areas (i.e., quality and experience). Given that the EAU model is a diagram/picture of the relationships between constructs, it is referred to as a model instead of a framework. Feedback to improve and validate the model was sought from a subject matter research expert from the University of Victoria's School of Health Information Science. The model was then presented to Island Health leaders who were key stakeholders for supporting EHR Adoption, use, and benefits realization at Island Health, including the Chief Medical Information Officer, the Executive Medical Director of Quality & Safety, the Director of Clinical Improvements & Informatics, the Director of Provider Learning & Knowledge Translation, and the Director of Clinical Learning & Knowledge Translation. Following iterative refinement (e.g., addition of "experience" construct) and organizational approval of the model, the EAU model was operationalized (described in the next section). In November 2017, based on feedback from Island Health's Director of Professional Practice, the EAU model was further revised to include a new meso-level construct that was not included in the reviewed literature: practice standardization. Since its development, the EAU model has been applied to conduct formative EHR evaluation studies at Island Health.

2.1. Key Benefit Areas: Quality and Experience

Quality and experience are the end-goals or key benefit areas of the EAU model. **Quality** includes the sub-constructs of accessibility/access [11,12], appropriateness [14] appropriate resourcing [17], client-centered services/acceptability [16], continuity of services [13], effectiveness [14], efficiency [13], health outcomes [11,12], integration [17], net cost [11,12], population focus/equity [14], productivity [11,12], relevance [18], safety [16], and timeliness [16]. **Experience** includes patient experience and provider experience, as earlier defined. The sub-constructs of quality are outlined in the table below, including corresponding definitions and source references.

Table 1. Sub-Constructs of Quality in Health Care

Sub-Construct	Definition	Reference
Accessibility/ Access	"Ability of patients and providers to access timely and equitable services."	BE/CAF [11,12]
Appropriateness	"Care provided is evidence-based and specific to individual clinical needs."	BC Health Quality [14]
Appropriately Resourced	"The health system should have enough qualified providers, funding, information, equipment, supplies and facilities to look after people's health needs."	Health Quality Ontario [17]
Client-Centered Services/ Acceptability	"Providing care that is respectful of and responsive to individual patient preferences, needs, and values and ensuring that patient values guide all clinical decisions."	Institute of Medicine [16]
Continuity of Services	"Patient care is coordinated across the continuum."	Island Health [13]
Effectiveness	"Care that leads to the best possible results."	BC Health Quality [14]
Efficiency	"Optimal use of resources to yield maximum benefits and results."	Island Health [13]

Health Outcomes	"Clinical outcomes and change in health status attributable to the eHealth intervention."	BE/CAF [11,12]
Integrated	"All parts of the health system should be organized, connected and work with one another to provide high-quality care."	Health Quality Ontario [17]
Net Cost	"Monetary avoidance, monetary reductions, savings."	BE/CAF [11,12]
Population Focus / Equity	"Distribution of health care and its benefits fairly according to population need."	BC Health Quality [14]
Productivity	"Efficiency, care coordination and net cost."	BE/CAF [11,12]
Relevance	"The services being provided must be relevant to the group of people being served."	Accreditation Canada [18]
Safety	"Avoiding harm to patients from the care that is intended to help them."	Institute of Medicine[16]
Timeliness	"Reducing waits and sometimes harmful delays for both those who receive and those who give care."	Institute of Medicine [16]

2.2. Micro-Level Components

Realizing the benefits of quality and experience is dependent on three constructs: EHR use behavior, user satisfaction, and time. **EHR use behavior** is "the frequency, duration, location, type or nature and flexibility of actual usage that took place" [11,12]. **User satisfaction** refers to "the subjective opinions of users in terms of their perceived expectations, information/system/services quality and use of the system" [11,12]. It is important to note that quality and experience benefits may be realized at different **time** points post-implementation of the EHR [19]. The time dimension is often missed in conceptual models for EHR adoption, use, and benefits realization.

The EHR use behaviour construct is influenced by five constructs: behavioral intention, performance expectancy, effort expectancy, social influence, and facilitating conditions. While **performance expectancy** is "the degree to which an individual believes that using the system will help him or her to attain gains in job performance" [10], **effort expectancy** is "the degree of ease associated with the use of the system" [10]. **Social influence** is "the degree to which an individual perceives that important others believe he or she should use the new system" [10]. **Facilitating conditions** refers to "the degree to which an individual believes that an organizational and technical infrastructure exists to support use of the system" [10]. Micro-level antecedents include **system quality** (i.e., technical aspects of HIT), **information quality** (i.e., characteristics of the data in the system), and **service quality** (e.g., for training and ongoing support) [11,12]. **Moderator variables** include gender, age, experience (i.e., work experience), and voluntariness of use [10].

2.3. Meso-Level Components

At the meso-level, there are four constructs that directly influence the micro-level: people, practice standardization, organization, and implementation. **People** refers to "all individuals or groups that are involved with the system" [12], whereas **organization** is "the strategy, culture structure, business process, information infrastructure, return on value and their relation to the system" [12]. **Implementation** is "the project plan regarding adoption, management and the fit of the system with the future and present operations" [12]. **Practice standardization** refers to the use of standard clinical practices in the organization. This construct was not identified in the frameworks reviewed from

the literature; instead, it was included as a lesson learned from Island Health's 2016 implementation of the EHR in Nanaimo, BC.

2.4. Macro-Level Components

Macro-level components directly influence the meso-level. These include: standards, governance, funding, and societal, political and economic trends [12]. **Standards** refers to "eHealth, organizational and professional practice standards" [12]. It should be noted that although professional practice standards may exist, it is important to evaluate their adoption at the meso-level (i.e., the aforementioned practice standardization construct). **Governance** is "the influence that governing bodies have on the organization and their attitudes towards [Health Information Technology]" [12]. Funding includes "the way the organization/project/individual receives funding" [12]. **Societal, political, and economic trends** refer to "public expectations, and the overall socio-political and economic climates toward technologies, eHealth and health care as a whole" [12].

2.5. Model Operationalization

To measure the EAU model constructs, over 130 metrics were identified at the health care organization, provider, patient, and population health levels. Corresponding instruments and methodologies to evaluate the metrics were also determined; they can be used for formative evaluation of any number of desired constructs.

3. Discussion & Conclusion

This paper contributes a conceptual model or "big picture" of the components of EHR adoption and use that are necessary to realize both quality and experience benefits. The EAU model is based on existing technology adoption/use theories in the information systems and health informatics literature. However, based on Island Health's EHR implementation experience, this model highlights a new benefit area (i.e., experience) for EHR benefits realization, as well as the addition of a meso-level construct (i.e., practice standardization). To the knowledge of the author, this is also the first model to (1) include the time dimension in benefits realization and (2) comprehensively include the multiple dimensions of the term "quality" in health care. The EAU model can be applied by decision-makers, practitioners, researchers, and evaluators to plan, implement, evaluate, and continuously improve EHR adoption and use for quality and efficiency benefits realization. Specifically, the implementation of this model highlights key causal relationships that may impact the intention and use of an EHR. As such, the model can be used to assess EHR readiness using instruments such as the UTAUT tool. Further, the moderating variables in the EAU model allow EHR project teams to develop customized end-user support to increase "Behavioral Intention" and "EHR Use Behaviour." Additionally, the relationship between "Facilitating Conditions" and "EHR Use Behaviour" suggests a need to invest in more post-implementation EHR education and training. The EAU model also emphasizes the time-sensitive nature of realizing some EHR benefits, which is helpful for implementation teams to communicate to end-users and decision-makers to ensure appropriate expectations shortly after Go Live. Additional research is needed to test this conceptual model to determine if it describes the reality of EHR adoption, use, and benefits realization. In particular, health care

organizations should evaluate the micro and meso levels of the model, as these tiers of the EAU model are highly influenced by organizational strategy and planning. It is recommended that national organizations such as Canada Health Infoway conduct an EHR evaluation at the macro-level to inform cross-national benefits evaluation evaluation efforts.

4. Acknowledgements

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Development of an Interprofessional Educational Electronic Health Record

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Abstract. This paper identifies issues relating to academic health record systems and outlines a project currently underway to develop an open source educational clinical information system to better support interprofessional health education.

Keywords. Academic Electronic Health Record, EdCIS, Interprofessional health education, Open Source Education

1. Introduction

Electronic Health Records (EHR) systems are being widely adopted in Canada and around the world. These systems allow for immediate and accurate availability of patient health records, vital to the delivery of appropriate health services. Expert interaction with EHR systems will be a mandatory part of the job of health professionals, not only for patient safety, but for eligibility to work in the field. Students in the health sciences will require training in these technologies as part of their education. Their acceptance, attitudes, and proficiency with these systems will be a key factor in their readiness and safety to practice. The learning needs of students in the health sciences could best be served with an academic version of an electronic health record system (AEHR) so that they can gain applied knowledge of how to use EHR systems in a realistic, safe, effective and patient-centred manner. This paper identifies issues associated with currently available systems and proposes the development of an open source AEHR. We envision this system would be customizable by instructors to meet student learning needs, and would be interprofessional in scope. The development of this AEHR is broader than a clinical EHR, integrated with characteristics and functions similar to a Learning Management System and applicable to all students in the healthcare field. It is also different than the use of existing EHRs that are adapted for use by pre-licensure clinicians

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(e.g., OSCAR Electronic Medical Record tailored for a clinic). We are thus referring to the tool in this AEHR initiative as an Educational Clinical Information System (EdCIS).

2. Environmental Scan and Literature Review

The notion of using an AEHR in health sciences education has been in circulation for a number of years. However, an environmental scan of the current landscape of AEHRs identifies a number of problematic areas.

2.1. Lack of access to suitable systems

Lack of access to a suitable AEHR is noted as the principal barrier for incorporating informatics competencies into the curriculum.[1] Many of the systems that have been studied were not fully functioning. For example, studies have focused on specific areas of health records such as medication administration [2] or documentation [3]. These do not provide a full picture of the affordances of a system for evaluation.

2.2. Lack of open source systems

There are a few examples of fully functioning systems that have been developed by academic departments [4]. Unfortunately, they were ultimately purchased by commercial interests and are either no longer available or are expensive for schools or students to purchase or license. Proprietary systems are not open source and the intellectual property (IP) rights are owned by corporate entities. It may not be possible for educators to customize these systems to meet specific learning goals and outcomes and any customization may become the property of the IP owner. In an effort to overcome this barrier, Lucas [5] described an educational institution partnering with a health care organization to use their system for educational purposes. Others [6, 7] have described using a web portal and cloud infrastructure for 250 simultaneous student users to access open source EHRs (e.g. OpenMRS, OpenVista). While these [6, 7] systems provided customizability by instructors and batching work for groups of students' they were not sustained long-term past their original research studies and several published trial runs with nursing, medical and health informatics courses.

2.3. Lack of interprofessional focus

While there has been considerable research conducted on the use of EHRs in medical education and a moderate amount on nursing education there is only a small body of work on AEHRs in interprofessional education [3, 6, 8, 9]. Furthermore, there has been much less research done on the use of AEHRs in interprofessional education in fields such as nursing, laboratory, medical imaging, health informatics and physiotherapy.

2.4. Lack of configurability for international markets

The largest North American market for commercial AEHR systems is in the United States, therefore available systems relate to professional practice in the US. This can be problematic for educators in Canada and elsewhere: for example, lab results are reported

in SI Units rather than Metric Units and since the system servers reside in the U.S. there are potential student privacy and security issues, which may preclude their use since many educational institutions prohibit the use of software residing outside of Canada. As well, some of the systems lack the internal controls needed to protect student privacy. As mentioned above, these systems have limited configurability which may limit their use.

3. System Implementation Issues

There is a large body of evidence indicating that implementing AEHRs into the curriculum can be challenging. Studies have reported faculty resistance due to lack of skills and experience with AEHR systems [1, 10-13]. However, faculty workload issues [1], lack of technical support [14], and technological stress [15] have also been implicated as barriers. It is commonly noted that the systems are often not intuitive or user friendly and there is a substantial learning curve associated with them – time that faculty may not have allocated to their teaching preparation time. Faculty engagement, training, and support are cited as key factors for successful implementation [1, 16]. Herbert and Connors [1] suggest the use of pilot projects to increase faculty buy-in, providing faculty with mentors, and ensuring that there are sufficient funds and resources to allow faculty release time so they may become familiar with systems before they become 'live'.

Even in 2018, Baxter and Andrew [10] note difficulties with internet connectivity resulting in limited, unreliable and unpredictable access to the program as a significant barrier for both students and faculty. Students may also feel overwhelmed learning the system at a time when they are already inundated with new information related to their program of study.

3.1. Integration with the curriculum

Another key factor in successful implementation is the thoughtful integration of AEHRs into the curriculum. As Chung and Cho [11] point out, transition from paper based records to electronic medical records "entails more than a mere replication of paper forms in an electronic format." (p. 87). Degagne et al. [16] call for a clear definition of learning objectives, goals, and competencies.

Borycki et al. [17] suggest there are two ways to integrate AEHRs into the curriculum. The first is referred to in their framework as 'loose coupling'. This describes training students on EHRs during a practicum experience where it is not linked to in-class learning. Alternately, 'tight coupling' refers to the use of an AEHR "as a teaching tool to deliver primary course content and track the quality of student learning experiences" (p.23). Borycki et al. [18] call for a holistic approach which considers "instructional, technical issues and nursing practice issues…to construct classroom activities that truly engage students to help them learn how to use technology effectively and ensure their EHR competency." (p.92)

4. AEHRs as Part of the Simulation Experience

Simulation has been adopted across many fields where real-life training or testing would be too dangerous or costly. Nishisaki et al.[19] point out that "healthcare, especially the complex hospital care required to treat serious diseases, falls in the category of a high hazard industry like aviation, chemical manufacturing, nuclear power generation, and the military"(p. 226). While simulation has always been part of healthcare education the recent development of high-fidelity simulators has enabled students to have realistic practical experiences in the safety of the classroom. Combining AEHRs with high fidelity simulation adds yet another dimension of realism to the students' learning experience.

Theories of adult learning can be used to explain how learning occurs during the use of simulation technology. The pedagogical approach is based on the constructivist approach of experiential learning, where learners are actively involved in a process of knowledge construction, as opposed to passively receiving information about EHRs. Cognitive learning occurs when students are able to process, integrate and assimilate new knowledge through direct experience and reflection. In addition, social learning theory suggests that people learn by observing others [20]. Thus, simulation experiences using interprofessional case study scenarios combined with an AEHR can be used to reinforce and complement learning and clinical decision making across disciplines.

5. Project

After determining the need for an AEHR in Canada the authors came together to articulate their shared vison and outline the technical and functional requirements to develop an EdCIS (Educational Clinical Information System). A sub group developed 8 health case studies [21] to use for content in the EdCIS. Through funding from the British Columbia (BC) Ministry of Advanced Education, Skills & Training, and with facilitation by BC Campus this group is working with a software developer and other stakeholders to create an open source interprofessional EdCIS to support students within healthcare programs with appropriately inputting, accessing, retrieving, and synthesizing electronic health data to provide them with the competencies required to safely deliver high-quality patient-centred care. A pilot ready prototype is anticipated for simulation lab testing for 2019. Figure 1 shows a high-level activity diagram with swim lanes depicting the relevant actors.

6. Conclusion

Today's clinical healthcare student may never see a fully paper patient chart in clinical practice, whereas most of today's clinicians and educators navigate EHRs with paper charts as their foundational reference. It is imperative that students in healthcare learn on electronic systems so that they can seamlessly integrate their electronic interactions into their relational practice with their patients and healthcare team members. Existing EHR learning systems do not meet the needs of healthcare teachers looking to provide their students with simulated immersive experiential learning to prepare them for safe patient

care. The intent of the EdCIS initiative is to provide a system that can be integrated into the healthcare learning environment to support students' transition from classroom and simulation lab to clinical practice in an ever-evolving technological environment.
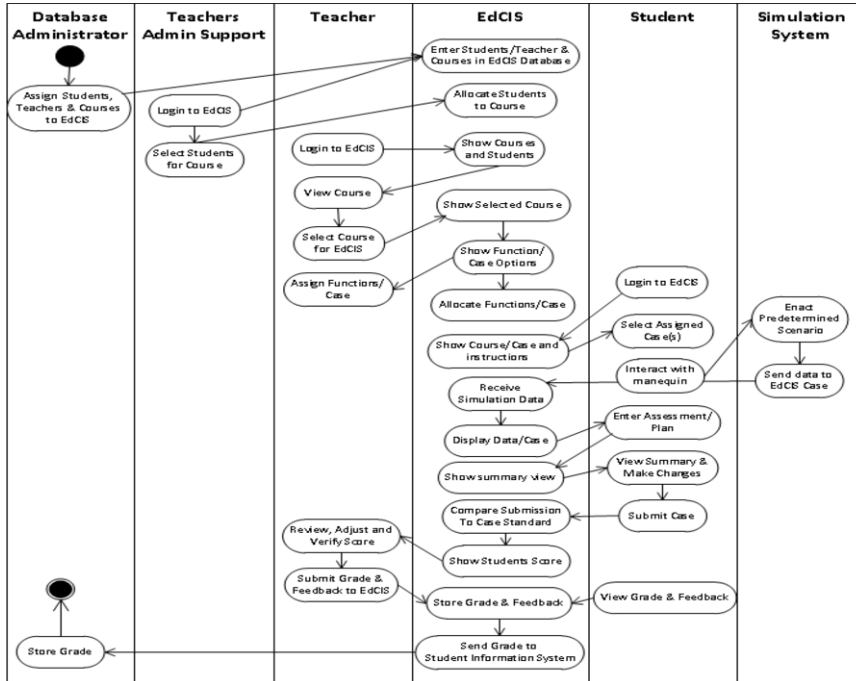

Figure 1. High- level Activity Diagram with Actors and Actions.

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Next Generation EHRs – What Problems Are These Systems Aiming to Solve?

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Abstract. EHRs elicit an array of different aspirations all underpinned by the widely held conviction that they can deliver benefits for patients, clinicians, researchers, IT vendors, policy-makers and society as a whole. While techno-centric visions abound, reflection on their history, the challenges evident in their design, implementation and evaluation and the limited evidence of their beneficial impacts over time is instructive. From a socio-technical perspective EHRs appear to be a set of 'wicked problems' unlikely to be resolved in favor of one position or another, but rather requiring judgement, nuance and negotiation around the kinds of problems we want these systems to solve. This paper presents some perspectives on important potential features for next generation EHRs and on the types of problems that these systems could aspire to solve. The focus is not on prediction but rather on actively shaping the kind of future that we desire and how EHRs will support its achievement.

Keywords. Electronic Health Records, Health Information Systems, Systems Integration

1. Introduction

Initiatives to develop new IT systems in healthcare are often characterized by techno-centric visions about how a particular technology, feature or function will deliver benefit. Difficulties related to a demanding implementation process and/or insights from evaluations of earlier failures tend to be marginalized, neglected and/or are left unexploited as important learning resources. In this context, the history of electronic health records systems (EHRs) is instructive. Important insights can be gained from a review of their specification and foci and the range of different aspirations that stakeholders have layered onto their delivery.

This paper critically reflects on how the EHR experience to-date may aid a reappraisal of priorities amongst these different aspirations and point towards the types of problems next generation EHRs should aspire to solve. These reflections occur in a context where most publicly funded health care systems globally have made huge investments in EHRs. Alongside promises of the transformative power of these systems it has been noticeable that reports of poor design, technology-induced errors and negative unintended consequences continue.

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Looking to the future, increasing amounts of health related data and information are being captured, analysed and exchanged under a vision of big data and automated data mining being the key to the delivery of health benefits from enhanced information timeliness and accuracy. For IT vendors such visions clearly support inflation in the feature and functional complexity of EHRs in ways intimately related to the underlying financial models of software sales. Questions about the utility, usability or effectiveness in terms of clinical or patient outcomes of such future systems continue to receive less attention than is perhaps advisable.

From a socio-technical perspective focused on drawing attention to the importance of users (patients, clinicians, researchers' et al), usability and context, it is evident that system features, or rates of adoption and use are not the only relevant metrics. Safety and quality, clinical and health outcomes, enhanced understanding, communication and care emerge as key for clinicians and patients alike. From this perspective the ability of future systems to support the integration and visualization of multiple data streams in ways that empower users with data rather than accentuate their anxiety and suspicion, are worthy of greater consideration. This is especially the case for patients as EHR users, where differences in technical, textual and health literacy and social determinants must be mitigated rather than be further exacerbated by the next generation of EHRs.

1.1. Contemporary perspectives from dominant EHR vendors

In September 2017 Epic Systems CEO Judy Faulkner announced that the 'E' in EHRs should be replaced with a 'C' meaning comprehensive. The Comprehensive Health Record (CHR) was described as being different from the traditional EHR in three ways: 1) It contains information that is not currently in EHRs including data on social determinants, eating and sleeping habits, obesity, and whether individuals are isolated/lonely. 2) Information on care beyond the hospital i.e. primary and community care. 3) Information on care traditionally managed by the hospital that is now managed via tele-health apps and mobile web [1].Epic's rival EHR vendors Cerner, Athena Health and eClinical-Works immediately responded with announcements that their EHRs were to incorporate new data types, such as social determinants, population health and precision medicine to make EHRs more "comprehensive" [2].Cerner CEO Zane Burke also promised to equip next-generation EHRs with interoperability in order for "data to flow freely" between Cerner's own Millennium EHR and other vendors' software. Similarly eClinical-Works' new EHR, version 11 consists of cloud-based connectivity, interoperability, intelligence with genetic screening for precision medicine, predictive risk models for population health, and patient engagement features including telehealth services [2]. All vendors continue to promise that these new digital features and functions will further enhance the delivery of benefits from EHRs/CHRs. But what problems are these features going to solve?

1.2. Patient/health records – an historical evolution

Patient records have a very long history. In Denmark patient records can be traced back to King Frederik the 5th (1723-1766) who founded the first hospital in Denmark in 1756 to treat and care free of charge for impoverished patients in Copenhagen. The King decreed that doctors should: *keep an orderly diary of the patients' condition, the nature of the disease, any occurrences, and the medicines, which are prescribed to them, and*

write down these very same occurrences with exceptional accuracy ...the diary is to remain in the hospital when he leaves the service [3].Ever since immense number of notes has been stored in paper forms, and the format of these paper records has been developed for more than 250 years. In the mid 1960's the first computer systems were developed to store the growing number of text notes and numeric lab results. The first systems imitated the paper record structures and very few elements had specific generic data structures.

In 1991 the American Institute of Medicine (IoM) published a report "The Computer Based Patient Record (CPR). An Essential Technology for Health Care [4]. The IoM report identified five objectives for future patient record systems: 1) They must support patient care and improve its quality; 2) Enhance the productivity of health care professionals and reduce the administrative and labor cost associated with health care delivery and finance; 3) They must support clinical and health services research; 4) They must be able to accommodate future developments in health care technology, policy, management, and finance; 5) Patient confidentiality must be maintained while these objectives are being met. Subsequently, the report was revised and updated in 1997 [5]. New trends in health care delivery, management, and research were appraised to broaden the vision of CPRs in two areas: population-based management of health through computer-based population records and citizen-based management of health through another variant of the CPR, the computer-based personal health record. Since these seminal IoM reports EHRs have become a synonym for computer-based systems that perform a broad range of functions related to documenting and managing patient care.

In 2015 the American College of Physicians published a policy position paper on clinical documentation including 5 recommendations on EHR systems design including [6]: 1) The need to optimize systems to facilitate longitudinal care delivery and care involves teams of clinicians and patients over time; 2) To support clinicians' cognitive processes during documentation; 3) To support "write once, reuse many times" and embed tags to identify the original source of information; 4) To reduce requirements on users to check boxes or otherwise indicate observations/actions where this data is already proven by documentation in the patient record; 5) To facilitate the integration of patient-generated data whilst maintaining the identity of the source of the data.

Significantly, information from IT vendors web pages claim that most, if not all, these features and functions are available in their EHR products. However, there is a lack of available evidence validating these claims. On the contrary, extensive complaints from clinical users about these EHR systems continue, as does evidence of unintended consequences [7][8], medical errors attributable to design glitches [9], templates filled with meaningless data fields [10], and excessive warnings and alerts causing fatigue [11]. EHRs also appear to be suffering from an IT productivity paradox [12] such that numerous common work tasks like ordering a medication that took seconds using pen and paper (or dictation) can take much longer using EHRs [13].

2. A Socio-technical Approach: Reflecting on Users, Usability and Context of Use

Comparison of visionary predictions and contemporary evidence/experiences with EHRs is salutary – the future seems never to arrive! From a socio-technical perspective it is

unsurprising that there are different ways of conducting and interpreting clinical work. In hospitals this work can be characterised as interpretative, multi-tasking, collaborative, distributed, opportunistic, interrupted and usually reactive. Whereas the model embedded in EHR design is usually objective, rationalized, linear, normative, localized (in the developer's mindset), solitary, and single-minded [14, 15]. To overcome this contradiction the design of the next generation of EHR systems should emphasize the problems and work tasks in context and in response to the needs of users if we are to produce a safe and sustainable next generation EHR fit for purpose

Adopting more agile design, implementation, and evaluation approaches would stimulate a stronger collaborative model between vendors and users. It is anticipated that this would generate solutions better adapted to open-ended clinical and care problems. Such a partnership points towards a different approach to defining contractual arrangements. As an example, a recent EHR tender in the Region of Southern Denmark lists a number of strategic, tactical, and operational principles to formalize these types of collaborative arrangements [16]. Similarly, the collaboration between CSC and the NHS Trafford Clinical Commissioning Group to establish the Trafford Co-ordination Centre, offers another alternative approach to IT systems development [17].

3. Wicked Problems Require Negotiation, Nuance & Care

From a socio-technical perspective EHRs appear to be a set of 'wicked problems' unlikely to be resolved in favor of one position or another [18]. To optimize next generation EHRs will require recognition of the need for nuance, negotiation and care when focusing on the kinds of problems we want these systems to solve. To aid reflection on the issues and challenges Figure 1 presents a simplified staged model from development to operation covering the EHR lifecycle.

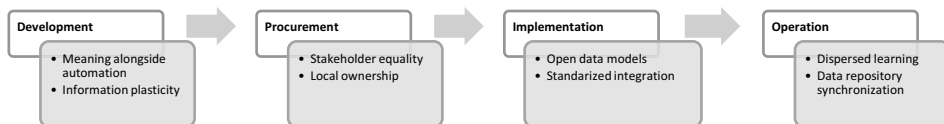| Development	Procurement	Implementation	Operation
• Meaning alongside automation • Information plasticity	• Stakeholder equality • Local ownership	• Open data models • Standarized integration	• Dispersed learning • Data repository synchronization

Figure 1 Challenges & issues for future EHR systems

Development stage: *Meaning alongside automation*; automated data analysis and learning should be counterbalanced by initiatives to integrate human participation (clinicians and patients) through meaningful interpretation. *Information plasticity* acknowledges that both input and output channels need to accommodate contextual customization for clinicians and patients alike. **Procurement stage:** *Stakeholder equality* catalyzing trust between vendors, buyers, operators, and end-users (clinicians and patients) to ensure true synergy. Establishing *local ownership* is of key importance in this regard, but requires a reconsideration of the technical power balance between vendor and buyer. **Implementation stage:** *Open data models* should be the starting point to ensure transparency, interoperability and adherence to long terms objectives of the health care system. In the same regard *standardized integration* using established regulated standards should be an immutable requirement regardless of the constraints it may exert on proprietary software modules. **Operational stage:** Accepting continuous change

necessitates new ways of deploying *dispersed learning* throughout and beyond health care organizations into patients' homes and communities. Broader integration will increase availability of data and information sources, and *synchronization of data repositories* must deal with trade-offs between speed, reliability, and capacity. Finally, as researchers we anticipate that this envisioned collaboration will extend beyond vendors and installation sites, to include evaluation to generate evidence and feedback on all stages to help extend learning beyond traditional non-disclosure boundaries.

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Thought Spot: Embedding Usability Testing into the Development Cycle

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Abstract. Usability testing is a vital component in the development of any digital innovation. Thought Spot, a mental health and wellness mobile application designed for and by transition-aged youth, underwent three distinct phases of usability testing (lab testing, field testing and heuristic evaluations). Testing highlighted that participants generally had a positive experience with the platform. Although some app functions were initially difficult for users, positive trends in learnability were observed. The key lesson learned from this process is the need for iterative testing timelines, concurrent with app development.

Keywords. usability testing, mHealth, student mental health

1. Introduction

Mental illness and substance use disorders are the leading cause of disability and total disease burden for youth in high-income countries [1]. In fact, about 20% of Canadian youth aged 15 to 24 have reported experiencing symptoms of mental illness and 8% have reported substance use concerns [2]. Unfortunately, only 36% receive the mental health or addictions support they need, leaving transition-aged youth at risk of long-term illness, unemployment, youth justice involvement or self-medication [3]. In addition, system access and navigation barriers along with stigma and confidentiality concerns make help-seeking difficult for this age group [4].

Thought Spot is a co-created and iteratively designed online and mobile platform to help reduce access-to-service barriers and confidentiality concerns for post-secondary youth [5, 6]. Its core function is to allow users to find and share health and wellness resource (spots) while providing a private space for them to track their thoughts and moods (thoughts).Using an interactive and crowdsourced map, users are able to search for relevant resources through geo-location and search filters/tags. Given that youth use the internet regularly [7] and often seek mental health information via web-based resources [8], Thought Spot has the potential to support this population in identifying useful services while promoting their mental health. The platform is currently undergoing

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an RCT to evaluate its impact on self-efficacy for mental health help seeking and health literacy amongst transition-aged youth [9].

Usability testing is widely used in the design of digital health interventions and more recently in the development of m-health applications [10]. App usability is one of the main factors determining app success, where failure to meet user demands can decrease effectiveness, efficiency, satisfaction and task performance [11]. End user feedback is critical for understanding what works, what doesn't work and where there are technical or user-interface gaps that might affect app performance or satisfaction.

The purpose of the present paper is to discuss the usability testing of Thought Spot, a multi-platform application, conducted under time- and resource-limited conditions.

2. Methods

Thought Spot was developed through a participatory design research process involving end-user consultations throughout its conceptualization and design. Transition aged youth played an active role in developing the content, the structure/functioning and the look and feel of the app through a range of co-creation methods including: a youth-led development team (Thought Spot Student Group), crowdsourcing/data workshops, co-design workshops and a hack-a-thon [5]. As a part of the iterative and participatory evaluation process, Thought Spot underwent distinctive phases of usability testing (lab, field and heuristic evaluations) over the course of three weeks. A total of 15 post-secondary students from the Greater Toronto Area (GTA) and two technical experts were recruited to complete usability testing across three platforms (desktop, iOS and Android). Following the REB protocol for Phase 1 of the Thought Spot study, numerous methods were used to recruit students for usability testing from three GTA schools (George Brown College, Ryerson University and the University of Toronto). Information for usability testing session was promoted through social media accounts (Facebook, Instagram and Twitter) of various academic departments and student organizations. Members of the research team also promoted usability testing sessions directly to students on campus.

2.1. Usability Design and Procedures

2.1.1. Lab Testing

Each platform (desktop, iOS and Android) was assigned five testers. Over the course of 90 minutes, each participant completed a demographic and technology use questionnaire, a series of 12 "think aloud" usability tasks, the Single Ease Question (SEQ) questionnaire [12], a Post-Study System Usability Questionnaire (PSSUQ) and a debrief interview [12]. Sessions were video recorded and detailed observations and notes were taken during the session by a second facilitator.

2.1.2. Field Testing

At the end of each lab testing session, participants were offered the opportunity to participate in a field test. Participants continued to use the same platform they were originally assigned during lab testing (five desktop, four iOS and three Android), and were asked to complete a list of tasks over the course of one week from their lab test date. At the end of field testing, participants completed a semi-structured interview (in-person or phone) and the PSSUQ questionnaire.

2.1.3. Heuristic Testing

Experts received detailed descriptions of the app and were asked to evaluate it using Nielsen's 10 usability heuristic principles and severity scale [13].

3. Results and Analysis

A total of 15 end user participants completed lab testing (10 females and 5 males), 12 completed field testing and one external subject expert provided incomplete heuristic results. The mean age was 20.9 years (SD = 2.66). In terms of technology use, 93.3% of participants rated their use as highly connected and 86.7% rated their comfort with technology as high.

The SEQ provides insight into user satisfaction and usability issues by asking users to rate the difficulty of a task [13]. On a 7-point Likert scale, with higher scores indicating a lower difficulty, the average score across all tasks was 5.2 (SD = 0.82). To determine which tasks were most difficult relative to each participant, individual SEQ scores were analyzed for their differences from a participant's average score across all tasks (Figure 1). The core features of 'find spot' and 'add spot' represented the most difficult tasks when completed for the first time, scoring 1.1 (SD = 0.6) and 1.2 (SD = 1.4) below average respectively. The third core feature 'add thought' scored 0.06 (SD = 0.5) below average when completed for the first time. Overall trends for SEQ scores suggest 'learnability' for difficult tasks (e.g., find spot, add spot and add a thought), with participants scoring higher during subsequent attempts for these tasks.

Grouping the results by platform-type provided some insight into the high variability of the scores. Desktop users had a significantly more difficult initial experience with the 'add spot' feature compared to iOS and Android. Further investigation during the debrief interviews highlighted that the workflow required to complete the task was unexpected for desktop users. Participants noted that they were using the search function, instead of the intended 'add spot' button, due to the similarity of the Thought Spot user interface with other map-based apps.
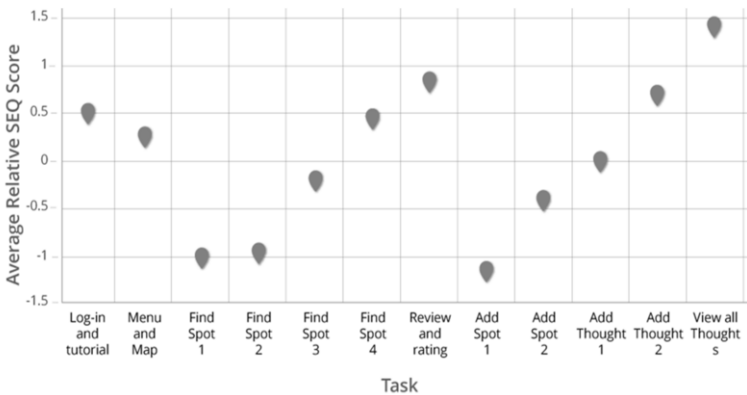
Figure 1. Average relative SEQ scores for post-task experiences are determined by taking the difference between each participant's individual scores from the average score given on all tasks.

Usability scores for the PSSUQ are presented in Figure 2 for both lab and field test-
ing. Specifically designed for scenario-based usability studies, the PSSUQ provides in-
sight into system usefulness, information quality and interface quality [12]. The lowest
scores were given to the PSSUQ statement "The system gave error messages that clearly
told me how to fix problems" with an average of 2.2 (SD = 1.8) on a 7-point Likert-scale
after lab testing, and 2.5 (SD = 1.4) after field-testing." These scores highlighted a need
for built-in error messages to streamline user experience. Lower field testing scores com-
pared with lab testing scores suggest decreased satisfaction and lower overall accepta-
bility of the platform after extended usage. However, it is possible that lab testing scores
were inflated due to observer bias, and functional and user interface issues may have
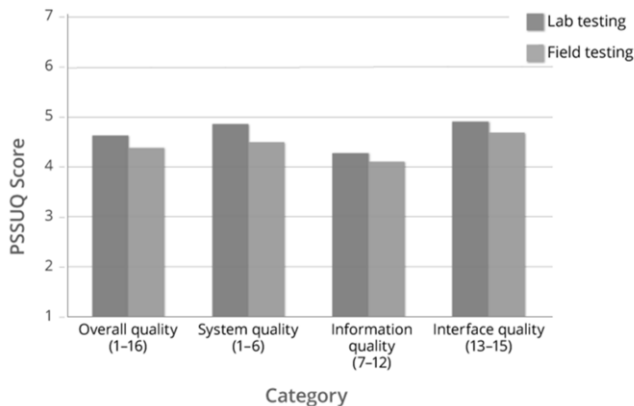hindered satisfaction during field testing.

Figure 2. Average PSSUQ scores for lab and field testing.

Despite the above issues, participants were generally pleased with Thought Spot's
interface quality. The only cosmetic issue concerned the spacing and overlay of icons on
the timeline menu.

4. Discussion

Usability testing is a key area of app development because usability can seriously affect
user satisfaction and adoption rates [11]. During our experience of this key step, we en-
countered unexpected constraints. Unforeseen complications during app development
pushed usability testing past its intended timelines and affected planned availabilities of
content-expert project staff for leading the testing process. The result was a decision to
move forward with testing some features that were considered functionally complete
while other features had known unresolved functionality issues. In addition, based on the
vital feedback from initial usability testing, Thought Spot underwent a documented func-
tional update two-thirds of the way into the process. The update was a necessary step,
despite the known limitations, given the importance of seeking usability feedback on key
app functionalities. Notably, caution is necessary when examining usability results with

or without changes to the product during testing. For instance, it is unclear if the differences between field and lab testing scores in Figure 2 are due to functionality issues hindering user satisfaction during field testing or observer bias inflating scores during lab testing.

The real-world challenges with the usability testing of Thought Spot resulted in interim rather than final usability testing of the app during its development. However, the interim testing afforded a greater opportunity for iterative design and made it possible for developmental changes. Exploring features that were confusing to users or that users interpreted differently than intended enabled developers to revise the design. In fact, knowing about functionality issues during testing gave developers greater flexibility to change course based on user feedback. For example, insight into the demanding process of adding a spot, a key feature of the crowdsourcing component of Thought Spot, encouraged the addition of autocomplete features. Moreover, interim testing highlighted the need for further development of key features such as the search function, which helped focus resources to optimize data organization and hygiene.

Given that Thought Spot is a multi-platform app, interim usability testing also allowed us to compare desktop and mobile platforms and to understand how to navigate trade-offs between these formats. For example, we found that the desktop platform had much greater stability compared with the mobile platforms, while the mobile platforms better use the application's portability and geolocation capabilities. The difference in stability between desktop and mobile platforms may have been a result of the development method where a single version of Thought Spot was created as a hybrid-app, making use of a "wrapper" for different operating systems, rather than creating multiple native apps. Along with stability, usability may have been affected by this choice, as users of different operating systems have different expectations in application workflow. Although developing a hybrid-app is less resource intensive, native apps offer a better user experience [14].

Several months of additional app development and testing (e.g., informal internal and external testing, user acceptance testing and stability testing) were necessary based on the usability testing findings before the app could be launched for a randomized control trial (RCT) to evaluate the efficacy of Thought Spot [9].

5. Next Steps and Recommendations

Consistent with the iterative approach to Thought Spot's development, there is an intention to continue evaluating the usability of the app as an endpoint to the RCT. An adaptation of the USE questionnaire [15] and open-ended usability questions are a part of the final survey study design. In addition, a purposeful sample of participants will be selected for semi-structured interviews to gain a deeper understanding of app usability for future iterations of Thought Spot.

The usability testing of Thought Spot demonstrated real-world challenges of resource constraints that arose due to unforeseen complications during app development. While testing during the development cycle may not be the best use of time as known errors and bugs are often reported, our experience resulted in valuable insight into the usability and design of the app, more opportunities for end-user engagement, the ability to utilize content-expert project staff resources under time constraints and provide developers with more opportunities for essential functional/design changes to the platform.

Based on Thought Spot's interim testing, we recommend in circumstances of limited resourcing to focus on testing features that are functionally complete but do not avoid testing features still in development. We also encourage concurrent app development along with key functional or usability updates during testing. Finally, detailed version logs of these updates should be maintained to overcome the instability of the in-development environment. The usability process was an essential component of the development of Thought Spot, and the continued partnership with end users will drive research and implementation of this application to improve student mental health.

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The eHealth Trust Model: A Patient Privacy Research Framework

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Abstract. Patient privacy concerns are often cited as a barrier to health information exchange (HIE) implementations; however, the current understanding of patient perspective is limited due to a fragmented approach to patient privacy research. The limited evidence suggests that the patient privacy perspective is context-dependent and may involve benefit-risk tradeoffs. A standardized approach to the contextual factors would allow for more consistent assessment, providing a better understanding or explanation of the contextual factors influencing the patient privacy perspective and their attitudes towards HIE. This paper describes the development of the eHealth Trust Model—an evidence-based theory-grounded conceptual framework intended to guide future patient privacy research.

Keywords. Privacy, Trust, Conceptual Framework, Health Information Exchange

1. Introduction

Privacy commonly refers to an individual's desire to control or have influence over data about themselves[1]. Patient privacy is an issue on the forefront of health information exchange (HIE) discussions, as HIE involves the process of exchanging personal health information (PHI) electronically between various points in healthcare[2,3]. Although HIE can improve healthcare[4,5], it may also be a source of patient privacy concern—an oft-cited barrier to HIE implementation[6,7]. The aggregation of PHI poses potential privacy risks as thousands of records may be accessed and/or disclosed with a single breach. Furthermore, the increased pace and extended reach of PHI (sometimes unbeknownst to the individual) may influence the patient's perceived control of their PHI, causing privacy concerns[7]. These concerns may erode patient trust in healthcare and undermine effective patient-provider relationships. Without trust, patients may withhold information or avoid seeking care in an attempt to protect themselves from the potential stigma, discrimination, and harm associated the unlawful PHI disclosure. These privacy protective behaviors may be detrimental to the patient care and health [8,9]. For this reason, protecting patient privacy is of fundamental importance.

From a policy perspective, protecting privacy requires a balance between the benefits of innovations against patient rights and interests[10]; however, the privacy

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discourse often fails to include the patient perspective[11]. The evidence suggests patient privacy needs may be overstated by the healthcare community, overlooking the context-dependency of the patient privacy perspective [12–15]. This context-dependency was highlighted in a recent systematic review[16], where 15% to 78% participants reported privacy concerns across the different studies. The review also found that the evidence was fragmented as theories/frameworks and standardized measures were used in only one-fifth of the studies. As a result, the *ad hoc* approaches limited each study's ability to incrementally contribute to a coherent, generalizable, and transferable explanation or understanding of the patient privacy perspective [17]. To provide a common frame of reference for future privacy research, the eHealth Trust Model (eHTM) was developed.

2. Proposed Privacy Framework: The eHealth Trust Model

2.1. Conceptual Foundation

The eHTM is an evidence-based, theory-grounded framework based on the Antecedent, Privacy Concern, Outcome model (APCO)[18]. While there have been a few comprehensive frameworks derived from extant privacy research[1,18,19], the APCO was selected because it was derived through an extensive multi-disciplinary review. Its broad scope was intended to guide future privacy research and allow researchers to adapt it for use in different contexts and disciplines.

The APCO is a high-level process model outlining the antecedents contributing to *privacy concern* and the resultant outcomes of those concerns. The antecedent constructs consist of *privacy experience, privacy awareness, personality, demographic, and culture*, while the outcome constructs include *perceived risk* and *behavioural reaction*. *Behavioural reaction* is the most prominent outcome since it represents an individual's intention to use an online service and/or technology. *Regulation* and *trust* are proposed to have reciprocal relationships with *privacy concern*, acting as both antecedents and outcomes The APCO also includes the notion of a privacy calculus—a cognitive risk-benefit analysis used by individuals to determine their *behavioural reaction*[20]. The privacy calculus is a common explanation of why individuals engage in information sharing behaviours despite voicing privacy concerns (i.e., the privacy paradox). This dissonance between attitude and behaviour occurs because the perceived benefits offsets the perceived privacy risks of using the technology or service.

2.2. Framework Development

A systematic review[16] and a qualitative study involving patient interviews[21] were conducted to inform the eHTM development. This foundational work was conducted at the Centre for Addiction and Mental Health (CAMH) with approval from their research ethics board (CAMH067/2015). The systematic review[16] assessed the current understanding of the patient privacy perspective of HIE. Insights on adaptations or expansions to the APCO were generated by mapping the evidence to the model. Despite identifying 59 studies, most of the linkages between the APCO constructs were tenuous either because they were infrequently studied, or the evidence was inconsistent in terms of directionality and statistical significance. Of the confirmed linkages, perceived quality of care had a significant effect in mitigating *privacy concerns*. Studies also confirmed that *privacy concerns* reduced patient willingness to share PHI or increased patient

privacy protective behaviours. The privacy calculus was also evident, where *perceived benefit* was positively associated with intention to use health information technology (HIT) and actual use; however, assumptions on the role of the privacy calculus in relation to *privacy concern* and *behavioural reaction* varied across studies. Based on the review findings, the following adaptations were made to the APCO:

- *Privacy concern* was changed to *privacy perspective* to encompass a greater range of privacy views and remove the negative framing of concern;

- *Demographic* was split into *demographic, tech savvy, and healthcare perception* to provide more specificity to patient characteristics;

- *Regulation* was changed to *policy and regulation* to include institutional privacy policies which govern PHI use; and

- *Privacy awareness* was changed to *eHealth awareness* to make it specific to healthcare and HIE.

Following the review, interviews with mental health service users were conducted to understand their privacy perspectives and to validate the constructs in the adapted APCO[21]. While patient participants believed that privacy was important given the stigmatic nature of their PHI, their degree of privacy concern varied depending on their patient experiences. Whether concerned or not, the participants were willing to share their PHI in HIE. They supported HIE because they wanted the best care possible— both directly through clinician or patient use, and indirectly through research and analytics. Participants also held a fatalistic view that privacy breaches are unavoidable in the current digital society and little can be done to protect their PHI privacy. Combined with a general unawareness of their patient privacy rights, participants placed a tremendous level of trust that the healthcare system and their providers will protect patient privacy.

To provide more depth to the *trust* construct, the Web-Trust Model (WTM) [22] was integrated with the adapted APCO. The WTM is an empirically validated model that uses the Theory of Reasoned Action [23] to explain the causality of trust on online behaviours. The WTM posits *disposition to trust* (i.e., the general tendency to willingly depend on others) and *institution-based trust* (i.e., beliefs that the structural conditions exist to ensure a trustworthy transaction) as antecedents to trust in a web-vendor. These antecedents influence the individual's *trusting beliefs* (i.e., perceptions about a vendor's attributes), which leads to *trusting intention* (i.e., decision to engage with the vendor).

Because the *trusting belief-trusting intention* linkage (WTM) mirrors the *trust-behavioural reaction* linkage (APCO), *trust* was renamed *trusting belief* to provide more specificity. This adaptation is appropriate because intention to share information may vary with the recipient. The other WTM constructs fit under the APCO high-level constructs, where, (1) *trusting intention* is represented under *behavioural reaction*; (2) *institution-based trust* is represented under *policy and regulation* and *healthcare perception*; and (3) *disposition to trust* is represented under *personality*.

2.3. The eHealth Trust Model

Mirroring the APCO, the eHTM follows an "Antecedent➔eHealth Trust➔Outcome" process. At the core of the eHTM (fig. 1) are three *eHealth Trust* constructs (i.e., *privacy perspective, trusting belief,* and *policy and regulation*), representing the patient attitude towards confidentiality—trust that the healthcare system (or provider) can and will

uphold its legal obligation to protect the privacy of the entrusted PHI. The eHTM suggests that a patient's *eHealth trust* is contextual, informed by their perceptions, experiences, personal dispositions, and environment. *eHealth Trust* is the primary determinant in a patient's *behavioural reaction* to HIE. These reactions can manifest as the willingness to share PHI, intention to opt-out, or intention to use patient-facing HIT. *Behavioural reaction* may also be influenced by the trade-offs between the *perceived benefit* of HIE and *perceived risk* to privacy (i.e., privacy calculus).
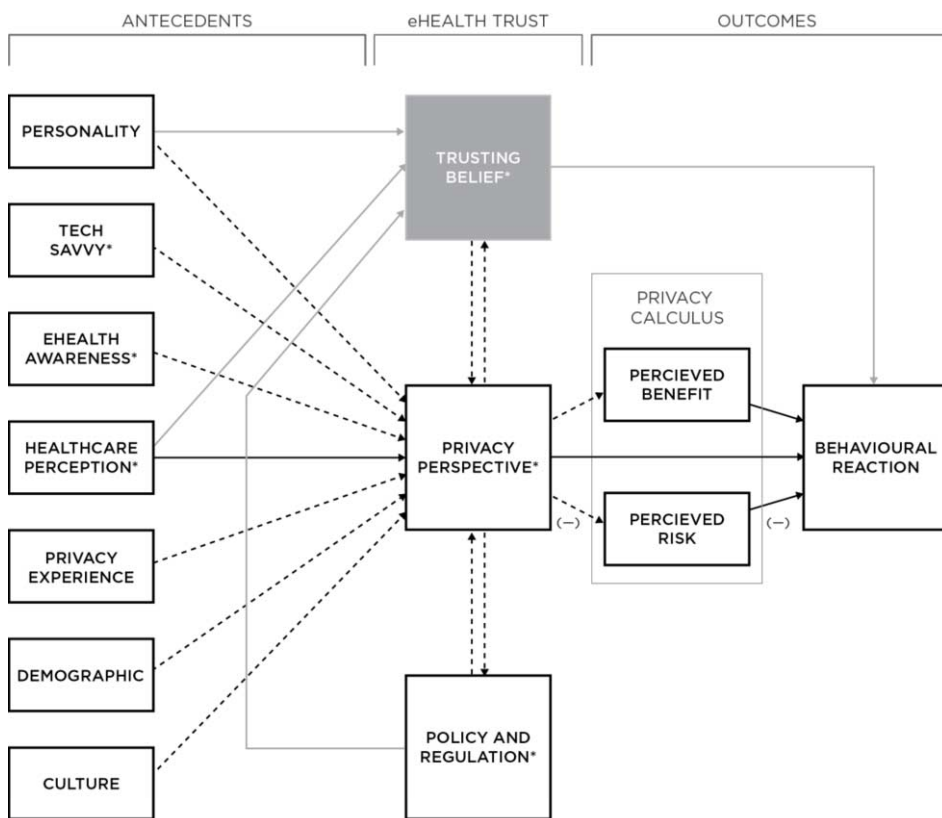
NB: asterix denotes eHealth Trust Model adaption or addition; light grey indicates adaptations from the Web-Trust Model; all arrows indicate positive association unless noted; dotted arrows indicate tenuous relationship between constructs.

Figure 1. The eHealth Trust Model

The status of the linkages in the eHTM were derived from the systematic review, patient interviews, and the WTM. The linkages included from the WTM (grey arrow) were confirmed through multiple studies by its authors[22]. As discussed, most linkages are tenuous as their relationships were unconfirmed or remain unclear. The confirmed linkages within the model assume there is a positive association between constructs unless otherwise indicated. The eHTM also assumes a positive framing for *behavioural reaction,* defined as "*an individual's intention to electronically share their PHI or use HIT*" (construct definition summary in Table 1). For instance, a positive *healthcare perception* will lead to a positive *trusting belief* and *privacy perspective* which subsequently leads to a positive *behavioural reaction*. A negative *privacy perspective*

may increase the *perceived risk* of HIE, thereby reducing *behavioural reaction* (i.e., opt-out of PHI sharing, non-use of HIT, exercise patient privacy rights).

Table 1. Definitions of eHealth Trust Model constructs (NB: * denotes original APCO constructs)

Domain Construct	Definition
eHealth trust	
Privacy perspective	An individual's beliefs, attitudes, and concerns about the electronic sharing of their personal health information.
Trusting belief	An individual's willingness to become vulnerable to the actions of another party.
Policy and regulation	An individual's knowledge of and attitudes towards the protection and use of their electronic personal health information.
Antecedents	
Privacy experience*	The extent to which individuals have been exposed to or have been a victim of information abuses.
eHealth awareness	An individuals' general awareness of health information technology. This includes experience with, knowledge of, and attitudes toward health information technology.
Healthcare perception	An individual's attitudes and beliefs about the healthcare system and their personal health.
Demographic	Differences based on the shared characteristics of a population.
Tech savvy	An individual's knowledge of, attitudes towards, and experience with technology.
Culture*	The attitudes, customs, and beliefs that distinguishes one group of people from another.
Outcomes	
Perceived benefit*	The degree to which an individual believes the electronic sharing of their personal health information can help themselves and others.
Perceived risk*	The degree to which an individual believes the electronic sharing of their personal health information will result in a loss or harm.
Behavioural reaction*	An individual's intention to electronically share their personal health information or use health information technology.

3. Discussion and Conclusion

With the increasing investments into interoperable HIT, it is important to understand patient privacy expectations on how their data is and will be used. The eHTM is a comprehensive evidence and theory-based framework intended to provide a logical and structured guide to thinking about patient privacy research, evaluation, and the discussion. By providing a common frame of reference, the eHTM aims to address the fragmented approaches to patient privacy research, allowing future research to incrementally contribute to the understanding of the patient privacy perspective. The foundational work presented here demonstrates the utility of a guiding framework (i.e., APCO) in building and extending the evidence. The work to date suggests that patient experience, value proposition, and trust are equally important factors to include in the discussion about patient privacy—all seldom explored in extant literature.

Like its predecessor in the APCO, the eHTM is intentionally broad to allow for the flexible application to suit various contexts and the informational needs of its users. The HIE framing focuses the eHTM on PHI uses rather than specific HIT, allowing for continued applicability as the digital health landscape evolves new innovative uses of PHI. This iteration of the eHTM will be further refined through a Delphi study focused on establishing content validity, marrying evidence and theory with the practical experience of privacy experts. Future research will leverage existing data from the Canada Health Infoway privacy survey [24] to establish criterion and construct validity of the model.

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Evaluation of Technology Use in an Inter-Disciplinary Patient-Centered Health Care Team

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Abstract. Health care services are facing challenges with carrying out individualised treatment to an ageing population prone to chronic conditions and multi-morbidities. The research project *Patients and Professionals in Productive Teams* aims to study different patient-centered teamwork service models. This paper presents an evaluation on the technology support in a patient-centered health care team providing services to elderly people with chronic conditions and multi-morbidities in the transition from hospital to a home setting. The team had employees both from a university hospital and municipal health services. Qualitative research methods were applied in the evaluation of the technology use and information flow. The results showed that two information systems were used, that were not integrated and caused double manual work and registrations by the health care professionals. A benefit was that information sharing was improved between the hospital and municipal health care services, but the constraint was added workload.

Keywords. health technology assessment, patient-centered care, information systems, electronic health record

1. Introduction

Health care organizations are facing challenges due to demographic changes in an ageing population, with growing numbers of individuals prone to long-term conditions and multi-morbidities [1]. One of the challenges is the organization of hospital services, that tends to have a focus on specialization and less patient focus around care needs [2]. This brings to light a need for understanding how to operationalize patient-centered, integrated and pro-active care. In this context, the research project *Patients and Professionals in Productive Teams* (3P) aims to study and share knowledge on health care services models run with different inter-disciplinary patient-centered teamwork approaches, also focusing on efficient technology support for collaborative work across health care organizations [3] The 3P-project started in 2015 and runs in a 4-year long period until the end of 2019. It is funded through Helseforsk, a cross-regional health research fund owned by the four Norwegian Regional Hospital Trusts [4]. The project is

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divided into 10 work packages targeting the different aspects of patient-centered teamwork service models, such as models for implementation, digitalized individual care plan, patient experiences and patient safety. Four innovation arenas utilizing patient-centered team models, located in different health regions of Denmark and Norway are included in the project [5][6][7][8]. This paper presents a study of the technology support and information flow in one of the innovation arenas, the University Hospital of North Norway, where a patient-centered health care team service was run as a collaboration between the hospital and surrounding municipalities providing community health care services to the citizens. The service model had the aim to support the independent life and self-management of elderly patients with a complex disease history and multi-morbidities in the transition from a hospital stay to a home situation, influenced by the Chronic Care Model [9][10]. This patient group is prone to frequent hospital admissions and re-admissions [11], and in this context, the service model aims to provide individualized care to patients with multi-morbidity after a hospital stay. The research questions (RQs) stated for the study were:

RQ1: *How does technology support the communication and information flow in an inter-disciplinary patient-centered health care team working in multiple locations?*

RQ2: *What are the benefits and constraints of the technology use in the inter-disciplinary team from a patient-centered care perspective?*

2. Methodology

A qualitative research approach was applied in the study, with the methods observations and semi-structured interviews [12][13]. Two visits were made to the innovation arena, the first one for three days and the second for five days. A total of 23 informants contributed to the study, with the professions nurse, physiotherapist, occupational therapist, physician and technician. Also, one patient and one family member contributed. The selection of the informants was made in collaboration with the leader of the patient-centered health care team. During the first visit in June 2017, individual interviews were made with a physician, patient and family member. Two paired interviews were made with two technicians and with a nurse and a physiotherapist to dynamically focus on technology and how telemedicine had been used in the team. A one-hour focus group interview was made with five nurses. In addition, a two-hour long workshop was organized with 14 participants having health professional background targeting the technology use and information flow in their collaborative work. The aim was to map out the experienced obstacles in the information flow within and between the involved services, and to outline optimal and technology support for the future.

During the second visit in November 2017, a field study was made with observations of communication processes and technology use in the staff room. Individual interviews were made with two nurses, specially targeting the user interfaces and functionalities of two separate information systems. In addition, they both made a thorough demonstration of the systems. A focus group interview with four nurses working in municipal home services was made. The data collection consisted of audio- and video recordings and annotations, that were thematically analyzed and categorized into three main groups. The Norwegian Centre for Research Data approved the study, with project number 53771 [14]. All informants participated voluntary and signed a consent form.

3. Results

The results are presented divided into three main topics: 1) the organization and workflow and 2) the technology and 3) the patient's access to information.

3.1. The Organization and Workflow

The patient-centered health care team was physically placed at a university hospital that was divided into two locations and financed by both municipalities and the hospital trust fund. The employees had the professions: nurse, physiotherapist, occupational therapist, physician and pharmacist. In addition, there were administrative and research staff. The team was established to support elderly people with chronic conditions and multi-morbidities in the transition from hospital to a home setting, also including other patient groups that could benefit from the services. The patients could be referred from hospital departments, municipal services or General Practitioners (GPs) for an evaluation of services from the patient-centered health care team. Each referral was evaluated by the inter-disciplinary team. When including a new patient, a meeting was usually organized with key people from the involved hospital ward, the patient-centered health care team and municipal services. In addition, relevant family members could be invited. The physician in the patient-centered health care team could be consulted. The patient-centered health care team made a personalized plan for the patient to support him/her in the transition period from the planning of the discharge and during the first weeks at home, in close collaboration with the municipal health services. The patient's contact person in the patient-centered health care team could consult the team's physician, the GP of the patient or other related health service providers such as the pharmacy or home nursing services when needed due to medical circumstances. The patient-centered health care team was available at day-time during weekdays and they could attend patients at home. The patients were enrolled to the services for a limited time.

3.2. The Technology

Two information systems were used in the patient-centered health care team to support the clinical workflow: 1) the hospital electronic health record (EHR) from the vendor Dips and 2) the municipal EHR Visma Profil. Both systems had to be used separately to carry out the team services and there was no system integration. All statutory medical documentation had to be made in both systems for permanent storage and the patient information was manually registered in both systems. In case of time constraint, the documentation could be made in one of the systems, printed out and scanned into the other system. All patient consultations were documented in both systems. Data storage was ensured by the two EHR systems located in two different organizations, and personnel in the team was given separate access to both systems using two different log-on procedures in two different PC's. When it comes to usability, Profil was described as a system designed for billing purposes of performed services, lacking a status overview of clinically complex patients. The documentation was differentiated by keyword banners in a menu, and there was no view to show content of "all banners" from a particular shift or day. Each banner had to be clicked on to show the content. Dips was described as a system with acceptable usability, but there was some information overload in the user interface. Quite many notes that had to be clicked on to read key information about the patient.

Figure 1. Using two information systems simultaneously, one in each screen.

3.3. The Patient's Access to Information

The patients in the health region had access to read their own EHR at the hospital through the National Health Portal (helsenorge.no). There was a secure log in procedure and access to all notes made by different professions. The patients did not have access to the information registered in the municipal EHR. Regarding physiotherapy, exercise and training at patient's home, there was a solution to support this with a tablet application. But it was experienced that this elderly patient group had limited digital literacy to be able to use such technology, and also regarding how to access their own hospital EHR information through the secured National Health Portal.

4. Discussion

This paper has presented a study of the technology use and information flow at a patient-centered health care team. The research questions (RQs) are answered based on the results.

Regarding RQ1, that asked about how technology supported the communication and information flow in the team. The study showed that to be able to support the information flow in the team providing services across different organizations, the professionals had to use two separate information systems with manual transfer of information between the systems. There was electronic communication with other health care providers such a GP or municipal services, but the telephone had a quite important function due to frequent lack of response to electronic messages.

RQ2 asked about benefits and constraints of the technology from a patient-centered care perspective. The study identified both strengths and weaknesses with the technology support. Addressing patient-centered care, it was beneficial that the service was run as a mobile service being able to attend patients at home. Due to limited resources in the team, a few visits regarding exercise and training could have been replaced with guidance through a tablet-PC. But most patients had limited digital literacy and could not use such technology. The individualized plan was beneficial for the patients, but one of the constraints was "Who owns the plan?". A plan made by hospital staff is not always followed by municipal health care services, because they have other ways of prioritizing

services. Another constraint in the daily operation, was the lack of response to electronic messages sent to other services, causing that the most reliable communication method was the telephone with verbal communication. The technical solutions used in the team were mainly designed for the information needs of health care professionals and not for involving patients. When patients are provided with a Tablet-PC solution to follow up own actions in their care plan, the user interface needs to include all actual functionalities and data access for the patient. It is not advisable to use general health portals and separate log-in procedures to have access to relevant data for daily treatment and follow-up.

This study had some limitations, such as using one research method and studying one patient-centered health care team within one health region. However, the respectable number of study participants with different professions and backgrounds meaningfully represented the group and contributed in multiple settings. Lessons learned from this study, indicate that EHR systems to a larger extent should support functionality for information flow within teams to avoid manual double work and verbal transfer of information by telephone. The main contribution lies on the evaluation of benefits and constraints that are applicable and transferable to other health care contexts. Future research agenda targets a further evaluation of the innovation arena evaluating possible new features of the systems and making a comparison with the results from the other three innovation arenas in the project.

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Using Simulation Technology to Improve Patient Safety in Airway Management by Practicing Otolaryngologists

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Abstract. Objective: Simulation technology provides a safe environment to learn crisis resource management in stressful clinical scenarios, such as the acute airway. While a number of surgical simulation studies have assessed trainees, there remains a paucity of data on simulation benefits for practicing physicians. The objective of this study was to investigate the impact of a simulation symposium on airway management for practicing otolaryngologists. **Methods**: Questionnaires (5-point Likert and open-answer questions) and interviews were distributed and conducted at a simulation symposium on airway management held at an annual meeting. **Results**: The majority of participants had no prior experience in simulation (62.5%). The data suggested a strong increase in comfort with airway management scenarios (2.93 to 4.09 (p<0.001)). Participants reported the symposium as relevant (4.68) and useful (4.67), with increased confidence about their knowledge of crisis resource management and team training (4.53). Qualitative data suggested great educational value for technical skills and communication strategies. **Conclusion**: Simulation with feedback may provide an opportunity for the practicing otolaryngologist to fulfill Continuing Medical Education and Professional Development requirements. This symposium allowed practicing otolaryngologists, including those in the community, to learn, develop, and refresh technical and communication skills while fulfilling certification requirements.

Keywords. Simulation, Crisis resource management, Education, Medicine, Otolaryngology, Continuing Medical Education, Continuing Professional Development, Patient Safety/ Quality improvement, High-fidelity simulation, PS/QI

1. Introduction

Sir William Osler revolutionized medical education in teaching centers across North America at the turn of the 19th century and, more than a hundred years later, his bedside approach to teaching continues to serve as a common model for medical education [1]. Although many of the principles underlying bedside teaching are still relevant and important, one limitation of Osler's practical training model is that the training agenda is determined by the need of the patient, not the learner [2]. This creates challenges

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regarding availability of clinical cases, discrepancies in exposure, and balancing patient safety and learning [3]. Simulation technology, using a variety of models representing whole or partial humans, allows a training agenda determined by the need of the learner [2].

Simulation technology is used extensively for educational purposes, particularly for medical students and residents [2-10]. Patient care scenarios created using simulation can be designed to allow learners to spend time learning in a safe, realistic environment during a lifelike and repeatable experience [2]. The medical literature, however, provides very little on using simulation to train practicing physicians.

The potential benefits of simulation may be extended from trainees to experienced surgeons. Simulation can be used to allow experienced surgeons to gain familiarity with new technology and to practice interventions in uncommon or complicated situations.

Crew resource management was originally developed by the airline industry to address errors secondary to inadequate teamwork, ineffective use of resources, and flawed communication [11]. Within medicine, an adapted and modified version of crew resource management is termed crisis resource management (CRM). Volk et al have shown that high-fidelity medical simulation used to teach critical decision skills and CRM principles have the capability to improve the crisis resource management skills of otolaryngology residents and fellows [12]. CRM principles have been utilized previously to develop a team building skills program [13].

The use of high-fidelity simulation technology for continued development of critical skills, decision-making, and group dynamics of practicing otolaryngologists deserves further study. To the best of our knowledge there has been no reported assessment of a simulation program for airway management involving practicing otolaryngologists.

2. Materials and Methods

We sought to develop, implement, and evaluate a simulation symposium in airway management for practicing otolaryngologists. This was a program evaluation study performed using mixed methods via questionnaire and interview both completed at the conclusion of the symposium. Ethics approval was granted by the University of Manitoba Health Research Ethics Board. Consent for the questionnaire and interview was obtained via paper consent form.

2.1. Subjects

All attendees of the Canadian Society of Otolaryngology – Head & Neck Surgery Annual General Meeting (CSO-HNS AGM) were invited to participate in the Simulation Symposium. Course faculty were comprised of a diverse international team of practicing otolaryngologists, residents, a medical student, and a research associate.

2.2. Setting

A 4.5-hour Simulation Symposium on Airway Management was held in the Clinical Learning and Simulation Facility (CLSF) at the University of Manitoba. The symposium sought to develop the following skills: acute airway management and effective collaboration and communication with other health team members.

2.3. Materials

The SSAM consisted of three high-fidelity simulation stations including: adult laryngeal trauma, pediatric stridor, and pediatric foreign body aspiration. These stations focused on critical decision-making, communication, and group dynamics as well as procedural interventions. These scenarios were previously developed and executed at McGill University with further use at other centers. Participants practiced technical skills with three hands-on skills stations during the simulation symposium. Participants were randomly assigned before the session into groups of three to four. The simulations used adult and infant high-fidelity mannequins, SimMan® and SimBaby® respectively (Laerdal, Wappingers Falls, NY). These mannequins were capable of simulating lung sounds, chest wall motion, ventilation through bag-valve-mask and endotracheal intubation, pharyngeal swelling, laryngospasm, pulse, IV access, and vocal sounds. Simulation and content experts, including otolaryngologists, Emergency Medicine and Anesthesiology physicians; nurses, medical students and research associates participated as simulator operators or "confederates" to add realism and represent members of an interprofessional team. Programmers operated the mannequins from a mirrored control room; the programmers manipulated the mannequin's physiologic and mechanical responses and the vital signs displayed on a monitor, as well as serving as "consultants" accessed by telephone. Debriefing sessions, led by otolaryngologists with experience in simulation, focused on fostering collaboration and embracing communication through open, safe discussion of participant decisions and actions during the scenario.

2.4. Procedure

Pre- and post-session questionnaires were used to assess participants' level of comfort in managing the emergent airway and overall opinion of the high-fidelity simulation experience. Course faculty provided feedback using a pre- and post-session questionnaire. Immediately following the symposium, participants were invited to take part in one-on-one semi-structured interviews with a member of the research team. Interview questions were modified, with permission, from the version developed by Cote et al [3].

Descriptive statistics were used to analyze questionnaire data. Interviews were analyzed using thematic coding of the transcriptions. Two independent raters developed initial themes, which were then summarized into organizing themes and finally global themes following a process of thematic networks. Continuous comparison of emerging themes was used to refine the codes in an iterative process. Discrepancies were resolved by discussion.

3. Results

Survey questionnaire responses were received from 19 participants and 13 course faculty. Professional experience ranged from <5 years to >20 years of practice. There were 37.5% of participants who had prior experience using simulation technology and 18.75% who had prior experience in crisis resource management simulation.

Participants believed the session was relevant, useful, interesting, not too difficult or easy, and that the overall quality of the simulation session was excellent with weighted averages of 4.84, 4.79, 4.89, 4.32, and 4.84 respectively on a 5-point Likert scale.

Participants reported statistically significant increases in comfort in managing acute airway problems following participation in the SSAM (Figure 1, p=0.001 for all airway topics, and p<0.001 for CRM). Interestingly, there was no observed statistical difference for increase in comfort when acting as a lead participant versus when acting as an assisting/observing participant (1.26 vs 1.11, p=0.49).
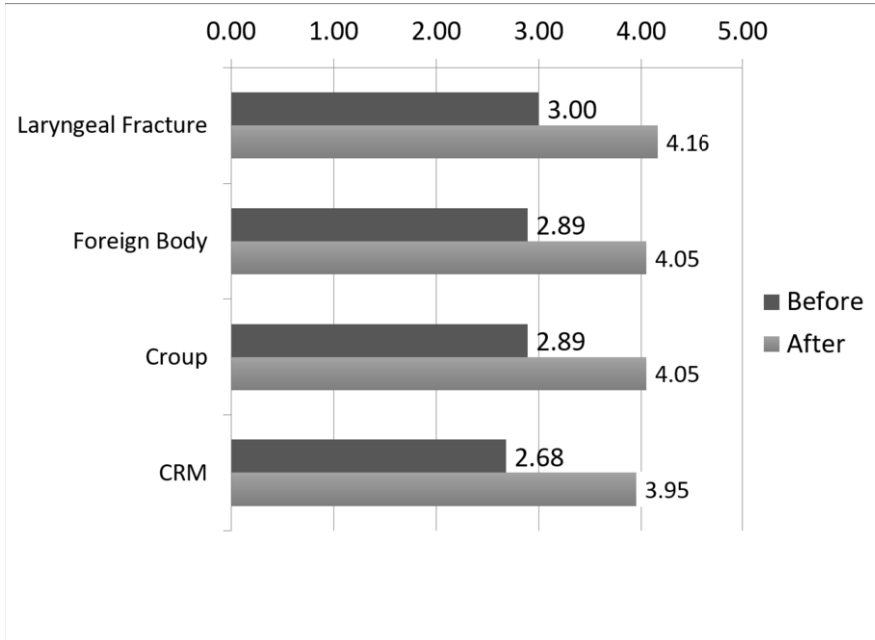
Figure 1. Participant comfort for dealing with acute airway topics and crisis resource management (CRM) before and after Simulation Symposium. 5-point Likert scale (1-Very low comfort, 5-Very high comfort). All differences are statistically significant.

The debriefing sessions received a broadly positive response as reported by participants. Participants gave a neutral response in their preference for a debriefer to be from their own profession versus a different profession, suggesting that this was not a necessity.

Overall opinions on the Simulation Symposium on Airway Management were very positive. Course faculty respondents believed that the course exceeded their expectations (4.31), met the stated objectives (4.31), and had an appropriate amount of time allocated (4.08). They would recommend the course to colleagues (4.54), look forward to the next simulation session (4.62), and believe that simulations sessions should be included in future meetings (4.70).

Interviewees overall had a consistent, very highly positive perception of the simulation session. Every interviewee believed that this method of training should continue because they perceived it as having a positive overall impact for the service and for patient care.

4. Discussion

Continuing medical education (CME) and professional development (CPD) for the practicing otolaryngologist to fulfill maintenance of certification requirements have traditionally taken the form of journal article readings, course participation, or meeting attendance. Simulation technology has been less frequently implemented as a means for otolaryngologists to fulfill their per annum requirements for ongoing learning. Simulation-based training is quickly becoming more relevant as the pace of surgical evolution continues to increase [14]. There remains much to learn regarding how simulation may be best leveraged for training and CME/CPD [14]. With changing CME requirements, it is becoming necessary for practicing otolaryngologists to receive feedback as part of their continued education. Simulation may provide an ideal opportunity for this rare occurrence to take place.

Simulation is typically only available in academic centers that naturally cater towards the needs of the medical trainee. Thus, otolaryngologists who practice in the community have limited access to simulation designed to provide the level of fidelity offered during the Simulation Symposium on Airway Management. Subsequently, faculty practicing in the community have less experience in simulation and may benefit greatly from its expanded and continued availability.

As a result:

1) The majority of our participants had no prior experience in simulation (62.5%).
2) Information in this area has not been as widely examined or reported in the literature.

The Simulation Symposium on Airway Management provided a rare opportunity for practicing otolaryngologists to participate in simulation – providing a chance to learn, develop, and refresh technical and communication skills as well as fulfill per annum maintenance of certification requirements. The authors believe that there is great potential benefit in incorporating simulation into the ongoing education of practicing otolaryngologists. This study was performed as the use of high-fidelity simulation with practicing otolaryngologists requires further validation.

The findings of our study are noteworthy in that we have clearly demonstrated that participants became more comfortable with management of the acute airway and that they would benefit from more opportunities to participate in simulation in the future. We feel that we have justified the need for expansion and broader access to acute airway simulation for practicing Oto-HNS surgeons.

A six-week follow up interview was planned to evaluate change in attitudes over time. However, due to a limited response rate by participants (n=2) the authors felt that this data was insufficient.

Our study addressed only Level 1: Reaction of The Kirkpatrick Model. Using our evaluation model, we were unable to assess to what degree our participants acquired knowledge or skills based on their participation.

Lastly, our study did not allow for a separate control group. For comparison, study participants were asked to retroactively express their opinions on high-fidelity simulation via survey and interview.

5. Conclusion

The findings in this study have demonstrated the benefit of increased comfort level, collaboration, and communication provided by simulation with practicing otolaryngologists as participants and may serve to justify the need for its expansion and continued use. As the use of simulation continues to increase, it has become important to expand its availability to include practicing otolaryngologists as participants. This expansion must be extended to include otolaryngologists practicing in the community. Further research in simulation with practicing otolaryngologists is required to investigate how increases in comfort level, collaboration, and communication affects patient safety.

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Towards a Clinical Analytics Adoption Maturity Framework for Primary Care

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Abstract. Clinical decision support systems are evolving with growing analytics capabilities towards pervasive use of artificial intelligence. Maturity models can guide the adoption of these new technologies in clinical practice to improve patient outcomes in primary care settings. Our literature survey identified the "Health Analytics Adoption Maturity Model" by Canada Health Infoway as a suitable basis for developing an adoption maturity framework with primary care focus. We follow a design-science research paradigm to develop a scientifically-validated mixed-method approach for assessing and guiding the evolution of clinical analytics capabilities in primary care. This paper summarizes the first phase of our research in progress.

Keywords. clinical analytics, decision support systems, maturity models, technology adoption, primary care

1. Introduction

Advances in patient-centered technologies and clinical decision support (CDS) systems have the potential to improve and automate elements of the diagnosis and treatment processes in primary care. This is made possible by a gradual shift from human-centered to machine-supported decision making through use of analytics capabilities that are evolving from descriptive, diagnostic, predictive, to prescriptive analytics. A new generation of "cognitive" systems is expected to further extend prescriptive analytics capabilities with pervasive use of artificial intelligence [1].

Several studies have shown that the implementation of new technologies does not always lead to adoption and improved patient outcomes in clinical practice [2]. Maturity models can offer tools to measure, evaluate, and guide the evolution of organizational capabilities, such as the use of analytics in CDS. There is a need to have implementable maturity models for CDS, so potential benefits of these tools can be achieved.

This paper describes research in progress towards a clinical analytics adoption maturity measurement methodology for CDS in primary care.

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2. Methods

Our study follows the seven guidelines of a design-science research paradigm to ensure an appropriate theoretical foundation for maturity model development. Design-science research seeks to achieve knowledge and understanding of a problem domain through creation, application, and evaluation of a designed artifact [3]. We reviewed several procedure models for the development of maturity models using design-science principles [4]-[6] and selected Becker et al.'s [5] procedure model for maturity model development to guide our approach while incorporating design decision parameters from Mettler's comparative study of maturity model development processes [6]. Methodologically, we will conduct research in three broad phases:

1. Research and development of adoption maturity model and methods

We will define the problem and conduct a literature survey to identify relevant prior work. The results of the literature survey will inform our development strategy and provide requirements for development of the initial maturity model and methods.

2. Application and evaluation of model and methods through socio-technical evaluation of analytics adoption maturity

We will apply and evaluate model and methods in a field study of a real-world primary care clinical analytics environment.

3. Reflection and refinement of model and methods

Working with feedback from the field study, we will make suggestions for refinement and extension of the model and methods for future work.

3. Initial Results

We have completed the first three steps of phase 1 (problem definition, literature survey, development strategy). Below is a summary of our initial results to date.

3.1. Problem Definition

Evaluation of system maturity and adoption in healthcare is complex as the domain is highly context sensitive. Healthcare has adopted maturity models for information systems in general terms with a specialized emerging area of research that focuses on health analytics maturity [7], [8]. Canada Health Infoway surveyed the state of clinical analytics in Canadian primary care based on interviews with a range of subject matter experts [9]. Infoway found that several existing analytics maturity assessment models had limited applicability for Canadian primary care settings, in part due to smaller primary care practice settings in Canada and different terminologies used by the mostly US-centric models. Clinical leaders interviewed by the authors felt that their profession could benefit from a customized framework that would (1) help primary care clinicians understand the target state for the use of analytics and the levels of maturity along its pathway; (2) recognize the capabilities that are required to progress along the pathway to each new level; (3) assess their organization's adoption and use of analytics to measure progress over time; and (4) plan for investments in capital and/or operations to advance

their organization toward the target state [9]. Based on these four requirements, Infoway proposed the "Health Analytics Adoption Maturity Model for Primary Care" and recommended further research and scientific validation to evolve the model to a state of readiness for adoption. However, the Infoway model needs tools to support operationalizing the model in the form of an adoption measurement framework, methodology, and guidance for improving adoption. Our research seeks to validate and operationalize the Infoway model for application in Canadian primary care environments.

3.2. Literature Survey of Maturity Models

Expanding on a systematic literature survey conducted earlier [8], [10], we reviewed relevant health information system (HIS) maturity models to determine suitability for primary care health analytics environments. Our intent was to identify primary care-focused maturity models that could form a basis for our adoption measurement framework and methodology. The models were grouped by their clinical focus areas and reviewed for specific mention of primary care maturity aspects.

Table 1. Summary of HIS Maturity Models with Analytics Elements and Primary Care Focus

Maturity Model Designation (Author, Year)	Main Field	Analytics Elements	Primary Care Focus
Quintegra Maturity Model for electronic Healthcare (Sharma, 2008)	Gen. Healthcare	No	No
IDC Healthcare IT Maturity Model (IDC, 2008)	Gen. Healthcare	No	No
IDC Mobility maturity model for healthcare (IDC,2013)	mHealth	No	No
HIMSS Electronic Medical Records Adoption Model (HIMMS, 2017)	EMR	Yes	No
HIMSS Continuity of Care Maturity Model (HIMMS, 2017)	Gen. Healthcare	No	No
Forrester Patient records/content management maturity model (Forrester Research, 2010)	EMR	Yes	No
Maturity Model for Electronic Patient Record (Priestman, 2007)	EMR	Yes	No
NEHTA Interop. Maturity Model (NEHTA, 2007)	Interoperability	No	No
NHS Infrastructure Maturity Model (NHS, 2011)	Infrastructure	No	No
Hospital Cooperation Maturity Model (Mettler & Blondiau, 2012)	Networking / Cooperation	No	No
PACS Maturity Model (Wetering & Batenburg, 2009)	PACS	No	No
Telemedicine Service Maturity Model (van Dick & Schutte, 2013)	Telemedicine	No	No
Healthcare Usability Maturity Model (HIMMS, 2011)	Usability	No	No
Adoption Model for Analytics Maturity (HIMMS, 2013)	Health Analytics	Yes	No
Infoway Health Analytics Adoption Maturity Model (Infoway, 2016) [9]	Health Analytics	Yes	Yes
TDWI Analytics Maturity Model (TDWI, 2014)	Gen. Analytics	Yes	No
Healthcare Data Quality Maturity Model (Pinto-Valverde et al., 2013)	Health Analytics	Yes	No
Business Intelligence Maturity Model for Healthcare (Brooks et al., 2013)	Health Analytics	Yes	No
Healthcare Analytics Adoption Model (Sanders et al, 2013)	Health Analytics	Yes	No

Only some of the models originated in academia providing access to the underlying development methodology. Most models were developed by private sector or national health organizations that limit the scope details and supporting methodology that are publicly accessible. In those instances, we relied on secondary sources to make our determination. We found that only a subset of models surveyed incorporate health analytics elements and only one model, the Infoway-proposed Health Analytics Adoption Maturity Model, specializes in a primary care context. While the Infoway model describes maturity stages and some associated characteristics for each maturity level in theory, it does not currently include any of the assessment methods required for practical application and evaluation in a real-world project. The model has not been applied and validated in field research yet.

3.3. Development Strategy

Based on our review of existing maturity models and prior research, we opted to design an adoption measurement methodology that aligns with and can be used to refine Infoway's Health Analytics Adoption Maturity Model. Our development strategy seeks to operationalize Infoway's model, to develop a mixed-method assessment approach that aligns with the model, and to evaluate and refine model and methods based on learnings from field research and application in a real-world project. We will also make recommendations on how to improve adoption maturity in target organizations. Through appropriate engagement, we will leverage the expertise of a panel of subject matter experts to help define requirements and to guide the evaluation of developed artifacts.

3.4. Iterative Maturity Model Development

Development will follow an iterative approach and it will incorporate several design decisions. Maturity models can be differentiated by maturity concepts of process-, object-, or people-focused maturity [6]. Infoway's model combines elements of all three concepts. It is multi-dimensional and has followed a practitioner-based design process which we will combine with a theoretical approach to merge knowledge bases for maturity levels, metrics, and corresponding improvement recommendations. The initial model for the first development iteration will incorporate maturity levels assigned across six dimensions. Separate maturity levels in the dimensions of Data, Analytics, Governance, IT Infrastructure, Skills / Capability, and Privacy & Security will contribute to an overall maturity level assessment. Table 2 shows model descriptions for maturity characteristics exhibited across six dimensions of the model.

Table 2. Health Analytics Adoption Maturity Model Dimensions (Infoway, 2016)

Maturity Level	Data	Analytics	Governance	IT Infrastructure	Skills / Capability	Privacy & Security
Level 3	All data available, optimized for use	Comprehensive data analytics including predictive & prescriptive, near and real-time	Shared, broad based ecosystem governance (connected health information network)	Enterprise data warehouse (EDW), business intelligence & visualization tools (e.g., SaaS)	Highly skilled and specialized resources	Risk management framework optimized for expanding use cases
Level 2	Most data are of high quality,	Standardized and automated	Formal, mature at local level;	Reporting tools, outsourced benchmarking	Designated leads for governance,	Data de-identification, risk

			shared governance for analytics networks	to external solution provider	informatics, privacy; analysis & reporting support	management framework & data sharing agreement(s)
	computable and comparable	metric reporting, benchmarking	shared governance for analytics networks	to external solution provider	informatics, privacy; analysis & reporting support	management framework & data sharing agreement(s)
Level 1	Data silos, some data standardization	Limited and basic, local, possibly multiple truths, and manually intensive	Immature at local level	EMR, other applications (e.g. Excel)	Basic analytical capability; practice improvement leadership	Training in relation to privacy and security obligations for handling PHI
Level 0	Inconsistent data capture, unstructured, inaccessible	Limited to none	Governance for analytics is not in place	Early EMR adoption (with focus on data entry)	Data entry	Limited to none in relation to analytics

4. Discussion and Conclusion

There is a clear need to understand and promote adoption of analytics capabilities in primary care. Maturity models can help identify capability gaps between a current state and a desired future state to guide further capability development. Our review of existing maturity models has shown that the field of analytics adoption research in healthcare is in its early stages with limited published results to date, only one model had an explicit primary care focus. This multi-phase research project will operationalize Infoway's model, develop a scientifically-validated mixed-method assessment approach, and provide recommendations for improving analytics adoption maturity in target organizations. We presented our initial results from the first project phase. Subsequent project phases will seek to empirically validate our proposed framework and to identify opportunities for future work. Analytics capabilities are expected to incorporate growing elements of artificial intelligence which will provide new opportunities for maturity research and future model evolution.

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From Siloed Applications to National Digital Health Ecosystems: A Strategic Perspective for African Countries

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Abstract. Substantial investment in digital solutions for improved health services has occurred in recent years in Africa. Digital Health provides for proven, beneficial applications in many different areas of health systems. It supports the transformation of healthcare delivery, and its potential is seemingly boundless. However, the deployed systems are in silos, and interoperability and integration are largely missing. There is no timely information for easy and quick decision making; there is no ability to track service levels across the whole health sector. What is missing is an integrated information system across all healthcare facilities nationwide. Such a Digital Health Ecosystem, the holistic application of information and communications technologies, services and applications, will support health systems and improve healthcare delivery, coordination and integration across providers. Based on global experience in resource-constraint contexts, core steps necessary to develop and implement such an ecosystem are explored, and four fundamental building blocks and their elements are developed. The results presented are succinctly integrated into six statements on lessons learned and recommendations.

Keywords. Digital health, ecosystem, open platform, Africa, strategy, foundational building blocks, interoperability

1. The Integration Challenge

Innovative digital solutions have become a major determinant for the improvement of well-being and economic growth worldwide [1]. They help African economies to overcome limitations and costs of physical infrastructure in important areas of social and commercial life [2]. The health sector is also benefitting from this trend. Substantial investment in digital technology solutions for improved health services has occurred in recent years in Africa [3,4]. African leaders who gathered at the African Ministerial Dialogue on Digital Health Leadership at the May 2017 World Health Assembly affirmed their commitment to digital health and identified the pathway towards realising strong Digital Health Ecosystems in their countries [5].

Digital Health provides for beneficial applications in many different areas of health systems. It supports the transformation of healthcare delivery, and its potential is seemingly boundless. E.g., the path-setting mHealth4Afrika application platform [6] provides for more effective and efficient care provision through an open source, multilingual digital health platform improving the quality of community based maternal and newborn healthcare delivery in rural health service points of Ethiopia, Kenya,

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Malawi, and South Africa. – Telemedicine makes specialist knowledge and improved treatment accessible in rural areas: In Tanzania, for example, teleconsultation equipment to support obstetric emergency care in rural and outmost areas was installed in ten upgraded rural health centres, four rural district hospitals and one regional hospital [7]. – Mobile health (mHealth) makes use of cell and smart phones as well as other mobile devices, a promising application field in Africa due to the relatively ubiquitous mobile telecommunication connectivity when compared to other modes of communication. Smart phones have been engineered to serve as local hubs or platforms to connect sensors and electronic measurement devices, printers etc. at the local level, and to connect to more complex systems at community centres and district hospitals. Worldwide known applications focus on pregnant women, like the UNICEF-supported MomConnect service in South Africa which links pregnant women and young mothers to healthcare centres [8]. – Digital health also helps to better support administration and management services. Triggered by the need to reduce endless waiting times for patients, in South Africa the Western Cape's Primary Health Care Information System [PHCIS] [9] focuses on managing patient throughput in primary care clinics through electronically drawing information on past clinic visits, creating electronic appointments, and providing patient and facility management tools for reporting purposes. – Improving Public Health surveillance is a core WHO goal for Africa [10]. Through the introduction of a mobile "Electronic Integrated Disease Surveillance and Response [eIDSR]" application by Sierra Leone's Ministry of Health and Sanitation weekly disease reporting drastically improved from occurring in 35% of health facilities to 96% [11]. – eLearning is another highly relevant application field. The Tanzanian Training Centre for International Health uses an audio teleconferencing service; and an online eLearning platform to teach health workers and nurses in maternal and perinatal health-care in rural areas [12].

However, such isolated eHealth investments do not yet comprehensively meet the needs of African countries. The core remaining challenge was neatly summarised in a recent statement on the "Enhancement of Rwanda National Digital Health Care System – 'Smart Health'" by the Ministry of Health: "The earlier interventions only focused more on routine reporting and disease surveillance systems. The deployed systems are in silos and there is no system that is integrated with another. There is no timely information for easy and quick decision making; there is no ability to track service levels across the whole health sector. Due to the silos of systems patient records are only limited to the health facility visited. … Multiple reporting systems impose a burden on health workers and make it difficult to access data for evidence-based decision-making. An increasing share of services delivered by the private sector, which does not report systematically, means that a growing piece of the epidemiological situation is missing. … There is no proper interoperability framework in place for all these systems. They were developed on different platforms and data stored in legacy systems. This has resulted in considerable duplication of effort and difficulty to access and consolidate data for evidence-based decision-making. Terminology and technology standards need to be implemented to ensure system interoperability" [13].

2. Objective

What is missing is a holistic information system integrating patient and other data across all health system organisations and actors nationwide. We call this a *Digital Health Ecosystem*, defined as

the holistic application of information and communications technologies to support and improve health services, their coordination, integration and management across all actors in a given geographic domain (local, district, national).

To meet interoperability requirements and be future-proof in resource-constrained environments, it should rest upon an open digital health platform.

Based on global experience in resource-constraint contexts, the goal of this paper is to sketch the core steps necessary to develop and implement such an ecosystem, and to specify fundamental building blocks. Key problems and barriers encountered as well as success factors and lessons learned will be discussed.

3. Methods

Methodologically, earlier work on describing, structuring and comparing national eHealth policies has benefitted this work [14]. And it builds upon analytical research undertaken, approaches developed and empirical surveys undertaken in the context of Africa-related studies, inter alia, the "Interoperable eSystems for Africa Enhanced by Satellites" Study for the European Space Agency's (ESA) eHealth for Sub-Saharan Africa (eHSA) Programme [15]. There an initial interoperability approach and roadmap towards designing and implementing national eHealth platforms in Sub-Saharan Africa (SSA) countries was developed, based on detailed statistical analyses of the respective economic and health system situation in 48 SSA countries, as well as empirical surveys with key decision makers in 24 countries. Further methodological and empirical input was derived from detailed case studies of national or district eHealth platforms and electronic health record (EHR) systems covering eight countries on five continents, which – to render analysis results comparable – where structured and presented empirical material in a framework similar to the one applied in the results section here.

Key methodological input is also derived from research on „Digital Health Ecosystems for African countries - Integrated framework and approach" which was undertaken for the Strategic Partnership Digital Africa (SPDA), Berlin/Germany, an initiative of the German Federal Government and industry supported by the German Corporation for International Cooperation (GIZ) [16]. A critical review of further research, reports, papers, and literature were undertaken, too.

Reference is also made to eHealth strategy toolkits and guides as published by WHO/ITU [17] and other organisations [18, 19].

4. Results

Concerning how to best move from siloed applications to national Digital Health Ecosystems, these results can be summarised:

4.1   Responding to policy priorities and stakeholder needs

Successful national Digital Health Ecosystems respond to health policy priorities and stakeholder needs. Establishing such an (open) platform is a complex, long-term and never ending venture. Global experience suggests that starting with a focused approach delivering early benefits to core actor groups is essential. Real benefits will convince physicians and politicians alike to continue, expand and support further development of digital health infrastructures. Such a needs-driven approach avoids a common pitfall of

digital health investments, namely technology push. "A lot of solutions have come from technologists and engineers who are excited by the technology, but at times, they are not starting with the true need. ... End-users must be central to the design. The problem with African countries is that e-health systems are not integrated and are instead run by different independent organisations" [20].

4.2 Four foundational building blocks for implementing a comprehensive Digital Health Ecosystem

When planning, implementing and maintaining a resilient Digital Health Ecosystem, four foundational building blocks need to be considered and analysed:

- Political agreement on an operational digital health strategy
- Development of a comprehensive roadmap translating the strategy into reality and targeting long-term sustainability
- Implementation of the chosen Digital Health Ecosystem
- Monitoring and evaluation of outcomes and results achieved to guide further progress.

Their logical relationship builds upon each other - respectively these blocks interact with each other - as shown in Figure 1.

Figure 1. Four building blocks for a resilient Digital Health Ecosystem
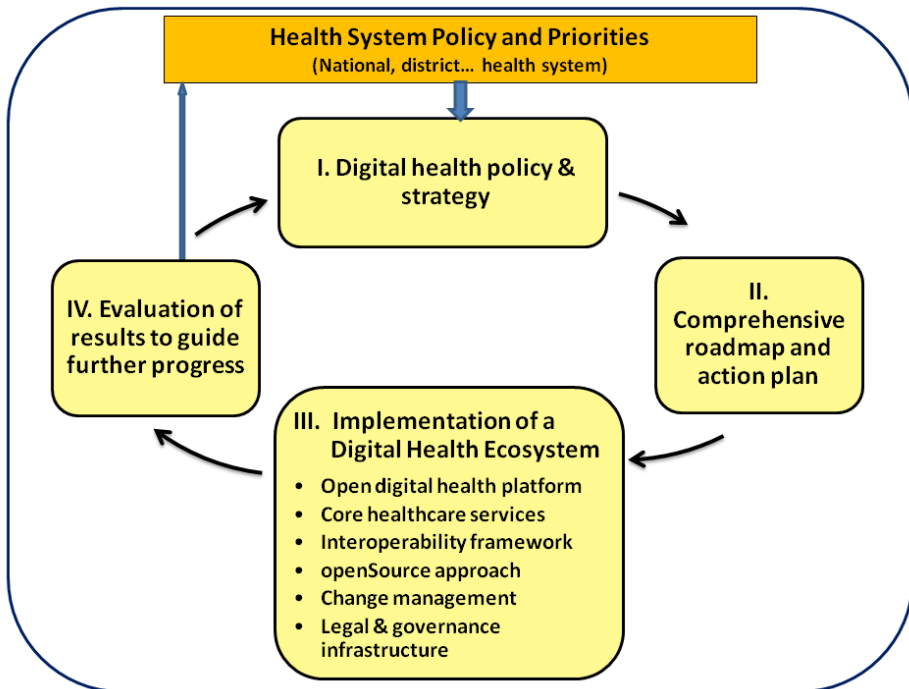
Understanding these building blocks, their contents and the action steps involved, as well as their logical relationship and how they interact with each other is mandatory for all involved in planning, developing, implementing and maintaining the Digital Health

Ecosystem – be they health policy decision makers, healthcare service providers, health professionals, patients, industry involved in implementation, donors and financiers.

4.2.1 Agreement on an operational digital health strategy

Guided by health policy priorities, it is fundamental to reach agreement across all stakeholders on an operational digital health strategy. Drafting together a strategic paper builds trust across all stakeholders who are involved in or impacted by the development of a Digital Health Ecosystem.

4.2.2 Development of a comprehensive roadmap

Drafting a digital health strategy is only a first, albeit necessary step towards establishing and maintaining a Digital Health Ecosystem. Translating the strategy into an operational roadmap with clear action steps and a realistic time frame is already a much more demanding task, and 'the proof of the pudding' comes with concrete implementation and continuous maintenance.

4.2.3 Implementation of a Digital Health Ecosystem

Six fields can be identified as particularly critical for successful implementations:

    (1) Open digital health platform :
        Open Digital Health Ecosystems implemented at the national or district level will help to overcome the common barriers experienced when relying on commercial system providers, like integrating new applications, transferring patient data to other applications, or changing the software supplier completely. An open approach allows apps and services from multiple vendors to work together such that there is a many-to-many substitutability between applications and services. This is based on common, open and standardised data models and application programming interfaces (APIs). In this way, open platforms liberate both data and applications making them portable and interoperable across different platform implementations [21].

    (2) Core starting services and applications
        From the wide spectrum of open platform infrastructure services and digital health applications and tools, a small set of priority services and application should be explored when analysing the needs for and benefits resulting from a national ecosystem. They may concern, e.g., essential eInfrastructure services like electronic identification and cyber security, eAdministration, electronic patient records (ePR) and other healthcare applications, eLearning, Public Health/eSurveillance. Starting small, but assuring the ability to scale up should be a particular concern [22].

    (3) Interoperability framework
        Interoperability must always be analysed in the context of the respective health system. This implies that interoperability requirements cannot be identified ex ante and as such, but rather need to reflect the data exchange and analysis needs of health system actors to be supported by the electronic tools and applications to be implemented. When planning and organising a comprehensive interoperability framework and tools, five domains should be analysed:

        • *Policy domain*

It is in the policy and strategy domain where high level decisions are needed on which data should become interoperable for which health policy needs, for which healthcare/clinical or public health purposes. Implementation measures must be foreseen to assure that these interoperability objectives are indeed reachable.

- *Governance and legal domain*
  Interoperability is concerned with accessing and exchanging data. Governance and legal/regulatory issues are core challenges when realising a certain degree of interoperability within national Digital Health Ecosystems. Usually it will be mandatory to clarify ownership and access rights, privacy, confidentiality and system security to respond to increasing challenges in this field, thereby strengthening trust and confidence of all stakeholders, particularly patients and health professionals.

- *Organisational domain*
  Securing interoperability is a long-term activity. eHealth interoperability frameworks therefore require dedicated organisational support structures and processes to not only guide and direct digital health infrastructure investments and controlling in this sphere, but to also run daily administration and production.

- *Document format, data modelling and coding domain*
  Here three levels of interoperability may be discerned:
  i. Technical interoperability (like correctly transferring a static paper document electronically, e.g. in PDF-format)
  ii. Structural interoperability (documents structured according to standardised headings, which may allow for regrouping and assembling information according to such headings)
  iii. Semantic interoperability (information and data are presented in a standardised clinical model and fully coded, thereby e.g. allowing for safe translation into other languages if international dictionaries are available)

- *Data sharing domain*
  The issue to be solved here is whether data should be stored in a central (or several linked, distributed) data repository(ies) where the authorised actors can directly access the (patient) data whenever they need them, or whether data are communicated via an exchange of messages, etc. Cloud storage of such data is becoming another option.

(4) Leveraging the 'open' approach
Globally, support and engagement for 'openSource' software, 'openData' access, 'openStandard' availability and 'openPlatform' approaches has gained great momentum, both in industrialised and resource-constraint environments [21]. This "open" movement is now ubiquitous, recognized across public and private entities as a fundamental course of action towards building interoperable, easy to use infrastructure components, as well as a critical factor for driving innovation in 'vertical' markets. The source code of software and tools developed by the open source community is not proprietary, it can be freely copied, modified and distributed; it is managed and continuously improved by engaged participants.

(5) The need for change management

Substituting hitherto paper-based recording and information exchange systems by introducing digital services is not simply a means for improving the efficiency of existing processes. A Digital Health Ecosystem with all its potential for the health system to evolve towards safer, better health for all and more efficient, integrated healthcare processes is quite different from what it was before. It enables substantial change in the way health professionals and others work together within and across organisational borders, share patient data, manage the resources of their organisation, supervise and guide the allocation of public funds, organise health system surveillance and quality control. Eventually, a different health system will emerge.

To guide and direct this process of moving from one state of the system to the other, professional change management is mandatory [23].

(6) Governance and legal framework

To function efficiently, reliably and amicably, open societies need a well-designed governance and legal framework. This equally applies to the health sector. What the term "governance" means is vague and disputed, and it has variantly been located from civil society level laws and regulations – "rules that guide the course of a system" or a country - to "rules of order" or procedures for small group activities.

At the level of health system governance, WHO has recently proposed the "TAPIC framework for analysing and improving health. [24]" It identifies and defines five mutually exclusive attributes of governance that influence the kind and consequences of decisions a health system makes:

- Transparency
- Accountability
- Participation
- Integrity
- Capacity

4.2.4 Monitoring and evaluation

An often neglected forth building block is monitoring and evaluation of outcomes and results and the impact achieved. This is indispensible for updating and adapting the ecosystem to changing and newly arising needs, i.e. it will support and help to guide further progress [17].

5. Lessons learned and recommendations

The results presented can be succinctly integrated into six statements on lessons learned and recommendations:

1) *Digital health facilitates reaching health policy goals and Universal Health Coverage (UHC)*
   When implemented appropriately, digital health is a great enabler towards better, safer and more efficient healthcare and UHC.

2) *Adopt the unifying approach of a national Digital Health Ecosystem*
   The reliable, sustained transformation of health systems through digital health requires a holistic vision driven by focused health system priorities and a unifying approach assuring that the deployed eHealth applications are integrated through a national digital health infrastructure platform – a Digital

Health Ecosystem. Such an open Digital Health Ecosystem is vendor and technology neutral and eliminates the expensive and much-dreaded vendor lock-in. It facilitates innovation also by smaller companies and start-ups facing lower barriers to market entry. It forces vendors to develop new business models and compete solely on quality, value, and service.

3) *Implementing a national digital health platform is a rather unique challenge*
Implementing and sustaining digital applications in the health sector is more demanding, complicated and time-consuming than in any other sector – healthcare is an extremely complex undertaking. At the district or national level, there is no one-size-fits-all platform solution readily available, each one has to be tailored to local policy priorities, needs, capacities and resources.

4) *Avoid Pilotitis – Focus on integration*
Stand-alone eHealth implementations and pilot projects that rarely reach scale and sustainability must be avoided. Focus on few healthcare and/or Public Health priorities to guide nation-wide investments. Assure coordination and integration across all actors and stakeholders, whether public/government institutions, charities, foundations, development agencies, or private investors.

5) *Four building blocks will guide towards successfully implementing a national Digital Health Ecosystem*
Just drafting a Digital Health *Strategy* will not do the job. Three further building blocks are needed: An actionable, realistic *roadmap* how to move from the strategy to implementation and long-term sustainability, six *implementation* elements (national platform; core services; interoperability guidance; leveraging the "open" approach – with respect to software, data models, APIs etc.; change management; governance and legal framework), and finally *measuring impact* to guide further development of policy and infrastructure.

6) *Establish the role of governments, development partners, and industry*
In a democratic society, national governments – controlled by parliament – are in the driver's seat concerning health system structures, regulation and financing. They have to guide determining the needs, priorities and procedures of investments in Digital Health Ecosystems. To avoid the disparate development of siloed eHealth applications and thereby loosing many of the potential benefits for improved healthcare, a national framework must set the conditions and requirements within which development partners should act in close coordination with public authorities. It follows that specifications in national Calls for Tender to industry must fully align with the national digital health strategy. A cooperative investment approach in which African governments, donor and industry representatives join forces is strongly advised.

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Privacy and Policy Implications for Big Data and Health Information Technology for Patients: A Historical and Legal Analysis

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Abstract. The consideration of privacy and policy implications for big data is essential to designing patient-centered health technology. A literature review demonstrated a significant gap to moving forward with information technology in healthcare. Ovid Medline and Google Scholar were searched to identify papers related to health technology, patient outcomes, and policy implications of Big Data. The findings of this research showed that despite a robust legal framework and clear outline of the legislation, there exists an innovative opportunity for health technologies to evolve and become patient-centered by integrating privacy and policy knowledge in health information technology. This historical legal analysis is valuable to health system leaders, decision-makers, health technology companies that are creating innovative platforms, and clinicians in both Canada and the United States.

Keywords. big data, privacy, health technology, patient outcomes, data linkages

1. Introduction

A core feature of a learning health system is the health data associated with in and around that system. The application of Big Data to health systems performance can improve health quality and is central to a learning healthcare system [1,2]. With the creation of a variety of health technologies including electronic health records, patient portals, mobile health applications, and artificial intelligence, this paper considers the health policy implications of integrating health care IT structures in hospitals, clinics, and homes. The intersections between the fields of big data, health law, and privacy legislation have allowed health services scholars to examine the applications of big data for patient safety and optimal patient outcomes. Health technology is an outlet that can provide a solution through user interfaces and interoperable systems to better connect health care sectors such as home care, community care, primary care, and hospitals.

Big data is the collection, storage, and analysis of large amounts of data in order to leverage existing trends within health systems performance. Defined in terms of the 3V's: volume, velocity and variety, big data can create linkable datasets, which

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traditionally have been unavailable in traditional health care delivery and processes [3]. This paper reviews current privacy legislation within the United States and Canada with regards to the application of big data. The heterogeneity of big data and its potential use within a new context of electronic health records, administrative data sets and patient-facing technologies calls into question whether current privacy legislation in Canada and the United States requires modernization in our current decade of digital health information age. Given that the law is a venue for health technology developers, clinicians, and policymakers to work with, we explore the application of big data to health technology development in the context of current legislation. In a fair and just civil society, the construct of case law in relation to the development of health technology should be considered by health technology developers, implementation specialists, patients, and health care providers.

2. Methods

This study adapted a scoping review framework approach using the Arksey & O'Malley in that a systematic, transparent and reproducible review of the academic and grey literature was undertaken [4,5]. The academic databases Ovid Medline, specific health law and policy journals, health law & ethics: Journal of Medicine Law and Ethics, Health Law and Policy, Annual Reviews of Medicine, and the grey literature consisting of Google Scholar and were searched. Authors used a combination of keywords and MeSH search terms including: "big data", "health law", "privacy", and "legislation". Academic databases and other review sources were searched in order to cast a wide net to retrieve credible studies and to minimize bias in the literature search. As per the Arksey & O'Malley framework, additional government publications were included to provide a historical analysis of the timeline for the development of privacy legislation.

3. Findings

3.1 Historical Analysis of Privacy Legislation in correlation with Health Technology considerations: Modernization of Privacy Legislation

A historical analysis of the legislation showed that the United States passed the *Electronic Communication and Privacy Act* (ECPA) in 1986 after Canada passed the *Privacy Act* of 1985. Specific to health information, the *Health Insurance Portability and Accountability Act* (HIPAA) was introduced in 1996 [5]). Canada recently amended *the Personal Information Protection and Electronic Documents Act (PIPEDA)* to include digital health records [6,7]. When considering privacy legislation and data sharing between Canada and the United States, within the legislation, there exists the possibility to create data sharing agreements between both countries for cross-comparative health services research studies [7,8]. An example of a research study that required data linkages across Canada is outlined in the paper by Chiu et al., where they describe immigration patterns, refugee, citizenship, and Canada's permanent resident data and vital statistics to Ontario's administrative datasets [9]. Health technology researchers, developers, and professionals can implement large scale, cross-comparative studies that utilize current data assets within North America.

There are differences in American and Canadian perspectives on the privacy legislation. Canadians typically trust the idea that the system protects their medical information and respects their privacy. Americans on the other hand have a heightened awareness of their data privacy laws, which may vary according to the state [10]. In an era where health technology innovations and electronic information sharing has dramatically increased over time, data is a public asset that can be used to improve the population health and the well-being of society. While policy development occurs at a more macro or health systems level, positive patient-centered outcomes are the goal of every health care professional. Technology can be a positive catalyst for improving health outcomes for patients.

3.2 The Canadian Perspective: Privacy Policy Development

In Canada, the *Privacy Act* of 1985 imposed obligations for 250 federal government departments to collect, use, and disclose personal health information. This health policy outlines the collection of personal health information that is stored in protected facilities, such as hospitals or other health care organizations [11]. It also considers public opinion and the ethical use of personal health information for purposes of research and advancing sciences [9]. The 2004 update of the *Personal Health Information Protection Act (PHIPA)* policy included a revision for health technology considerations. The legislation is different from PIPEDA as includes not only electronic health information but also external information as well [10]. According to this Act, there are ongoing audits by the privacy commissioner. For example, the update includes giving permission to prescribed entities-for example, the Canadian Institute for Health Information (CIHI) and the Institute Clinical Evaluative Sciences (ICES), Cancer Care Ontario (CCO)-to receive de-identified health data for the purposes of health systems planning, delivery, and design [10]. This legislation further outlines the role responsibilities which hospitals, primary care providers, and other interdisciplinary professionals have in protecting information in patient records.

In Canada, the *Personal Information Protection and Electronic Documents Act* (PIPEDA) of 2005 outlined the role of health records and technology such as the use of electronic documents and electronic payment options. It requires organizations to obtain consent from patients prior to the storage of their electronic medical record. Under this legislation, organizations can conduct data linkages while also protecting the privacy of patients and families through the process of re-identification of personal health information [7]. Organizations such as the ICES, Health Quality Ontario (HQO), CCO, CIHI, and other federal and provincial non-governmental agencies are governed under this federal legislation. In Ontario, health technology companies and private businesses are also governed by this legislation if they are creating linkages between data sets. Core elements of this legislation include: ensuring data is de-identified, small cell counts are suppressed, and that personal health information is not identifiable by a member of the public. As new health technologies modernize over time, it will be important from a patient-centered care perspective to ensure that health technology companies are in accordance with their local privacy legislation.

3.3 The United States: Considering Health Technology Developments and Integrating them into Health Policies and Legislation

Within the United States, the process of the development of health technology and their privacy legislation occurred earlier in comparison to Canada. The *Electronic Communication and Privacy Act (ECPA)* of 1986 states that Americans are protected from unreasonable search and seizure of data that is transmitted through new "emerging technologies" such as pagers, email, and cell phones [12]. This privacy policy was created to ensure that citizens are protected from unreasonable searches of their personal communication devices. This policy assisted organizations such as hospitals and primary care facilities in the management of their own health data. The implications of this legislation included the possibility of allowing organizations to aid in the process of health data management. It continues to evaluate new and novel technologies such as iPads and other devices for sharing and storing data. This legislation is monitored on a regular basis and there is ongoing policy evaluation conducted by the Privacy Commissioner.

There are several ethical implications of the *ECPA* of 1986. This legislation requires modernization to reflect the variety of current technologies that are used in health care. For example, how can technological innovators design and implement new technologies such as iPads, and encrypted technologies that meet privacy standards [12]. Also, how are these health technologies currently being used in hospitals across North America to ensure that they are both safe for patients, families, and health care providers in preventing privacy breaches? The current political climate in the United States impacts how legislation is operationalized at the front lines. The ECPA has many implications for the integration of new, emerging, and innovative health technologies in the health care sector.

4. Conclusion

Both the United States and Canada have had their own journey as two modernized, high income nations. This paper draws inspiration from two nations in their journey towards designing innovative health technologies in the context of existing privacy legislation. It presents a historical perspective in the evolution of the privacy legislation, the ethical implications, and highlights how key privacy legislation can be considered in the process of health technology development. This legislation has implications for both for-profit and not-for-profit industries and specialties such as digital health and mobile health.

Despite the evolution of this legislation over time, the law within both countries has not yet evolved to incorporate advances in health technology. Co-designing technologies that pool health information such as monitor health apps, remote monitoring devices or larger electronic health datasets can lead to a more patient-centered and family-centered health care system for all Canadians. Engaging clinicians, policymakers, and patients through organizations such as the Canadian Medical Association, Canada Health Infoway, and others can ensure that that there is synchrony with the common values of professional institutions, government, for-profit and not-for-profit companies, which include creating a patient-centered health care system.

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Simulation of eHealth Scenarios with Role-Play Supported by an Interactive Smartphone Application

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Abstract. The transformation and digitalization of health services foresees a need for recruiting individuals with the combined knowledge of technical and health sciences. Education of young people in the domain of eHealth is an important contribution in the on-going digital transformation process. In this context, the research project *High School Students as Co-researchers in eHealth* aims to introduce technology-supported health care scenarios and research methods to young students in the Southern region of Norway. As a part of the project, simulation of eHealth scenarios was made in a clinical research laboratory together with high school students and experienced researchers. In the simulation, role-play was used to carry out the scenarios. To inform the roles, the tasks and their associated actions, an interactive smartphone application was used. This paper presents the simulation procedure and how the interactive smartphone was developed and used to guide the scenarios.

Keywords. Simulation, Health care modeling, Education and Training

1. Introduction

Health and social services are changing rapidly due to digitalization, and there is a need for individuals with a combined competence of computer and health sciences [1][2]. Combining health, organizational and technical issues is relevant for improving the technology-supported work processes. There is also a need for recruiting young people to contribute in the workforces of the future. At the University of Agder in Southern Norway, there has been a Centre of eHealth with a clinical research laboratory since year 2010 [3], where eHealth technology can be tested both in an early conceptual phase and during development regarding technical functionality, but also regarding impacts on organizational and clinical working procedures by use of multi test-room simulations were the interactions are observed and evaluated.

To introduce young people to eHealth, the research project *High School Students as Co-researchers in eHealth* was run as a collaboration between the University of Agder and high schools in Southern Norway, to allow high school students enrolled in a project

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course to learn about eHealth and research methods [4]. One of the learning objectives was to actively experience eHealth and as a learning method, a practical simulation was carried out in the eHealth research laboratory together with experienced researchers, where different eHealth-related scenarios were tested and carried out as a role-play. This paper presents the simulation procedure and how an interactive smartphone application was developed to inform the roles, tasks and their associated actions for the role-play used in the simulation of the eHealth scenarios

The research questions stated were: *How can simulation introduce high school students to eHealth in an educational and learning perspective? How can a smartphone application be used to guide the task flow in simulation of eHealth services?*

2. Methodology

As a part of the research project *High School Students as Co-researchers in eHealth,* 40 high school students taking a specialization in general studies, participated in an eHealth laboratory simulation during one day in September 2018. The high school students were 16 years old. The students carried out eHealth scenarios as a role-play together with researchers.

The project was led by the University of Agder and seven researchers within the domain of eHealth, having inter-disciplinary background from health informatics, computer science and health science were involved. In addition, one master student in Information and Communication Technology (ICT) was responsible for the conceptual and technical development of the interactive smartphone application used in the simulation. The role-play scenarios for the eHealth simulation were developed based on the experiences, results and technology from the research projects *Model for Telecare Alarm Services* [5][6] and *United4Health* [7][8], both performing several complex multi test-room simulations using the eHealth research laboratory infrastructure [9].

The high school student project was funded by the Research Council of Norway [10] with grant number 283737 and run during the year of 2018.

3. Results

3.1. The Simulation Procedure and Scenarios

The learning outcome of the simulation procedure was how technology can help patients and support health service providers, by experiencing the different roles in a typical telecare or telemedicine scenario, by testing and interacting with devices. The simulation started with a short introduction about two scenarios to be carried out. Based on two pre-defined scenarios, the students in groups of 6-8 participants were assigned roles. The first scenario targeted a telecare situation which was: a) patient at home with a fall accident and triggering a telecare alarm with a GPS geolocation and communication device, b) telecare alarm service operator receiving alarm and communicating with patient and relevant services, c) municipal home nurse on duty for home visits, using a mobile phone device, d) family member with mobile device, e) physician and ambulance service with a mobile device and f) a group of 6-8 students observing in the observation room and following the interactions. The second scenario was a telemedicine situation which was: a) a patient performing measurements (pulse oximetry) regarding chronic obstructive

pulmonary disease (COPD) using a tablet device, b) family member to be notified, c) municipal home nurse for home visit, d) general practitioner for medical advises and e) a group of 6-8 students observing in the observation room. After each scenario a group debrief was made, where the students reflected on the scenarios and discussed how to improve them. The group switched the roles internally between the scenarios, to experience the situation through different roles.

3.2. The Laboratory Infrastructure

An eHealth laboratory was used that had three separate test rooms and one control- and observation room. The laboratory infrastructure is described in Figure 1. Test room 1 represented the alarm centre, Test room 2 a public health house and Test room 3 the patient's home. In the control- and observation room, the simulation was followed simultaneously on 4 large monitors, one for each camera source and one for merging the sources. Interactions between the test rooms were made only through technology and were guided by an interactive smartphone application. In each room, there was a moderator from the research team guiding through the simulation.

3.3. The Interactive Smartphone Application

To describe the roles and the associated tasks, the interactive smartphone application *eHealth role-play* was used. The application was developed as a basic web application using JavaScript, HTML and CSS. By basing the application on the web platform, it ensured cross platform compatibility, allowing the application to be accessed on any device having a web browser.
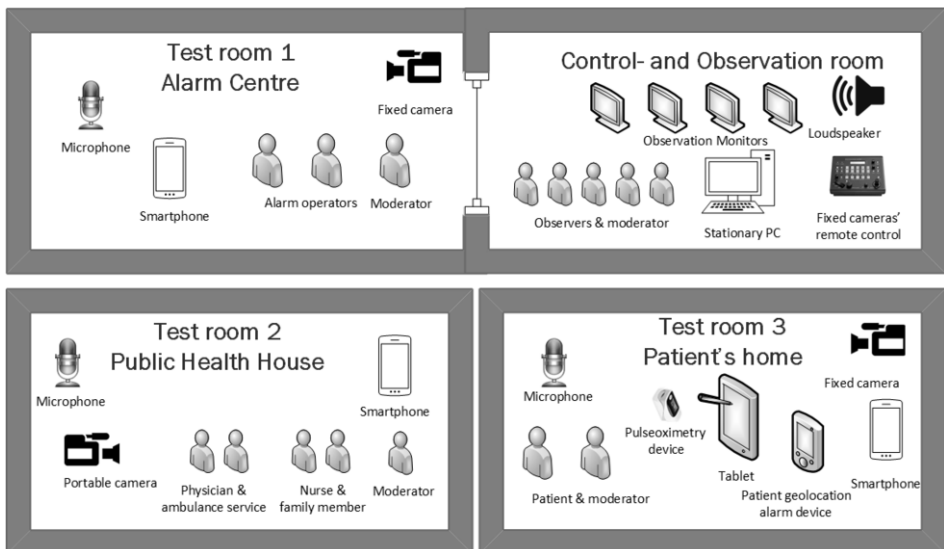
Figure 1. The eHealth laboratory with a multi test room set-up.
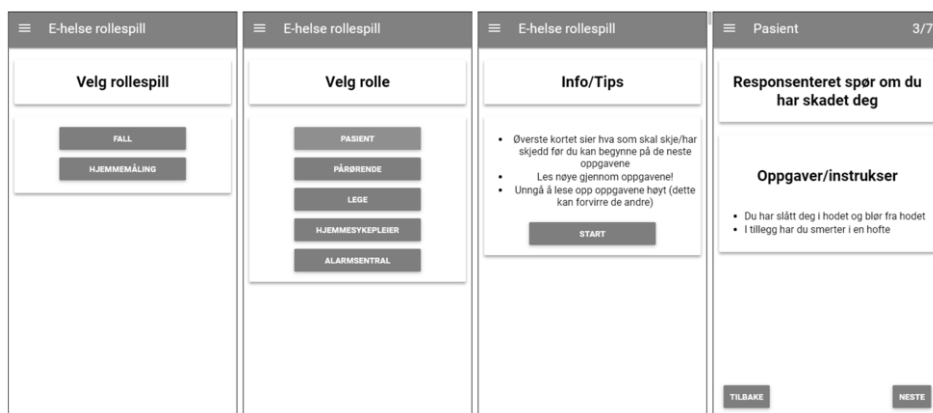
Figure 2. Screenshots from the smartphone application "eHealth role-play". From the right: 1) Start screen with choice of scenario, 2) Choice of role, 3) Information about the task flow and a start button, 4) A task with instruction and a next button to continue in the scenario.

Upon opening the application, the user could select a scenario and then an associated role for the chosen scenario (Figure 2). Before presentation of the first task, a screen would display information about the tasks, explaining to the user the task triggers and guidelines to ensure a good experience for all the participants in the role-play. When a user chose to start by pressing the start button on the screen, he/she was presented with the first stage of their role. Each of the roles had several stages that guided the user through the role-play. In each stage, there was a task trigger in the top card, which described the task trigger and task description. In this instance, the task trigger described what would have to occur before the user could start on the tasks in the bottom card. Once the user completed the tasks in the bottom card, he/she was able to go forward to the next task by pressing the next button. The progress between the stages was dependent on the different participants in the role-play, which could negatively affect the flow in the scenario and the experience of the role-play for the participants if the tasks were not followed precisely.

Regarding the user experience with the smartphone application, the students used their own device to access the application on the web before the start of the simulation. There were initially some technical issues that were solved with a mobile hot spot solution. As the students had limited experience from health services they needed introduction to the different roles and having one moderator in each test room for guiding both in the role-play and regarding the use of the smartphone application was required.

4. Discussion

This paper has presented how high school students were taught the concepts of eHealth technology by applying theory into practice through laboratory simulation. Regarding the first research question on how to introduce students to eHealth in a learning perspective, the method of practical simulation in laboratory provided a student-centered approach endeavoring an early understanding of eHealth concepts. The simulation and role-play in the eHealth laboratory allowed the students to understand and experience realistic situations were technology would support the actors (health care providers, patient and family members) in handling the situation. About the second research

question on how to guide the task flow in simulation, the interactive smartphone application *E-health role-play* was used instead of a traditional paper-based role description and task list. The idea was to use a device that all participants brought with them and knew well. The application replaced the use of paper instructions and informed each participant about their role and the next task to perform. The moderators during the simulation were active and experienced researchers in eHealth, and the scenarios aimed to provide the students with insights and hands-on real problems to solve, but also reflecting on-going and recent research projects. As there is a need for recruiting new people into the eHealth domain, hopefully, some of the high school students will choose a related education and join the inter-disciplinary work force in the future.

This paper has some limitations, such as describing simulations made with students from one single high school. However, the paper has shared experiences and lessons learned regarding simulation as a teaching method for young students with the learning objective basic understanding of eHealth concepts. To conclude, the approach with simulation of eHealth service in clinical laboratory together with high school students and researchers provided the students with hands-on experience on real situations and how technology can be used. The interactive smartphone application replaced traditional printed papers and guided the task flow, even though there were issues that could be improved. Future work would include extension of the project period and recruit a larger number of high schools for enrollment. In addition, the smartphone application could be further refined by developing a new task handling solution based on the basic trigger concept described by Schulz in Listening to Teachers' Needs: Human-centered Design for Mobile Technology in Higher Education [11].

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Describing Telenurses' Decision Making Using Clinical Decision Support: Influential Factors Identified

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Abstract.
Objective: Understand the cognitive processes of telenurses' decision making with the use of health information systems (HIS), specifically Clinical Decision Support Systems (CDSS). In addition, identify the factors that influence how telenurses use CDSS.
Methods: Eight telenurses were recruited to manage two call scenarios in a clinical simulation. The call encounters were video recorded and the phone calls were audio recorded. The screens were also recorded to capture the HIS navigation. After the call was completed, the recordings were played back for the telenurse and discussion ensued regarding any issues with the system; this encounter was also recorded for further analysis.
Results: Several factors were identified that influenced how telenurses made decisions while using the CDSS. It was found that the decision ladder model could be applied to describe telenurse strategies while using CDSS. The purpose of this paper is to describe the emerging factors that influence telenurses' decision making during a clinical simulation study in a telenursing call centre.

Keywords: Telenursing, Clinical Decision Support Systems, Health Information System, Decision Making

Introduction

Registered nurses (RN's) who work in hospital settings have provided advice over the telephone informally for many years. Historically, nurses have educated patients and answered their health-related questions in many contexts: in the emergency department, in their homes, and in public health units. [1]. In the past there were few standardized protocols available to these nurses and therefore, they relied solely on their experience and clinical judgment to offer health advice. With the advent of evidence based nursing and the modernization of health care using health information technology, we have seen a substantive change occur over the past 20 years. Today, nurses use electronic medical records (EMRs) and CDSS with the most recent evidence based information available to them to support their decision-making in differing contexts and with varying patients. Yet, little is known about how nurses make decisions in technology oriented settings and how technology can be refined to better support nursing practice. Therefore, the focus of this work is to describe telehealth nurse decision making in a context where nurses use CDSS in conjunction with EMRs as well as the human, organizational and

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technological factors that affect this work. In preparation for this research, a human ethics review was completed and approved.

1. Background: Review Of the Literature

A review of the literature identified an abundance of information available about critical thinking and decision making in general nursing practice. In terms of telehealth, however, there were only a limited number of studies available. The review of the literature highlighted some themes pertinent to critical thinking in relationship to how telenurses make decisions using CDSS. First, it was noted that stress and fatigue were factors in how telenurses make decisions. Interestingly, telenurses reported that when they were tired and under stress (i.e. high call volumes) they relied more heavily on the CDSS [2]. Second, in terms of experience, a telenurse may disagree with a resultant disposition based on some previous knowledge or experience and may choose to 'upgrade', or, recommend for the caller to seek care sooner. This practice is more commonly seen in expert telenurses as opposed to novices. This observation is in alignment with Benner's research findings in that "the ability of a nurse to focus and act upon contextually bound nuances automatically is a characteristic of expertise" [3]. The literature was sparse in terms of specifically addressing cognitive aspects of decision making which was important in the justification of this research.

2. Methods

A qualitative approach was chosen to perform this research as the researcher was concerned with exploring the experience of decision making in when a telenurse used a CDSS. Furthermore, as the researcher was exploring the underlying cognitive processes of decision making, it was important that the various concepts that underpin these processes emerged as well as their linkages.

2.1. Participants

An invitation to participate in the study was sent by email to all of the telenurses within call centre A. The email explained the purpose of the study as well as the expectations of the participants in terms of the time requirements and an explanation of the simulation. Eight telenurses (who were all female) accepted the invitation. Twenty- five percent (n=2) of the participants worked as a telenurse between 6-10 years while 75% (n=6) worked between 11-20 years; therefore, all of the participants were very familiar with the HIS. Telenurses had an average of 20.6 years of experience working as a RN.

2.2. Setting

Call center A was selected as the telenurse call centre for this study. The researcher reviewed the representative user, the setting as well as the representative task(s). In this study, a telenurse within a typical workstation at the call centre was selected for this
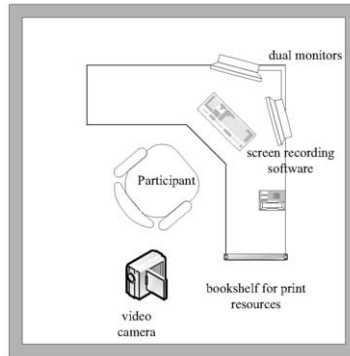
Figure 1: Telenurse Workstation Design

study in order to maintain a naturalistic setting. Figure 1 illustrates the workstation design in terms of how a telenurse interacts with the telephony and the HIS. The location of the workstation in relationship to the call center was arranged so that there were no disruptions or distractions to other telenurses on live calls.

2.3. Materials and Technology

Two simulated call scenarios were tested. One involved a caller with urgent symptoms of a heart attack, and the other consisted of a new postpartum mother with symptoms of a potential mastitis and her newborn baby. These were chosen with the premise that they would both follow a different pathway along the decision ladder, as described by Rasmussen's model that describes levels of generic tasks that experienced decision makers may go through, from activation of attention to goal setting and then action planning (i.e., one case demonstrated urgency in order to assess along with the use of heuristic shortcuts described in the model, while the other was more complex and more likely to be addressed in a more linear fashion) [4]. In essence, these two scenarios would follow a different pathway in terms of workflow. These two scenarios were validated as examples of common calls at Centre A by the Quality Management nurses and the Clinical Educators.

2.4. Procedure

Borycki et al discussed the use of clinical simulation as a methodology used by health professionals to enhance and improve clinical knowledge as well as evaluating the use of HIS and as such, this methodology was utilized to understand telenurses' workflow [5]. These encounters were audio recorded by specialized telephony and videotaped to monitor the tele1nurse's interaction with the HIS. The computer screens were recorded by Camtasia© software so as to offer further data in how the telenurse used the CDSS [6]. Upon completion of the call, a cued recall approach was used where the researcher played back the audio and computer screen recordings for the telenurse and she was asked to comment on her decision making experiences. These verbalizations were also audio recorded for further analysis. After the call was played back, the researcher asked open ended questions in order to clarify these verbalizations. This cued recall approach served to extract data in truly understanding a telenurse's cognitive processes [6].

3. Findings

The audio data from the call encounter provided simulated data in order to see how a telenurse truly practices. The screen recordings offered data of how a telenurse navigated the HIS, and specifically, the CDSS. Comparisons were done between the call handle time (CHT) from the audio data with the number of the screens navigated.

The post-task cued call approach questionnaire was integral in acquiring knowledge regarding the call encounter. This data was helpful in catching moments where the telenurse was thinking about something, perhaps about the HIS or what she was thinking might be going on with the caller, but did not explicitly discuss with the caller. This was where the tacit knowledge became explicit and thus, offered more insight to telenurse practice and the decision making process.

Video data also captured the telenurse using the HIS whereby the intention was to identify any telenurse reactions or any evidence of "picture building" [3]. Telenurses use this technique as a way of trying to visualize what the caller experiences; for example, the telenurse may touch their own arm or leg to understand where the potential problem is located. Years of experience and area of specialty were included as data. The intent of these questions was to ensure that any factors influencing decision making, whether it may be informing the use of short cuts, or more foundationally, enlightening general workflow.

4. Results

A number of factors were identified that influence telenurses' decision making. A corresponding quote from a nurse is added to highlight an example of the factor. These are identified in Table 1.

Table 1: Factors that Influence how Telenurses Make Decisions while using CDSS

Factor	Quote from Telenurse (T) and Researcher (R) Conversation
1. Professional experience – areas of expertise as a nurse	T: I know what the typical symptoms are there of a heart issue and if it's pretty well all of them. My past experience as a telenurse and working in emerg
2. Knowledge and education	T: my nursing experience, education and judgment, really basic nursing knowledge… any telenurse who's graduated should be probably saying the same thing, as well as previous calls from others that have had chest pain.
3. Knowledge/familiarity of the CDSS – equates with length of service	T: and we'll take a look here at the symptoms you're experiencing okay, specifically I'm looking at chest problems [in CDSS] okay, with that chest pain…okay, so, um chest pain or pressure or a strange feeling in the chest, you're having, right?
4. Call complexity (here identified as managing two or more callers as opposed to one)	T: …I didn't see it, and then of course when I went to the baby, I guess I could have manipulated the system in a different way, I could have opened a new service [new EMR], and then I would have had the baby's demographics
5. Personal experience - areas of expertise as an individual (i.e. breast feeding mom)	T: I mean I knew what the symptoms [of mastitis] were, just from my own knowledge, and from our CDSS, and I've had a couple of kids myself, as well as mastitis
6. System problems and/or component problems	N: Again, trying to find the information about the urinary norms, and that hover thing being so hyposensitive [web link]

All of the factors contributed in some fashion toward both call scenarios, and this was important to identify in terms of some generalizability across other potential call scenario.

5. Discussion

5.1. Implications For Practice

This study was conducted to learn more about telenurses and their decision making processes when using HIS. Such work may help other call centres in reviewing telenurses' work processes. Academic institutions that provide nursing and health informatics courses can review this research in order to better prepare students for telehealth nursing practice. Nursing informatics associations such as the Canadian Nursing Informatics Association (CNIA) can also use this research as a framework for guiding competency reviews or performance appraisals. Regulatory bodies may also want to review this research to enhance policy making surrounding telehealth nursing practice. Future studies should explore how telenurses consider utilizing the factors that influence decision making as compared to CDSS recommendations on their own.

6. Limitations

No male telenurses responded to the invitation to participate in the study; therefore, there was potential gender bias in terms of the second scenario whereby a breast-feeding mom was experiencing potential signs of mastitis. As previously mentioned, some of the participants have had personal experiences with breast feeding and developing mastitis; and this experience was reported to have been very influential in telenurses' decision making.

7. Conclusion

This research study was performed with the goal of understanding how telenurses make decisions while using a CDSS. The literature review revealed that there were few studies published on this subject. Furthermore, even fewer studies used clinical simulation as a research methodology; and in this study, it was clearly valuable in obtaining data that was important to understanding the factors that influence telenurses' decision making. Rasmussen's Decision Ladder was valuable in understanding how telenurses distinguish urgent calls to more complex in terms of the process (i.e. using heuristic shortcuts versus a more linear path) [4]. Health IT/software organizations need to better understand how telenurses use HIS to better align with telenurses' decision making. In addition, the factors identified that influence telenurse practice also need to impact organizational policy and education so as to maximize a telenurse's usability and confidence with using the HIS. Therefore, this research can serve to bridge the gap between the telenurse and the technology.

8. Conflict Of Interest/Funding

The author had no conflict of interest regarding this this study. There was no funding provided for this research.

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Usability Analysis of Contending Electronic Health Record Systems

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Abstract. In this paper, we report measured usability of two leading EHR systems during procurement. A total of 18 users participated in paired-usability testing of three scenarios: ordering and managing medications by an outpatient physician, medicine administration by an inpatient nurse and scheduling of appointments by nursing staff. Data for audio, screen capture, satisfaction rating, task success and errors made was collected during testing. We found a clear difference between the systems for percentage of successfully completed tasks, two different satisfaction measures and perceived learnability when looking at the results over all scenarios. We conclude that usability should be evaluated during procurement and the difference in usability between systems could be revealed even with fewer measures than were used in our study.

Keywords. usability, evaluation, measurement, procurement, electronic health record system

1. Introduction

Usability of electronic health record (EHR) systems is a continuous topic of discussion. Usability is defined as effectiveness [1], efficiency [1, 2], satisfaction [1, 2], learnability [2], and errors [2]. Usability testing is an established method for analyzing the usability of an IT system [2] and different measures can be used to quantify usability [3, 4]. Usability evaluation methods have been used increasingly in health informatics field since 2005 [5]. However, EHR systems' usability continues to be inadequate and physicians are dissatisfied with them [6]. In a recent study, two leading EHR systems' usability was compared in ordering tasks and differences were found both between vendors and within different implementations of the same system [7].

Comparisons of user performance between EHR system implementations are not widely available. The purpose of this study was to measure and compare usability of two contending EHR systems. Usability testing was performed as part of a large-scale procurement of a client and patient information system for specialized and primary health care as well as social care in autumn 2014 in Finland [8]. In this paper, we report the measured usability of the two systems based on the data gathered during usability testing in procurement. Based on the data, we discuss the main usability challenges users face when using two of the leading EHR systems.

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2. Materials and Methods

2.1. Study Design, Setting and Participants

A within-participants usability testing study was conducted between two contending EHRs (Epic and Cerner) during a governmental IT system procurement in Finland. This study was part of the second phase of the procurement, and comprised three user scenarios and user groups. The scenarios and the tasks in them were selected to represent typical tasks of physicians and nurses, which are relevant and of high importance from the viewpoint of EHR system use and patient safety. Clinical experts and usability specialists from the procurement office prepared the three scenarios: ordering and managing medications by an outpatient physician (19 tasks), medicine administration by an inpatient nurse (12 tasks) and scheduling of appointments by nursing staff (14 tasks). The contending vendors configured their existing systems to best meet the needs of the scenarios. Identical fictitious patient data was given to the vendors to be used in the test.

A paired-user usability testing method was used [9], because the users were not familiar with the EHRs beyond seeing demonstrations. Participants received standardized instructions to complete each task as a team. They watched a training video prepared by the vendor of maximum 7 minutes. The pairs were instructed to switch the person using keyboard and mouse when the first half of tasks were completed. This order was reversed for the second EHR. The moderator, who was a usability specialist, read each task aloud and gave it in written format, but did not assist with task performance.

Testing was done in two small conference rooms at the procurement office. Both vendors provided the software and hardware setup for testing. The procuring organization provided wifi connection, identical monitors, mouse and keyboard. Audio, screen capture, mouse click, keystrokes and satisfaction rating data was collected during testing. The test moderator documented user performance using a separate device [10]. The same usability specialist moderated the tests for the same scenario on both vendors' EHR systems. Before testing, the usability specialist prepared herself for the testing by using the EHR system utilizing detailed instructions for correct performance of tasks provided by the vendor, and with the help of a clinical expert.

Physicians and nurses from each user group were recruited from procuring organizations' staff. Testing was conducted during their normal working hours without additional compensation. Three pairs of users tested each scenario, totaling 18 participants. All had several years of experience with clinical work and use of EHRs.

2.2. Measurements, Outcomes and Analysis

The participants filled a consent form and a demographic survey. A maximum of 12 minutes was given for each task. Task time, task success and errors during the user performance were recorded. Both users used feedback devices (positive and negative responses) during the tasks and once more after each task. All data was captured with a hardware solution [10]. After completion of all tasks or reaching maximum testing time (90 minutes), the users answered a standardized usability questionnaire (SUS [11]).

Measures reported in this paper are: (1) percentage of successfully completed tasks (effectiveness), (2) errors made during task completion (deviations from optimal path), (3) perceived learnability (learnability factor from SUS questionnaire [12]), (4) user satisfaction during testing, and (5) after testing was completed (SUS). Successful completion of a task was based on the goal of each task and the optimal path provided

by the vendor; errors were allowed during task completion. The percentage of successfully completed tasks were calculated out of those completed within testing time. Errors were defined as deviations from the optimal path. The errors were divided into small and large (0.5 and 1 points, respectively) and reported for successfully completed tasks. User satisfaction during testing was defined as the percentage of tasks with more positive than negative markers from both users combined. Perceived learnability and SUS score were standard measures from the SUS questionnaire [11,12]. To quantify usability, all data was analyzed for each task, test session and scenario separately. Task success, errors and satisfaction data during testing (incl. SUS) was transformed into and calculated with MS Excel.

3. Results

We refer to the EHR systems with letters X and Y to prevent disclosure of the specific vendors. An overview of the results is presented in Table 1.

3.1. Scenario 1: Ordering and Managing Medications

The first scenario comprised 19 tasks. Within given time, the pairs completed on average 13 tasks with system X and 17 tasks with system Y. Effectiveness for system X (59.0%) was lower than for system Y (90.4%).

Table 1. Results of measures for all three tested scenarios.

Scenario	Usability measures	System X Mean (SD)	System Y Mean (SD)
Ordering and managing medications	Tasks time to complete (count) (N=19)	13 (2.8)	17 (2.4)
	Successfully completed tasks (%)	59.0	90.4
	Errors (deviations from optimal path) (points/task)	2.6 (0.6)	1.6 (0.5)
	Perceived learnability (score)	22.9 (19.7)	58.3 (20.0)
	Satisfaction during testing (%)	28.2	78.8
	Overall satisfaction (SUS score)	32.5 (12.2)	70.8 (9.5)
Medication administration	Tasks time to complete (count) (N=12)	12 (0)	12 (0.5)
	Successfully completed tasks (%)	50.0	62.9
	Errors (deviations from optimal path) (points/task)	3.0 (0.7)	2.9 (0.2)
	Perceived learnability (score)	27.1 (13.3)	35.4 (15.2)
	Satisfaction during testing (%)	47.2	71.4
	Overall satisfaction (SUS score)	25.4 (16.1)	70.0 (11.6)
Scheduling appointments	Tasks time to complete (count) (N=14)	14 (0)	14 (0)
	Successfully completed tasks (%)	52.4	76.2
	Errors (deviations from optimal path) (points/task)	1.3 (0.3)	0.7 (0.3)
	Perceived learnability (score)	27.1 (13.3)	50.0 (23.9)
	Satisfaction during testing (%) *	26.2	40.5
	Overall satisfaction (SUS score)	41.3 (12.1)	64.6 (10.2)
Overall (all scenarios)	Successfully completed tasks (%)	53.8	78.3
	Errors (deviations from optimal path) (points/task)	2.3	1.6
	Perceived learnability (score)	25.7	47.9
	Satisfaction during testing (%)	33.3	64.3
	Overall satisfaction (SUS score)	33.1	68.5

* Data completely unavailable for one pair, and partly available for one pair due to technical problems with data gathering. The results are calculated for both systems based on the same pairs.

With system X, the pairs had more deviations from optimal path of completing the successful tasks than with system Y (mean 2.6 vs. 1.6 error points). The users rated both their satisfaction during testing (28.2%) and overall satisfaction SUS score (32.5) with system X much lower than system Y (78.8% and 70.8). The perceived learnability score for system X was lower (22.9) than for system Y (58.3), although there is large deviation.

With system X, all three pairs failed in completing the same three tasks. With system Y, at least one pair completed correctly all tasks, and two or three pairs completed correctly 18/19 tasks. In both systems, two tasks had high error points (2.5 to 8 points) from more than one pair. The tasks difficult to complete were related to documenting a change in the dosing history of a medication, and marking a medication on a pause either in the past or in the future. The latter had also high error points in system Y. The pairs had a high number of errors also on tasks that related to ordering a medicine with different dosing in the morning than evening, and gradually changing dosing.

3.2. Scenario 2: Medication Administration

The second scenario included 12 tasks, which almost all were completed with both systems by all pairs in time. Key measures were (system X / system Y): effectiveness (50.0% / 62.9%), error points (3.0 / 2.9), satisfaction (47.2% / 71.4%), SUS (25.4 / 70.0) and perceived learnability (27.1 / 35.4). Meaningful differences are in effectiveness and satisfaction (incl. SUS) in favor of system Y.

With system X, three tasks were either not prepared correctly or had missing system functionality, and were thus not completed successfully. All pairs failed in completing one of the tasks. With system Y, one task had missing system functionality and all pairs failed in completing one of the tasks. There were three tasks that only one pair completed correctly. The tasks the pairs had trouble with related to administering and documenting an order for an infusion, adding times for next administrations, updating the list of medications per physician orders, and documenting the administration of all oral medications at once. Two tasks in both systems had high error points (4 to 11) from more than one pair. The tasks included infusions, documenting physician orders, cancelling an already documented administration, and returning to home medications before discharge.

3.3. Scenario 3: Scheduling Appointments

The third scenario included 14 tasks, which all pairs completed within the allocated time. Key measures were (system X / system Y): effectiveness (52.4% / 76.2%), error points (1.3 / 0.7), satisfaction (26.2% / 40.5%), SUS (41.3 / 64.6) and perceived learnability (27.1 ±13.3 / 50.0 ±23.9) with large deviations. Meaningful differences are in effectiveness and satisfaction (incl. SUS) in favor of system Y.

With system X, the pairs could not complete six tasks, because of either missing system functionality or problems with preparations. One task only one pair completed correctly. In system Y, one task did not have correctly prepared data and no pair completed one of the tasks. The pairs struggled in completing tasks related to checking whether patient receives notifications from appointments and to which phone number, removing a notification from an appointment, as well as scheduling a series of three appointments two days apart. With system X, one task received high error points (3.5 to 4) from two pairs. With system Y, two of the tasks had high error points (4.5 / 5.5) from

one pair. The tasks were related to rescheduling an appointment, scheduling a series of three appointments and changing the default duration of the appointment.

3.4. Overall results

System X received lower ratings in all measures when looking at the results over all scenarios. There were great differences with regards effectiveness (53.8% / 78.3%), satisfaction (33.3 % / 64.3%), SUS (33.1 / 68.5) and perceived learnability (25.7 / 47.9).

4. Discussion and Conclusion

Our paired-user usability testing study revealed a difference between the two systems. Successful task completion rates were lower for system X in all three scenarios, and lowest in medication administration (50% vs. 62.9%). Greatest differences were in ordering and managing medications. In system X, more tasks had missing system functionality or were not prepared correctly, which accounts for some of the differences in effectiveness in scenarios two and three. However, missing functionality ultimately means user goals not being met; this constitutes an important factor in usability.

The first scenario showed a clear difference in deviations from the optimal path. In the other two scenarios, the differences were not so apparent. Both systems had very high error points for certain tasks in medication administration, while in scheduling the error points were quite low. For system Y, despite low error points and high effectiveness, the user satisfaction ratings were the lowest in scheduling. System X user satisfaction ratings were low for nurse scenarios, and even lower for physicians. In contrast, system Y user satisfaction ratings were highest for physicians. The overall SUS score of 33.1 for system X is unsatisfactory while the score of 68.5 for system Y is acceptable [4].

Both systems are mainly used in the USA. Accordingly, the differences of the tasks in our scenarios (Finnish context) and the original workflows (US context) can be assumed similar for both systems, and are thus not likely to explain the findings. However, configurability capabilities may vary between the systems.

Two limitations deserve to be discussed. Firstly, the users had not been trained to use the systems; apart from the short introductory video and some of them had watched demonstrations earlier in the procurement. Secondly, the vendors had optimized their system for the procurement and thus the systems used did not necessarily match any existing system configuration.

User experiences and dissatisfaction have been used as a basis for EHR system usability criticism [6]. However, usability comparisons based on user performance are not widely available. A similar previous study [7] mainly focused on efficiency. We used several different usability measures to get a reliable view on the usability of the systems from different perspectives for procurement purposes. Our study revealed a clear difference in usability between the two leading systems in all three scenarios and user groups. Our results show that overall all measures can reveal a similar state of usability and similar differences between systems.

Aligned with previous literature [13], we recommend usability testing when procuring EHR systems with varying number of measures depending on desire of further use of results. Our study utilized several measures, but results indicate that also fewer measures could be considered in a pure comparison situation.

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Smart Home Interactions for People with Reduced Hand Mobility Using Subtle EMG-Signal Gestures

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Abstract. Smart home technology is receiving significant attention. This is largely in response to an increase in the size of demographic those who require assistance due to reduced mobility, in particular, older adults. Smart home technology enables the assistance individuals with limited mobility need for their daily routines: these limitations can be addressed using modern ambient assisted living technologies. In particular we discuss the benefits of using electromyography (EMG) sensors to capture gestural input that would normally be difficult to sense in the absence of such sensors. With EMG, we can provide user control of a smart environment through the use of gestures based on muscle activity of the hands. This paper will focus on presenting the benefits of EMG technologies that can potentially assist individuals with hand mobility issues. We will describe the current state of EMG sensory technologies and their role in shaping gesture-based interaction techniques. We present our approach using such EMG signals and demonstrate their value in a smart home scenario. Finally we introduce the concept of subtle EMG gestures and build a better understanding of how we might improve accessibility for those with limited upper limb motion.

Keywords. elderly assistance, assistive technology, electromyography, home care, gesture-control

1. Introduction

Accessibility generally refers to the design of products, devices, services, or environments for people who experience some physical or mental limitations [1]. The issue of accessibility is the most prevalent among older adults [2–4], with major contributors to limited accessibility being ageing and long-term or chronic conditions caused by injury and illnesses [5–7]. These limitations and conditions affect cognitive, perceptual, and motor abilities. Motor issues connected with shoulders, hands, forearms, and wrists joints coupled with low flexibility of both joints and muscles as well as their weakness, may all result in poor manual dexterity, slower motions, reduced strength, reduced fine motor control, decreased range of motion, and most importantly, reduced grip force of hands and fingers[8, 9]. We will hereinafter refer to these hand limitations as hand mobility issues despite the extent of their severity.

Many countries are experiencing a huge demographic shift, where the proportion of the older adults is rapidly increasing. According to many credible global organizations (e.g., United Nations and WHO), the global population aged 60 and over

has tripled since 1946 and 1965. It is expected that this population group will continue to grow significantly in the future. Nearly 21% of world population will be over 60 years old and is projected to more than double its size in 2015, reaching nearly 2.1 billion by 2050 [43]. It is widely accepted that significantly more work is needed in order for our society to make a smooth transition to accommodate this demographic shift.

A wide range of sophisticated technologies are being produced within the realm of smart homes (e.g., remotely programmable automated functions and systems). The key aim of a smart home is to improve comfort, energy savings, and security for the residents in the house. Due to these significant benefits, smart homes are endorsed by a variety of credible organizations (e.g. World Health Organization, United Nations, etc.) [10]. This is presumably because a growing rate of ageing population cannot be supported by simply increasing the number of caregivers [10]. Human Computer Interaction (HCI) as a field of research focuses on designing the interaction interfaces between people and computers and plays an important role in the studying of smart homes. Ambient Assisted Living (AAL) as a branch of the Human Computer Interaction (HCI) field specifically focuses on the upcoming challenges and objectives of providing those living independently with various supporting technologies. We would like to consider potential methods to accommodate individuals with limitations in using smart home technologies.

2. Background

2.1. Hand Gestures

Generally, users utilize movements of hands, head, face, and other parts of the body to interact with virtual objects. Furthermore, studies have investigated how older adults use gestural inputs during their interactions with technologies [11–16]. Research supports the use of hand gestures over other interaction methods with respect to learning time. Not surprisingly, hand gestures have become one of the most preferred input methods [17]. Hand gestures can offer a fast and effective medium for controlling and communicating with intelligent devices. Additionally, robust and effective gesture recognition technologies allow us to control a variety of applications with articulated prosthetic hands [18], a mobile device, and intuitive game interfaces [19].

Among many other hand gesture techniques, soft computing (software development) techniques offer new perspectives on the application of electromyography (EMG) signals in the control of devices in a smart home environment. EMG signals refer to biological signals produced by the neuromuscular system when users perform any muscle movements (e.g., contractions). It allows effective extraction of informative signal features in case of high interference between useful EMG signals and strong noise signals [20]. There are two types of EMG recording electrodes: surface [21] and intramuscular [22]. While intramuscular sensors require a needle electrode to be inserted directly into a muscle, surface EMG sensors record muscle activity from the surface of the skin and require only direct skin contact in the region of the specific muscle(s) [23]. Moreover, both commercial and research prototypes have demonstrated a great potential for machine learning to decode surface EMG signals and enable natural gesture recognition [24–27]. Compared to their original bulky form (e.g., Biopac MP150 EMG system with many electrodes) [28], modern EMG sensors have progressed significantly. One of the most recent EMG sensors, the MYO Armband designed by Thalmic Labs, is

a wireless armband that contains 8 medical grade stainless steel EMG sensors and a highly sensitive nine-axis IMU [27]. Although the form is quite simple, it is a very powerful tool for hand gesture recognition as well as arm movement tracking. Moreover, MYO has a set of built-in gestures designed for commercial purposes. The goal of the MYO is for easy and comfortable interaction with technologies using hand gestures, which fit our research purposes quite nicely.

2.2. Smart Home for Older Adults

While population is ageing at such a growing rate, we must prepare for the potential financial impact we face in caregiving costs. Meanwhile, smart homes are gaining popularity worldwide. Health-care institutions and medical facilities are particularly interested in helping people stay home longer, not only to minimize costs, but also to support older adults' independent living [29]. Living independently without any assistance can be physically and psychologically difficult, while living with the support of smart home technology (e.g., biological data monitoring with a movement sensor) will likely provide comfort to older adults, their family, and caregivers. Constant monitoring of the physical and mental state of the older adult should allow family and caregivers to be aware of any changes that he/she displays (e.g., the fridge door has not been opened for the last 12 hours, indicating an older adult is not eating). Remote health monitoring is a central component in the global vision of the smart home [29]. An additional category of applications is meant to facilitate independent living and provide remote seamless control of the environment for those with mobility issues. [30].

3. Applications

Many studies have been conducted to test the abilities of the Myo Armband for both medicine [31, 32] and human-computer interaction (HCI) [33–35].

Gestural interfaces in HCI based on EMG recognition have produced a range of applications for controlling smart home devices [36], mobile devices, wheelchairs, prosthetic robotic hands, and mobile robot navigation. To navigate a wheelchair in a real indoor environment, Moon et al. [37] for example, controlled an electric-powered wheelchair left, right, and forward with a corresponding elevation of shoulders. Further, robotic arm manipulations and robot navigation control systems have shown their potential in various studies using different EMG configurations [38–41].

In bio-medical engineering, EMG sensors are frequently used in prosthetic amputee rehabilitation applications to enable trans-radial hand amputees to regain a significant portion of their lost-hand functionality; using robotic hand prostheses [42]. This area of research specifically relies on the precision of the EMG data obtained from the sensor attached to the amputated limb. NinaPro, a well-known public database, contains datasets of jointly recorded surface EMG signals for predefined sets of gestures. Their goal was to establish scientific benchmarks to test for movement recognition and algorithms for force control.

Abduo et al. investigated the MYO Armband accuracy compared to the NinaPro database to find out whether the MYO can be used as a cheaper alternative for the prosthetic hand EMG sensor and build a generic extendable surface EMG interface, namely, an open source solution that can be used to further study the performance of various EMG sensors [42].

4. Motivation & Research Problem

The primary motivation behind this research is to understand, and ultimately, support the older adults, specifically when they face physical restrictions in their everyday lives. The ageing population might put an unfortunate strain on younger generations seeking to care for the older population (e.g., nearly a half of the Canadians aged 15 and older give care to some of their family members or close people [44]). Therefore, we suggest that applying smart home technologies and improving the seamless control of the smart environment via hand gesture-based interfaces might ease the difficulties caregivers face. Smart home technologies can be employed in both homes and hospitals to facilitate care and protect older adults' independence. Smart homes present a great potential to maintain users' well-being, quality of life, and confidence, when designed and used properly.

Although, the hand gesture-based interactions are common in HCI and represent a reliable interaction modality for the smart home environment, the majority of studies often focus on gestural input engaging young adults, leaving a wide gap between the young designers' personal experience and the experiences of the older users [17] and their aptitude characteristics which implies having any hand mobility issue. Currently existing and studied EMG-based hand gestures are designed without taking corresponding measures to address the physical limitations. Clearly, such studies are needed to employ various technologies to facilitate older adults' lives. Myo Armband is a good example to illustrate the issue, since using the device, we believe, introduces two main problems a senior population might face when using it: a) Existing built-in hand gestures may induce arm fatigue quickly, even for younger users, and, b) People with motor limitations or dysfunctions might find it hard to perform such gestures.

4.1. Existing Technical Limitations

Apart of the design we draw three major limitations using the EMG devices. Firstly, a sensitivity level is highly hardware-dependent and is defined by the frequency rate: the number of sensor measurements made per second. Secondly, machine learning models to process raw EMG data and train the system to recognize specific patterns as needed. The models and algorithms have different properties so it is very important to employ the algorithms which best suit for the problem, however, again, the accuracy thoroughly depends on a hardware that is used. Lastly, studies show that nearly perfect performance (95% to 98% rate of success) can be achieved when using the suitable machine learning methods [45–53], however, weaker or physically limited muscles may not produce EMG signals of sufficient intensity and may have more noise contamination, which reduces the accuracy of the recognition. The substantial lack of user studies involving older adults makes the performance only statistically significant for young users leaving the results of the performance for older users undefined. As a result two previous limitations may also be highly dependent on this factor.

5. Potential solution

When designing the gesture interface, in general, it is important to understand, categorize, as well as reflect their physical capabilities and aptitude in the design of both the hardware and the software [17]. To better understand and feel the gesture interactions

within the environment, using an inductive approach, we developed the gesture-interaction, human-tracking perception system (Fig.1) to control a set of smart-home lights using the MYO Armband in the simulated room environment. The system setup comprised of the Microsoft Kinect (a body skeleton tracker), Myo Armband, and custom software developed to support interaction by combining these devices. Kinect helped to recognize spatial deictic gestures (e.g. pointing at objects). MYO, with its IMU(inertial measurement unit) and EMG sensors on board, allowed measurement of hand orientation in space and the recognition of particular gestures. Together, the devices and software gave us the ability to control Philips Hue bulbs using various continuous and discrete gestures. We successfully developed a system and controlled floor lamps using the MYO Armband, with its simple built-in gestures.

Figure 1. Gesture-interaction, human-tracking perception system. For more details, please, see
https://www.youtube.com/watch?v=sBx2zvBriyo

Throughout the implementation of the system, we discovered difficulties using the built-in MYO gestures that are related to EMG sensing, as they require high-level tension movements to work (e.g. clenching a fist), producing fatigue that greatly decreases the accuracy of the device in a short period of time. We reasonably inferred that this difficulty would be magnified when used by people with hand mobility issues, making MYO difficult or even not possible for them to use. The approach of the existing problem we propose lies in a consilience of two areas of research and building a bridge between them by studying the surface EMG devices from both a biomedical engineering and an HCI perspective. Biomedical engineering, as a field, extensively studies the relationship between surface EMG sensors and hand kinematics to improve robotics hand prosthesis, which implies the notion of subtle/fine gestures or movements detection [54]. HCI is more shifted toward studying user groups and the best fit design solutions of the interface of interaction.

There are very few studies in HCI which specifically emphasize the importance of the subtle gesture. Wan et al. built custom hardware combining the EMG sensor with force sensitive resistors[55]. Thus, their system deals with subtle hand movements or the single finger movements as well as the combination of fingers and hand movements with very high accuracy. However, authors never mentioned using their technology as a possible application for older adults. Of particular interest and relation to our research is the work of Abduo et al. [42] as they structured together the medical and HCI purposes of the MYO Armband and looked at this commercial product from the medical viewpoint. Our approach will extend the results of this work by shifting attention to the use of EMG sensors in smart home environments, adapted for a "weak" hand with mobility issues for purposes of a fine gestural control.

6. Conclusion

This research will provide a number of benefits to both HCI and Health-care communities. As one of the directions of Ambient Assisted Living, this research attempts to explore a technical solution for finer EMG-based hand gestures to accommodate diverse groups of people in our society, including older adults who may require frequent or daily assistance. Our hope to support older adults in living independently with technological solutions is shared by many people worldwide. Safe and comfortable independent living is what many of us in our society desire (e.g., older adults themselves, their family members, and caregivers). We hope our proposed solutions, by using EMG sensors to enable the use of gestures in smart homes, offer a potential support for gradual but meaningful life style changes.

Acknowledgement

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Design for a Canadian Digital Health Policy & Practices Observatory

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Abstract. Canada has struggled to make digital health a reality. We identified 6 key issues that appear to impede progress: 1) an inability to coordinate the actions of a rapidly evolving set of stakeholders, 2) patients who lack the ability and resources to play a meaningful role in health system decision-making, 3) world-class innovation that doesn't reach the market, 4) an inability to kick-start interoperability projects that can catalyze system transformation, 5) an inability to procure early-stage innovative technologies at scale, and 6) an inability to share data seamlessly across organizational silos for patient coordination and care, health system management and research. We propose a set of policies and practices that can help Canada assess, monitor and provide feedback to stakeholders and citizens on how well they are progressing toward seamless digital health.

Keywords. Digital health, policy, observatory, innovation, patient empowerment, procurement, interoperability

1. Introduction

The healthcare system in Canada continues to evolve rapidly. Investments made over the last 30-40 years have paid off: Canadians are living longer and with fewer disabilities. However, Canadians are now living with more chronic diseases than ever before [1], putting greater pressure on the system and placing more responsibility on them for the management of their own health. Concurrently, health care information and communication technologies are being developed at an accelerating rate.

As Canada moves into this brave new world, it requires new policies, perspectives and practices that will enable it to embrace change and thrive in a rapidly changing healthcare world. Our new policies and practices need to take into consideration the complex interactions that are necessitated by a more complex stakeholder environment. And those policies and practices need to be coordinated to ensure synergies between players and ensure that they all benefit from the investments and efforts put into the system.

We propose a policy observatory to assist in outlining the factors for success and for providing an independent and objective assessment of how well Canada and its political

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processes are moving toward achieving important pillars and practices for the digitization of the healthcare system [2].

2. Methods

We conducted a stakeholder analysis to identify key stakeholders in the health information technology arena. We identified the key needs of each stakeholder using business analysis methods. We obtained feedback through key informant interviews and email review of a first draft of the proposal for a digital health policy observatory (N=7). Ongoing feedback and discussion allowed for iterative improvements and progress with this initiative.

3. Evolving Role of Existing Stakeholders and New Stakeholders

Over the last 6 decades, key stakeholders in the Canadian healthcare system have consisted of provincial Ministries of Health which have had both a policy and a funding role; patients who have illnesses and their caregivers; and healthcare providers who diagnose and treat illnesses. Increasingly, this list of stakeholders has grown to include researchers, knowledge disseminators and vendors. In addition, it has also seen dramatic shifts in how these stakeholders interact.

As the number of healthcare information and communication technologies increases, researchers are required to confirm their benefit to Canadians and to the health care system. Knowledge disseminators, such as charitable organizations, play an increasingly important role in collating the exploding health care literature and evidence-base, summarizing it and making it accessible to patients, caregivers, and providers in the form of guidelines. Technology vendors are playing and will continue to play an increasingly important role in enabling in-clinic research, scaling up knowledge translation to the point of care, and bringing advancements in computing technologies such as machine learning and artificial intelligence to bear on important unmet medical needs.

4. Key Issues Facing the Healthcare System

As Canada moves forward, it faces the following issues: 1) difficulty in coordinating the efforts and incentives for multiple stakeholders to move together in tandem, 2) patients who lack the ability and resources to participate meaningfully in system change, 3) innovation policies that generate world-class innovations that do not reach the market, 4) an inability to kick-start interoperability projects that can catalyze system transformation, 5) an inability to procure early-stage innovative technologies at scale and 6) an inability to share data seamlessly across organizational silos for improved patient coordination and care, health system management and research [3].

5. A Digital Health Policy Observatory Can Show the Way

Canada needs new policies and practices to help drive the healthcare system toward implementation of digital health technologies in a way that benefits all stakeholders. We propose the following policies and practices to ensure engagement, innovation and sustainability.

5.1. Multi-stakeholder governance structures for system management

Increasingly, the new and old stakeholders need to coordinate their efforts through ongoing dialogue and discussion based on information from a variety of perspectives and sources. Multi-stakeholder governance should become a normative practice in all important digital initiatives in the healthcare system. Conflicts of interest will be managed through transparency and openness, rather than through avoidance.

5.2. Patient engagement and empowerment policies

Scotland's Patient Rights Act [4], for example, enshrines educating patients about their rights to both a safe environment and confidentiality, provides them access to their own records and the capacity to give feedback, and enables them to be active participants in healthcare decision-making and execution. These policies need to accommodate a variety of patient preferred roles and allow patients to decide to what extent they wish to engage with the system [5, 6].

5.3. Federal and Provincial innovation policies that support dissemination of invented-in-Canada technologies

Despite strong R&D investment and achievement, few Canadian innovations are able to reach the scale and spread required to realize transformative change. There is urgent need therefore, to provide a platform that encourages the dissemination of home-grown technologies, aligned with Canadian health system structures and processes (e.g., publicly funded system, provincial billing processes), into patient care, while achieving responsible stewardship of both limited procurement budgets and previous R&D investment [7].

5.4. An interoperability research agenda

True interoperability continues to elude the healthcare system. This is because interoperability is not only a technical problem, but also requires alignment of people, processes and economics. More research is required to understand the governance needs, the business cases and the economic arguments for interoperability so that all stakeholders have a clear roadmap of how to achieve it and how they stand to benefit.

5.5. Technology and innovation procurement policies

Current procurement policies favor incumbents, large organizations and established products. Increasingly, innovation is coming from smaller start-ups with new products based on new technologies. Without progressive procurement policies, stakeholders cannot be blamed for avoiding unacceptable risks when procuring innovation, but

subsequently lose out on the value that innovation brings. A lack of progressive procurement policies stifles innovation.

5.6. Policies for the governance of shared health information

Data exists in organizational silos today. For us to benefit from newer technologies and advances in data analytics, data needs to be shared more widely, more rapidly and with greater ease. Policies and regulations that enable faster sharing for greater benefits while maintaining confidentiality and data security are desperately needed. An example of such policies is an initiative of the Government of Israel to create a central repository of de-identified health data from EMRs and other systems, which will be open to researchers in local academic institutes and industry for free or a small fee [8].

6. Mandate and Expected Outcomes

It is expected that the Digital Health Policy Observatory will:

- Establish an observatory of digital health policy and practices in Canada;
- Develop credible, respected, transparent and easy to understand policy assessment tools;
- Conduct assessments of policies and practices that can help us move the digital health agenda forward;
- Provide a credible, independent and unbiased source of high quality information about digital health progress in Canada;
- Influence the development of digital health policies and practices in Canada in a manner that is consistent with the best interests of society and the stakeholders who work to make healthcare a valuable cultural asset in Canada.

7. Call to Action

We are currently at the proposal stage and are inviting interested parties to join on a volunteer basis to help establish the Canadian Digital Health Policy & Practices Observatory.

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Strategies in Electronic Medical Record Downtime Planning: A Scoping Study

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Abstract. PURPOSE: This review will identify dominant themes, common to published articles that discuss downtime planning in a clinical setting. These common themes will represent key considerations for healthcare organizations' comprehensive downtime plans. METHOD: A scoping study was performed using search results from PubMed, CINAHL and Medline. The 4 articles meeting the inclusion criteria were analyzed for common themes and findings. RESULTS: Four common themes were found in the included articles: 1) Communications plans, 2) Procedure review and revision, 3) Managing system availability and 4) Preparing staff for handling incidents. CONCLUSION: Organizations must have comprehensive downtime plans available to ensure continuity of patient care during the periods of limited availability. A comprehensive downtime plan that includes these four strategies can become the framework for a set of organizational procedures that ensures the best possible access to vital patient information before, during, and after a downtime event.

Keywords. electronic health record, healthcare information system, EMR, EHR, HCIS, downtime mitigation, contingency planning, patient safety

1. Introduction

With Electronic Medical Record (EMR) systems being deployed in healthcare organizations, clinician reliance on these systems for patient information has increased. When those systems experience downtimes, they create gaps in information and care processes that can have an effect on patient safety and the continuity of care of patients [1-3]. Data gathered from incident reporting tools, as well as in depth analysis of laboratory information systems (LIS) study turnaround times have provided valuable insights into the clinical impact of downtime events. Such analysis of the data in conjunction with observations of effects of downtimes on clinical workflow during a downtime event help to illuminate gaps in formal downtime plans that need to be addressed. In this review the authors will identify key themes emerging from the literature focusing on downtime planning in a clinical setting. These common themes represent key considerations for healthcare organizations' development of comprehensive downtime plans.

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2. Method

Following a scoping study methodology [4], searches were performed on CINAHL, PubMed and Medline for articles including the terms "downtime", "planning" and "electronic medical record" (EMR) as well as grouped with similar terms "emr", "electronic health record" (EHR) and "ehr". A total of 16 articles published before May 2018 were returned from all sources. Nine non-duplicate articles advanced to title screening where four articles were excluded. One additional article was excluded after abstract screening as shown in the flow diagram in Figure 1. Four articles were included in the review as they referred to downtime planning. A narrative review of the abstracts was conducted for key words and information that would allow for the research questions to be answered [5]. The findings from these works were summarized and collated to identify common topics and subjects across studies.

3. Results

Few published studies exist at this time regarding downtime planning. In particular, authors have noted that there is a gap in training frontline providers and little guidance overall in preparing downtime procedures [3,6,7]. "Research on EHR downtime, particularly in acute hospital settings, is in its infancy" [3]. Despite this gap, several common themes still emerged. Recommendations for process improvement to reduce the clinical impact of planned and unplanned EMR downtime events were the most common themes that emerged. The authors found that mitigating downtime effects allowed for
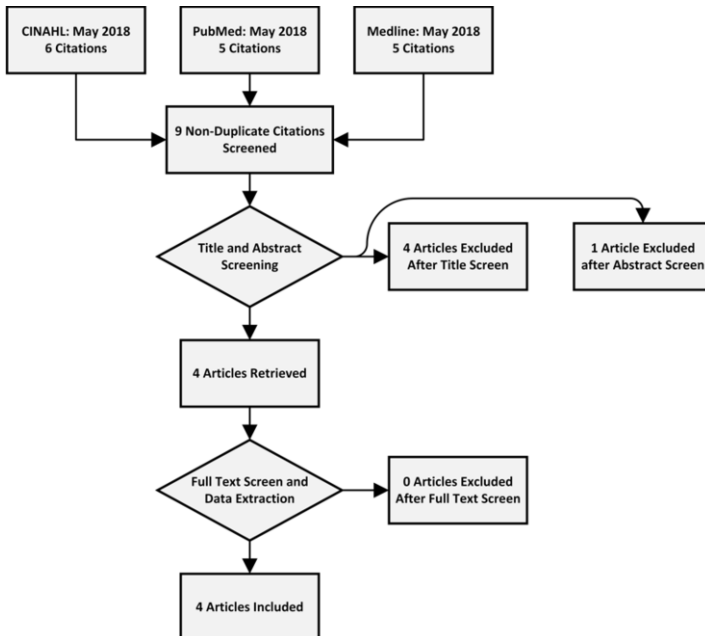
Figure 1. Study Selection Flow Diagram.

there to be a focus on processes, equipment and procedures before, during, or after a downtime so that there would be minimal adverse effects on patient safety and continuity of care. The identified studies further focus on four main thematic areas to be considered when planning for downtime events, namely communication plans, procedure review and revision, managing systems availability and preparing staff for downtimes. In the next section of this paper the emergent themes will be discussed in more detail.

3.1. Communication Plans

Keeping the organization informed about downtime events is critical to clinical operations. In planned downtime scenarios, communication plans can insure that clinical units have an opportunity to best plan for the potential workflow and staffing changes needed in advance. During a downtime, departmental and clinical managers should be notified as needed so that they can adjust staffing levels or ensure that preprinted forms or medication administration records (MAR) are on hand prior to the planned downtime [3,8]. In some situations, key stakeholders may be invited to participate in downtime planning sessions. In both planned and unplanned systems downtimes, staff notifications are essential as they make affected staff aware of the downtime and any known expectations for the duration of the downtime. These communications can take the form of any combination of overhead paging and emails to affected staff [8]. Depending on the expected length of the downtime event, researchers have documented that in-person rounds to affected areas to assist with downtime procedures and initiating action plans is an asset. Involving the senior leadership team in these rounds can also demonstrate support for the process in patient care areas [8]. It is essential that communication plans include methods for exchanging important patient care information such as orders and results between departments such as clinical units and the lab or pharmacy are essential to address from a patient safety perspective [3,8]. When the health information systems have reached an acceptable level of stability and availability, informing staff of the 'all clear' will allow for a smooth transition back to normal operations. Following both planned and unplanned downtime scenarios, appropriate follow-ups with clinician and administrative stakeholders in affected areas who can provide feedback on the process should be included as an activity for planning future downtime events [3,8].

3.2. Procedure Review and Revision

Established procedures for patient care systems downtimes are a necessity in clinical areas. These processes should be formal, documented plans that are reviewed on at regular intervals and revised appropriately to maintain their currency [3,8]. For some areas, informal plans or workarounds may exist between staff familiar with full downtimes, or functional downtimes when only a portion of the system is unavailable [3]. These informal practices should also be captured and documented so that clinical managers and technical staff are aware of the processes and may suggest improvements to improve availability of systems, reduce the severity of downtime events, and minimize the impact to patient care [3,8]. Following a downtime event, these processes and procedures should be reviewed with key stakeholders so that formal downtime documentation can be updated to best reflect the processes that best maintain continuity

of care in clinical areas. These processes will also include the procedures required to capture required clinical information so that patient information can be after the system returns to a normal state [3,8]. Processes and procedures should also be reviewed on a recurring basis to capture changes to the clinical workflow that have occurred since the last review. Organizations may choose to review these processes semiannually and establish a downtime committee to be responsible for involving the appropriate stakeholders from clinical practice, organizational management, health information systems and communications departments [8].

3.3. Managing System Availability

Planning for downtime includes initiatives that an organization undertakes to increase system redundancy and availability. These plans can reduce the likelihood of an unintended downtime, or mitigate the effects of such occurrences when they do occur. Backup systems can include items such as uninterruptable power supplies (UPS) and standby emergency power generation. Backup systems can also include data archives or repositories to provide an alternate source of clinical data for long downtime periods [3,9], or for recovering clinical information in a disaster recovery situation. Distributed or clustered systems may be built out so that planned maintenance can be performed with minimal interruption to system availability and data integrity. Redundant systems can be staged at a 'warm site' to provide alternate electronic systems in the event of an unplanned downtime, however, they may take time to bring fully them online and accessible to clinical staff throughout the organization [3,8,10]. These redundant systems may be best used in an unplanned, extended downtime since they are not typically instantly available, and some time may be needed to reconcile any data captured in a redundant system once the primary system returns to service [8]. Backup media such as tape, or an offsite, disk-based archive can preserve clinical data and systems states to reduce the time required to restore the organization's systems to a functional state so that the clinical information can be restored [8,10].

3.4. Preparing Staff for Handling Incidents

To ensure continuity of patient care and a consistent application of downtime policies and procedures, all staff affected by downtime should be appropriately trained in downtime procedures. Studies in this review found that while all organizations surveyed had trained their staff on their documented downtime procedures, over two thirds of those organizations do not perform regular downtime drills on any shift [10]. Regular, unannounced downtime drills can further educate staff to documented downtime procedures. Combined with procedure review, these drills can also serve to refine the established downtime documentation and provide more insight to the information required during a downtime [3,8,10]. Many organizations also choose to equip organizational units with downtime documentation toolkits that are designed or refined as a result of live downtime scenarios, downtime testing and downtime drills. These toolkits can provide preprinted forms to facilitate information capture, and streamline the back loading process when the system returns to normal functionality [3,8]. Regular testing of downtime equipment is not being performed by the organizations surveyed in the included studies. Although all of the included organizations have uninterruptable power supplies in their organization, only half of these organizations perform monthly testing. Less than 80% of the organizations included tests of their emergency electrical

generators on a monthly basis, 21% of them did not have fuel storage that would last for more than two days despite 96% of the organizations stating that they have standby emergency power generators [10].

4. Discussion

Systems downtime is inevitable in today's clinical settings. In a survey of large integrated health systems in the United States, 95% of the respondents reported to have had experienced at least one unplanned downtime event in the past three years. In the same survey, 70% of those organizations experienced at least one unplanned downtime lasting longer than eight hours in the same three years [10]. Clinicians are becoming more dependent on the advanced alerting features, which are common in many current EMR deployments [3]. These alerts can notify of potentially harmful interactions, particularly in medication orders. During downtime scenarios, it is important to consider what actions can be taken to preserve the integrity of the patient information available during normal operations.

Establishing in depth plans for downtime scenarios can prepare technical, and clinical staff and managers for downtime events when they occur. These plans include preparing patient information ahead of a downtime so that as much information as possible is available to the clinical users. These plans also can help clinical staff prepare for capturing the appropriate information during the downtime, and facilitate entering the captured information in to the EMR when it becomes available again [8,10]. These methods can help provide a continuous level of patient care during downtimes.

Clinical users, technical staff, and organization management should have frequent status updates during unplanned downtimes. These users also benefit from as much advanced notice as is appropriate to the situation so that they can prepare for a planned downtime. Strong, established communications plans should include notifications to appropriate staff at the beginning of a downtime to announce that clinical staff should now be following downtime procedures. During a downtime, clinical staff benefit from regular status updates so that they may stay informed of the expected end of the downtime. Following the outage, clinical staff must be informed that it is safe to return to normal procedures. In a planned downtime situation, senior organization staff should be informed of the outage details so that staffing levels can be made in advance, and to ensure that the clinical units have all the relevant patient information possible before entering into downtime procedures [8]. The subject organizations that were studied in the included articles all reported that staff receive training in downtime procedures. It was found, however, that less than a third practiced regular, unannounced, downtime drills on any shift at least annually [10]. Testing of downtime procedures does not need to be limited to clinical staff. Downtime testing and downtime training should include day to day users of the system, as well as regular, scheduled testing of backup and redundant systems designed to mitigate the effects of downtimes [8,10]. Managing system availability can reduce the likelihood of a failure, though maintenance must still be regularly performed and may create the need for planned downtime events. Regardless of the nature of the downtime, organizations should take the time following any planned or unplanned downtime to review how well the downtime procedures were understood on the clinical units and what can be done to strengthen their downtime procedures [8,10]. Downtime procedures should be reviewed at least annually to ensure that they continue to meet the needs of the clinical unit [8].

5. Conclusion

EMR downtimes are inevitable. Regardless of whether the downtime was planned for routine maintenance, unplanned, partial or a complete outage, organizations must have comprehensive downtime plans available to ensure continuity of patient care during the periods of limited availability. Downtime planning includes strategies to reduce the likelihood of unplanned outages or mitigating the effects of unplanned outages with backup and redundant systems to manage availability. Communication plans must be established to keep clinical and technical staff informed of critical outages, and provide escalation procedures to the organization's management. It is essential that clinical staff know how to follow downtime procedures through training, or even unannounced downtime drills. Organizations must also keep their downtime plans current with frequent reviews, especially following any outage or downtime drill. This review process can capture or correct clinical staff's workflow during periods of limited availability. A comprehensive downtime plan that includes these strategies can become the framework for a set of organizational procedures that ensures the best possible access to vital patient information before, during, and after a downtime event.

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Design and Usability Evaluation of Mobile Cloud Healthcare System for Diabetes Prevention

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Abstract. In this study, a mobile cloud healthcare system was implemented to assist middle- and old-aged people with diabetes preventive healthcare. First of all, a prototype system was developed. It was a system relying on data mining computing technology and big data analytics. Besides, it was constructed under the environment architecture of VMware cloud computing. This mobile cloud healthcare system was developed via mobile devices. Its purpose was to set up a diabetes preventive healthcare service for users, and to further assess the usability of this mobile cloud care system.\

Keywords. Mobile Cloud Healthcare System, Big Data Analytics, Usability Evaluation, Diabetes Prevention

1. Introduction

To prevent the development of chronic diseases, many researchers have proposed mobile healthcare measures and tools in the recent years [1-3]. Mobile cloud healthcare systems are equipped with the capability to provide users with auxiliary healthcare anytime and anywhere. Through the assistance of the system, it can effectively provide middle- and old-aged people with personalized preventive healthcare services [4].

In this study, a mobile cloud healthcare system for diabetes prevention has been developed to help the middle- and old-aged people with preventive healthcare measures as early as possible. The system was constructed under the VMware cloud computing environment, which provides ever-present Internet services for the system, so as to facilitate the establishment and analysis of backend personalized databases. Through big data mining algorithms, the system also provides a service to recommend health education information.

Finally, by means of experimental tests in this study, the subjects' usability of this mobile cloud care system were analyzed and assessed as a reference for subsequent system function improvements and relevant studies.

2. Methods and Material

2.1. Implementation of system

The prototype system development was set up on VMware Cloud on Apache Web Server as the system server. Users could browse and use the system via smartphones for personalized diabetes preventive healthcare. The system function architecture is shown in Figure 1. The functions of this mobile healthcare system proposed by this prototype system includes the following feature:

- Personal Health Record (PHR) and Health Alerting Assistant: The function can provide the users record personal health indices, and search their Personal Health Record with user interfaces. With Health Alerting Assistant, this function can provide the users with health indices analysis and health notifications, such as HbA1c and BMI.
- Collaborative Recommendations of Diabetes Health Education Information: The data sets provided on the UCI Machine Learning Repository website were used in this study. The data sets were preprocessed via the Apriori algorithm in Weka software [5] to perform data mining on the data sets, so as to analyze the correlation patterns between relevant disease symptoms. The health education information of the relevant symptoms was recommended with regard to these correlation patterns. In an automatic recommendation way, the health education information of diabetes-related complications or daily healthcare information were provided to users in need by the system. The relevant care & health education information was provided by medical institutions.
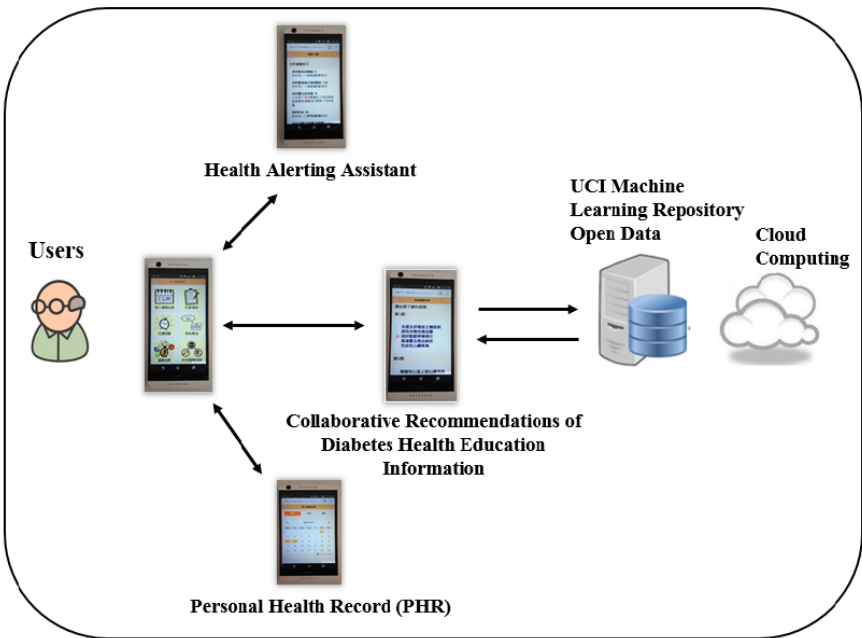
Figure 1. The Architecture of Mobile Cloud Healthcare System.

In this study, the Task-Technology Fit (TTF) theory was adopted to examine the users' usability assessment of mobile cloud care systems. Experimental tests and questionnaire surveys were employed to understand users' usability evaluation of this mobile cloud care system.

2.2. Usability testing method

2.2.1. Subjects:

The subjects in this study were ages 41 to 80 (32 males, 28 females). A total of 60 valid questionnaires were collected.

2.2.2. Usability Testing:

To ensure content validity, the measures for the constructs used in this study were adopted from the literature. This study consists of four constructs: task characteristics [6], technology characteristics [6], task-technology fit [6], and user intention [7]. The questionnaire is designed with a 7-point Likert-type scale (Strongly Disagree = 1 point; Disagree = 2 points; Somewhat Disagree = 3 points; Neither Agree nor Disagree = 4 points; Somewhat Agree = 5 points; Agree = 6 points; Strongly Agree = 7 points).

According to Hair et al. [8], Cronbach's α values should be higher than 0.7. The result of this study indicates that the values of Cronbach's α are higher than 0.7. This shows that the constructs of this study are of good internal consistency [8]. According to Hair et al. [8], the value of factor loadings should be higher than 0.5 [8]. The values of factor loadings of all the constructs in this study are higher than 0.5. This indicates that the measurement indices are of good reliability. The AVE (Average Variance Extracted) value is suggested to be higher than 0.5 [8]; such value is of good convergent validity. The values of AVE of this study range from 0.63 to 0.75. It can be interpreted as good convergent validity.
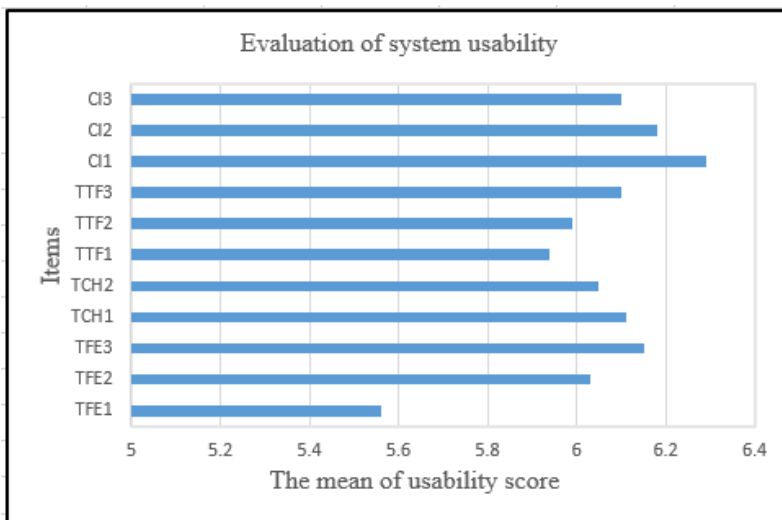
Figure 2. Evaluation of system usability.

3. Results

The subjects in this study were ages 41 to 80 (32 males, 28 females). A total of 60 valid questionnaires were collected. The means and standard deviations of each question are shown in Table 1 and Figure 2.

Table1. The Analysis of usability testing

Items	mean	Standard deviation	Constructs
TFE1	5.56	1.083	Task Characteristics
TFE2	6.03	0.891	
TFE3	6.15	0.878	
TCH1	6.11	0.768	Technology Characteristics
TCH2	6.05	0.783	
TTF1	5.94	0.837	Task-Technology Fit
TTF2	5.99	0.824	
TTF3	6.10	0.744	
CI1	6.29	0.623	Intention to use
CI2	6.18	0.764	
CI3	6.10	0.761	

4. Discussion and Conclusion

The analysis result shows that the subjects had high demand in personalized diabetes preventive healthcare, and that they also agreed that the functions of the mobile cloud healthcare system for diabetes prevention matched up with their needs of preventive self-care. In particular, the subjects considered that the "Collaborative Recommendations of Diabetes Health Education Information" could help him or her to do well with diabetes preventive healthcare; its average usability assessment value of 6.10 is higher than both "Health Alerting Assistant" (5.94 in average) and "Personal Health Record (PHR)"(5.99 in average).

Generally speaking, the average use intention value assessed by the subjects is higher than 6.0, indicating that the subjects had use intentions towards the mobile cloud healthcare system for diabetes prevention.

In this study, the mobile cloud healthcare system for diabetes prevention was developed on the basis of cloud computation. It is hoped that a personalized diabetes preventive healthcare service can be provided to assist users in daily preventive self-care. Currently, only a prototype system was developed in this study. It is hoped that, in the future, several medical care staffs and users of different groups can be qualitatively interviewed to obtain relevant opinions for the enhancement of relevant system functions, so as to better meet the users' needs in the future.

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Rule-Based Data Quality Assessment and Monitoring System in Healthcare Facilities

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Abstract. Measuring and managing data quality in healthcare has remained largely uncharted territory with few notable exceptions. A rules-based approach to data error identification was explored through compilation of over 6,000 data quality rules used with healthcare data. The rules were categorized based on topic and logic yielding twenty-two rule templates and associated knowledge tables used by the rule templates. This work provides a scalable framework with which data quality rules can be organized, shared among facilities and reused. The ten most frequent data quality problems based on the initial rules results are identified. While there is significant additional work to be done in this area, the exploration of the rule template and associated knowledge tables approach here shows rules-based data quality assessment and monitoring to be possible and scalable.

Keywords. Electronic health records, data quality, data quality assessment

1. Introduction

Data Quality Assessment (DQA) in healthcare and health-related research is not new. The earliest reports of data processing in clinical research included accounts of data checking [1-9]. In the therapeutic development industry, with the 1962 Kefauver Harris Amendment to the Food, Drug and Cosmetic act a New Drug Application (NDA) had to show that a new drug was both safe and effective and companies began to use rules to check data in support of NDAs for consistency. In fact, fear that notice of an errant data point would substantially delay a regulatory submission prompted a process in the therapeutic development industry of running often hundreds of rules for a clinical study and contacting the data provider in attempts to resolve each discrepancy against the source, i.e., the medical record [10]. The discrepancies often numbered in the tens of thousands for a small study of a few hundred patients. It is not uncommon for 10-30% of the cost of a clinical study to be spent on data cleaning [11]. This practice, albeit mediated by risk-based approaches [2] continues today in therapeutic development and is the standard of practice [3].

In healthcare, however, there is no source against which to resolve data discrepancies. With alert fatigue common for critical decision support algorithms, few would consider flagging data discrepancies as clinicians chart patient information. Further, aside from being used by physicians and other members of care teams in

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decision-making, widespread secondary use of routine clinical data is a fairly recent phenomenon. The current national emphasis on secondary use of healthcare data for research has been prompted by the large upswing in Electronic Health Record (EHR) adoption over the last decade [4], and federal support for institutional clinical data repositories for research [5] over the same period.

Today, the value of data quality assessment in healthcare has not been well studied or articulated. Though there have been reports of fixing data quality problems identified through attempts at data use, institutions have been hesitant to allocate even limited resources toward systematic DQA and improvement. For these reasons DQA in healthcare has received relatively little attention as an institutional priority or as a research agenda.

In early work, Carlson et al. (1995) successfully used rules to identify discrepancies in data used for clinical decision support in intensive care units (ICUs) however interventions based on the rules were not described [12]. In 2003, Brown et al. tested data quality rules to find data quality problems and improve data quality in EHRs. EHR information quality was then tracked and results were reported to clinicians, to encourage data quality improvement [13][14]. Around the same time, De Lusignan et al. reported a similar rules-based approach where data quality check results were collated and fed back to the participating general practitioners as an intervention to improve data quality [15]. Most recently, Hart and Kuo (2017) reported rule-based discrepancy identification and resolution in Canadian home health data with a few hundred data quality rules [16]. Records failing validation were reported back to the responsible staff for correction and re-submission. They reported a greater than 50% decrease in rejected records across three domains in six months [16]. Thus, in small studies of limited scope, rules-based approaches applied within a systems-theory feedback loop approach have been shown effective.

This research in healthcare DQA is motivated by (1) recent increases in national attention towards secondary use of healthcare data for research through broad programs such as the National Institutes of Health funded Healthcare Systems Research Collaboratory[2] and the Patient-Centered Outcomes Research Institute[3] funded through the Affordable Care Act, (2) national emphasis on use of healthcare data for organizational performance assessment and improvement, i.e., Accountable Care Organizations, (3) almost ubiquitous availability of rich healthcare data in most institutions, and (4) lack of methods for DQA, specifically assessment of data accuracy, demonstrated effective in healthcare. We seek to demonstrate and evaluate a rule-based data assessment and monitoring system in healthcare.

2. Methodology

The methodology entails adaptation and application of rules-based data error detection to health system data. Rules were first gathered from public sources such as healthcare third party payers and research networks. Additional rules acquisition methods and sources were also probed including expert interviews, writing rules for data elements

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[2] Available from http://www.rethinkingclinicaltrials.org.

[3] Available from http://www.pcori.org.

from health record screens and writing rules for data elements used in EHR decision support algorithms. A high-level implementation architecture diagram is provided as

Figure 1. High level architecture.

Figure 1. Today and for the results presented here, the data quality assessment and monitoring system was run on our institutional data warehouse. The system has three main components, (1) rule templates, (2) knowledge tables for rules, and (3) rule results tables. Rule templates and knowledge tables are used to store and manage rules. Outputs of the system are stored in rule results tables and visualization monitoring reports are executed based on them.

The approach was designed to support three modes of use: (1) identification of potential data errors for monitoring them over time, i.e., data quality monitoring, and (2) to inform remediation of existing data, i.e., a find and fix list, and (3) to prompt root cause investigations for important problems and monitoring the impact of process or system interventions in Plan-Do-Check-Act type improvement cycles.

2.1. Rule Templates

To identify candidate rules, we first looked to existing rule sets. These included the publically available Observational Health Data Sciences and Informatics (OHDSI) formerly Observational Medical Outcomes Partnership (OMOP) rules, the Healthcare Systems Research Network (previously HMORN) rules [17], and the Sentinel network rules [18], and age and gender incompatible diagnosis and procedure lists from third party payers such as insurance companies. We also utilized rules written for an internal project using multi-site EHR data [19]. Rules were also identified from data elements used in predictive analytics algorithm, data elements used in performance measures used by major payers. In an exploratory project, we also assessed our institution's Epic Electronic Health Record (EHR) screens for anesthesiology to identify data elements for which rules could be written. All combined, these activities produced over 6,357 individual logic statements or rules.

Management of this many initial rules conflicted with our goal of scalable rule management and maintenance over time. Inspired by the rule abstraction in Brown's work [14], we sorted the rules according to patterns in the rule logic. Rules sharing a topic and logic structure were abstracted into a single rule template. An example of such a rule template is Flag the record if GENDER is equal to some invalid gender and DIAGNOSIS is equal to a corresponding invalid diagnosis. The clinical information in the rules (in the example the list of gender – diagnosis incompatibilities) was extracted and compiled into a knowledge table against which the rule template runs. This categorization yielded twenty-two different rule templates. The twenty-two rule templates were further categorized into five higher-level types: incompatibility, value out of range, temporal sequence error, incompleteness and duplication. These correspond to the following Kahn 2016 criteria [20]: value conformance, relational conformance, completeness and plausibility. Incompatibility means one data value is logically incompatible with another data value, such as patient gender is incompatible with

diagnoses. Value out of range is defined as the value of a record is out of the limits compatible with life or grossly incompatible with product labeling, such as drug dose, lab result, or date of birth is before 1880. Typos or wrong units could cause these errors. Temporal sequence templates focus on any two dates occurring in an invalid order. For example, date of encounter cannot be earlier than date of birth for an adult. Incompleteness is defined as occurrence of a data value that is expected but missing. Univariate checks for missing values were not included because they are easily quantified through data profiling approaches. The rules consist of multivariate and record-level incompleteness checks, i.e., when one record is present, but the other one is absent. For example, a procedure is present but there is no corresponding encounter record. Lastly, duplication, also a multivariate type data quality check, is defined as multiple occurrences of events that can physically happen only once, for example a patient with two hysterectomies.

2.2. Knowledge Tables

As described above, we compiled or identified a knowledge table to support each rule template. The purpose of the knowledge table is to condense what may eventually be thousands of individual rules down to one template and a knowledge table that can be expanded or edited as medical coding systems change or new knowledge becomes available and shared among institutions. In this way, we purposely separated the rule logic from the knowledge. Twenty-two rule templates are easier to develop and maintain more than 6,000 rules.

3. Results

6,357 rules (covered by eleven templates) have been programmed, tested and executed over our institutional data warehouse containing data from 1.46 million patients from nine facilities and four different EHR systems   A total 55,966 discrepancies were identified by these rules.

The number of rules is the number of records in a knowledge table supporting a rule template. The number of triggered rules is the number of knowledge table records that identified one or more discrepancies, the number of discrepancies is the count of the number of times the data were found to be in exception to the rule. Rule results are

Table 1. Rule results summary

Template Name	Number of Rules	Number of triggered rules	Discrepancies
Age and DIAGNOSIS (incompatibility)	130	33	2,701
Age and PROCEDURE (incompatibility)	5,205	329	3,157
Gender and DIAGNOSIS (incompatibility)	79	18	3,710
Gender and PROCEDURE (incompatibility)	640	16	111
Gender and clinical specialty (incompatibility)	5	2	42
DRUG and DIAGNOSIS (incompatibility)	18	3	1,115
DRUG and PROCEDURE (incompatibility)	36	2	505
DRUG and LAB (incompatibility)	6	1	299

LAB Result (value out of range)	78	36	22,028
Demographics data elements (value out of range)	8	8	17,776
Two Dates in invalid order (temporal sequence error)	152	29	4,522

grouped by rule template (Table 1). However this format for communicating data quality assessment results does not directly inform action by clinical departments. For example, when considering invalid dates, the dates could come from anywhere in the health system; clinical departments care about the patients seen in their clinic. A way to partition rule results into groups meaningful to clinical leaders and information technology professionals was needed.

To explore this and to better use rule results to investigate and inform interventions for data quality problems, we manually grouped rule results identifying similar data quality problems and calculated the frequency of distinct problems as the number of records fired across all rules for that group. For example, both ICD-9 code: V39.01(caesarean section) and ICD-10 code: Z38.5(twins) should be used for newborns. However, two rules from age and diagnoses incompatibility identify the two codes are used for some patients who are over 20 years old. We grouped the results from the two rules together as identifying the same problem: assignment of infant codes to mothers and vice versa. Based on our manual groupings, the ten most frequent data quality problems are presented in Table 2 ranked by frequency.

Grouping rule results by problem (or root cause where known) category provided lists that we could use to work with clinical leaders and IT professionals to investigate the problems.

4. Discussion

There are multiple possible causes of the 22,028 instances of invalid lab results occurring across 36 different lab tests. Possible causes include problems with the sample, problems with the instrumentation, recording mistakes, or incorrect units. Further grouping the rule results by lab test and data source would likely divulge the machine/s or process/s responsible for the discrepancies. Presentation of overall results and the groupings by lab test and data source as a trend-line over time may further

Table 2. Data Problems Ranked by Frequency

Data Quality Problem	Number of Discrepancies
Lab results that are physically impossible or otherwise incompatible with life (36 different lab tests)	22,028
Dates of encounters, diagnoses, medications and procedures occurring more than one year before birth date	3,325
Age inconsistent procedures	3,132[4]
Assignment of infant codes to mothers and vice versa	
Infants with Adult codes	2,666
Adults with infant codes	358
Height greater than 3 meters.	2,472

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[4] Assignment of infant codes to mothers and vice versa are not included.

Blood pressure values greater than 500 mmHg.	2,292
Weight greater than 300 kg.	1,581
Respiratory rate greater than 200 breaths per minute.	587

inform troubleshooting and eventual remediation or intervention. We found this to be true for all rule results regarding measured physical quantities. Similarly, partitioning rule results for date-related discrepancies by data source and as a trend-line over time would facilitate troubleshooting and eventual remediation or intervention.

The 3,132 instances of age inconsistent procedures are likely problems in medical coding. In these cases, a patient's age was inconsistent with ranges defined by CPT procedure codes. Many CPT codes represent same procedure but performed on different age ranges, for example, 99381, 99382, 99383, 99384, 99385, 99386 and 99387 (Initial comprehensive preventive medicine evaluation and management of an individual). Similarly, the 2,666 adults with infant diagnoses codes and the 358 babies with adult diagnoses codes, are likely coding problems. Presentation of code-related rule results by code would make these issues easy to investigate with Health Information Management professionals working in medical coding.

The rule templates for Diagnosis and corresponding Drug and Diagnosis and corresponding lab were programmed. For example the rule checking for Aspirin prescription in patients with ischemic heart disease identified 1,090 instances' on exception. However, these patients may have had a contraindication to Aspirin therapy making these instances possibly valid. The rule checking for presence of an HbA1c lab test in patients with diabetes identified 178 instances of exception. However, HbA1c wasn't commonly used till the turn of the century. Older data in the warehouse predate guidelines changes and may be valid. In these two examples, natural variation and changing practice respectively explain the exceptions as possible not data problems. Continued use of these rules for data quality monitoring would require customization. There are many examples where this is the case. For obvious reasons, to date, we have excluded rules such as these where exceptions could be conditionally valid. However, we note that the effort in including the additional conditions may be worth the increased relevance of data quality monitoring results to clinical practice and facility administration.

As previously reported [21], identification of knowledge sources was challenging. Knowledge sources did not exist and could not easily be identified for half of the twenty-two rule templates initially identified. While this remains a challenge today, collaborative approaches to building these knowledge sources are possible as evidenced by multiple publically identified knowledge sources. Though the number of possible rules is quite large, in even modest data sets, the actual combinations that are (1) capable of detecting data error with strong discriminatory power, i.e., finding data error rather than odd clinical practice, and (2) capable of detecting problems of interest and utility, seem tractable. For example, attempts to identify additional rules by writing them for data elements from clinical specialty EHR screens and decision support algorithms turned up few additions (73 from Anesthesiology EHR screen data elements and 64 for EHR decision support data elements respectively).

It has taken eighteen months to identify rules and knowledge and to develop a system from which to run them and access results. Architecting the system to run on a standard common data model will significantly decrease the time and expertise needed for health systems to use the approach. Institutions should be able to add new rules and knowledge

and turn rules on and off to tune the output to those problems of interest to the health system.

5. Conclusions

Assessing the quality of EHR data is necessary to improve data quality yet doing so systematically represents uncharted territory in healthcare. This study illustrated a potentially scalable framework with which data quality rules can be organized, shared as rule templates and knowledge tables, and applied in healthcare facilities to identify data errors. Though the results reported here are preliminary, we have demonstrated that rule-based data quality assessment identifies real data problems. While there is significant additional work to be done in this area, the exploration of the rule template and associated knowledge tables approach here shows the approach to be possible, the number of rules likely tractable and their management scalable.

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Cancer Phenotype Development:
A Literature Review

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Abstract. EHR-based, computable phenotypes can be leveraged by healthcare organizations and researchers to improve the cohort identification process. The ability to identify patient cohorts using aspects of care and outcomes based on clinical characteristics or diagnostic conditions and/or risk factors presents opportunities to researchers targeting specific populations for drug development and disease interventions. The objective of this review was to summarize the literature describing the development and use of phenotypes for cohort identification of cancer patients. A survey of the literature indexed in PubMed was performed to identify studies using EHR-based phenotypes for use in cancer studies. Specific search criteria were formulated by leveraging a phenotype identification guideline developed by the Phenotypes, Data Standards, and Data Quality Core of the NIH Health Care Systems Research Collaboratory. The final set of articles was examined further to identify 1) the cancer of interest and 2) the different approaches used for phenotype development, validation and implementation. The articles reviewed were specific to breast cancer, colorectal cancer, ovarian cancer, and lung cancer. The approaches taken for phenotype development and validation varied slightly among the relevant publications. Four studies relied on chart review, three utilized machine learning techniques, one took an ontological approach, and one utilized natural language processing (NLP).

Keywords. electronic health records, secondary data use, phenotype development, computable phenotypes, cancer phenotypes

1. Introduction

In the United States, cancer is the second leading cause of death exceeded only by heart disease. It is estimated that nearly 1.7 million new cancer cases will be diagnosed and approximately 600,920 cancer deaths are anticipated in the US in 2017, which translates to about 1,650 cancer [1]deaths per day (or 1 in every 4 deaths). [1] In 2030, the American Cancer Society predicts 21.6 million new cancer cases and 13.0 million cancer deaths worldwide, compared to 14.1 million cases and 8.2 million deaths in 2012. [1] Although advancements have been made in cancer prevention and treatment, cancer still remains a major public health concern as the global burden of disease experiences considerable growth. Cancer research, therefore, continues to be a national priority.

Secondary use of EHR data shows promise toward generating new hypotheses as well as answering open questions, and is being pursued on multiple fronts. Computational phenotyping, for example, is a technique that leverages EHR data to develop algorithms for cohort identification based on the data collected in the clinical

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environment. A patient's historical data can be used to help identify disease, potentially before significant outwards signs or symptoms have been exhibited. Traditionally, phenotype development has relied on claims data or conventional clinical data sources, but has not historically leveraged big data sources or biological (or genomic) data. More recently, the concept of "deep phenotyping" has emerged that aims to gather more specific details on patients and diseases by considering genetic variations among individuals and analyzing the potential connections between such variations and disease subtypes. [9]

Phenotyping, therefore, has become a tool that can be implemented by healthcare facilities and researchers to more accurately identify patients with particular disease characteristics and to better predict treatment and prevention strategies targeted at individual patients meeting specific phenotypic criteria. As we transition to the age of "Precision Medicine," phenotyping (specifically deep phenotyping) provides the opportunity to improve healthcare by accounting for the variability across cohorts and among individual patients. Thus, the objective of this paper is to summarize the existing literature on computational phenotyping, specifically for the purpose of cohort identification of cancer patients.

2. Methods

A survey of the literature indexed in PubMed was performed to identify studies using EHR-based phenotypes for use in cancer studies. Specific search criteria were formulated by leveraging a phenotype identification guideline developed by the Phenotypes, Data Standards, and Data Quality Core of the NIH Health Care Systems Research Collaboratory [2]. The criteria included the search terms: ***cancer, phenotype,*** *and* ***electronic health records*** (and alternatives for each).

Alternatives for cancer included: melanoma, tumor, and carcinoma. Since we are only interested in breast, colorectal, ovarian and lung cancers, the words breast, colorectal, ovarian and lung were used as the key words in the search criteria. Phenotyping, computational phenotyping, and deep phenotyping were included as search terms as alternatives for phenotype. Several variations of electronic health records were used, including: EHR, EMR, and electronic medical record (Table 1).

Table 1. Alternative words for Electronic Health Record

Alternative words
Electronic Medical Record
Medical Record, Electronic
Medical Records, Electronic
Record, Electronic Medical
Records, Electronic Medical
Electronic Medical Records
Health Record, Electronic
Health Records, Electronic
Record, Electronic Health
Records, Electronic Health

The MeSH terms were also leveraged in order to address the various levels of specificity of the search terms. For example, the parent category for electronic health records in MeSH is "Medical Records Systems, Computerized", some other alternative words were also used in the search (Table 2).

Table 2. Alternative words for Medical Records Systems

Alternative words
Automated Medical Record Systems
Automated Medical Records System
Medical Record System, Automated
Medical Record Systems, Automated
Medical Records System, Automated
Medical Records System, Computerized
Computerized Medical Records Systems
Computerized Patient Medical Records
Medical Records Systems, Automated
Automated Medical Records Systems
Computerized Medical Record System
Computerized Medical Record Systems
Computerized Medical Records System
Medical Record System, Computerized
Medical Record Systems, Computerized
Automated Medical Record System
Medical Records, Computerized
Computerized Medical Records
Medical Record, Computerized
Computerized Medical Record
Record, Computerized Medical
Records, Computerized Medical

The search criteria also excluded words such as gene and cell to avoid publications specific only to biological phenotypes versus computable phenotypes. After retrieving the search results from PubMed, researchers manually reviewed all the titles and abstracts to filter out the papers that are not about the cancer of interest or those not about computable phenotypes.

3. Results

An initial full-text search yielded 571 articles, which was narrowed down to 32 articles by restricting on keywords and limiting the full-text criteria. After a detailed review of the remaining individual manuscripts, 23 articles were excluded as they were not directly

related to computable phenotyping. Of the 9 remaining articles: 5 were specific to breast cancer, 2 were specific to colorectal cancer, 1 to ovarian cancer, and 1 to lung cancer.

For the nine remaining articles, the approaches taken for phenotype development and validation varied slightly among the relevant publications. 4 studies relied on chart review. 3 utilized machine learning techniques. 1 took an ontological approach. Finally, 1 utilized natural language processing (NLP). The search results are shown in Figure 1.

Figure 1. Search Results
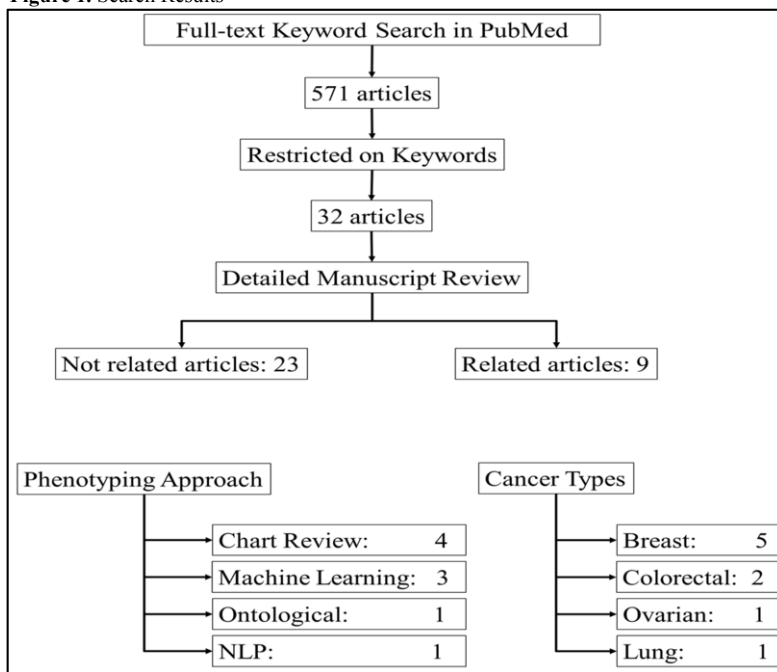
4. Conclusion

EHR-based computable phenotypes can be leveraged by healthcare organizations and researchers to improve the cohort identification process. The ability to identify patient cohorts using aspects of care and outcomes based on clinical characteristics or diagnostic conditions and/or risk factors presents opportunities to researchers targeting specific populations for drug development and disease interventions.

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Analysis of Anesthesia Screens for Rule-Based Data Quality Assessment Opportunities

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Abstract. A rules-based data quality assessment system in electronic health record was explored through compilation of over six thousand data quality rules and twenty-two rule templates. To overcome the lack of knowledge sources and identify additional rules or rule templates, thirty-three anesthesia (perioperative period) EHR screens were reviewed. We analyzed the data elements appearing on anesthesia screens and relationships between them to identify new data quality rules and rule templates relevant to anesthesia care. We present the review process as well as new rules and rule templates identified. We found decomposition and analysis of EHR screens a viable mechanism for acquisition of new data quality rules and proved the number of rules likely tractable and their management scalable.

Keywords. Electronic health record, data quality

1. Introduction

A rule-based data quality assessment system has been developed to identify and monitor data discrepancies in healthcare facility Electronic Health Record (EHR) systems [1][2]. In the system, the rules are categorized and managed according to rule templates. The rules categorized into the same rule template share same topic and logic structure. An example of such a rule template is *Flag the record if GENDER is equal to some invalid gender and DIAGNOSIS is equal to a corresponding invalid diagnosis*. The clinical information in the rules (in the example the list of gender – diagnosis incompatibilities) was extracted existing rule or knowledge resources and compiled into a knowledge table against which the rule template runs [1][2]. The existing twenty-two rule templates identify likely errant data through incompatibility, physically impossible values, invalid temporal sequence of events, absence of expected co-occurrence and impossible duplication.

As previously reported, identification of knowledge sources for data quality rules in healthcare was challenging. Through consolidation of existing rule sets we distilled a set of 6,357 rules across the eleven rule templates [2]. Knowledge sources did not exist and could not easily be created for half of the twenty-two rule templates initially identified. This remains an impediment to rule-based data quality assessment and monitoring in healthcare. A second challenge lies in identification of the rule templates themselves.

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The work presented here address both challenges by assessing extent to which new rules can be identified, through methods from clinical trials data cleaning.

2. Background

EHR adoption rates were at 96% in US hospitals and 87% in clinics [3] yet the quality of healthcare data remains questionable. Reports of errors in healthcare data are numerous and impact secondary data use and potentially patient care and safety [4-14]. When error rates grow the value of data for physicians as consumers of data may be diminished. Attempts to manage this problem with rule-based quality assessments have succeeded but only on a small scale and healthcare datasets are rapidly increasing in size [15]. In 2003, Brown et al. presented data quality probes to find data quality problems and improve data quality in EHRs [16]. Data errors can happen at every step in a clinical encounter including assessment, data entry, data retrieval, information interpretation and action. Data quality probes consisted of a rule implemented as a query in a clinical information system to find the inconsistency between two or more associated data items. EHR information quality was then tracked using the number of flagged exceptions to the rules and results were reported to clinicians, to encourage improvement.

Recent studies have pushed forward beyond the reporting of data quality to the correction of the errors found and thus the improvement of the healthcare data within the system[17]. Haart and Kuo (2017) used rule-based discrepancies to measure, report and resolve data quality problems [18]. Data quality rule results were used as feedback to healthcare providers who made corrections. The work reported a greater than 50% decrease in data errors over six months.

Our approach goes a step further and provides a scalable framework with which data quality rules can be shared as templates and knowledge tables to be used for improvements across health systems. In previous work we identified rules from existing literature, grouped them into sets of logical impossibility and inconsistency and devised a rules management approach which allows for sharing and reuse at multiple institutions [1]. In this research we address the need for extending and testing the set of rules to cover areas of the EHR not addressed in other rule sets. This work specifically focuses on anesthesia-related data elements in perioperative care.

3. Methods

New mechanisms are needed for the acquisition of data quality rules in healthcare. Toward this aim, we have taken advantage of EHR screens as a resource for identification of important data elements. We apply rule identification methods commonly applied in clinical trial data cleaning [19]. Different from clinical trials that use a high sensitivity screening approach and broadly identify discrepant data, we are concerned only with definite errors [20]. Data error identification can be approached by using rules that focus on logical inconsistencies, physically impossible values and nonsensical relationships between data values. Logical inconsistencies are discoverable by examining the electronic forms where data are captured; these issues are often easily apparent from a data collection form. To identify potential rules, each data element of a form is evaluated at several levels. The most basic level is the individual data element where physically impossible values are identified. At the next level, relationships between data elements

on a form are evaluated to identify any where illogical sequence or relative magnitude can be exploited to identify data errors. Finally, interactions between data elements on one form and those on other forms are examined for exploitable relationships. Each screen is carefully reviewed, taking into consideration all the possible combinations of data elements to determine which of these are impossible, unlikely, and necessarily exist (or not). In this manner, thirty-three anesthesia screens from our institutional EHR were reviewed by two independent reviewers to identify new rules and rule templates.

4. Results

4.1. Identification Of Rules

In our institutional anesthesia and perioperative care EHR screens, there are five modules recording anesthesia procedures including orders, preprocedure, intraprocedure, postprocedure and out of operating room procedure. In one week, we looked through all five modules. All the new potential rules were identified on the lab data elements and temporal sequence of events on intraprocedure screens. We didn't identify any new rules from the other four modules.

4.1.1. Intraprocedure Lab Results

Lab and other measured quantity results are recorded in intraprocedure screens and are important parameters that effect clinicians' decision making. Data error in measured quantities could be caused by several reasons, including problems with the sample, problems with the instrumentation, recording mistakes, or incorrect units.

Table 1. Additional Rule Knowledge Identified in the Intraprocedure EHR Screens

Lab Test	Valid Low	Valid High	Units
infusion	0	77	ml/kg
blood loss	0	77	ml/kg
FiO2 (fraction of inspired oxygen)	10	100	%
ETCO2 (End tidal CO2)	20	60	mmHg
PaO2(Partial Pressure Oxygen)	30	200	%
PRBC NR (270-350 ml/unit)	0	2	
platlet (200 ml/unit)	0	2	
plasma (200 ml/unit)	0	2	
cell saver	0	77	ml/kg
systolic Noninvasive Blood Pressure(NIBP)	10	500	mmHg
diastolic Noninvasive Blood Pressure(NIBP)	10	500	mmHg
mean Noninvasive Blood Pressure(NIBP)	10	500	mmHg
systolic invasive arterial blood pressure	10	500	mmHg
diastolic invasive arterial blood pressure	10	500	mmHg
mean invasive arterial blood pressure	10	500	mmHg
Central venous pressure (CVP)	0	20	mmHg
pulmonary artery systolic pressure	5	100	mmHg
pulmonary artery diastolic pressure	5	100	mmHg
pulmonary artery mean pressure	5	100	mmHg
Intracranial pressure (ICP)	0	50	mmHg

These problems can be resolved for future data and the existing errant values flagged. Thus, data quality rules to identify data errors in measured physical quantities may be beneficial. All identified measured physical quantity rules were accommodated

into one of the twenty-two rule templates: Numerical quantity out of range. After reviewing intraprocedure screens, 20 new rules were identified (Table 1) and added into a knowledge table.

4.1.2. Intraprocedure Temporal Sequence

Seventy-eight events can be added on anesthesia procedure screens. Temporal relationships between them were analyzed to identify any two event dates occurring in an invalid order. For example, it is impossible that *anesthesia start* happens after *anesthesia stop*. Also, most of events cannot happen before date of birth or after date of death. This type of error was accommodated by our existing temporal sequence rule template. This analysis produced 58 new temporal sequence error rules (truncated list shown in Table 2) for addition into the knowledge table.

5. Discussion

This extracted set of rules demonstrates the large number of opportunities for errors to occur in the EHR. Thirty-three anesthesia screens were reviewed to identify new rules and rule templates of consequence to patient care. The rules established here apply to individual data elements and relationships between elements on and among electronic anesthesia forms which are used during patient care. The measured physical quantity constraints apply only to the individual numerical results but the temporal relationships evaluate temporal relationships between data elements.

Table 2. Temporal Sequence Rules

Date 1	Invalid Order	Date 2
anesthesia start	after	anesthesia stop
start data collection	after	stop data collection
intubation	after	Extubation
pause billing time	after	resume billing
handoff	after	transport to ICU
procedure start	after	procedure finish
intubation	after	one-lung ventilation
intubation	after	two-lung ventilation
LMA applied	after	airway removed
transport to ICU	after	procedure start
start in OR recovery	after	stop in OR recovery
Date of birth	after	anesthesia start
Date of birth	after	induction
anesthesia start	after	Date of death
induction	after	Date of death
deep sedation	after	Date of death
intubation	after	Date of death
anesthesia stop	after	Date of death
emergence	after	Date of death
LMA applied	after	Date of death
Extubation	after	Date of death

Because studies have shown that improvements in healthcare data quality can result from rules-based analysis and reporting processes [17], we undertook this work to evaluate rule identification methods from clinical trials for use in healthcare. When we

analyzed the EHR screens, we discovered that less than 50% of the information on the screens was in structured form and conducive to checking. We identified no data elements outside of measured physical quantities, dates and times that were conducive to such checking. Based on the limited clinical specialties and services, application of the clinical trial rule identification methods is tractable within EHRs.

As noted in our earlier work, structured knowledge sources for physically impossible measured physical quantities do not exist. The approach used was to talk with clinicians and identify ranges outside which a data value would most certainly be in error. However, procedural errors such as taking a blood draw down stream from a saline infusion can and do in reality cause values outside these ranges. Thus, we anticipate that ranges will require refinement.

Data discrepancies in EHR data are potentially of concern for patient care as well as problematic for secondary data use. Reusable avenues are clearly needed for quality monitoring rules and tools. Currently there are not generic rules pertinent to multiple institutions which means that the data quality inspection must always be built anew. This research moves use towards that interoperability. The results of this work provide a part of a continually growing ruleset resource that can be used and shared in a community manner. We plan to adopt the OMOP Common Data Model so that the rules and knowledge tables can be used at any institution willing and able to implement the data model. The cost and benefit to healthcare facilities for doing so remains to be demonstrated.

6. Conclusion

This work demonstrates the value of using existing EHR screens for acquisition of new rules for use in data error identification. Based on the number of rules identified here, the approach appears to be feasible. The anesthesia component of these rules developed in this research is an important first step into assessing the viability of mechanisms for acquiring new rules. Future work is needed since it is crucial that these rulesets to cover data important to healthcare facilities. The anesthesia rule extension is the first step towards capturing logical impossibility and inconsistency in EHR data for general application.

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Data Profiling in Support of Entity Resolution of Multi-Institutional EHR Data

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Abstract. Information Quality (IQ) is a core tenant of contemporary data management practices. Across many disciplines and industries, it has become a necessary process to improve value and reduce liability in data driven processes. Information quality is a multifaceted discipline with many degrees of complexity in implementation, especially in healthcare. Data profiling is one of the simpler tasks that an organization can perform to understand and monitor the intrinsic quality of its data. This case study demonstrates the application of core concepts of data profiling to entity resolution of multi-institutional Electronic Health Record (EHR) data. We discuss the benefits of using data profiling to better understand quality issues and their impact on entity resolution and how data profiling might be augmented to increase utility to clinical data.

Keywords. Electronic health records, information quality, data profiling, entity resolution

1. Introduction

1.1. Information Quality

Information Quality (IQ) is an emerging discipline concerned with maximizing the value of an organization's information assets and assuring that the information products meet the expectations of those who use them [1]. IQ is a continuously growing and important field for data management practices. While IQ methodology is quite mature in other sectors, many IQ practices have not achieved significant penetration in healthcare. Unfortunately, reaching full maturity in understanding the translatability of and applying these techniques is something that takes considerable time and resources. Data profiling is one of the easiest techniques to apply to existing data to get an initial understanding of the basic quality of data.

1.2. Data Profiling

Data profiling is a series of techniques that allow an organization to view summary statistics and other metrics usually at the data element level. These small but informative summaries of data have been shown useful for data quality assessment and monitoring

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in other disciplines [2]. Though it is possible to identify row or data value level anomalies using data profiling, it is most often applied to identify potential quality issues at the data element level, for example outliers for numeric fields or pattern frequencies for text or semi-structured fields. This is an important distinction compared to more complex IQ techniques that involve rule-based methods that operate at multiple levels within a data store.

Data profiling includes frequencies, such as the number of null, distinct, and unique values. Distinct values represent the number of non-null values that are different from one another. Unique values represent the number of values that have no duplicates. The format of and the data type for each field can also be used to identify maximum and minimum values, outliers, special characters and pattern frequencies. The latter, pattern analysis, parses the data in each field and represents character classes with different symbols. The simple statistics obtained through data profiling are very useful in selecting match fields for use in deterministic and probabilistic record linkage, which was the focus of our case study. Ideal data elements used in matching are those that are very low percent null or blank, and very high percent distinct and unique. Data profiling also has utility beyond facilitating match field selection. Data quality has previously been shown to impact matching results [1]. Data profiling results help identify data cleaning and standardization that should be undertaken during or prior to attempted match finding. Thus, we posited that data profiling would be a good approach to quickly assess data quality aspects pertinent to entity resolution.

1.3. Entity Resolution

Entity resolution (ER) is the process of determining whether two references to real world objects in an information system are referring to the same object or to different objects [1]. In contrast to the simplicity of utilizing data profiling, ER is a much more complicated process to understand and implement. One important requirement of properly implementing ER as a process for data integration in an organization, is to have some basic understanding of data quality at the reference (row or tuple in a database) and field (attribute or column in a database) level [3,4]. This demonstrates a need for data profiling before quality proficient ER processes can be designed and implemented in an organization. The ER processes discussed in this paper are based on the Fellegi-Sunter model [5,6].

2. Methods

There are multiple scenarios for ER in healthcare: (1) within EHRs to identify split charts – instances of data for the same patient stored under two medical record numbers, (2) within facility Master Patient Index (MPI) management – identifying and removing duplicates from an MPI, (3) between facility ER, such as that occurring in Health Information Exchanges, and (4) between different datasets for secondary use of health care data. All of these rely on understanding the quality of the fields to be used for ER. Thus, we tested the application of simple data profiling techniques to inform selection of match fields and inform data standardization performed prior to and during record linkage operations of ER between a longitudinal community registry [7,8] and EHR data from a group of local federally qualified clinics. We focused our efforts on ER between multiple datasets to support secondary use of healthcare data in research. Two unique

cases were identified for data profiling and Entity Resolution: (1) data from a community registry to be linked to data from the EHRs of a group of local, federally qualified clinics, and (2) data from the data warehouse of an academic medical center.

3. Results

Within the registry data, there were 10,069 records with 30 potential match field attributes. The data profiling statistics in Table 1 demonstrate the completeness of attributes in the dataset. Less than 0.06 % of the data in the primary address (StreetAddress) field were impacted by missing values, although, SecondaryAddress showed a high null rate, 95.17%. The pattern analysis in data profiling shows the outlier values. Once identified, those issues could be (and were) mitigated during the ER process.

Table 1. Data Profiling of Registry Data

	Null	%	Distinct	%	Unique	%
ParticipantID	0	0	10069	100	10069	100
FirstName	0	0	2496	24.79	1566	15.55
MiddleName	299	2.97	32	0.32	5	0.05
ID	0	0	10069	100	10069	100
LastName	0	0	4352	43.22	2744	27.25
suffix	9851	97.83	9	0.09	2	0.02
DOB	0	0	8126	80.7	6482	64.38
DeceasedDate	9960	98.92	105	1.04	101	1
Gender	2	0.02	2	0.02	0	0
Ethnicity	101	1	3	0.03	0	0
Race	75	0.74	8	0.08	0	0
PreferredLanguage	0	0	2	0.02	0	0
StreetAddress	6	0.06	8365	83.08	6875	68.28
SecondaryAddress	9583	95.17	297	2.95	224	2.22
City	9	0.09	355	3.53	225	2.23
State	5	0.05	41	0.41	13	0.13
Zip	21	0.21	392	3.89	257	2.55
MailingStreet	3	0.03	8357	83	6856	68.09
MailingAddress2	9591	95.25	289	2.87	219	2.17
MailingCity	4	0.04	361	3.59	235	2.33
MailingState	2	0.02	40	0.4	14	0.14
MailingZip	8	0.08	407	4.04	272	2.7
HomePhone	2406	23.9	6366	63.22	5137	51.02
WorkPhone	7266	72.16	2158	21.43	1940	19.27
Mobile	2816	27.97	7093	70.44	6937	68.89
PFirstName	4570	45.39	48	0.48	8	0.08
PMiddleName	6249	62.06	12	0.12	1	0.01
PLastName	3068	30.47	54	0.54	8	0.08
PracticName	4570	45.39	13	0.13	2	0.02
RecruitmentStatus	1	0.01	2	0.02	1	0.01

In the registry dataset, some of the records had the exact same values for different attributes (Table 2). For the high percentage of similarity, the user may only want to use one of the attributes that has a high percentage of completeness.

Table 2. The Percentage of Similarity between Registry Attributes

	TotalSame Count	%	BothNull	%	BothNot Null	%
Street Address	9591	95.25	2	0.02	9589	95.23
Secondary Address	10030	99.61	9568	95.02	462	4.59
City	9925	98.57	3	0.03	9922	98.54

State	10046	99.77	4	0.04	10042	99.73
Zip code	9835	97.68	9	0.09	9826	97.59
Work phone	2004	19.90	1951	19.38	53	0.53
Mobile phone	419	4.16	203	2.02	216	2.15

Within the EHR data, there were a total of 25,924 records and 10 potential match field attributes. Several attributes revealed a high null rate (Table 3), for example, *Date of Birth*, *MiddleName*, and *Alternative address* having 42.34%, 66.01%, and 98.31% null values respectively. Conversely, the *LastName*, *FirstName*, *Sex*, *Address*, *City*, and *State* were very complete. Further analysis of the EHR data also identified several outlier values, for example: (1) in the *Date of Birth* field, the minimal value is 999 which was an obvious typographical error, (2) some patterns in the name fields contained special characters (periods, brackets, quotes), and (3) in the *Address*, *State*, and *Zip code* fields, the minimal value was zero.

Table 3. Data Profiling of Clinic EHR Data

	Null	**%**	**Distinct**	**%**	**Unique**	**%**
Date of Birth	10977	42.34	10012	38.62	6438	24.83
Sex	0	0	2	0.01	0	0
LastName	0	0	7015	27.06	1532	5.91
FirstName	17	0.07	4327	16.69	709	2.73
MiddleName	17113	66.01	49	0.19	7	0.03
Address	29	0.11	12546	48.40	3529	13.61
Alternate address	25485	98.31	210	0.81	56	0.22
City	126	0.49	193	0.74	48	0.19
State	126	0.49	22	0.08	4	0.02
Zip code	358	1.38	235	0.91	55	0.21

3.1. Fields Selected for Entity Resolution

The goal of the ER process is to identify which records belong to the same real world entity. To accomplish this task, the patient's contact information was needed. Based on the data profiling, six attributes were chosen during the design of the ER match rules: *FirstName, LastName, Date of Birth, Address, City,* and *Sex*. The reason these attributes were selected was due to the fact that (1) the attributes appeared in both data sets, and (2) the attributes had a low percentage of null values and a high percentage of unique values in each dataset. For EHR data, reducing false positives is more important than reducing false negatives, which is why the attributes with the high percentage of unique values were selected.

4. Discussion

Other industries have seen significant advances in information quality methods. While we might like to apply them in healthcare and health-related research, their utility should be critically evaluated first. If for nothing else, because the data in health contexts tend to be more context dependent, high dimensional, and today, documented largely in the absence of input constraints. This case study represents one small step towards discovering an application for general cross-sector data quality approaches to data in a clinical research context. Many other approaches exist and remain largely untested in healthcare and health-related research.

This case study is limited to the application of data profiling of two datasets in the context of a research project. While data profiling has been applied routinely and proven effective in informing match fields used for record linkage in other industries, one case study is not sufficient to broadly recommend use in healthcare and health-related research. Although, based on the case study, the approach certainly demonstrated utility, and broader use in health data record linkage contexts is necessary. Further, testing the approach over input datasets or highly varying data quality would also be informative.

5. Conclusion

Data profiling is a technique used in IQ efforts to better understand the basic quality of data. It allows organizations to analyze data for quality issues at the data element level. We leveraged data profiling techniques to assess self-reported registry and EHR data. The summary statistics generated offered insight into key features of the data, i.e., the format of the data, pattern frequencies, and the number and percentage of null, distinct, and unique values. This preliminary effort was helpful in describing the aspects of the data impactful to the subsequent ER processes. The profiling results were used to inform the selection of the match fields for the ER work and also highlighted a need for data cleaning and standardization.

6. Funding Acknowledgement

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EHR Usage Problems: A Preliminary Study

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Abstract. Electronic health record (EHR) systems were initially developed to
improve health care delivery by facilitating the healthcare professionals' access to
electronically-stored patient information, but problems are regularly reported in the
literature. We present here a preliminary study conducted at a 950-bed university
hospital. They have implemented an EHR in 2012 to remove their paper-based
system. After few years, physicians complain that the EHR is "*too complex*", "*too
slow*", "*unsatisfying*", and "*which interacts with too many health software*". This
preliminary study was based on individual interviews inspired from critical incident
technique with 9 hospital professionals (physicians and pharmacist) to establish a
global diagnostic of the EHR's usability failures/difficulties and their potential
impacts. Results show that professionals faced to many constraints impacting their
work but more importantly the patient care, with recent outstanding examples. This
work is a first step of a larger study to help the hospital to map usability failures,
their context of use and associated risks/impacts, and to provide solutions to fix it.

Keywords. Usability, EHR, Patient Safety, Medical informatics applications

1. Introduction

Electronic health record (EHR) systems aim to improve healthcare delivery by
facilitating healthcare professionals' access to electronically-stored patient information
[1].Yet, numerous researches have shown that poorly designed health technologies
(including EHR) influence negatively the process of patient care, clinician workflows
and health professionals work [1–5]. In the case of EHR, many physicians confront
problems while using them. They often feel frustrated due to their complexity, and to
their lack of intuitiveness and of efficiency; they consider their use as time-consuming
and source of errors [3,6]. Consequently, supported by several studies [2,6,8–10],
medical associations [11,12] provide software designers and healthcare facilities with
recommendations to facilitate usage of EHR. Nowadays, it is known that successful
implementation of EHR depends on a combination of technical, social and organizational
factors [3,12]. Nonetheless, dramatic accidents due to EHR's usability problems, for
instance, are still reported [13].

We present here a preliminary study conducted in a 950-bed university hospital. In
2012, an EHR was implemented to substitute for the paper-based system. Due to many

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physicians complains about the EHR, the chief information officer (CIO) created an *EHR group* approved and supported by the hospital board. The group was composed of the CIO and 14 medical and pharmaceutical specialists involved in the deployment and improvement of the EHR. Initially, this group was in charge of facilitating the EHR usage by improving the system, based on the physicians' and pharmacist's needs or complaints. Trained hospital technicians and physicians developed and modified add-ons to adapt the EHR to local needs. Unfortunately, this strategy reached quickly its limits. The French market being not a priority for the EHR company due to its small size, the latter did not provide enough and fast services to the hospital.

In 2017, the *EHR group* and the hospital board decided to explore how the EHR impacts the user's activities and cares delivered to patients in order to improve the ease and safety of use. For this purpose, the *EHR group* asked our human-factors team to explore and to take stock on related issues with the EHR and to understand more precisely *i)* the difficulties met by physicians and pharmacists while using the EHR and *ii)* their usability causes (EHR weaknesses), and *iii)* their potential impacts on the work situation. This paper presents a preliminary study providing an overall diagnostic of physicians' and pharmacists' difficulties and their potential impacts.

2. Methods

This study was conducted from April to July 2018. Data were collected by one HF master student during her field practicum and one experienced HF expert through individuals interviews with members of the *EHR group*. These interviews aimed at obtaining a detailed analysis of the difficulties experienced by daily users.

Interview protocols were inspired by Flanagan's critical incident technique [14]: participants were asked to list all weaknesses of the EHR, to remember problems they have met when they used it, and, if possible, to illustrate them with an actual situation they faced. Contrary to Flanagan's method, the participants were not asked before the interview to prepare examples of faced situations. Participants profession/specialty and experience were also collected. Interviews were supported by a grid and were audio-recorded.

All data were transcribed and analyzed by the HF trainee; results from the analysis were cross-checked by the HF expert. The analysis aimed at identifying potential underlying usability flaws that could negatively affect the use of the EHR, if any. More precisely, the analysis allowed to link usability weaknesses of the EHR, to their impact on the work situation and/or patient safety. We also noted the frequency each weakness was cited.

3. Results

3.1. Overall results

Nine interviews (average time 50 min) were conducted with participants from various specialties (laboratory pharmacist, clinical pharmacist, anesthetist, radiologist, infectious disease specialist, cardiologist, emergency physician and two neurologists). Six *EHR*

group members did not answered the invitation. Overall, interviewees reported 55 different weaknesses of the EHR.

3.2. Most reported usability weaknesses and their impact

Most reported weaknesses concerned information inaccessibility, technical difficulties and missing functionalities (cf. Table 1): issues such as "too many clicks", "slow network", "too many tabs", "problems of browsing" appeared during the medical round, the discharge letter writing, the order of tests or medications, the patient information gathering, and the lab tests results search. The most expressed impact on the professional's work practices is the waste of time; two physicians estimated they lose 1h30mn per medical round due to network slowness, bugs and difficulties to retrieve the relevant information. Furthermore, they also reported damages for patients (e.g. delayed patient care) along with a dramatic accident partly due to usability problems.

Table 1. Most cited EHR's usability weaknesses and their impacts.

Usability Weaknesses (nb)	Consequences on the work situation
Too many tabs. Around 7 tabs consulted per patient during a medical ward. (7/9)	Waste of time to have a complete overview of the patient case, leading to an increase of the cognitive workload; relevant information is missed.
EHR not presenting all relevant information. Data are scattered across the EHR and between the EHR and other software (7/9)	Data are missed; clinicians waste their time switching between several software; they sometimes ask nurses for the needed information
EHR not detailing information. Scales of diagrams for blood pressure or temperature cannot be adjusted. (4/9)	Data about arterial pressure or temperature are not readable and cannot be correctly interpreted, whereas a half a degree evolution is a crucial information in pediatrics or geriatrics.
Lab results are not easily accessible. Data are scattered amongst several tabs in the EHR with various levels of detail and between the EHR and the laboratory information system (LIS). (5/9)	Results are missed; clinicians waste their time switching between the EHR and the LIS; clinicians regularly call the lab to find the results and to know whether a taking of blood is already prescribed or performed.
Interface is not personalized. Each clinician accesses the same homepage with the same information. (4/9)	Waste of time to access relevant contextualized information; relevant data are missed.
Alerts not relevant. There are too many alerts without severity distinction. (4/9)	Virtually all alerts are overridden without being read first, leading to missing potentially critical information, such as treatments coming to an end, incorrect dosage or potential drug-drug interaction.
No information on already ordered radiological exam and blood tests. Prescribers or technicians cannot know whether a patient has a radiological exam already planned or recently done. (4/9)	Duplicate demands leading to double irradiation, double injection of contrast agent, double blood test, or to use wrong test tubes; systematic cross-checking leading to professionals' stress.
Complex browsing. Screens with up to 5 scrolling bars simultaneously; no dual windows; no automatic save of data entered, etc. (5/9)	Clinicians waste their time switching between tabs; notes and data entered are lost when switching to another tab without saving first; clinicians are lost in the software, leading sometimes to abandon.

3.3. Detailed instance: a medicine facility in quarantine

One interviewee reported a noteworthy instance that occurred a few days before his interview. This section depicts this situation where the combination of organizational and EHR usability weaknesses led to quarantine the internal medicine facility following the discovery of a patient infected by multidrug resistant bacteria (MRB) (Figure 1).
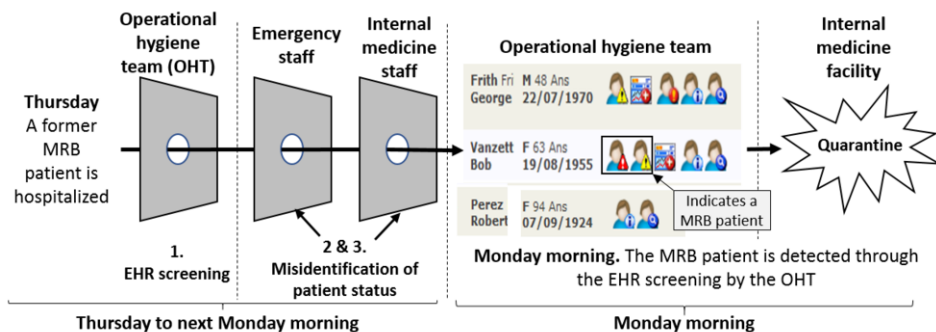
Figure 1. Schematic representation of the key facts that led to the quarantine of the internal medicine facility. Numbered elements represent the broken barriers that should have prevented from the occurrence of this incident (cf. main text). The screenshot represents the icons indicating a MRB patient in the EHR patients list. *(fictive patient case).*

On a Thursday morning a patient with several previous MRB diagnostics was admitted to the emergency department. His most recent MRB results were negative and so, no specific hygienic actions were undertaken. Emergency staff followed the procedure and prescribed a new MRB test at patient admission. The result was positive and confirmed a few days later but none of these results was noticed until next Monday; the patient was transferred to the internal medicine facility, while specific hygiene procedures should have been carried out. Normally, this incident should have been stopped by three barriers during the patient care process:

EHR screening by the operational hygiene team (OHT). The OHT is expected to check the presence of MRB patients in the hospital each Monday by screening icons in the EHR patients' list. This barrier was inefficient because the OHT perform the screening only on Monday while the patient was admitted on Thursday.

Display of patient status. As soon as the positive MRB results are available, two icons appeared next to the patient name. Only the association of the two icons (screenshot in Figure 1) means a positive MRB result; separately, each icon has another meaning (respectively risk of fall and special diet). Icons are visible to the whole staff. Yet, the emergency and the internal medicine staffs misinterpreted the combination of both icons; they did not know its meaning rendering this barrier inefficient.

The positive status of the patient was identified only on the next Monday by the OHT during the weekly EHR screening. This discovery immediately led to quarantine the whole internal medicine department: human resources were completely reorganized, strict hygiene measures and patient care procedures were implemented, the facility was decontaminated, all new suspicious patients in the ward were MRB tested, and recently discharged patients were recalled. This problem caused the dissatisfaction of the professionals regarding the EHR: they pointed out the absurdity of the use of a combination of two icons to indicate a MRB patient while both icons have other meanings.

4. Discussion

This preliminary study based on interviews adapted from TIC indicates that the concerned EHR is source of constraints and errors, with risks for patients care. Results are consistent with the literature: there are still well- known usability failures that hamper the use of EHR (e.g. clinicians skip the alerts; users do not know how to go on; prescribers are placed under pressure) [5,7]. The main limit of the study was to restrain the interviews to the members of *EHR* group because of their role in the physician's complaints centralization. Nevertheless, it also constitutes a strong base to carry out a more detailed analysis of the usability causes to those problems in order to propose solutions to the *EHR group* of the hospital. In further researches, we will first implement an ergonomic inspection of the EHR, and then perform systematic observations in several facilities *i)* to observe the EHR usage, *ii)* to link usability failures/difficulties with their associated risks/impacts, and *iii)* to provide solutions to fix them.

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Surgeon and Assistant Point of View Simultaneous Video Recording

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Abstract. Video recording has become a very common practice in surgery and is one of the paramount methods to teach proper surgical techniques. Traditionally it has been limited by a variety of factors including cost, the need for constant camera reposition, and the use of external photographers, which is both costly and labor-intensive. We describe the use of dual modified point of view (POV) GoPro head mounted cameras to record synchronized POV surgery for the purpose of training surgical assistants. POV cameras are inexpensive, easy to use and manipulate. The GoPro camera was mounted using a head strap on both the surgeon's and surgical assistant's head, providing different optimal views. We used the GoPro Hero4 Silver for the surgeon and the GoPro Hero3+ Black Edition for the assistant. The lens used was optimized for our purposes. With the modified camera for the primary surgeon, the magnification was satisfactory in recording of fine details, and provided a usable depth of field and field of view. We found that using two synchronized POV GoPro head mounted cameras was an innovative way to record otolaryngology surgery and provided excellent video footage which can be used for the education of both surgeons and surgical assistants.

Keywords. video recording, surgical education, surgery

1. Introduction

The challenge of training a surgical assistant (fellow, resident, scrub nurse) is that often the assistant does not see the primary surgeon's perspective, and therefore may be assisting in a suboptimal matter. As there is very little data relevant to training surgical assistants, video recording surgery may be a useful tool to enhance the experience of trainees working from the surgical assistant position. Video recording has proven to be helpful for training medical residents and fellows in the details of surgical technique, as well as emphasizing instrument ergonomics [1,2]. Innovative training programs need to ensure the surgical competence of its trainees, which can be assisted with video capture and reflective review of surgeries [3]. It is also crucial for physicians to be constantly evaluating and improving their surgical techniques to ensure better surgical outcomes. One method of attaining this is by using point of view (POV) cameras that offer high definition video recording from the "surgeon's perspective".

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In this study we describe a novel technique of surgical video recording, using two synchronized, modified head mounted POV cameras: one on the surgeon's head and one on the surgical assistant's head. We demonstrated this technique to be used for training surgical assistants in otolaryngology surgery.

2. Methods

The study adhered to the principles of the Declaration of Helsinki. All patients involved in the study consented to surgery and the intra-operative recording of video and still images.

Subjects included patients above age 18 years undergoing head and neck surgery who consented to video recording. The setting occurred in a quaternary head and neck oncology surgical service. Materials included the recording system, which comprised of two head mounted POV GoPro cameras (GoPro, San Mateo, CA). The recording procedure was as follows. For the primary surgeon, we used a GoPro Hero4 Silver (GoPro, San Mateo, CA) set to 1080P on narrow recording at 48fps, with spot metering and the low light functions turned on. This model was modified to yield higher magnification through a 5.4mm f/2.5 aftermarket lens with a 60° field of view (Peau Productions Inc, San Diego, CA). This lens was pre-focused to a working distance of 17 inches, which is the same as the working distance for our surgical loupes. For the assistant, a GoPro Hero3+ Black Edition (GoPro, San Mateo) with the stock lens was utilized with similar settings. The stock lens was focus-free. Synchronization of the video feeds was accomplished by having both cameras record the digital output from a stopwatch to establish a frame of reference for subsequent video editing.

3. Results

Surgery was successfully recorded from both the primary surgeon's and assistant's POV. Using the stock lens for the assistant provided a wider field of view that enabled viewing of surgical ergonomics. Synchronizing the assistant's video feed with that of the primary surgeon allowed the assistant to understand how their instrument placement and use affects the primary surgeon's work (Figure 1).

At the same time, the modified camera for the primary surgeon provided sufficient magnification to show delicate surgical details as a learning reference for the trainee. The modified lens also afforded a usable depth of field for the primary surgeon. This setup worked best without the waterproof housing, as the protective lens would push on the aftermarket lens and change the focus of the camera. Overall, the impression was that the primary surgeon's POV at high magnification was most conducive to learning the details and intricacies of the surgery. Thus, surgical fellows and residents would likely benefit most from reviewing a recording from the surgeon's POV. The assistant's perspective was likely more beneficial to full-time surgical assistants, medical students, and scrub nurses, where optimal placement of retractors, suction, and other instruments minimalizes obstruction of the surgical field. Both primary surgeon and assistant did not find the recording gear to be hindersome in performing their tasks, nor straining.
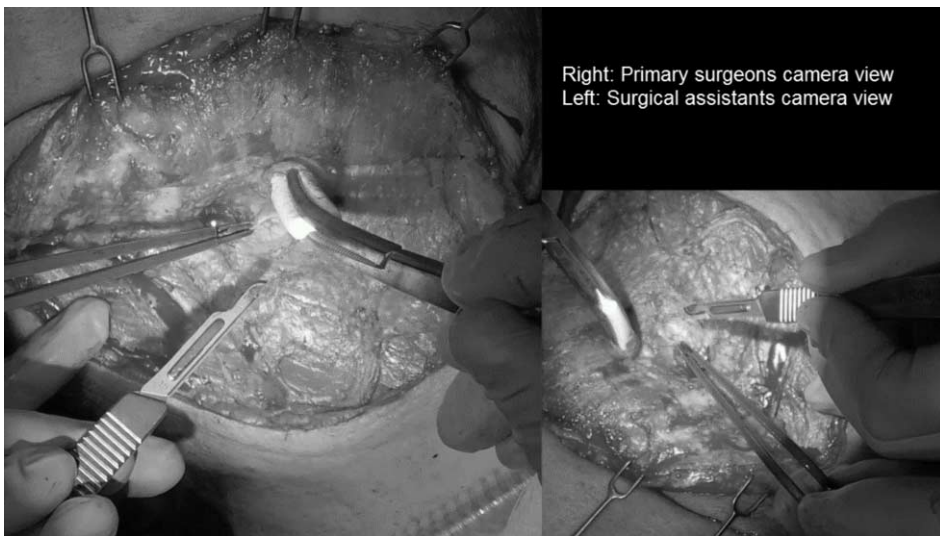
Figure 1. Synchronized video feed point of view stills of the surgical assistant (left) and primary surgeon (right) during otolaryngology surgery. Head mounted GoPro Hero4 Silver (GoPro, San Mateo, CA) was used for the surgeon with a 5.4mm f/2.5 aftermarket lens with a 60° field of view (Peau Productions Inc, San Diego, CA), and a head mounted GoPro Hero3+ Black Edition was use for the surgical assistant.

4. Discussion

This is the first study recording surgical video from an assistant's POV, with a synchronized video feed from the primary surgeon's POV. Again, this paper emphasizes that for surgical trainees, the most valuable perspective is the surgeon's POV. Thus, the majority, if not the entirety, of the case should be recorded using a head-mounted camera on the primary surgeon, using high magnification to appreciate delicate tissue dynamics. Surgical ergonomics may be appreciated by using a synchronized wide field camera [3].

The assistant's POV is less intuitive and less conducive to learning surgery or ergonomics. However, the surgeon's and assistant's simultaneous POV video feed is very useful in appreciating how the quality of an assistant's retraction can either facilitate, or sabotage, the primary surgeon's work. We feel that this approach would be particularly helpful for medical students to prepare them for their first surgical rotations. It would be also advantageous to use this type of video footage to train residents and other surgical assistants who are unfamiliar with a new technique or are seeking to improve their skills.

This work has implications in structuring video libraries. The ideal video library would have magnified, primary surgeon POV recordings of all procedures, variations, complications and subsequent management. For the most part, the primary surgeon POV recordings would include the entire surgery. Synchronized primary surgeon and surgical assistant video would be most useful in shorter segments that illustrate particular maneuvers rather than entire surgeries. For example, a synchronized video may first demonstrate proper technique with the assistant using retractors to provide the surgeon a clear, unobstructed view of the surgical field. Then, a short, synchronized segment shows poor assisting technique, where poor placement and tension on the retractors hinders the surgeon's work.

In an ideal surgical video library, the surgeon's POV videos would cover the breath of different disciplines, as well as have the depth of details to fully understand the procedure. The target audience would include primary surgeons, fellows, residents, and possibly medical students. It would comprise the vast majority of the content. In contrast, simultaneous surgeon and assistant POV recordings would likely be more broad, shorter, and focus on specific maneuvers that are generally applicable to multiple surgical specialties, such a retractor placement, use of suction, surgical sponges, and vessel ligation. The target audience for the simultaneous surgeon and assistant POV videos would likely include full time assistants, scrub nurses, and medical students.

Although we believe our method of recording is an improvement over existing methods, challenges still exist. Neck strain due to the head-mounted camera can be a concerning aspect for the surgeon, especially when there is additional head-mounted equipment, such as a headlight or loupes. With the GoPro camera itself, the battery life, storage capacity, and its ability to wirelessly transmit are issues that need to be optimized. Additionally, an assistant is still needed to periodically check the orientation of the camera on the surgeon's head. Finally, the need to synchronize the two camera feeds makes video editing more onerous.

When recording surgical video on a wide-scale, the cost, convenience and performance of the set-up need to be considered [4]. Standard approaches to recording macroscopic surgery are limited by a variety of factors. Overhead recording systems are expensive and require frequent repositioning during surgery to follow the surgeon's actions. Using an external videographer to record the surgery can be tedious and expensive, may interfere with the procedure, and can increase the risk of infection. Traditional video recording methods are further limited because they do not capture surgery from the surgeon's perspective, which would be ideal for teaching purposes and can enhance simulation training [3]. As video recording in the operating rooms becomes more common, further innovations for easier, cost-effective, and ergonomically savvy surgeon-directed methods will become increasingly important [5].

We feel that POV cameras are the future of high-definition surgical video recording. Studies using GoPro cameras have been used to record orthopedic and general surgeries, where operating room nurses controlled the camera remotely using an iPad app, thereby reducing surgeon distractions. The images and videos were found to be good quality, aside from the brightness due to the overhead lighting, and the surgeon did not report any head or neck strain due to the head strap [6]. GoPro cameras have also been used effectively in oculoplastics, intraocular surgery, plastic surgery procedures and spine surgery [7-10]. Google Glass is another common device that has been used to record surgery, with real-time transmission of the surgeon's perspective. Both the image and audio quality have shown to be adequate for the viewers, however, short battery life, neck strain and the operating room lights causing excessive picture and video brightness were limitations of the Google Glass platform for intraoperative recording [11]. A study using Google Glass in otolaryngology surgery found that it improved surgical workflow, surgical education, and allowed for remote supervision that may have use in teleophthalmology [12]. Comparing Google Glass to GoPro cameras for surgical video recording has shown that technical specifications, battery life, and ability to wear concurrent loupes while operating favored GoPro, but Google Glass provided more comfort, was easier to use [13]. Both of these devices provide POV video recording that can be used to produce synchronized surgeon and assistant POV recordings for teaching purposes.

5. Conclusion

This novel use of dual POV cameras provides a simultaneous and comparative POV between the surgeon and assistant, which may be valuable in preparing medical students for their surgical rotations, as well as teaching residents and other surgical assistants how to optimally perform new techniques. The compact design, simplicity, and ability to capture the surgeon's POV highlights the GoPro technology as a useful tool for the future of video-assisted surgical education.

6. Conflict of interest

No conflicts of interest exist in the publication of this paper.

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Assessing the Alignment of Objectives, Instructional Activities, and Assessments in a Biomedical Informatics Curriculum

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Abstract: The objective of this research was to assess the alignment of course learning objectives, instructional activities, and course assessments in a Biomedical Informatics curriculum. Each syllabi in the curriculum was reviewed and scored according to a validated rubric. Disagreements among reviewers adjudicated by consensus. Only low and moderate levels of alignment were identified. The results indicated the needs and goals of courses could be more effectively met with faculty investment in syllabi redesign and clarification to achieve course objectives. Root causes included word choice in learning objective statement as well as lack of consideration of instructional scaffolding by the course developer.

Keywords. curriculum, alignment, taxonomy, learning objectives

1. Introduction

A notable assumption in the educational development of any academic field is the variability of faculty knowledge of teaching and learning theory, curriculum development techniques, and instructional design principles. This assumption has traditionally been grounded in the notion that faculty at institutions of higher education are primarily trained as researchers in their scientific fields of study. The curricula of scientific fields such as Biomedical Informatics do not include formal coursework in teaching and learning theory, curriculum design techniques, or instructional design principles. However, there is a significant expectation that faculty serve as the primary developers of courses and the curriculum in which the courses compose. As the nature of faculty work, this charge does not offer a systematic avenue for formal faculty preparation in ensuring that the needs and goals of students will be met. This charge is heavily grounded in the idea that the needs and goals of the learners extend beyond the teacher-centered approach to teaching and learning that is heavily associated with traditional pedagogical practices. This significant reliance on pedagogical practices presents a significant concern for designing a biomedical informatics curriculum to meet the goals and needs of adult learners.

Both instructional designers and faculty must partner to build and maintain curricula [1]. This collaboration will ensure the technical components of educational development are used to provide learning standards and expectations that are traditionally found in academically rigorous, programs of study. Therefore, the primary research question examined the alignment of course learning objectives, instructional activities, and course

assessments within the 28 courses in the biomedical informatics' graduate program curriculum.

2. Background

2.1. Biomedical Informatics Graduate Education at UAMS

With no degree programs to represent the full spectrum of biomedical informatics, the University of Arkansas for Medical Sciences (UAMS) broadened the range of the state's training opportunities by developing a 15 credit hour graduate certificate, a 36 credit hour Professional Master's degree, a 36 credit hour Master of Science degree, and a 55 credit hour Doctorate of Philosophy in Biomedical Informatics. The newly expanded program includes four tracks; Translational Bioinformatics, Imaging Informatics, Clinical Informatics, and Clinical Research Informatics. This included the development of 28 new courses designed to reflect the competencies of both practitioners and scholars in the domains of the biomedical informatics spectrum. The development of the syllabi for the courses was facilitated by the Department of Biomedical Informatics' Curriculum Committee. Given the significant value of the Department's faculty as content experts in their respective fields and not as instructional designers, there was a significant need to integrate instructional design expertise to examine the degree to which the courses were designed to meet the objectives articulated in each syllabus through the use of instructional activities and assessments.

2.2. Fink's Taxonomy of Significant Learning

As the conceptual framework for the instrument used in this study, Fink's Taxonomy of Significant Learning is widely viewed as an evolutionary stage of Bloom's Revised Taxonomy in the context of examining how learning occurs. Fink's Taxonomy is grounded in the notion that a change must occur in the student before learning occurs [2]. This is reflected in the significant emphasis of the Fink's Taxonomy on blending the cognitive and affective domains. This emphasis is a distinguishing feature of Fink's taxonomy and significantly represents the rationale for its categorization as an evolutionary stage of Bloom's Revised Taxonomy. Additionally, the nature of the Fink's Taxonomy is relational while the nature of Bloom's Revised Taxonomy is hierarchical. The relational nature of the Fink's Taxonomy is evident in the six learning dimensions of the taxonomy. The six learning dimensions of the Fink's Taxonomy include Foundational Knowledge, Application, Integration, Human Dimension, Caring, and Learning How to Learn. These dimensions represent the various realms and ideas of how a student's affective activities work in a collaborative manner to produce significant learning.

In the context of the UAMS biomedical informatics graduate curriculum, the foundational knowledge dimension represented the element of developing students who have a comprehensive understanding of biomedical informatics concepts to support a student's ability to remember and explain the intricacies of the concepts. The application dimension allows faculty and instructional designers to examine the kinds of critical, practical, and creative thinking as well as skills that students should be able to do [2]. As an interdisciplinary field, biomedical informatics education could substantial benefit from utilizing the integration dimension's focus on a student's ability to make connections

within and beyond the ideas, people, and concepts of biomedical informatics [2]. In addition, the human dimension examines what students should learn about themselves and their interactions with others in the biomedical informatics profession such as ethical, civil, and cultural principles [2]. The caring dimension of the taxonomy examines changes that occur within a student such as feelings and interests in the development of computational tools used to improve human health. As the final dimension of the taxonomy, the value of a student's ability to learn how to learn aligns with nature of adult learning which is heavily grounded in intentionally and reflectively, self -directing one's own learning [2]. Developing or expanding any biomedical informatics graduate program presents an enormous challenge for faculty and instructional designers. Each of these six dimensions offered a guided approach to assessing a curriculum to ensure that its design would effectively train students to develop and apply computational tools to biomedical data. Additionally, the literature substantiated a need to provide assurance that the curriculum and its embedded competencies are designed to prepare students for roles in the biomedical informatics workforce [3]. An assessment using these six dimensions provided an adequate level of assurance.

2.3 Alignment of Syllabi Components

The examination of alignment offered a significant distinction between a course's intended design and its actual design. The basis of the concept of alignment is described by academic fields in various ways. To some scholars and practitioners its basis is considered to be the process phase of training and development [4]. To other scholars and practitioners, it is referred to as the ADDIE model of instructional design [5]. Regardless of how the alignment process is referred to, the process offered a systematic process for creating, organizing, and assessing instruction. This systematic process contains five steps which include (1) analyzing the learning needs of the biomedical informatics students (2) designing measurable learning objectives based on the identified needs (3) developing instructional activities to meet the learning objectives that were developed based on the identified needs of the students (4) implementing the instructional activities and (5) evaluating the instructional activities based on their ability to yield the outcomes noted by the learning objectives [5]. Each step of the design process is dependent on its preceding step [5]. This sequential process of steps represents the concept of alignment. Therefore, the most significant benefit offered by the concept of alignment is its ability to ensure that a course's learning objectives are being met by the instructional activities and assessments of a course.

3. Methods

3.1. Objective

The objective of this study was to examine course alignment within the developing biomedical informatics graduate curriculum to understand the extent to which courses were capable of achieving learning objectives.

3.2 Study Design

A validated syllabi rubric was used to review and score the instructional design components of 28 graduate-level courses in the UAMS Biomedical Informatics graduate curriculum using three rounds of review to gain agreement on how each of the 15 components of the rubric should be scored. This study did not involve human subjects. Course syllabi served as the primary data source for the instructional designers' scoring. The data provided by the scoring of the syllabi was analyzed univariately. Syllabi were previously designed by 15 faculty in the Department of Biomedical Informatics using a standard syllabi template. The template included elements that are traditionally found in syllabi such as a list of learning objectives, instructional activities, a description of course assessments, and ect. Thus, the template used to create the initial syllabi provided an adequate amount of information for assessing the alignment learning objectives, instructional activities, and course assessments.

3.3 Instrumentation

The syllabi review rubric served as the instrument for assessing the measurability of the learning objectives and their alignment with the instructional activities and course assessments. The rubric focused on identifying the presence of five categories that supported the examination of alignment. These five categories were (1) the presentation of measurable learning objectives and longer-ranging goals, (2) instructional activities, (3) assessment activities, (4) a fully articulated course schedule, and (5) the overall learning environment. These five categories represented the Fink model's taxonomical structure for classifying the 16 components of the syllabi rubric. Palmer et al. provided ample examples for what should be considered as evidence of the 16 components. These examples offered a structured process for identifying evidence of components in the syllabi and scoring the level of evidence in each syllabus. For example, component 2 of the rubric is designed to assess the measurability of the learning objectives in the syllabus. Palmer et al. provided background information on interpreting the measurability of a learning objective including a notation of the difference between a learning goal and a learning objective. Each of the 16 components were categorized according to Palmer et al.'s work as highly important, moderately important, or less important. In terms of the scoring of the 16 components, the strength of evidence found in the syllabi is reflected on an ordinal scale of measurement using rating of strong evidence, moderate evidence, and low evidence.

3.4 Data Collection and Analysis

Data was collected using three rounds of review. Consensus adjudication was used for its ability to provide agreement among the expert opinions of the instructional designers and the frequency of its historical use in healthcare. The use of the technique sought to gain agreement among the instructional designers for scoring each of the 15 of the 16 components of the syllabi rubric for each of the 28 courses in the curriculum. Data was not collected on the third component of the syllabi rubric because of its difficulty associated with assessing the item without content knowledge of the curriculum. The faculty subsequently assessed the third component of the rubric independently of this study. The scoring of the syllabi was conducted over a 90-day period. The first round of

the consensus technique was used as a method of allowing each instructional designer to score each syllabi independently of the other instructional designers. A significant element first round's design was to allow for independent interpretation of the syllabi scoring rubric with subsequent rounds eliminating the variation in the interpretation of the rubric through consensus. The instructional designers were charged with providing qualitative feedback on the level of evidence found on each of the 15 components of rubric in each syllabus. Second and third rounds of review were used to facilitate robust discussion and clarification on the rubric's scoring system, the instructional design principles being scored, and the amount of evidence of the 15 components in the rubric.

4. Results

4.1. Findings

The mean, as a descriptive statistic, was calculated on all of the components of the syllabi rubric for the courses. Component #14 specifically assessed the alignment of objectives, instructional activities, and assessments. Scores for Component #14 in each course was averaged and produced a mean score of 1.64. Table 1 provides means for all of the components of the rubric.

Table 1. Mean scores of syllabi rubric components.

Component Number	Syllabi Component	Mean
1	Learning goals encompass full range of Fink's dimensions of significant learning	1.18
2	Course level learning objectives are clearly articulated and use specific action verbs	1.86
4	Objectives and assessments are aligned.	1.64
5	Major summative assessment activities are clearly defined	1.60
6	Plans for frequent formative assessment with immediate feedback	1.61
7	Assessments are adequately paced and scaffolded	1.75
8	Grading information is included but separate from assessment; it is aligned with objectives	1.71
9	Course schedule is fully articulated and logically sequenced	1.79
10	Tone is positive, respectful, inviting	1.46
11	Fosters positive motivation, describes value of course, promotes content as a vehicle for learning	1.25
12	Communicates high expectations, projects confidence of success	1.25
13	Syllabus is well organized, easy to navigate, requires interaction	2.07
14	Classroom activities, assessments, and objectives are aligned	1.64
15	Learning activities are derived from evidence-based practices	1.86
16	Learning activities likely to actively engage students	1.75

4.2. Discussion

The mean score provided an overall reflection of the curriculum's alignment. The overall mean score on the components ranged from 3 (strong evidence) to 1 (low evidence). The mean score of 1.64 produced by Component #14 indicated a moderate level of alignment between objectives, instructional activities, and assessments. The moderate evidence reflected by the mean of 1.64 suggested a significant need to redesign the syllabi to increase the strength of the learning objectives, instructional activities, and course assessments. Standardized syllabi templates and other aids could support increases in alignment. The results indicated a lack of evidence to support a declaration that alignment existed within the courses of the biomedical informatics curriculum. The moderate evidence found in the reviews were highly reflected by the means of the 15 components noted in Table 1. With increased evidence of alignment, a declaration could have been made that the instructional activities and assessments were designed to carry out the learning objectives of the courses.

4.3. Limitations

A limitation of the study involved the number of instructional designers who conducted the reviews of the syllabi. The ideal number of formally trained, instructional designers scoring the syllabi could have been more. However, institutional resources limited the amount of investments in this internal approach to increasing the alignment. Only three of the institution's instructional designers were both formally trained and available to invest time in performing the syllabi reviews. Given the nature of the consensus technique's ability to account for variance in solicited opinions, there is high confidence that the rigorous discussions of the technical elements of the rubric and the rubric's systematic design adequately reflected the amount of evidence found in each syllabus. The components of the syllabi could have also been more clearly articulated by course directors to ensure adequate evidence of alignment between the learning objectives, instructional activities, and assessments.

5. Conclusions

The results of this study emphasized the technical importance of integrating instructional design principles into the development of curricula in biomedical informatics. More specifically, instructional designers are formally trained, professionals who seek to guide the development of instruction to meet the needs and goals of students. Their expertise will complement the acquisition of the dynamic, knowledge bases that exists within biomedical scientists and educators.

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Nursing Informaticians Address Patient Safety to Improve Usability of Health Information Technologies

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Abstract. With the introduction of Health Information technology, the potential for unintended consequences can occur. Island Health developed a Quality Assurance review process to evaluate and identify opportunities for system optimization, education and engagement, policy changes, as well as identify unintended consequences of Electronic Health Record (EHR) implementations. The Patient Safety Learning System was utilized to audit and evaluate reported safety events for system breaks and opportunities, practice and policy, as well as workflow implications. The findings were then reported to the reporter, leadership, and through governance structures. This process identified that 242 reported patient safety events in 1 year has resulted in 30 (13.7%) of these events leading to EHR System optimization. Ultimately Island Health's Nurse Informaticists foster a culture of safety through their QA/QI Patient Safety event investigations which improve system usability and ultimately Patient Safety.

Keywords: Patient Safety, Nurse Informaticist, Quality Improvement, Clinical Informatics

1. Introduction

Today patients and the health care systems they access are more complex than ever before. Health care systems are fraught with resource, financial, and social challenges that can make providing care increasingly difficult all while layering on top complex technical systems and practice variance. Health information technologies are being introduced into the Canadian health care contexts at an increasingly rapid pace to help address, and attempt to improve these issues. Electronic Health Records (EHRs) being implemented have potential or realized benefits including "better quality of medical care, greater efficiencies, and improved patient safety" [1] however despite this, unintended or undesirable consequences will almost certainly be experienced with their use [1] [2], especially after an implementation.

Being that the ultimate goal of Nursing Informatics is to "improve the health of populations, communities, families, and individuals by optimizing information management and communications" [3]. Nurse Informaticians (NIs) are uniquely skilled to investigate and address patient safety concerns through the careful evaluation of the

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workflows, individual users' clinical practice, organizational policies, as well as the design and use of an EHR. Island Health NIs are utilizing their honed critical thinking skills, clinical experience, and their developed NI competencies to address reported patient safety events in an effort to improve system usability and ultimately safety and improvement of patient outcomes. This paper presents processes utilized by Island Health NIs in using the provincial patient safety-reporting database and quality assurance reviews to evaluate and identify opportunities for system optimization, education and engagement, policy changes, as well as to identify the unintended consequences of EHR implementations. This process has allowed NIs to promote a culture of safety as we continue to advance the digital health strategy and associated health information technologies while continuing to improve the health and care of our patient population.

2. Methods

Island Health's NIs are uniquely skilled and positioned to investigate and evaluate patient safety concerns as it relates to the EHR. The NIs are clinical practice leads with at least five years of clinical experience in the areas they support and are also the lead designers as it relates to all technology integrated workflows and the EHR. Their unique knowledge allows them to view reported patient safety events holistically— organizational policies, best practice standards as well as individual clinical practice, workflows, and system design and usability. This is completed through the use of a standard tool, a refined investigation process, as well as a feedback loop and reporting mechanism.

2.1. Patient Safety Learning System at Island Health

Island Health utilizes the province of British Columbia's Patient Safety & Learning System (PSLS) as a reporting tool that helps health care professional report, manage, and share learning to continuously improve quality care and organization safety. PSLS is a web based tool that supports reporting of adverse events, near misses, and hazards that occur in all health care settings [4]. This tool provides a summary of the reporters understanding and interpretation of events, in an objective manner focusing on system and process rather than individuals. Information provided (such as patient identifiers, safety event details, and opportunities for improvement) are key pieces of information that helps with the beginning steps of the investigation.

When Island Health activated their Electronic Health Record, the PSLS system implemented a new data field asking if the computer system contributed as perceived by the reporting clinician. This field allowed for the creation of a quality improvement/quality assurance process as it related to the implementation and continuous optimization of the EHR.

2.2. Investigation Process

The investigation process begins with a manual data pull from the PSLS system, generating a report listing events where it was identified that a computer system contributed. This data audit is manually completed by a PSLS Coordinator using the report generator from the PSLS system twice per week (Mondays and Thursdays) and is then distributed to the appropriate NI for review.

The NI reviews the PSLS system for all reported information which is then utilized as the QI/QA clinical chart audit within the EHR. While completing the chart audit several key factors are used as supplementary information including organizational policies, professional standards of practice, approved workflows, as well as system configuration and design. If reviews determine that there are processes or practices that involve ancillary teams (lab, diagnostic imaging, and pharmacy) those supporting informatics teams are involved to help investigate those processes.

Upon completion of the full QA/QI investigation a clinical informatics summary findings reports is created, including clarification if the EHR contributed or not to the safety event in relation to design or configuration. If a break in the design has been identified or there is opportunity to optimize the EHR in a way to improve usability and ultimately enhance patient safety and clinical outcomes, the organizations technical change management process is followed to affect the most appropriate change.

Timeliness for the NI investigation process to be complete are expected to be no more than one week from the receival of the data audits, which supports a timely turnaround of information. a responsive turnaround time for an NI review is important as the primary handler responsible for the PSLS (the clinical lead for the organizational care department) has a commitment of a 12-week turnaround time for a complete review.

2.3. Feedback Loop and Reporting

Where a system change is not required the summary findings are uploaded into the PSLS database as NI Investigation and findings. This summary report provides recommendations back to the primary handler of the event (generally the supervisor or manager of the reporting clinician) as it relates to policy, practice, and workflow.

Where system changes are required, the system change ticket number is logged in the summary findings report, in the PSLS Event. To close the loop with the initial reporter, and continue to foster the culture of safety at Island Health, a directed communication is developed for the initial reporter, notifying them of our appreciation that their identification of a patient safety event in relation to the EHR has contributed in a specific system change.

All Nurse Informatics Summary findings are collated on a monthly basis into a summary and a full report that is presented to the Electronic Health Record Quality Council. The summary provides a listing of system changes that are occurring because of reported events as well as itemizing the numbers of events as related to practice, education, and organizational processes. To those who govern the EHR System, this reporting structure provides transparency into the continuous quality improvement work that is occurring to optimize health information technologies as related to improving patient care and safety.

3. Results

As a result of this process development, in a one-year time period (July 2017 to July 2018) there were 3,620 reported patient safety events at 3 Island Health facilities, enabled with advanced Clinical Information System technology, of which 242 were indicated that the computer system contributed in some way resulting in a review by the NIs (Figure 2). Of these 242 events, 9.5% (n=23) were not investigated by Clinical Informatics as they related to external or ancillary systems, not the EHR. Of the 219 events that were

investigated by Clinical informatics, 13.7% (n=30) identified events led to specific system changes that were enacted to improve user experience, system design and ultimately patient safety. In total, the events that were reviewed and deemed that the system directly contributed to the event that occurred resulted in 0.4% (n=1) of system configuration being removed from production and redeveloped.

The remaining 86.3% (n=189) event findings were related to practice, process and policy which were reported to the appropriate operational clinical leadership groups for review and action. This 86.3% was still also examined in the context of EHR design themes which has led to a review of Clinical Decision Support in relation to alert fatigue, medication safety process and practice as related to bar coded medication administration (BCMA), the electronic medication administration record, and the closed loop medication system. It is believed through these processes end users are experiencing increased usability and patient safety as PSLS reported events are decreasing (Figure 2) and voiced concerns regarding patient safety has decreased.
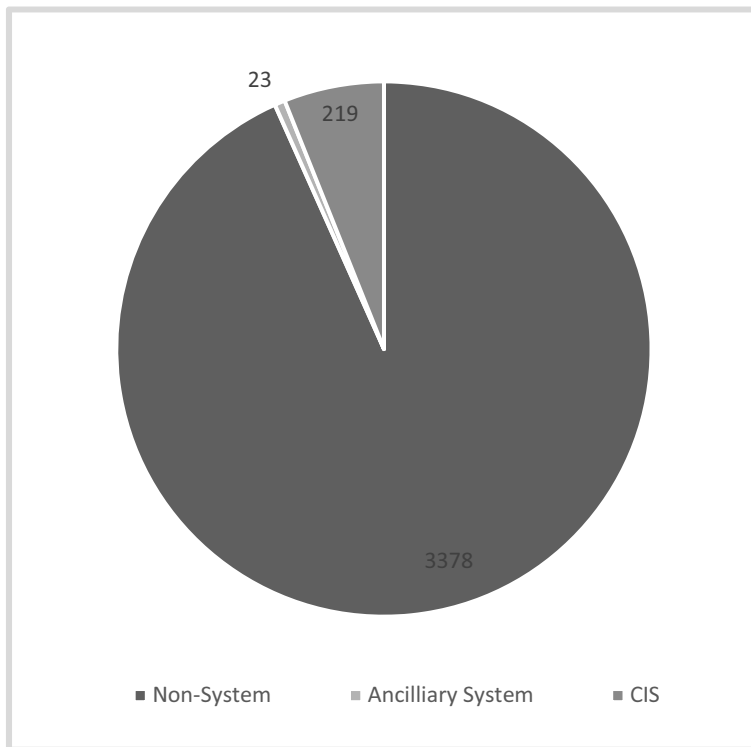
Figure 1. Number and Type of PSLS reported events from July 2017 to July 2018. PSLS reports including those that were reported without a computer system contributing (non-system), and those reported as having computer systems contributing to the event (either Clinical Information Systems or Ancillary Systems)
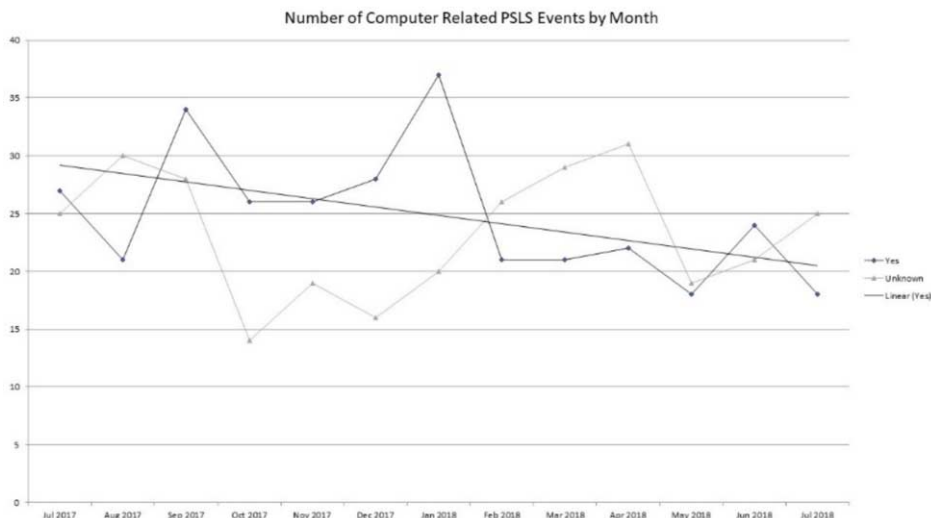
Figure 2. Number of PSLS events that a reporter has deemed computer related is declining (linear line) between July 2017 and July 2018.

4. Discussion

Despite there being ample literature that identifies that the introduction of technology into clinical practice can lead to an increase in errors related to usability [5-7], there continues to be implementations fraught with errors, usability concerns, and potential impacts to patients. There have been frameworks published within the literature that speak to the important of address HIT induced errors [8], specifically having processes available for reporting these errors; however equally important is the need to evaluate practices, processes, and policies that may have impacted and led to a technology-induced patient safety event [9].

A case example (see table 1) that highlighted the importance of reporting as well as examining the entire context of a patient safety event (policy, practice, process, and education) is of electronic ordering of Medical Orders for Scope of Treatment (MOST). The system optimization enabled the visualization of a patient's MOST order across the care continuum, across encounters and in an easily visualized part of the EHR. This event led to a fulsome review and analysis of workflow, practice, and policy between Clinical Informatics, our Advanced Care Planning Quality Committee, clinical end users, as well as patient advisors. Beyond the system optimization led by the NI, a recognition that the policy could use revision, that educational materials would now need to be updated, as well as identification that an engagement strategy to deal with the practice of ordering and updating MOST upon hospital admission would be required to be successful in the addressing of the patient safety event.

Table 1. This table demonstrates the information that is provided within the data audit report for NI review of the ability to view MOST within the EHR.

Reported Event	How Computer System Contributed
Patient found to be unresponsive so a Code Blue was called overhead. I have provided treatment to this patient before and knew of an existing DNR-advising the team. MOST was not addressed on this admission therefore the nurse insisted patient had full code status. Advanced directive available in powerchart files, and MOST was found to be previously documented on a previous admission.	Despite RN's checking chart for MOST status, kept insisting status to be C2. There are too many places in system in which you can find a MOST status. MOST status does not carry over from previous admissions, negating purpose of advanced care planning. This is big flaw in computer system which promises one patient, one record. This is critical information that should be readily available to bedside clinicians, even if not addressed during current admission.

The strengths noted through these processes are timely evaluations of reported events that include several key factors related to clinical use of the EHR (practice, policy, education as well as the CIS architecture), as well as using existing tools and reporting processes to allow end users to identify their perception of how technology impacted patient safety as well as their suggesting for improvement. Despite having a strong culture of safety as evident by the volume of self-reported incidents, there are several key limitations to our process. Patient safety reporting is voluntary so there is potential that there are several safety events and opportunities that are not reported and our understanding of the proportion of events that are computer related may not be represented. Another key limitation is that an end user may not understand if a computer system had contributed to the event and therefore may not report it as one, or may report that it did when it did not as evident by the 86.3% of events that were investigated and found to be related to process, practice, or an educational gap.

To enhance the likelihood of an effective patient safety-based quality improvement process for your EHR consider the following:

- Engage your quality and safety structures to align processes
- Be transparent with your end users regarding process, timelines, recommendations, and system changes
- Engage appropriate stakeholders as necessary for changes related to process, practice, policy, and education.

Making your processes transparent, quality and patient safety focused, and timely with regular feedback loops will continue to foster a culture of safety and continuous quality improvement for your EHR.

5. Conclusion

Island Health's Clinical Informatics Quality Assurance/Quality Investigation processes as related to patient safety events continues to promote a culture of safety that has allowed the NIs to identify situations and opportunities to improve or redesign workflows and system configuration as related to the EHR. Although there are limitations of these processes, the NIs are continuing to address patient safety through improving usability of the health information technologies that have been implemented focusing on the entire context of the event. This paper has highlighted that Island

Health's health professionals reporting of patient safety events has been fundamental in our ability to provide continued improvements to both our HIT as well as patient safety; These processes have provided insight to our organizational leaders on the implications to practice, policy, and workflows; ultimately to "improve the health of populations, communities, families, and individuals by optimizing information management and communications" [3].

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A Socio-Technical and Lean Approach Towards a Framework for Health Information Systems-Induced Error

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Abstract. The evaluation of Health Information Systems (HIS)-induced medication errors is crucial in efforts to understand its cause, impact and mitigation measures when trying to minimize errors and increase patient safety. A review of evaluation studies on HIS-induced medication errors was carried out, which indicated the need to further structure complex socio technical aspects of the subject. In order to satisfy this requirement, a new framework was introduced for the evaluation of HIS-induced error management in clinical settings. The proposed HO(P)T-fit framework (Human, Organization, Process and Technology-fit) was developed after critically appraising existing findings in HIS related evaluation studies. It also builds on previous models related to HIS evaluation, in particular, the HOT-fit (Human, Organization, Process and Technology-fit) framework, error model, business process management, Lean method, and medication workflow. HOPT-fit incorporates the concept of fit between the four factors. The framework has the potential to be used as a tool to conduct a structured, systematic, and comprehensive HIS evaluation.

Keywords. Medication error, management, evaluation, business process management, case study. Socio-technical, fit, Lean

1. Introduction

Health Information Systems (HIS) has become an integral part of global healthcare systems. Evaluation of these systems is essential to ensure the effective implementation and positive impact of HIS on healthcare delivery, including patient safety. HIS-induced errors have been highlighted as one of the most important topics in patient safety. More work on technology-induced errors is needed to understand it [1]. To evaluate the actual performance of any life-critical technology, detailed measures are required. Safety is part of a sociotechnical system as both people and clinical implementations contribute to the challenge of producing safer health care. Most unintended and hazardous effects of HIS come from socio-technical interactions [2].

Therefore, it is essential to understand the interaction between socio-technical issues related to the impact of HIS and patient safety. Borycki et al., [3] argued that integrated approaches based on cognitive and socio-technical aspects would enable interactions from a more holistic perspective between the two aspects and impact of HIS on clinical tasks in healthcare organizations. However, related studies are limited, yielding to huge knowledge gap in the two areas [2; 4].

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The paper reviews evaluation approaches for of HIS-induced errors and proposes a new framework for the evaluation of HIS-induced errors that incorporates comprehensive dimensions and measures of HIS effectiveness and the fit between the human, organization, process, and technology factors. This proposed framework in HOPT-fit (Human, Organization, Process and Technology-fit) would be potentially useful for conducting a structured and thorough evaluation study. It could also assist researchers and practitioners to unfold the complexity of HIS-induced error evaluation. The new framework is based on previous models on error evaluation, HIS evaluation, Business Process Management (BPM), and Lean methods. When developing this model, problems and methods related to HIS evaluation highlighted in the selected Health Informatics literature were discussed. Furthermore, the proposed model of HIS evaluation was presented to explore its applicability for improving current error models.

2. Theoretical Background

Patient safety can be improved or diminished based on how HIS is designed, implemented and applied [4]. HIS-induced errors are medical errors that are related to the overall stages of system development life cycle (SDLC) and HIS interactions with its socio-technical aspects [3]. Threats to patient safety include poor user-interface design, poor workflow and complex data interface. Adverse events could be caused by almost any interaction in the care system, at any time when providing care, and in all healthcare locations.

Evaluation approaches to technology-induced errors were developed based on different domains including technical, sociological, economic, human and organizational. Thus, a number of established and commonly used frameworks related to technology-induced errors were reviewed to identify the evaluation dimensions and measures (Table 1). The analysis showed that evaluation measures overlapped and complemented each other. In order to complement the four models, analysis was also conducted on related models and theories namely socio-technical [5], organizational change theory [6], clinical process management [2], and Lean method.

2.1. HOT-fit Framework

The HOT-fit evaluation framework [5] for HIS features comprehensive dimensions and measures of 'technology', 'human' and 'organisation' factors (Figure 1). Based on its comprehensive dimension, HOT-fit is not only used to evaluate HIS performance, efficiency, and its impact in various studies [5] but also systematically guide error evaluation according to the process phase and level of the three factors. Many HOT-fit measures overlap with those of technology-induced errors and human factor/ ergonomics [7], which can be structured systematically according to the HOT-fit framework.

Table 1. Selected error evaluation frameworks

	Reason's Model [8]	The London Protocol [9]	Leape's Model [10]	Borycki's Model [2]

Technology		Technology	Design
			   missing aid/ manual
			Implementation
			Information availability
			Alerts, Reminders
				Design
				
				Implementation
				   simulation, testing

Human	Slip (attention) Lapse (memory) Mistakes (Rule-based, knowledge-based) Violation (routine, exceptional, sabotage)	Patient Individual (Staff) (knowledge & skills, health) Team (communication, supervision & help, structure)		Training

Organization	Working condition (e.g. poorly planned duty roaster, high workload, job training)
	Proactive risk management approach
	Error management:
	   Limit the error
	   Tolerate the error
	Holistic participation
		Work environment (staffing, workload, equipment)
		Management (financial, structure, policy, standards, & goal safety culture & priorities (defence/ barriers)
		Context (economic & regulatory, external link)
			Work setting:
			   psychological precursors (stressful work condition)
			Management
			Job training
			Extent of error measurement
			Periodic data collection
			Evaluation
			Focus group
			Observation
			Chart review
			Simulation
			Reporting
				Ongoing monitoring mechanism
				Error analysis
				Investigation protocol
				Risk management
				Collaborative teamwork
				Education
				Report system

Process	Design	Task
		   design & structure
		   clarity
		   protocol
		   test results
		   decision-making aids
			Design flaw
			   unclear purposes & optimising method
			   missing human principles: Alerts, Reminders
				Workflow changes

3. Proposed Evaluation Framework

The proposed evaluation framework was developed after having critically appraised the findings of existing evaluation studies on HIS-induced errors. It also makes use of previous error models for categorizing evaluation factors, dimensions and measures. The HOT-fit framework was extended by upgrading selected evaluation measures to become evaluation factors and dimensions due to its significant contribution to error incidents and mitigation. The addition of the features is explained (Figure 1):

1. Process factors and its dimensions: Clinical stages, BPM, and Lean.
2. Error and mitigation measures in technological, human, organizational and process factors (structured list of error measures is under construction).
3. Dynamic "holes" in all four factors that represent latent and active failures. The holes are prone to hazards when they are aligned together. In contrast, if the following layer can defeat the flaw of the previous defence layer,

hazards can be avoided as they are diverted away, instead of passing through the whole system.
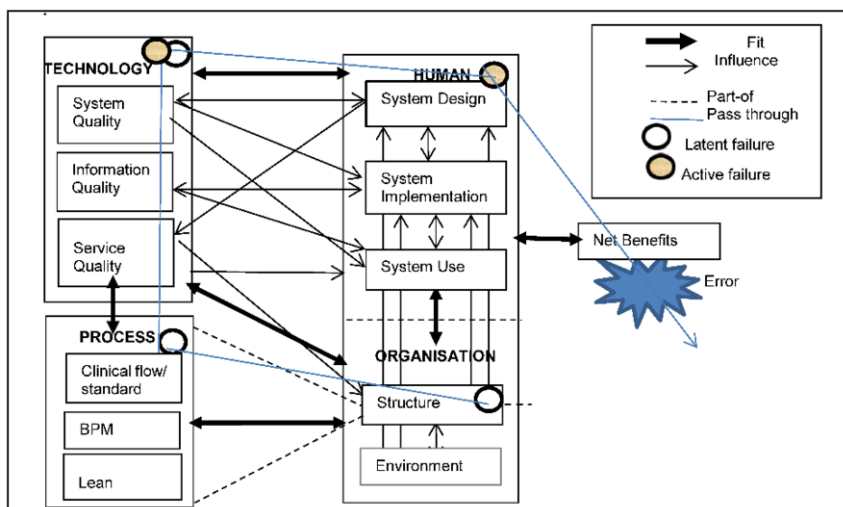
Figure 1. Human-Organization-Technology-Process Fit (HOPT-fit) Framework

The four factors and the effects by HIS correspond twelve interrelated dimensions of HIS success: System Quality (measures of the information processing system itself), Information Quality (measures of IS output), Service Quality (measures of technical support or service), System Development (processes and issues in a SDLC), System Use (recipient's consumption of IS output), User Satisfaction (recipient's response to System Use), Organisational Structure, Organisational Environment, Process and Net Benefits (overall IS impact that include HIS-induced errors). As part of the organizational element, process is featured as one of the factors and this encapsulation is represented using the dashed line (Figure 1) that links process and organization. Process is central to error failure and management because errors are commonly triggered during the execution of a process. This study proposed three dimensions for process, namely the clinical stages, BPM life cycle, and quality thinking using Lean methods. As the study focused on medication errors, it examined medication stages and its compliance to the 5 rights as in right drug, dose, route, time, and patient. Process management can be assessed according to various stages of BPM, whilst process quality and safety can be examined using Lean methods which have proven to improve clinical outcomes, enhance patient safety and reduce error [11]. The fit concept between technology, human, organisation and process is complex, subjective and abstract [5].

4. Conclusions

This paper has identified the problems, reviewed the existing methods and proposed a new evaluation framework for HIS-induced errors. In the search for an appropriate,

comprehensive approach to evaluation, a number of existing frameworks for IS error models in Health Informatics were analysed. The review suggests that there is a need to improve existing HIS evaluation methods. The strengths and limitations of these frameworks were discussed and used as a basis for the new proposed framework, namely the HOPT-fit. In addition to the literature review, this framework builds on the HOT-fit framework, the Leavitt Model, previous error models, BPM, and Lean methods. In order to validate its usefulness, this framework needs to be tested in clinical settings. Findings from the fieldwork could be used for further improving and refining this framework. The framework should be applied flexibly, depending on different contexts and purposes; emphasis should be given on the most important dimensions and measures.

5. Acknowledgement

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Applying a Pneumatic Interface to Intervene with Rapid Eating Behaviour

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Abstract. Higher eating rates are positively correlate with obesity. In this paper, we propose the design of a new eating utensil that can reduce eating rate by interfering with eater's ability to eat quickly. This utensil can change its rigidity and shape by deflating itself to interfere with eating. In this study, a low fidelity proof-of-concept prototype device has been designed to provide physical resistance in order to help people reduce their eating rate. The proposed prototype could be used to demonstrate the feasibility of applying a pneumatically actuated shape-changing interface to embed physical resistance into an eating utensil.

Keywords. Technology-supported interventions, pneumatic interface, inflatable structure, shape-changing interface, eating rate, eating behavior detection

1. Introduction

Obesity is a serious epidemic in current North America [2][20], and researchers have linked eating rate, or how much food people eat within a short interval, to obesity [21]. Previous research shows that, reducing eating rate, or eating slower, could reduce caloric intake [27] and lower eating rate could minimize the risk of increasing Body Mass Index (BMI) and obesity [21]. Clearly, having good eating habits is important. To achieve this goal, numerous interventions have been applied in various settings. For instance, some studies have manipulated eating rate and investigated the energy intake in experiment [27], while others have leveraged digital interventions to help modify people's eating behavior [28]. However, these interventions are relatively difficult to be applied in everyday life. For example, some require elaborate experimental settings in a laboratory [3] while others might require setting up extra devices and equipment which is not easy to carry with, such as a special scale to record every time people eat [11,12]. Such rather burdensome tools and settings might discourage users to continue to improve their eating habits. Thus, we propose the development of an eating utensil, which is compact and easy to carry. This utensil has the important ability to intervene with users' food intake behavior to modify their eating rate. Users of the proposed utensil should be able to improve their eating behavior independently and without additional equipment.

Regarding eating utensils, the use of light and/or vibration signals are two of the most commonly applied methods to provide feedback as interference. These feedback methods have been applied to commercial eating devices such as the 10s Fork [15].

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However, studies [7,9,10] have shown such feedbacks were not obvious to the participants and that the slower eating rate induced by the device did not help to reduce the amount of their food consumption. Evidently, there is a need to embed feedback mechanisms within eating utensils, which are obvious to the users in order to effectively influence eating rate and food consumption.

We introduce physical resistance onto an eating utensil, which can physically burden the user and we hypothesize that this will slow their eating rate. This is achieved by changing the stiffness and shape of the eating utensil. To evaluate the feasibility and effectiveness of doing so, we developed a low fidelity utensil prototype, which provides physical resistance via a pneumatic shape-changing interface, whereby the handle of the eating utensil becomes soft and bends when a user is trying to eat too quickly. We plan to demonstrate the feasibility of embedding physical resistance onto an eating utensil to improve people's eating rate.

The next essential function to enable the device to improve eating behavior is to accurately detect users' food intake. Prior studies have examined various modalities, such as pictures, motion and voice, to detect eating moment [31]. Based on these projects [31], we plan to apply the Inertial Measurement Unit (IMU) to the eating utensil. This will allow us to detect users' eating behavior, which has been demonstrated in a previous project [30].

We are now in the early stages of developing the prototype, which could recognize intake behavior and provide physical resistance using a pneumatic actuation. Subsequently, we will conduct experiments to test the acceptability of our prototype, and empirically test the efficiency of the physical resistance in reducing the eating rate and food consumption. To our knowledge, this project would be the first attempt to apply a pneumatic shape-changing interface in an eating utensil to provide physical resistance in an actual eating environment.

2. Related Work

In this section, we discuss the literature on eating rate; the techniques used to detect eating and provide feedback; behavior modification technologies; and shape-changing interfaces.

2.1. Eating rate and health

Eating rate likely plays a role in personal health [21,27]. For example, Ohkuma, et al. [21] conducted a systematic review of studies focusing on the relationship between eating rate and obesity and concluded that eating quickly is positively correlated with increased BMI and obesity. Moreover, Robinson et al. [27] also systematically reviewed studies which manipulated eating rate and showed the impact on food intake and hunger; they reviewed factors such as verbal instruction from researcher(s), altering food texture, manipulating food delivery and computerized feedback. Robinson et al. [27] found that a decreasing eating rate was associated with reducing energy intake. Thus, decreasing the eating rate is a key to help reduce energy intake. Bolhuis and Keast [3] found that participants who ate with a spoon had a higher eating rate than those who used a fork in a laboratory setting; these two groups of participants spent similar time on four different lunch sessions, but generally, spoon users consumed more. These findings suggest that the choice of eating utensil likely affects users' eating rate.

2.2. Techniques to detect eating and provide feedback

Various devices exist to detect eating behavior, with a subset which provides feedback and intervention when necessary. The 10s Fork [15], a commercial smart fork mentioned earlier, can provide feedback on eating rate through vibration. The fork counts the time interval between each bite and vibrates when the interval stays within a programmed threshold. Hermans et al. [6,9] conducted a qualitative study on the 10s Fork to investigate user experience with the device and their attitudes regarding acceptability, and perceived efficacy. Hermans et al. [6,9] found the 10s Fork was comfortable to use and sufficiently accurate. However, participants felt they were not the target user and thus lacked the motivation to continue using it after experiment. Hermans et al. [7] also conducted a between-subject laboratory experiment on the effect of the 10s Fork; they found that the vibrotactile feedback on the 10s Fork could successfully reduce the number of bites per minute when users were eating quickly. However, that slower eating did not lead to a reduction in food consumption.

Kadomura et al. [17] introduced the Sensing Fork, a smart fork to recognize eating behavior and the color of food. To provide positive feedback on good eating behavior, the researchers also prototyped the Hungry Panda game [16]. This game provided users with visual feedback according to the eating behavior detected by the fork. In the second version of the game, the researchers addressed the issues of picky eating and distracted eating for Japanese children [18]. The longitudinal, in-the-field study showed that the system developed by Kadomura et al. was acceptable to the participating children and could potentially improve children's eating behavior [18].

Smartwatches have gained popularity as tools to promote and improve general health and wellness [26]. Thomaz et al. [30] presented a practical approach, which leveraged an inertial sensor from a smartwatch to identify eating moment of users; they conducted a semi-controlled lab study to train an eating moment classifier based on inertial sensor data, then validated the classifier in two in-the-wild studies. The inertial sensor was able to effectively detect user's eating behavior. Compared with other modalities such as first-person images captured by camera and acoustic sensing data captured by earbud, inertial sensing promises to be beneficial since it will not interfere with users' privacy [31]. Mirtchouk et al. [19] concluded that the combining of multiple sensing modalities and focusing on personal in-the-wild data could improve accuracy.

Several other devices have been used to measure food consumption. One such device, the Mandometer [11], employs a scale to assess food consumption by tracking the weight change of the meal and provides users with visual feedback on a smartphone. Using computer vision techniques also allows for the recognition of the food being eaten. This technique was applied to another device, SmartPlate [12]. Equipped with a weight tracking plate and a supplementary smartphone application, the SmartPlate analyzes the pictures of food, and provide visual data on meal. Devices such as Mandometer and SmartPlate require a weight scale and a smartphone.

2.3. Behavior digital interventions

Rose et al. [28] reviewed 27 studies on digital interventions for improving the diet and physical activity behaviors of adolescents. The digital interventions include web sites, text messages, games, multicomponent interventions, emails, and social media. The researchers found digital interventions that incorporate education, goal setting, self-monitoring, and parental involvement had a significant effect on behavior change.

Hermsen et al. [8] reviewed studies on digital technologies for changing habits and found that feedback generated through digital technology could effectively disrupt undesired habits.

2.4. Shape-changing interfaces

One way to modify behavior is through generating physical interference that limits users' movements. Al Maimani and Roudaut [1] explored the use of jamming technology, changing the stiffness of a suit to restrict users' body movement for a haptic game; they studied different material and particles for jamming and compared the size of patches of the suit in their experiment. Delazio et al. [4] introduced a wearable pneumatic interface to provide force and vibration to the upper body; they conducted a series of user studies to validate their approach and provided prototype applications in virtual reality. Pohl et al. [24] designed a pneumatic strap, which could provide compression feedback on the body. This device inhibits physical movements based on compression, and it was incorporated in a jogging game. These three approaches suggest that physical resistance generated in shape-changing devices, is feasible.

Regarding shape-changing interfaces design, Qamar et al. [25] reviewed material science and Human-computer Interaction (HCI) literature on various approaches for shape-changing device design, one of which being the use of pneumatic actuation. He et al. [5] introduced a pneumatic armband with tactile sensations and explored different possibilities for human-device interaction. To provide notifications, Pohl et al. [22] generated compression feedback from pneumatic actuation and an inflatable structure. They produced some prototypes to study the compression feedback, and compared compression and vibrotactile feedback [23]. Sareen et al. [29] introduced a design and fabrication technique for making pneumatic artifacts and showed that their interfaces are strong enough to withstand various weights. Several commercial eating utensils has the ability to be bendable, such as the Sure Hand Bendable Utensils [14]. It is an assistive device to aid older adults for dining food. To solve hand tremor issues, Liftware provides Liftware Steady and Liftware Level, two products to support people who experience limitations in mobility [13].

There are various technologies focusing on eating behavior, however, to date, there are no studies on applying pneumatic actuation to eating utensils. We plan to develop a utensil that can leverage a pneumatic interface to provide physical resistance to certain eating behavior.

3. Methodology

Our first goal is to validate the feasibility of embedding physical resistance into an eating utensil. We first conducted design brainstorm sessions to gather and compare different design ideas for the type of physical resistance used to intervene with a high eating rate. Based on these sessions, we decided on the shape-changing interface design, as a pneumatic actuation idea has not been explored thoroughly as an eating intervention. Also, a pneumatic actuation is safe in the eating context.

Our research team has been developing low fidelity prototypes (Figure 1) containing a small pump, a mini solenoid valve, and an air bag. The handle of the eating utensil is pneumatic, and can change its rigidity and shape by inflating and deflating. The inflating behavior of the device increases the air pressure of the pneumatic part, providing stiffness

to facilitate eating. Deflation the device reduces the rigidity of the handle to interfere with eating (See Figure 1, right image).
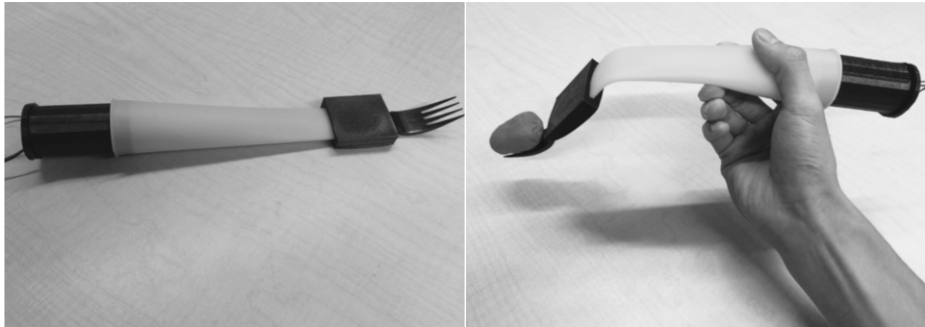
Figure 1. A very initial low fidelity prototype that shape-changes the utensil. It bends when deflated, thereby intervening with the eater's behavior.

4. Future work

As described above, although there are numerous devices that attempt to improve eating behaviors, there is a need for further exploration in identifying appropriate technological interventions for assisting with eating behaviors. For a future study, we plan to develop a prototype, which can detect eating behavior using a motion sensor, and provide various levels of physical resistance. When fast eating is detected, physical resistance should be applied via changing the stiffness and the shape of the device. The current prototype is approximately twice as a normal eating. Work is needed to reduce the device size for further studies.

Evaluation of the design will be based on the results of a series of experiments with a next-stage prototype. First, we plan to investigate the user experience as it relates to comfort and acceptability at various levels of physical resistance as the stiffness of the device changes. We will then conduct a study of the efficiency of this resistance in reducing eating rate to demonstrate the feasibility of our design idea and its potential effect for changing and improving people's eating behavior.

5. Conclusion

Eating is an important daily activity that is related to everyone's health. Improper eating behaviors can lead to various health issues such as fast eating rates have been shown to correlate with obesity [21], while a slow eating rate could reduce energy intake [27] and the risk of increasing BMI and obesity [21]. Existing approaches that introduce interventions to a user's eating behavior are either unobvious to the user, or dependent on extra devices. In our approach, we are proposing a design that embeds physical resistance into an eating utensil to help fast eaters reduce their eating rate. To verify the feasibility and effectiveness of the idea, we are building proof-of-concept prototypes that provide physical resistance to the user's eating behavior via changing the stiffness and shape of the device. To the extent of our knowledge, it would be the first prototype that leverages a pneumatic shape-changing interface to introduce physical resistance via an

eating utensil. Based on the prototype, we plan to conduct a series of user studies to assess the user's experience and prove the efficiency of the solution on reducing users' eating rate. We will evaluate our design based on the results of the experiments to investigate whether the physical resistance in eating utensils could help people reduce their eating rate.

Acknowledgement

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An Ontology Approach for Knowledge Representation of ECG Data

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Abstract. The number of features that can be extracted from ECG signals has increased with the advancement in signal processing techniques. At the same time, there is an increase in research efforts to support efficient and effective analysis and interpretation of these signals. In this paper, we propose the use of ontology for knowledge representation and discovery of ECG data. Given the lack of a widely acceptable standards, the use of ontology can support the establishment of common understanding of the kind of knowledge that can be extracted from the ECG data and shared among various heterogeneous systems. The proposed ontology is both platform and application independent. Furthermore, it is possible to enrich the proposed ontology with new knowledge that may not explicitly be expressed in the data.

Keywords. Ontology, Knowledge Representation, Semantic Web

1. Introduction

With recent progress in hardware development and information technologies as applied to the electrocardiogram (ECG) signal, increased attention has been paid to the development of computational intelligence (CI) techniques for signal representation and interpretation [1]. ECG Signal investigation can support medical practitioners in the diagnosis, in prognosis, and in follow up procedures. For instance, Hearth Rate Variability (HRV) analysis can help physicians in examining cardiac health as well as conditions related to the autonomic nervous system of patients [2].

A number of standards and formats have been proposed for ECG data storage. Most widely known open source digital formats include SCP-ECG[1], HL7 aECG[2], and DICOM Supp. 30[3]. All three formats are supported by Standard Development Organization (SDO) [3, 4]. The complexity and range of these formats make the process of developing integrated medical decision support systems a challenging task. Numerous mapping methods have been proposed to convert between formats. Options of exchange protocols include binary, eXtensible Markup Language (XML), and ontology-based protocols. While XML is widely accepted as a standard for representing and exchanging data, XML covers syntax and grammar levels, but not the semantic level of a given domain [5]. Furthermore, since most formats do not support storage of content or context meta-data in signals [6], the use of ontology has been proposed to provide semantic and

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[1] Standard Communication Protocol for computer assisted ECG

[2] Health Level 7 annotated ECG

[3] Digital Imaging and Communication in Medicine supplement 30

interoperable representation of ECG data [4]. The use of ontology affords the creation of application-independent representations [7]. Ontology is a representation of a domain in terms of concepts and relationships that can be communicated between people and heterogeneous and distributed systems [8].

Knowledge acquisition, coupled with the processing of biomedical signals, such as ECG, provides a valuable paradigm for advancing medical diagnosis. Furthermore, computerized interpretation of signals becomes very beneficial when it is understood by a human and may be examined easily in the form of what-if questions [1]. Proposing an ontology-based decision support system for ECG data augments medical knowledge by using interoperable semantic representations [2]. The rest of the paper is organized as follows. Section 2 provides an overview of ECG signals. Related research work is described in section 3. A brief description of the conceptual modeling based in ontology is presented in section 4. In section 5 we present the proposed implementation of our approach, and in section 6 we provide discussion and conclusion.

2. ECG and the Function of the Heart

The heart is a critical organ that functions as a pump to circulate blood in the body. A heartbeat represents a sequence of atrial contraction and relaxation followed by ventricular contraction and relaxation. The ECG is used to identify arrhythmia, and to indicate a disturbance in rate, rhythm, or conduction. Three basic waveforms represent the heart's electrical activity on the ECG monitor: P wave, QRS complex, and the T wave. Combined, they are called PQRST sequence. These waveforms are separated into segments and intervals, representing particular events in the depolarization-polarization cycle of the heart: PR interval, PR segment, ST segment, and QT interval. On the ECG graph, the horizontal lines measure the duration of the waveforms in seconds, while the vertical lines measure the voltage or amplitude of the waveform in millimeters. In a five-wire ECG system, two leads can be monitored using a lead selector on a monitor: leads placed on the arms and legs allow to view leads I, II, II, AVR, AVL, and AVF. A chest lead placed in a specific position allows to monitor lead V1 to V6 [9].

3. Related Work

Representing knowledge through an ontology construct has been proposed in various medical areas such as Electronic Medical Records (EMRs) [8], preoperative medical assessment [10], personal diabetic-diet recommendation [11], complex and chronic health conditions [12], and wellness recommendation systems [13].

In the domain of ECG signal representation and interpretation, most of the research efforts have been focusing on the use of ontology to support classification and diagnosis. For example, there is an ECG-based decision making system for evaluating the ECG and HRV properties related to a given person which leads to detailed information about the health quality level of that person [2]. There is a knowledge-based system for arrhythmia classification of ECG signals based on ontologies and feature extraction rules [14]. Another example is a methodology for developing an ontology for a patient profile in the complex and chronic health conditions domain [12]. A controlled vocabulary was developed to generate concepts representing the community perspectives of domain knowledge. Then an ontology was developed to present a patient profile to provide

deeper levels of semantic expressiveness. The use of ontologies and rules have been also proposed to classify annotated ECG signals into different arrhythmia types [14].

4. Conceptual Modeling and Ontology Design

Conceptual modeling is the process of describing a subject domain by analyzing and revealing, for particular purposes, entities, relations among them, any applicable constraints, and behaviors of entities [15]. Conceptual models are important tools for providing formal descriptions of various aspects of a given domain. Using an ontology language as a conceptual modeling grammar provides a method for including the semantics of the domain as part of the conceptual model, and can be subjected to automated processing and reasoning. Ontology languages have features not available in other existing conceptual modeling techniques. Specifically, ontology languages have features that enable representations of semantic relationships among domain concepts and domain rules [16]. According to [17] the use of ontologies in the biomedical field can be useful to formalize the design of models for connections between business representations and clinical, anatomical, and electrophysiological concepts. Also, the use of ontologies can offer interoperability capabilities and seamless translations of medial and technical knowledge. We can use ontology to check the quality of data by detecting unexpected incompleteness, or data inconsistencies [15].

5. Ontology Design Results

The block diagram of the proposed approach is shown in Figure 1.
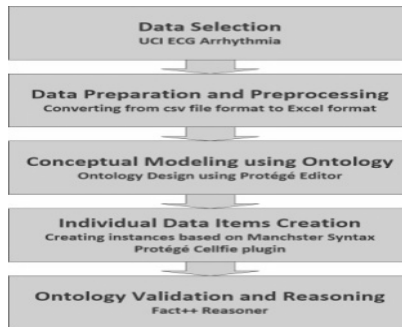
Figure 1: Block diagram of proposed approach

The Cardiac Arrhythmia Database obtained from the University of California at Irvine (UCI), machine learning repository, is used in this research [18]. The dataset has 279 attributes, 206 of which are linear and the rest are nominal. There are 452 instances and 16 classes. Class 01 refers to normal ECG, classes 02-15 refer to different classes of arrhythmia, and class 16 represent unclassified data. Missing values are denoted by the question mark symbol "?".

The ontology design consists of creating entities, object properties, data entities, instances and various axioms in order to establish required restrictions. There are two

kinds of relationships in domain ontology: association relation and instance relation. An association relation denotes a semantic link among concepts and among instances. An instance relation defines the link between concepts and their relative instances [2]. The design was created using Protégé 5.2.0 [19] the ontology editor.

Examining the dataset reveals that the data items represent information related to patients, arrhythmia classes, and ECG signal features. Furthermore the ECG features are grouped into general features and into common features for all the 12 channels in the signal. The ontology design starts with the creation of classes as shown in Figure 2a. Data properties are used to represent corresponding data items in the dataset as shown in Figure 2b. Each data property item defines a domain and a range. The domain indicates the class that this data item belongs to, and the range identifies the data type. For example, age is a member of *Patient* class and has *xsd:Integer* as a data type. The design also includes defining object properties, which are used to map relationships between instances in the dataset. For instance, *hasArrhythmiaClass* restriction allows a patient instance to be associated with a particular arrhythmia class. Object properties are shown in Figure 2c.

2 (a): Class hierarchy   **2 (b):** Data property hierarchy   **2 (c):** Data property hierarchy

Figure 2: Ontology Design using Protégé Editor

We can visualize the proposed ontology as shown in Figure 3 using OntoGraf plugin.

Figure 3: Graphic representation of the ECG ontology

In order to create instances to represent the data records for the patients, we used Cellfie, a plugin for Protégé. This plugin allows the creation of Ontology Web Language (OWL) axioms via a spreadsheet through flexible mapping based on Manchester OWL Syntax. Figure 4a and Figure 4b show the rules for adding individual patients and signal instances respectively.


```
Rule:

Individual: @A* (mm:prepend("p"))

Types: Patient

Facts:

age  @B* (xsd:Integer mm:replace("?",–99)),
sex  @C* (xsd:Integer mm:replace("?",–99)),
height @D* (xsd:Integer mm:replace("?",–99)),
weight @E* (xsd:Integer mm:replace("?",–99)),
hasArrhythmiaClass @JV*,
hasECGRecord @A* (mm:prepend("signal"))
```

```
Rule:

Individual: @A* (mm:prepend("signal"))

Types: ECG_Signal

Facts:

qrsDuration @F*  (xsd:Integer mm:replace("?",–99)),
prInterval @G*  (xsd:Integer mm:replace("?", –99)),
qtInterval @H*  (xsd:Integer mm:replace("?", –99)),
tInterval  @I*  (xsd:Integer mm:replace("?",–99)),
pInterval @J*( xsd:Integer mm:replace("?",–99)),
vectorAnglesOnFrontPlaneOfQRS @K* (xsd:Integer mm:replace("?",–99) ) ,
vectorAnglesOnFrontPlaneOfT @L* (xsd:Integer  mm:replace("?",–99)),
vectorAnglesOnFrontPlaneOfP  @M* (xsd:Integer mm:replace("?",–99)),
vectorAnglesOnFrontPlaneOfQRST @N* (xsd:Integer mm:replace("?",–99)),
vectorAnglesOnFrontPlaneOfJ @O* (xsd:Integer mm:replace("?",–99)),
heartRate @P* (xsd:Integer mm:replace("?",–99))
```

4 (a): Rule syntax for adding Patient instances.   **4 (b):** Rule syntax for adding ECG Signal instances

Figure 4: Rule Syntax

In the syntax code, $@A*$ references all rows in column *A* within the spreadsheet. For each object type, we map the corresponding data property to the corresponding column. For example, *age* is mapped to column *B* in the spreadsheet. The code iterates through all available rows. Missing values are encoded as "-99". The final result consists of an ontology with 145265 axioms, 16 classes, 38 data properties, 3 object properties, and 6344 individual counts. Furthermore, the ontology was validated for consistency and coherence using FaCT++ Reasoner.

6. Discussion and Conclusion

The ECG is a widely used method for monitoring and evaluating the functional status of the heart's electrical conduction system. Many formats and standards have been proposed for representing and storing ECG data. The lack of a common standard is challenge in developing and implementing medical decision support systems. In this paper, we presented an approach of using an ontology to represent and store ECG data. The use of ontology has the advantage of making the data representation readable by humans as well as machines. This approach of ontology design is still format specific, but it is application and platform independent; and it can be considered in the design of service-oriented healthcare applications.

While the proposed approach supports classifications and signal interpretations, our proposed approach also contributes to the development of knowledge representation and discovery in this area. The use of the proposed ontology can support the discovery of assertive and inferred facts about the data based on an investigative approach in the form of what-if analysis. For example, a physician may need to infer the relationship between age and certain ECG signal properties**.**

Future work includes the investigation and development of data mining techniques to support further knowledge discovery with respect to extracted data from ECG signals.

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Training as an Intervention to Decrease Medical Record Abstraction Errors Multicenter Studies

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Abstract: Studies often rely on medical record abstraction as a major source of data. However, data quality from medical record abstraction has long been questioned. Electronic Health Records (EHRs) potentially add variability to the abstraction process due to the complexity of navigating and locating study data within these systems. We report training for and initial quality assessment of medical record abstraction for a clinical study conducted by the IDeA States Pediatric Clinical Trials Network (ISPCTN) and the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) Neonatal Research Network (NRN) using medical record abstraction as the primary data source. As part of overall quality assurance, study-specific training for medical record abstractors was developed and deployed during study start-up. The training consisted of a didactic session with an example case abstraction and an independent abstraction of two standardized cases. Sixty-nine site abstractors from thirty sites were trained. The training was designed to achieve an error rate for each abstractor of no greater than 4.93% with a mean of 2.53%, at study initiation. Twenty-three percent of the trainees exceeded the acceptance limit on one or both of the training test cases, supporting the need for such training. We describe lessons learned in the design and operationalization of the study-specific, medical record abstraction training program.

Keywords. Data collection, data quality, chart review, medical record abstraction, clinical data management, clinical research informatics, clinical research

1. Introduction

We define medical record abstraction (MRA) as a process in which a human manually searches through an electronic or paper medical record to identify data required for

secondary use [1]. Abstraction involves direct matching of information found in the record to the data elements required for a study. Abstraction also commonly includes subjective tasks such as categorizing, selection of one value from multiple options, coding, interpreting, and summarizing data from the medical record as well as objective tasks such as transformation, formatting, and calculations based on abstracted data. The extent to which MRA relies on subjective tasks is variable and based on the design and operationalization of individual studies. Some studies constrain abstraction toward objective tasks while others rely to a greater extent on human interpretation and decision-making. Studies relying on data found in narrative parts of the record or on data equally likely to be charted in multiple places frequently require the latter. The subjective aspects of MRA differentiate it from other data collection methods in clinical research that are largely reliant on objective processes. Further, others have characterized medical record abstraction as having a higher cognitive load than other data collection and processing methods[2]. A pooled analysis of data quality among clinical studies relying on MRA found MRA to be associated with the highest rates of error in data collection and processing (mean 960, median 647, standard deviation of 1,018 errors per ten thousand fields)[3]. For these reasons, we gave special consideration to quality assurance and control of the MRA process.

As evidenced by historical and current regulatory guidance on the topic,[4, 5] the medical record remains a major source of data for clinical studies. Although many studies today can be conducted with electronically extracted data, smaller studies often do not have the resources to write and validate computer programs to extract data. Additionally, many data elements are not consistently collected or available in structured form and variations in definition, collection and charting of EHR data complicate manual abstraction and electronic extraction in multisite studies. Thus, Electronic Health Record (EHR) adoption does not obviate the need for MRA. Abstractors using EHRs as the data source must still manually search through the record to identify needed data values. EHR abstractors remain hampered by many of the same issues affecting abstraction from paper charts. Further, MRA remains a primary method for validating algorithms for electronically extracting data from healthcare information systems[6]. Thus, for the foreseeable future, many studies will continue to rely on data abstracted from medical records.

Given the continued reliance of clinical studies on MRA and high MRA error rates, data accuracy from MRA remains a concern. To address the concern, a recent review produced a systems theory-based framework for data quality assurance and control of MRA processes[1]. We have applied the framework on a clinical study conducted by the National Institutes of Health, Environmental influences on Child Health Outcomes (ECHO) Program's IDeA States Pediatric Clinical Trial Network (ISPCTN)[7] and the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) Neonatal Research Network (NRN) and report results from the initial phase of that implementation.

2. Background

2.1. Data Accuracy from the Medical Record Abstraction Process

Data have been abstracted from medical records since the earliest days of medical record keeping. Concern about quality of data abstracted for secondary use from medical records dates back at least to the year 1746 [8].

Many have questioned the accuracy of data abstracted from medical records. As early as 1969, researchers described the association of MRA with poorly explained processes, inconsistency, and error[9, 10]. Notable reports have continued to question medical records as a data source [11-14] and recent reviews have confirmed persistence of error rates that call into question the fitness of data abstracted from medical records for secondary use [3, 15, 16].

To detect and correct abstraction errors in clinical trials regulated by the United States Food and Drug Administration, clinical trial monitors routinely visit study sites and compare data on the collection form to the medical record in a process called source data verification. However, MRA data error rates are usually not measured in this process. Thus, they are neither documented nor presented with the analysis. In general, risk-based monitoring [17] decisions about which sites, cases, and data to monitor are made *sans* quantitative data quality evidence. Likewise, MRA error rates are rarely reported in secondary analysis studies. In a recent review, less than 9% of included studies reported an error or discrepancy rate, 0% of the included studies stated the source of data within the medical record, half failed to mention abstraction methods or tools, and only 42% mentioned training or qualification of the abstractors [1]. Thus, Feinstein et al.'s 1969 intimation that medical record reviews are, "governed by the laws of laissez faire" remains characteristic [10].

2.2. The Medical Record Abstraction (MRA) Quality Assurance Framework

Zozus, et al. first introduced the MRA Quality Assurance and Control framework in 2015 and provided evidence-based guidelines for ensuring the accuracy of data abstracted from medical records [1]. The framework treats MRA as a system with inputs and outputs. Some inputs to the MRA system such as abstractor training and abstraction guidelines are controllable while others such as the quality and content of the medical record are not. Research teams use ongoing measurement of MRA system outputs, i.e., data accuracy or some surrogate thereof, to indicate when changes to controllable inputs are needed to achieve a more desirable result. A system is considered capable when changes in controllable inputs are sufficient to achieve the desired result – some systems by design are not capable. In the case of a clinical study reliant on abstraction, lack of capability occurs when the data in the medical record are frequently missing, highly variable, or so poorly documented that they cannot be reliably or accurately abstracted.

The systems theory-based framework describes two essential mechanisms to achieve the desired data accuracy from MRA: (1) quality assurance — prospective actions taken such as abstractor training, standard procedures, and job aids to assure adequate accuracy, and (2) quality control — measurement of error or discrepancy rates and use of the measurements to guide adjustments to controllable inputs to the abstraction process such as abstraction tools, procedures, and training. The framework describes four areas where *a priori* activities to assure data accuracy should be

considered: 1) choice of the data source within the medical record, 2) abstraction methods and tools, 3) abstraction environment, and 4) abstractor qualification and training.

In the MRA system, re-abstraction by the same or different person to identify discrepancies, intra- or inter-rater reliability respectively, is used as a surrogate for data accuracy. The feedback, then, consists of data discrepancies that are reported to the abstractors or otherwise used to inform changes to the controllable inputs to decrease the discrepancy rate. Thus, the re-abstraction, actually a measure of reliability, is used as a quantitative and surrogate indicator of data accuracy as feedback to control the abstraction error rate. Use of intra- or inter-rater reliability as a surrogate measure of accuracy is not without consequence. In an area such as MRA, where the underlying data source is characterized by inherent variability and uncertainty, it is possible to force consistency at the expense of accuracy.

In this study, we aim to demonstrate, describe and report operational challenges encountered in implementing initial abstractor training and assessment as a quality assurance measure in clinical study relying on abstracted data.

3. Methods

This observational and empirical study was conducted in the context of the Advancing Clinical Trials in Neonatal Opioid Withdrawal Syndrome Current Experience: Infant Exposure and Treatment study (ACT NOW). Briefly, the ACT NOW CE study is an observational study of clinical practice in Neonatal Opioid Withdrawal Syndrome (NOWS). The ACT NOW CE study is conducted in units across all levels of neonatal care from well born nurseries to intensive care units at thirty clinical sites across the United States. ACT NOW CE data are collected through medical record abstraction performed locally at participating sites. The study is being conducted to characterize and quantify variability in current clinical practice, and to identify associations to be tested in future studies — all toward improving NOWS treatment outcomes. To assure data quality, training in the medical record abstraction process for the study was designed and implemented. Timing of the training and short study start-up time drove differences in planned versus delivered training.

Training as Designed: The planned training included the following. (1) A pre-training exercise in which sites used the ACT NOW CE abstraction guidelines to abstract two cases from their EHR. (2) A didactic portion where the trainer facilitated discussion of challenges sites faced in the abstraction of the two pre-training cases and then walked through a complete abstraction of a training case. The training was assessed through (3) an assignment to independently abstract two standardized training cases. Trainee abstraction of the two standardized training cases was reviewed by the data coordinating center. The number of errors was to be counted and feedback on errors was to be provided to the trainee. If the acceptance criterion was exceeded, the trainee was to be provided with two additional standardized cases to abstract. If the acceptance criterion was not be met within six cases, the plan was to seek a different person at the site to serve as an abstractor.

Training as Delivered: The training was altered in response to operational challenges. As delivered, the training contained no pre-training exercise (1 above) and included the following. (2) The didactic portion of the training consisted of the trainer reviewing the abstraction form with trainees and discussing anticipated abstraction

challenges. This included demonstration of abstraction for key data using a standardized training case. For ISPCTN abstractors, because the ISPCTN is a new network, the training was assessed through (3) an assignment to independently abstract two standardized cases as stated above. Similarly, the abstraction for the two standardized cases was reviewed and the number of errors counted. Trainees were told the number of errors but did not receive individual feedback regarding the errors they made. If the acceptance criterion was exceeded, the trainee was provided one, rather than the planned two, additional standardized cases to abstract.

To assure transfer of training, the training was followed by an independent re-abstraction of the first three ACT NOW CE study cases. Discrepancies between the original abstraction and the independent re-abstraction were programmatically identified through the web-based Electronic Data Capture (EDC) system for the study. The same acceptance criterion used in the training was applied (an average of less than four discrepancies per case, fewer than twelve discrepancies across the three re-abstracted cases). Following the re-abstraction, a call was held to review the discrepancies. The independent local abstractors were also required to attend the medical record abstraction training and meet the acceptance criterion.

Because large differences in error rate calculations have previously been demonstrated in the literature,[18, 19] we use the error/discrepancy rate calculation method described in the Good Clinical Data Management Practices (GCDMP)[20] and similarly defined an abstraction error or discrepancy as any meaningful difference in the abstracted value and the standard or re-abstracted value unless ambiguity in the abstraction guidelines was found to be the cause. Further, we calculated error/discrepancy rates using all fields on the abstraction form as well as using only populated fields on the form. The latter uses only fields populated with data as the denominator and provides a conservative point estimate of the error/discrepancy rate. Calculating both "all field" and "populated field" rates provides both an optimistic and a conservative measurement.[19] Data from training cases were documented to evidence study training and abstractor qualification for compliance with Good Clinical Practice.[4]

This study of a training intervention (IRB#217927) consisted of (1) secondary use of EHR data at our institution to create the seven standardized and redacted training cases based on real patients with NOWS cared for in a neonatal intensive care unit, and (2) secondary analysis of abstraction error rates on the cases used in training. This training study received a determination of not human subject research as defined in 45 CFR 46.102 by the University of Arkansas for Medical Sciences Institutional Review Board (IRB).

A confidence interval approach was used to assess point estimates of the error rate. The ACT NOW CE study data collection form contains 258 fields. To set the acceptance criterion, we conservatively estimated 316 relevant fields for two abstracted cases. If eight errors are found across the two standardized training cases (2.53% error rate), the corresponding 95% confidence interval using Pearson's exact is (1.10, 4.93). The goal of training was to achieve an error rate for each abstractor of no greater than 4.93%. Error rates were assessed at both the abstractor level and at the overall, across all abstractors. Error rates are normalized to errors per 10,000 fields for comparisons across cases having differing numbers of fields. The actual field count for the ACT NOW CE abstraction form is 317 fields. This field count was used for the "all field" error rate. The denominator for the error rate calculation is the number of trainees (69) multiplied by the number of fields on the abstraction form for a total denominator of

21,873 fields. The actual number of fields populated on the standardized cases was, 64 and 71 fields for cases one and two respectively. The denominators for the "populated field error rates" were similarly calculated using these field counts.

4. Results

4.1 Error rate results

The error rate across all abstractors (Table 1) fell within expectations and was below the average MRA discrepancy rate reported in a recent pooled analysis[3]. In total, sixty-nine site abstractors including those designated as re-abstractors for the quality control process were trained. Two hundred and eight errors occurred on training case 1 across all abstractors and three hundred and fifty-five errors occurred on training case 2 across all abstractors. The acceptance criterion for individual abstractors was exceeded twice for case 1 and sixteen times for case 2. Of note, the patient in case 1 did not receive any pharmacologic treatment whereas case 2 did receive pharmacologic treatment. The latter pharmacologic case was designed to be more difficult to abstract. As expected, abstractors considered it so.

Table 1: Overall Error Rate Estimate Range

Training Case	Errors	All Field Error Rate* (95% Conf. Interval)	Populated Field Error Rate* (95% Conf. Interval)
1	208	95 (83, 109)	471 (410, 538)
2	355	162 (146, 180)	725 (654, 801)

*Error rates are normalized to errors per 10,000 fields.

Overall, 16 (23%) of the trainees exceeded the acceptance limit - greater than eight errors across both of the standardized training cases (Figure 1). These trainees went on to complete one or more additional standardized training cases. Figure 1 shows the distribution of number of trainees with each error count in case 1, case 2, and across both training cases combined. Both the mean and range of the number of errors per case were higher in case 2.

Solicited and informal responses from trainees, data coordinating center staff, and study leadership in face-to-face meetings, email, and teleconference settings were generally supportive of the assertion that the abstraction training was helpful. The coordinating center found the training helpful in setting the expectation for consistency and revealing areas of ambiguity in the abstraction guidelines as well as differences in clinical process and documentation across the sites. However, development and provision of the training also encountered challenges. These challenges and feedback from the aforementioned stakeholders informed updates to the abstraction guidelines and data collection form.

4.2 Ambiguity and gaps in the abstraction guidelines identified through the training

The training identified instances of inconsistency and ambiguity in the abstraction guidelines. The training surfaced several examples of data commonly documented in multiple places in the EHR such as values charted in flow sheets as well as progress
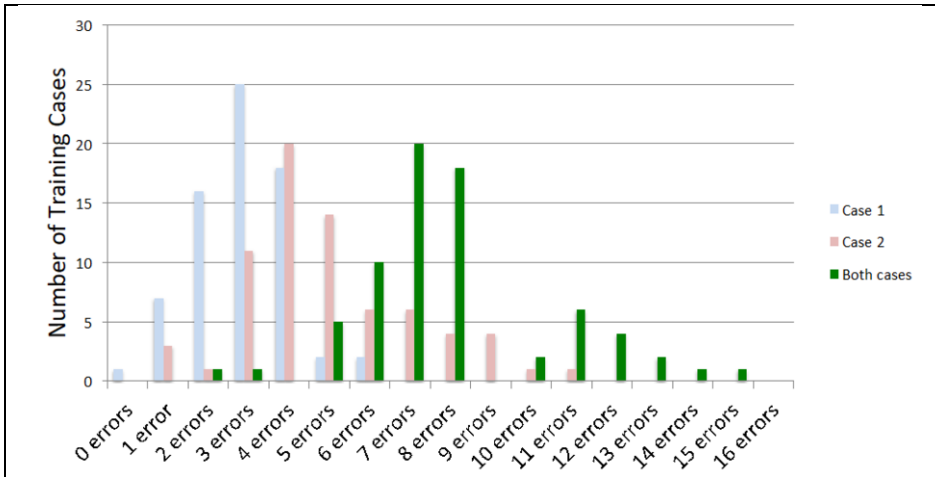
Figure 1: Frequency Distribution: Errors Across Trainees for the Two Training Cases
The "Both cases" category in the figure is the sum of errors across both cases by trainee.

notes and summaries. Usually, there was a preferred source or location for the information. For example, non-pharmacologic support information from the flow sheet was deemed closer to the original capture and more contemporaneous with the time of observation and therefore preferred over the same information that may also be documented in nursing or physician notes. Charting practices varied by site. Another site-to-site difference that the training surfaced concerned differences in receipt and documentation of prior care for babies transferred from other facilities. Babies transferred into some study site facilities are accompanied by paper records and typically lacked maternal information. When sent, these paper records are scanned and uploaded into the EHR by some facilities. Scanned records are harder to find and information contained within are usually not directly searchable, necessitating reading every page in order to abstract the case. Further, some participating facilities transferred the babies back to the referring institution upon discharge. Transfer in and transfer out of the site's facility led to, at a minimum, more tedious and time consuming abstraction, and in some cases, inaccuracies in the data abstraction process and missing data. The research team identified that it was unclear to abstractors whether transfers to other institutions should be considered discharges or not despite this being defined in the abstraction guidelines. The training also surfaced differences in the definition of nonpharmacologic care and discharge planning processes. Finally, the training surfaced variability in EHR implementation and use at sites with respect to the percentage of the study data found in structured form versus text notes. Additional examples are enumerated in the appendix.

4.3 Operational challenges encountered in delivering abstraction training

We also encountered challenges delivering the training as designed. Differences between the planned training and the training as delivered are described in the methods section. The example abstraction of key data in the didactic portion of the training and the standardized training cases were based on the Epic EHR and were not as helpful to

sites using other EHRs. Further, the standardized training cases used real and redacted data; abstracting from redacted cases was not reflective of abstraction in the real world. The team manually creating and reviewing the standardized training cases did so by pulling data from multiple patients; trainees detected errors in the initial training cases such as more than one gender being listed and babies' weights remaining static for multiple days. These errors distracted and confused trainees and emphasize the importance of careful test case preparation for MRA training. Following the training, due to time constraints, the coordinating center team provided written feedback involving the trainees' score and common errors, rather than detailed individual feedback for the trainee or site to reinforce the abstraction guidelines. An additional implementation challenge concerned the timing of the training. The start-up time was very compressed and successful completion of the training was required prior to starting the study at IDeA State sites. The training was designed with a pre-training exercise for sites to abstract two cases from their local EHR. The purpose of this activity was to ensure that sites attended the training session prepared with problems encountered using the abstraction guidelines to abstract from their local EHR; in particular, to help identify instances of the abstraction guidelines being too general or the presence of study data requirements which could not be met through the local EHR. Multiple sites were not able to do this as the training was done during site start-up. Many sites did not yet have IRB approval and were not able to use existing data for training in this way.

Multiple site study coordinators commented that the QC process following the training was more helpful than the standardized cases. The QC process consisted of local re-abstraction of real study cases using the local sites' EHR followed by individual feedback.

4.4 Resources required to develop and operationalize the training

Resources required to undertake the training were significant. Creation of the seven training cases necessitated a secondary data use application to the central IRB for the study taking five hours to write and submit. Creation of the standardized training cases took 54.25 abstraction hours plus 7 hours for double independent manual review of the redaction on the cases. Clinical operations staff at the coordinating center spent additional time preparing the training. Each of the sixty-nine trainees attended or viewed the training and spent an estimated two hours per abstraction case. Clinical operations staff at the coordinating center then spent an average of twenty-five minutes reviewing the abstracted training cases and identifying errors. Successful completion of the training was required prior to a site starting the study. To support independent abstraction for during-study quality control, two trained abstractors were required at each site. Training in abstraction added to the burden of other required trainings and occurred during the hectic start-up time period of the clinical study.

5. Discussion

Abstraction error rates of 95 and 162 errors per 10,000 fields on the two standardized training cases are favorable compared to an earlier pooled analysis (mean 960, median 647, standard deviation of 1,018 errors per ten thousand fields)[3]. We use the "all

fields" error rate because this is most comparable to how the rates for the earlier pooled analysis were calculated. Possible reasons for the favorable comparison include (1) the presence of detailed abstraction guidelines, a corresponding structured abstraction form and detailed training, (2) trainee awareness that the abstraction error rate on the training cases would be measured, and (3) the ACT NOW CE study abstraction may have been easier on average than studies in the pooled analysis. Further, the error rate on the standardized training cases is a snapshot of the first two cases for each abstractor. Thus we expect the true process capability (error rate) lies below this.

Choosing the acceptance criteria required balancing: (1) requiring an error rate that would not adversely impact study conclusions, (2) keeping the training time as low as possible, and (3) including enough cases to decrease uncertainty in the point estimate. Our choice of using two standardized training cases in the initial batch, and an acceptance criterion of eight or fewer errors across the two standardized training cases provided reasonable assurance that the error rate for each abstractor would not likely be greater than 4.93%, the upper limit of the 95% confidence interval. This acceptance criterion has face validity in that it seems obtainable given the recent pooled analysis[3] and is low enough such that we would not expect an adverse impact on the intended analysis. Further, abstraction of two training cases was estimated at study onset to take between two and four hours per case. Thus, the estimated training burden and time delay was acceptable to the study team. It is important, however, to be clear that the point estimate and associated confidence intervals achieved by this approach are for the overall abstraction error rate, i.e., over all fields on the data collection form. Achieving reasonable confidence intervals for only the subset of fields used for any specific analysis of the ACT NOW CE data would have required significantly more training cases. Indeed, error rate acceptability was based on the overall error rate and conclusions as to the acceptability of the error rate of any one data element would have considerably higher uncertainty.

Sites expressed that they would have preferred abstraction training using their in-house EHR. However three problems arise with this approach: (1) the need for short study start-up time necessitated training prior to IRB approval at a site, yet data could not be accessed at sites prior to IRB approval, (2) training on the local EHR would require either the trainer to be expert in all site EHRs or use of a local independent assessor to detect abstraction discrepancies, and (3) using local independent assessors sacrifices the ability to measure accuracy. Using standardized cases permits measurement of accuracy as opposed to reliability between two independent raters equally likely to be in error. Whereas training using local site EHRs is possible in a single site study or a study in multiple facilities with similar implementations of the same EHR, it is less feasible in a large multi-center study. Given this limitation, the need for abstraction training, and the desire for an accuracy as well as reliability assessment, we suggest the following training process.

(1) Standardized cases are prepared using an example EHR and the abstraction form.

(2) A trainer discusses and demonstrates each component of the abstraction guidelines on an example standardized training case., for site abstractors and re-abstractors.

(3) A small number of standardized training cases are distributed to trainees, abstracted by trainees and graded with feedback on errors provided to each trainee. The error rate is used to qualify abstractors and abstractors must meet a

study-specific acceptance criterion on the standardized cases prior to abstracting for the study.

(4) Following IRB approval at each site, a representative sample of charts is abstracted by the designated site abstractor and re-abstracted by an independent abstractor at the site.

(5) The abstraction and re-abstraction are compared and reviewed with the abstractor, the re-abstractor and the coordinating center. The discrepancy rate is quantified, and discrepancies and their root causes are discussed to reinforce training and improve the abstraction guidelines.

This proposed abstraction training process preserves the ability to assess accuracy and abstraction guidelines as early as possible as well as shifts as much training as possible prior to IRB approval. The process also provides for a monitored transition to abstraction from the local site EHR and ability to asses performance of the abstraction guidelines across site-to-site and EHR-to-EHR variability prior to study start.

6. Limitations

Our results are observational. We were able to standardize the abstraction process, guidelines and form, however, as is the case in most multi-center studies no control could be exerted over the local site EHRs or clinical documentation practices. With respect to the training, the standardized cases used were created from our EHR and thus, the accuracy measurement may not have been representative of accuracy of abstraction from the local site's EHR, i.e., a threat to the validity of the accuracy measurement. Threats to generalizability include our results representing medical record abstraction training for only one study in one clinical area. The percentage of study data available in EHRs varies by institution and clinical specialty and individual study as do the location of data within the EHR and the processes by which they arrive there. However, the challenges and lessons learned in developing and delivering medical record abstraction training in the context of a multi-center study are not dependent on the study or clinical specialty.

7. Conclusions

Given the twenty-three percent of trainees exceeding the acceptance criteria, the training and quantification of the error rate was deemed necessary to assure that data are capable of supporting study conclusions. Though few studies report active quality control of medical record abstraction or associated discrepancy rates, given the results of the previously reported pooled analysis and our own early training experience, i.e., the magnitude and variability of the error rate, we deemed the planned ongoing independent re-abstraction and measurement of inter-rater reliability on a sample of cases throughout the study to be necessary. Based on the literature and our experience here, we recommend undertaking MRA training for multi-center studies that rely on data abstracted from medical records.

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Appendix: Operational lessons Learned

1. We initially wanted training cases from three institutions so site-to-site variability would be reflected in the standardized training cases. One of the institutions did not have the time to submit to their IRB for approval for secondary use of data to create the cases or to create the training cases. Two institutions created de-identified, standardized mock cases for training. Training cases were provided hard-copy and from the two institution's EHRs. rather than training on cases from multiple EHRs.

2. Study coordinators at the coordinating center were used to create the standardized training cases. Directions to the study coordinator were not sufficiently clear and suffered from the following problems: (1) The initial cases consisted of printed "evidence" to support the completed data collection form rather than a representation of the full chart from the NICU stay. (2) In remediating the first issue, because the cases had been redacted, it was not possible to locate the initial example in the EHR and the case was filled-in with pages from other patients. This caused inconsistencies in gender and care progression across the initial two cases that required further correction. (3) Items were missed in redaction despite two independent reviews of redaction. Because of quality issues with consistency and redaction of the cases, additional redaction work on the cases was required.

3. The initial training plan was designed based on sites abstracting two cases from their institutional EHRs and following the study abstraction guidelines prior to the training. The purpose was that trainees would come to the training sessions with questions. Because sites were in start-up at the time of the training, most training occurred prior to IRB approval for each site. Thus, sites were not able to do the pre-training assignment and entered the training, in some cases, without having attempted to use the abstraction guidelines.

4. There were significant concerns from the study team that the training would delay study start-up. More time upfront and better planning would have allowed more notice to sites and prevented site start-up delays due to the training. Providing time on task estimates to trainees/sites in advance would have also helped sites plan time for the training.

5. In the training, we encountered several cases where abstractors who care for NOWS babies regularly had difficulty with adhering to the abstraction guidelines. Based on discussions with the abstractors and clinical operations at the coordinating center, we have come to believe that the abstractors relied on their clinical knowledge rather than the abstraction guidelines. We note that the 2015 review and Delphi process also uncovered the debate over advantages and disadvantages of using clinical abstractors.[1] Based on our experience to date, we as well remain undecided on the issue. The solution proposed by one study abstractor was to state explct operationalizations as definitions of key data items, such as "rooming in" or other non-pharmacological interventions.

6. Abstraction trainees were provided their error rate and general "common mistakes and problems". Due to tight start-up timelines and concerns about the abstraction

training delaying study start-up, most abstractors did not receive individualized feedback on their specific errors.

7. Sites distributed abstraction tasks differently. PIs at some sites took the training with the intent of serving as the independent abstractor for the study. Most sites provided study coordinators and research nurses, while others sent research assistants who enter data to the abstraction training. A statement of the intended and target audience, as well as pre-requisite knowledge such as knowledge of the local EHR or chart at the site and knowledge of local clinical documentation practices, would have helped sites select abstractors. Though this would not alleviate the variability of personnel skills or the need to assign available people where availability of experienced abstractors is limited.

8. The abstraction training revealed gaps in the abstraction guidelines. The gaps were provided to the study PIs who chose which to incorporate. In all, nine changes to the abstraction guidelines were suggested based on the training experience. We include these and others that have arisen since.

    a) Both test cases were deliveries of a caucasian female with no mention of ethnicity. Some sites selected "Not Hispanic or Latino" vs. "Unknown or Not Reported". We emphasized in the abstraction guidelines that if the medical record did not document ethnicity, it should be recorded on the data collection form as "Unknown or Not reported".

    b) A related situation occurred regarding the baby's race. Multiple sites recorded the mother's race where the baby's race was not found in the record. The data collection form was updated to only require the mother's race.

    c) The data collection form asks sites to select the location/nursey type: (Level 1,2,3,4 or pediatric unit). The most common deficiency was that sites did not select all locations where the infant(s) received care. The abstraction guidelines were updated to emphasize (bolded and underlined) "ALL".

    d) The data collection form asks if there were any diagnoses recorded in the medical record that may have contributed to a lengthened hospital stay other than NOWS, and the most common non-NOWS factors selected are: social, hyperbilirubinemia, and respiratory illness. Hyperbilirubinemia and/or respiratory illness may have initially been a problem list item, however, was resolved early during the subject's hospital stay. The most recent guidelines had already clarified how to handle this situation.

    e) The maternal section of the data collection form asks if the prenatal care was adequate, inadequate, none, or unknown. The EHR documentation for training case 001, stated that prenatal care was limited. Many trainees selected "Inadequate" vs. "unknown". The MOP defines inadequate prenatal care as less than 3 visits or prenatal care started in the 3rd trimester. The abstraction guidelines at the time stated that, "if the only information was the word limited, unknown should be selected". No further updates were made.

    f) The non-pharmacologic section of the data collection form requires selection of the non-pharmacologic support the infant received from the following list: Rooming-in, Clustered care, Swaddling, Kangaroo Care/Skin-to-Skin, Low Lights, reduced noise, Parental Education, Non-Nutritive Sucking/Pacifier. …. Some abstractors left this section blank or indicated minimal support. These items are typically found in the flowsheet assessments and progress notes/record. The abstraction guidelines and training were updated to indicate the values from the flow sheets as the primary source and notes secondary.

g) The Scoring/Assessment System section of the data collection form requires indication of the assessment system. Both training cases did not state which assessment tool was used, however, scores were provided. Because this is generally a facility-level decision, we assume that hospitals only use one scoring system and know the system. Therefore, where not stated in the EHR, the data collection form may serve as the source docment for this data. We assume that facilities can produce documentation of an institutional decision to use a particular scoring system.

h) The data collection form asks, "Where was the infant discharged or transferred to" and uses the following response list: home with parent, home with relative, home with foster parent, transferred to another hospital, or transferred to outpatient treatment center. For training case 2, it was not documented in the test EHR data with whom and to where the infant was discharged. Most abstractors indicated that the infant was discharged with the parent. Unknown was not an option for version 3.0 of the data collection form. The data collection form was updated to replace "home with foster parent" as a response option with "home with foster/adoptive parent". "Other, specify" was added as an option for this question in the subsequent version of the data collection form.Abstraction training and guidelines were modified and updated training emphasized referencing the abstraction guidelines.

i) In the same section, the data collection form asks whether outpatient follow-up was planned/scheduled prior to discharge. For training case 001, the discharge follow up was scheduled with Dr. [REDACTED] at the [REDACTED neighborhood name] Clinic. Most abstractors selected, "Primary Care Physician" vs. "Neonatal Follow up Clinic or "Other, specify". The abstraction guifelines and training were updated to emphasize that information not explicitly stated in the EHR should be reported as unknown.

j) A post-training question arose regarding classification of infants born in an ambulance enroute to the hospital. The abstraction guidelines define infants born in an ambulance as outborn.

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Subject Index

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545

Author Index

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