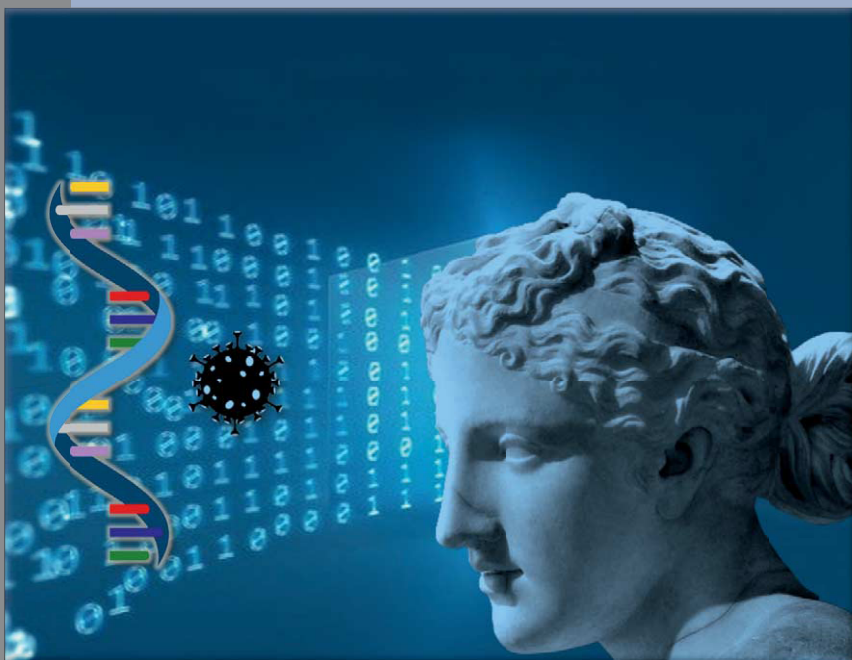


The Importance of Health Informatics in Public Health during a Pandemic



Editors: John Mantas
Arie Hasman
Mowafa S. Househ
Parisis Gallos
Emmanouil Zoulias

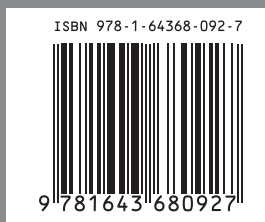
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The COVID-19 pandemic has increased the focus on health informatics and healthcare technology for policy makers and healthcare professionals worldwide.

This book contains the 110 papers (from 160 submissions) accepted for the 18th annual International Conference on Informatics, Management, and Technology in Healthcare (ICIMTH 2020), held virtually in Athens, Greece, from 3 – 5 July 2020. The conference attracts scientists working in the field of Biomedical and Health Informatics from all continents, and this year it was held as a Virtual Conference, by means of teleconferencing, due to the COVID-19 pandemic and the consequent lockdown in many countries around the world.

The call for papers for the conference started in December 2019, when signs of the new virus infection were not yet evident, so early submissions were on the usual topics as announced. But papers submitted after mid-March were mostly focused on the first results of the pandemic analysis with respect to informatics in different countries and with different perspectives of the spread of the virus and its influence on public health across the world. This book therefore includes papers on the topic of the COVID-19 pandemic in relation to informatics reporting from hospitals and institutions from around the world, including South Korea, Europe, and the USA.

The book encompasses the field of biomedical and health informatics in a very broad framework, and the timely inclusion of papers on the current pandemic will make it of particular interest to all those involved in the provision of healthcare everywhere.



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THE IMPORTANCE OF HEALTH INFORMATICS IN PUBLIC HEALTH DURING A PANDEMIC

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The Importance of Health Informatics in Public Health during a Pandemic

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Preface

This volume contains the accepted papers of the ICIMTH (International Conference on Informatics, Management, and Technology in Healthcare). The Scientific Programme Committee presents to the academic and professional community of Biomedical and Health Informatics the scientific outcomes of the ICIMTH 2020 Conference, which was held virtually from 3 to 5 July 2020 in Athens, Greece.

The ICIMTH 2020 Conference is the 18th Annual Conference in this series of scientific events, gathering scientists working in the field of Biomedical and Health Informatics from all continents.

This year the Conference was held as a Virtual Conference, by means of teleconferencing interactive platforms and equipment, due to the COVID-19 pandemic and the consequent result of lockdown of most of the countries in the world.

The call for papers started early, from December 2019, when no sign of the new virus infection was evident. During the first appearance of the virus in China in mid-January, until mid-March when it first appeared in Italy, most papers submitted were on the usual topics as announced on the Call for Papers. Papers collected after mid-March until early May were mostly focused on the first results of the pandemic analysis with respect to informatics at different countries and with different perspectives of the spread of the virus and the influence on Public Health across the world. So, we are proud in these proceedings to have included papers on the topic of the COVID-19 pandemic in relation to Informatics reporting from different hospitals and institutions of the world from South Korea, to Europe, and the USA.

We are examining the field of Biomedical and Health Informatics in a very broad framework, presenting the research and application outcomes of Informatics from cell to populations, including a number of technologies such as Imaging, Sensors, and Biomedical Equipment and Management and Organisational aspects, including legal and social issues and setting research priorities in Health Informatics. Essentially, Data, Informatics, and Technology inspire health professionals and informaticians to improve healthcare for the benefit of patients.

It should be noted that the Proceedings are published as Open Access with e-access for ease of use and browsing without losing any of the advantages of indexing and citation in the biggest Scientific Literature Databases, such as Medline and Scopus, that the series of Studies in Health Technology and Informatics (SHTI) of IOS Press provides.

At the end of the deadline we had 160 submissions, from which after reviewing we have accepted 110 as papers to be included in the volume proceedings.

The Editors would like to thank the Members of the Scientific Programme Committee, the Organising Committee, and all Reviewers, who have performed a very professional, thorough and objective refereeing of the scientific work in order to achieve a high-quality publishing achievement for a successful scientific event.

Athens, 30.05.2020

The Editors,

John Mantas, Arie Hasman, Mowafa S. Househ, Paris Gallos and Emmanouil Zoulias

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Contents

Preface	v
<i>John Mantas, Arie Hasman, Mowafa S. Househ, Parisis Gallos and Emmanouil Zoulas</i>	
Scientific Programme Committee and Reviewers	vii
Unsupervised Machine Learning for the Discovery of Latent Clusters in COVID-19 Patients Using Electronic Health Records	1
<i>Wanting Cui, Daniel Robins and Joseph Finkelstein</i>	
Application of Social Network Analysis of COVID-19 Related Tweets Mentioning Cannabis and Opioids to Gain Insights for Drug Abuse Research	5
<i>Sunmoo Yoon, Michelle Odlum, Peter Broadwell, Nicole Davis, Hwayoung Cho, Nanyi Deng, Maria Patrao, Deborah Schauer, Michael E. Bales and Carmela Alcantara</i>	
E-Health in Norway Before and During the Initial Phase of the Covid-19 Pandemic	9
<i>Rolf Wynn</i>	
Setting up an Easy-to-Use Machine Learning Pipeline for Medical Decision Support: A Case Study for COVID-19 Diagnosis Based on Deep Learning with CT Scans	13
<i>Aikaterini Sakagianni, Georgios Feretzakis, Dimitris Kalles, Christina Koufopoulou and Vasileios Kaldis</i>	
Evidence-Based Health Intelligence with Globally Localized Epidemic Knowledge Base: Merging Pathological Data, Socio-Environmental Data and Intervention Knowledge Data	17
<i>Eun Kyong Shin and Jong Hun Lee</i>	
Epidemiological Analysis of the Covid-19 Epidemic in Greece	21
<i>Stelios Zimeras, Konstantinos Chardalias and Marianna Diomidous</i>	
Application of Topic Modeling to Tweets as the Foundation for Health Disparity Research for COVID-19	24
<i>Michelle Odlum, Hwayoung Cho, Peter Broadwell, Nicole Davis, Maria Patrao, Deborah Schauer, Michael E. Bales, Carmela Alcantara and Sunmoo Yoon</i>	
200 Years Since the Birth of Nursing Informatics?	28
<i>Helen J. Betts and Graham Wright</i>	
Remote Monitoring of Patients in Quarantine in the Era of SARS-CoV-2 Pandemic	33
<i>Irene Karampela, Markos Nikolopoulos, Evangelos Tzortzis, Theodora Stratigou, Georgios Antonakos, Marianna Diomidous and Maria Dalamaga</i>	

Safety Justification of Healthcare Applications Using Synthetic Datasets <i>George Despotou, Stuart Harrison, Sean White and Theodoros N. Arvanitis</i>	35
Lessons Learned: Implementation of a Nationwide Innovative E-Learning Module for Health Enabling Technologies <i>Joana M. Warnecke, Ju Wang and Thomas M. Deserno</i>	39
The Mishandling of Anonymity in Terms of Medical Research Within the General Data Protection Regulation <i>Daniel Nasseh</i>	43
Legal Challenges for IT Service Providers in Pharmacogenomics <i>Lea Meier, Kevin Tippenhauer and Murat Sariyar</i>	47
Comparison of Machine Learning Algorithms for Classifying Adverse-Event Related 30-Day Hospital Readmissions: Potential Implications for Patient Safety <i>Antoine Saab, Melody Saikali and Jean-Baptiste Lamy</i>	51
Semiautomated Approach for Muscle Weakness Detection in Clinical Texts <i>Gleb Danilov, Michael Shifrin, Yuliya Strunina, Konstantin Kotik, Tatyana Tsukanova, Tatiana Pronkina, Timur Ishankulov, Elizaveta Makashova, Alexandra Kosyrkova, Semen Melchenko, Timur Zagidullin and Alexander Potapov</i>	55
Confirmatory Factors to Nursing Practice for Patient Safety of Nurses in Kalasin Hospital, Kalasin Province, Thailand <i>Areeauey Abhichaya, Leethongdissakul Songkhamchai, Srichaikul Buavaroorn and Thiabrithi Surasak</i>	59
Patient Awareness of the Severity of Their Information and Medication Management-Related Adverse Events <i>Kaija Saranto, Samuli Koponen, Hanna Kuusisto and Eija Kivekäs</i>	63
The Quality Improvement Information System for Surveillance and Monitoring for Patient Safety and Personal Safety in Kalasin Hospital, Kalasin Province, Thailand <i>Areeauey Abhichaya, Leethongdissakul Songkhamchai, Srichaikul Buavaroorn and Thiabrithi Surasak</i>	67
Iconic Visualization of Sickle Cell Patients Current and Past Health Status <i>Al Hassim Diallo, Gaoussou Camara, Moussa Lo, Ibrahima Diagne and Jean Baptiste Lamy</i>	71
Using Machine Learning Algorithms to Predict Antimicrobial Resistance and Assist Empirical Treatment <i>Georgios Feretzakis, Evangelos Loupelis, Aikaterini Sakagianni, Dimitris Kalles, Malvina Lada, Constantinos Christopoulos, Evangelos Dimitrellos, Maria Martsoukou, Nikoleta Skarmoutsou, Stavroula Petropoulou, Konstantinos Alexiou, Aikaterini Velentza, Sophia Michelidou and Konstantinos Valakis</i>	75
Process Coverage and Use Case Support of Health Registry Software in Germany <i>Jürgen Stausberg, Sonja Harkener, Udo Altmann and Johannes Drepper</i>	79

Enhancing Medical Education with Data-Driven Software: The TrainCoMorb App	83
<i>Dimitrios Zikos, Neli Ragina and Oliver Strong</i>	
Evaluating the Students' View of Medical and Paramedical Sciences About Perceived Benefits and Barriers of Virtual Social Networks for Learning Purposes	87
<i>Khalil Kimiafar, Alireza Banaye Yazdipour and Masoumeh Sarbaz</i>	
Visualization of Potential Drug Synergies	91
<i>Jean-Baptiste Lamy</i>	
Use of Natural Language Processing for Precise Retrieval of Key Elements of Health IT Evaluation Studies	95
<i>Verena Dornauer, Franziska Jahn, Konrad Hoeffner, Alfred Winter and Elske Ammenwerth</i>	
Local Distortion Hiding Algorithm in Medical Data: A Case Study Using CART	99
<i>Georgios Feretzakis, Dimitris Kalles and Vassilios S. Verykios</i>	
Development of a Presentation Interface for Seismo- and Ballistocardiographic Data	103
<i>Nico Jähne-Raden, Marie Cathrine Wolf, Stephan Sigg and Ulf Kulau</i>	
Visualization of Drug Interactions for Supporting Medication Review	107
<i>Abdelmalek Mouazer, Karima Sedki, Rosy Tsopra and Jean-Baptiste Lamy</i>	
Determining Role of Social Factors in Adoption of Electronic Health Records by Nurses	111
<i>Linus K. Chirchir, Wilson K. Aruasa and Stanley K. Chebon</i>	
An Approach Based on Preference Learning for Identifying Experts Reasoning in Antibiotic Treatment	115
<i>Karima Sedki, Chaymae Lakrafli, Jean-Baptiste Lamy and Rosy Tsopra</i>	
eHealth Literacy Training Among Carers of Older People and People with Dementia: A Modified Delphi Survey	119
<i>Areti Efthymiou, Ioanna Menikou, Antonis Stylianides, Nikoletta Geronikola, Irina Ilieva, Ivana Kancheva, Manuela Tagliani, Rita Seneca, Beata Mintus, Paraskevi Sakka and Evridiki Papastavrou</i>	
Innovation in Cancer Treatment: The Impacts of Robotic-Assisted Surgery Adoption at the Brazilian National Cancer Institute	123
<i>Antônio Augusto Gonçalves, Sandro Luís Freire De Castro Silva, Claudio Pitassi, Marcus Brauer, Sandra Gois and Saulo Barbara de Oliveira</i>	
The Confirmatory Factor Analysis of Quality Assurances Among Medical Laboratory in the Primary Care Units: Roi – Et, Thailand	127
<i>Wipada Chanmonthon, Songkhamchai Leethongdissakul, Wachara Eamratsameekool and Satianpong Siwina</i>	

Application of Geographic Information Systems (GIS) to Analyse and Detect the Risk of Chronic Diseases in the Elderly	131
<i>Niruwan Turnbull, Jaturong Som-Ard, Witaya Yoosook, Savitree Ratanaopad Suwanlee, Thanyarat Chaiyakarm, Nachalida Yukalang and Suwanan Mattra</i>	
Personalized Biomechanic Models: Factors Affecting Shoulder Motion	135
<i>Gesthimani Antoniadou, Thomas Theocharis, Nefeli Chatzistefani and Maria Kallergi</i>	
DONOR-FINDER: A Web Tool for the Automatic Comparison of Genomic Profiles in ART	139
<i>Aurora Sucre, Saioa Garcia-Longarte and Alba Garin-Muga</i>	
K-Means Clustering in Monitoring Facility Reporting of HIV Indicator Data: Case of Kenya	143
<i>Milka B. Gesicho, Ankica Babic and Martin C. Were</i>	
Coping with Information Technology Downtime in Hospitals: A Scoping Study	147
<i>Jackline Bamdeg and Thomas Schmidt</i>	
PrositNG – A Machine Learning Supported Disease Model Generation Software	151
<i>Monika Pobiruchin, Richard Zowalla, Maximilian Kurscheidt and Wendelin Schramm</i>	
Implementation of a Secured Cross-Institutional Data Collection Infrastructure by Applying HL7 FHIR on an Existing Distributed EMR Storages	155
<i>Katsuya Tanaka and Ryuichi Yamamoto</i>	
Towards an Architecture for the Interoperability of Hospital Information Systems in Burkina Faso	159
<i>Lydie Simone Tapsoba, Yaya Traore and Sadouanouan Malo</i>	
The HiGHmed Didactical Framework for Online Learning Modules on Medical Informatics: First Experiences	163
<i>Marie-Louise Witte, Marianne Behrends, Nils-Hendrik Benning, Ina Hoffmann, HiGHmededucation Consortium and Oliver Johannes Bott</i>	
Assessment of HIV Data Reporting Performance by Facilities During EMR Systems Implementations in Kenya	167
<i>Philomena N. Ngugi, Milka B. Gesicho, Ankica Babic and Martin C. Were</i>	
Validation of an Automatic Wrist Blood Pressure Monitor in a Critical Care Setting	171
<i>Irene Karampela, Maria Dalamaga, Theodora Stratigou, Georgios Antonakos, Markos Nikolopoulos, Evangelos Tzortzis and Marianna Diomidous</i>	
Wireless Monitoring Through Wearable Devices in the ICU: Are We Close?	175
<i>Marianna Diomidous, Maria Dalamaga, Markos Nikolopoulos, Evangelos Tzortzis, Theodora Stratigou, Georgios Antonakos and Irene Karampela</i>	
A Method of Justifying Confidence in the Safety of Digital Health Interventions	179
<i>Stuart Harrison, George Despotou and Theodoros N. Arvanitis</i>	

Integrating Socially Assistive Robots into Japanese Nursing Care <i>Markus Kolstad, Natsu Yamaguchi, Ankica Babic and Yoko Nishihara</i>	183
A Comparative Study of the Arden Syntax and GDL Clinical Knowledge Representation Languages <i>Jeroen S. de Bruin, Rong Chen, Andrea Rappelsberger and Klaus-Peter Adlassnig</i>	187
The Classification of Scientific Literature for Its Topical Tracking on a Small Human-Prepared Dataset <i>Gleb Danilov, Timur Ishankulov, Yuriy Orlov, Mikhail Shifrin, Konstantin Kotik and Alexander Potapov</i>	191
Association Between Number of Actionable Pharmacogenetic Variants and Length of Hospital Stay <i>Joseph Finkelstein, Frederick Zhang and Manuel Cabrera</i>	195
Using Long Short-Term Memory (LSTM) Neural Networks to Predict Emergency Department Wait Time <i>Nok Cheng and Alex Kuo</i>	199
Automated Nerve Fibres Identification and Morphometry Analysis with Neural Network Based Tool in MATLAB <i>Michał Kopka, Wiktor Paskal, Adriana M. Paskal, Piotr Pietruski, Ryszard Kopka and Paweł K. Włodarski</i>	203
Using PM-TOM for the Minimization of Adverse Drug and Gene Interactions in Therapies for Common Multi-Diseases <i>Adnan Kulenovic and Azra Lagumdžija-Kulenovic</i>	205
Students' Perceptions on Chatbots' Potential and Design Characteristics in Healthcare Education <i>Natalia Stathakarou, Sokratis Nifakos, Klas Karlgren, Stathis T. Konstantinidis, Panagiotis D. Bamidis, Constantinos S. Pattichis and Nadia Davoody</i>	209
Charting Early Developmental Trajectory of a Pilot Rare Disease Registry in Slovenia <i>Dalibor Stanimirovic, Eva Murko, Tadej Battelino and Urh Groselj</i>	213
Introducing DRGs into Greek National Healthcare System, in 27 Weeks <i>John Sarivougioukas and Aristides Vagelatos</i>	217
Health Record Index: Secure Access of Cloud-Stored Healthcare Data <i>Athanasios Kiourtis, Argyro Mavrogiorgou, Konstantinos Vidakis and Dimosthenis Kyriazis</i>	221
Evaluating Interactivity in VR Healthcare Applications Using Analytics <i>Stelian Nicola and Lacramioara Stoicu-Tivadar</i>	225
Meta-Analysing Methodological Quality of Published Research: Importance and Effectiveness <i>Izet Masic and Slobodan M. Jankovic</i>	229

Availability of Standardized Electronic Patient Data in Nursing: A Nationwide Survey of Austrian Acute Care Hospitals <i>Renate Nantschev and Elske Ammenwerth</i>	233
Nursing Staff's Awareness of Processing Personal Data According to GDPR <i>Vasiliki Markopoulou, Alexandra Nieri, Joseph Liaskos, Emmanouil Zoulias and John Mantas</i>	237
Cross-Correlation Based Automated Segmentation of Audio Samples <i>Emilian-Erman Mahmut, Stelian Nicola and Vasile Stoicu-Tivadar</i>	241
Google Trends and Seasonal Effects in Infodemiology: A Use Case About Obesity <i>Angelo Basteris, Marjan Mansourvar and Uffe Kock Wiil</i>	245
Quantification of Lower Limb and Spine Muscle Activity in Manual Patient Handling – A Case Study <i>Anna Brinkmann, Conrad Fifelski, Sandra Lau, Christian Kowalski, Ole Meyer, Rebecca Diekmann and Andreas Hein</i>	249
Urgent Need for Developing a Framework for the Governance of AI in Healthcare <i>Mansoor Ali Baig, Mohamad A. Almuhaizea, Jumanah Alshehri, Mohammad Shouki Bazarbashi and Fahad Al-Shagathrh</i>	253
Initiative Quality Assurance Culture for Medical Laboratory Activities in the Primary Care Units Staff: A Case Study in Roi Et, Thailand <i>Wipada Chanmonthon, Songkhamchai Leethongdissakul, Wachara Eamratsameekool and Satianpong Siwina</i>	257
Illustration of Clinical Decision Support System Development Complexity <i>Jendrik Richter and Stefan Vogel</i>	261
Digitalizing Nursing in the Bavarian Swabia Region of Germany – Presentation of the Joint Project CARE REGIO <i>Michael Örtl, Felix Holl, Marina Fotteler, Frank Kramer, Andreas Mahler, Dominik Merli, Elisabeth Veronica Mess, Stefanie Schmid, Alexandra Teynor, Petra Friedrich and Walter Swoboda</i>	265
Online Education for Vaccination Competence Among Health Sciences Students <i>Dimitra Perifanou, Eleni Konstantinou, Aija Ahokas, Xavier Palomar Aumatel, Joan Carles Casas Baroy, Daniela Cavani, Paola Galbany Estragues, Paola Ferri, Cinzia Gradellini, Kristina Grendova, Sari Lahti, Michaela Machajova, Montserrat Romero Mas, Daniela Mecugni, Anne Nikula, Janka Prnova, Carme Roure Pujol, Heli Thomander and Evanthia Sakellari</i>	267
User-Centred Design of a Mobile Application for Chronic Pain Management <i>Berglind F. Smaradottir, Asbjørn J. Fagerlund and Johan Gustav Bellika</i>	272
Data Sharing in Pharmaceutical Supply Chains – Case European Medicines Verification System <i>Laura Levänen, Olli Halminen, Henni Tenhunen and Timo Seppälä</i>	276

Integration of International Classification of Diseases Version 11 Application Program Interface (API) in the Rwandan Electronic Medical Records (openMRS): Findings from Two District Hospitals in Rwanda	280
<i>Michael Mugisha, Jean Baptiste Byiringiro, Melissa Uwase, Theophile Abizeyimana, Berchmas Ndikubwimana, Nadine Karema, Michele Kayiganwa, Candide Tran Ngoc, Nenad Kostanjsek, Can Celik, Donada Marc, Celestin Twizere and David Tumusiime</i>	
An Analysis of the Growth in Uptake of OpenWHO's Online Learning Resources for COVID-19	284
<i>Richelle George, Heini Utunen, Melissa Attias, Amy Sy, Ngouille Ndiaye, Corentin Piroux and Gaya Gamhewage</i>	
Campus Mental Well-Being: Opportunities for Digital Health	288
<i>Lua Perimal-Lewis and Patricia A.H. Willams</i>	
Transition Requirements from Problem List to an Overarching Care Plan for the Support of Person-Centered Care	292
<i>Felix Cillessen and Jacob Hofdijk</i>	
Guideline-Based Decision Support System for Nursing Homes: A Case Study with the Management of Malnutrition	296
<i>Abir Abdellatif, Jacques Bouaud, Joël Belmin and Brigitte Seroussi</i>	
Using openEHR in XDS.b Environments – Opportunities and Challenges	300
<i>Reto Wettstein, Angela Merzweiler, Maximilian Klass and Oliver Heinze</i>	
Global Access to OpenWHO's Online Learning Resources for COVID-19	304
<i>Heini Utunen, Melissa Attias, Richelle George, Ngouille Ndiaye, Corentin Piroux, Michael Reza Farzi, Amy Sy and Gaya Gamhewage</i>	
Accessibility and Web Quality Information for People with Disabilities in Healthcare Structures	306
<i>Maria Panagiotopoulou and Maria Tsirintani</i>	
Fitbit Accuracy Depends on Activity Pace and Placement Location	310
<i>Chenhao Wei, Daniel Robins and Joseph Finkelstein</i>	
Factors Affecting Medical Tourism Destination Selection in Greece	314
<i>George Bartzis, Dafni Kaitelidou, Angeliki Bistaraki and Olympia Konstantakopoulou</i>	
A Protocol Entry Catalog for Intraoperative Neuromonitoring – Steps Towards an Ontology	318
<i>Chantal Zbinden, Moritz Strickler, Murat Sariyar, Thomas Bürkle and Kathleen Seidel</i>	
Generation of Realistic Synthetic Validation Healthcare Datasets Using Generative Adversarial Networks	322
<i>Eda Bilici Ozyigit, Theodoros N. Arvanitis and George Despotou</i>	
Decision Support System for Selection of e-Health Interventions	326
<i>Dahbia Agher, Marc Fouque, Matteo Brandi, Karima Sedki, Rosy Tsopra, Pierre Meneton, Sylvie Despres and Marie-Christine Jaulent</i>	

Multidisciplinary Approach for Education in Healthcare Management: Case Study from Montenegro	330
<i>Ivana Ognjanović, Ramo Šendelj and Elske Ammenwerth</i>	
Towards Intelligent Integration and Sharing of Stem Cell Research Data	334
<i>Kirill Borziak, Tianye Qi, John Erol Evangelista, Daniel J.B. Clarke, Avi Ma'ayan and Joseph Finkelstein</i>	
Model Driven Approach for Development of Person-Centred Care in Stroke Rehabilitation	338
<i>Ivana Ognjanović, Roman Lewandowski, Ramo Šendelj, Dalia Kriškčiūnienė and Jevto Eraković</i>	
Supporting Active Pharmacovigilance via IT Tools in the Clinical Setting and Beyond: Regulatory and Management Aspects	342
<i>Pantelis Natsiavas, George I. Gavrilidis, Zacharoula Linardaki, Georgia Kolangi, Evgenia Gkaliagkousi, Chrysanthos Zamboulis and Marie-Christine Jaulent</i>	
Association Between System Usage Pattern and Impact of Web-Based Telerehabilitation in Patients with Multiple Sclerosis	346
<i>In cheol Jeong, Jiazhen Liu and Joseph Finkelstein</i>	
Rules Based Data Quality Assessment on Claims Database	350
<i>Mary A. Gadde, Zhan Wang, Meredith Zozus, John B. Talburt and Melody L. Greer</i>	
Challenges of the Slovenian Healthcare System Exposed in Hospitals' Recovery Plans	354
<i>Tatjana Jovanović</i>	
Disparities in Racial and Ethnic Representation in Stem Cell Clinical Trials	358
<i>Irena Parvanova and Joseph Finkelstein</i>	
A 3D Surface Fitting Layout for Complex Networks Visualization	362
<i>Laura Broască, Versavia-Maria Ancușa and Horia Ciocârlie</i>	
Using Big Data to Predict Outcomes of Opioid Treatment Programs	366
<i>Wanting Cui, Keren Bachi, Yasmin Hurd and Joseph Finkelstein</i>	
Classification of Intracranial Hemorrhage Subtypes Using Deep Learning on CT Scans	370
<i>Gleb Danilov, Konstantin Kotik, Anna Negreeva, Tatiana Tsukanova, Michael Shifrin, Natalya Zakharova, Artem Batalov, Igor Pronin and Alexander Potapov</i>	
Public Private Partnerships Delivering Smart Health to Combat the Tsunami of Noncommunicable Diseases	374
<i>Kannan Subramaniam</i>	
Introducing an Ontology-Driven Pipeline for the Identification of Common Data Elements	379
<i>Anas Elghafari and Joseph Finkelstein</i>	

Evaluating the Use of a PRO Questionnaire in Clinical Practice <i>Sissel Graakjær Bøgh Pedersen, Nicole Safavi Andersen, Ann Bygholm and Mogens Laursen</i>	383
Obstructive Sleep Apnea: A Prediction Model Using Supervised Machine Learning Method <i>Zahra Keshavarz, Rita Rezaee, Mahdi Nasiri and Omid Pournik</i>	387
Transfer Physical Therapists Knowledge: A Pre-Test to Minimize the Complexity of Physical Therapists' Quality Assessment of Shoulder Exercise Performance <i>Birgit Saalfeld, Lena Elgert, Bianca Steiner and Klaus-Hendrik Wolf</i>	391
A Digital Clinical Guideline Based on HL7 Arden Syntax for the Treatment of Children with Traumatic Brain Injury <i>Sergei B. Arseniev, Valeri G. Amcheslavskiy, Valeri I. Lukianov, Andrea Rappelsberger and Klaus-Peter Adlassnig</i>	395
Statistical Analysis of Air Pollutants Concentration and Health Information Related to Respiratory Disease Patients in Bangkok, Thailand <i>Wisit Thongkum, Santisith Khiewkhern and Sawan Thitisutthi</i>	399
Google Maps: Prevalence and Distribution of Uncontrolled Type 2 Diabetes Mellitus in Kalasin Province, Thailand <i>Patcharin Phuwilert, Santisith Khiewkhern, Kasama Wongprachum and Teerasak Phajan</i>	403
From Many to One: Designing a Unified Flowsheet in the EMR to Replace Multiple Disparate Devices <i>Daniel Robins, Martijn Figee, Helen Mayberg and Joseph Finkelstein</i>	407
Sun4Patients Web Platform: Facilitating Long-Term Monitoring of Stroke Patients <i>George Papastefanatos, Stefanos Papastefanatos, Eleni Korompoki, Petros Galanis, Olympia Konstantakopoulou, Iliana Karagkouni, Parisis Gallos, George Ntaios, Kostas Vemmos and Olga Siskou</i>	411
System of Criteria for Treatment Evaluation of Acromegaly in Bulgaria <i>Evgeniy Krastev, Dimitar Tcharaktchiev and Emanuil Markov</i>	413
Discrepancy Between Personal Experience and Negative Opinion with Human Papillomavirus Vaccine in Web Forums <i>Pierre Karapetiantz, Bissan Audeh, Agnès Lillo-Le Louët and Cédric Bousquet</i>	417
Access of Stroke Patients' to Optimal Healthcare Technology in Greece: Messages to Policy Makers <i>Olga Siskou, Eleni Korompoki, George Ntaios, Evangelos Tsampalas, Helen Alexopoulou, Ioannis Kalliontzakis, Aspasia Kouridaki, Argyro Tountopoulou, Ioanna Kouzi, Sofia Vasilopoulou, Haralampos Milionis, Hara Evaggelou, Efstathia Karagkiozi, Apostolos I. Hatzitolios, Christos Savopoulos, Athina Myrou, Efstathios Manios, Georgios Mavraganis, Anastasia Vemmou, Daphne Kaitelidou, Petros Galanis, Stefanos Papastefanatos, Olympia Konstantakopoulou, Iliana Karagkouni and Kostas Vemmos</i>	421

Semantic Web of Things (SWoT) for Global Infectious Disease Control and Prevention	425
<i>Arash Shaban-Nejad, Jon Haël Brenas, Mohammad Sadnan Al Manir, Kate Zinszer and Christopher J.O. Baker</i>	
Exploring Unsupervised Query Paraphrasing to Identify Relevant Search Phrases for a Literature Review	429
<i>Laura-Maria Peltonen, Miretta Tommila and Hans Moen</i>	
Applying Artificial Intelligence to Predict Self-Reported Poor Health Among Black and Hispanic Caregivers with Mild Cognitive Impairment	433
<i>Sunmoo Yoon, Nicole Davis, Michelle Odum, Hwayoung Cho, Peter Broadwell, Maria Patrao, Michael Bales, Carmela Alcantara and Mary Mittelman</i>	
Effective Design of Serious Games for Children with Chronic Diseases: The Role of Parents and Caregivers	437
<i>Dimitra Pappa, Emmanouil Zoulias and John Mantas</i>	
Developing Patients' Experiences Database After Hospital Discharge: Another Step in Improving Stroke Care	441
<i>Olympia Konstantakopoulou, Petros Galanis, Daphne Kaitelidou, Iliana Karagkouni, Eleni Korompoki, George Ntaios, Kostas Vemmos, Stefanos Papastefanatos, George Papastefanatos, Evangelos Tsampalas, Helen Alexopoulou, Ioannis Kalliontzakis, Aspasia Kouridaki, Argyro Tountopoulou, Ioanna Kouzi, Haralampos Milionis, Chara Evaggelou, Efsthia Karagkiozi, Apostolos I. Hatzitolios, Christos Savopoulos, Athina Myrou, Georgios Mavraganis, Anastasia Vemmou and Olga Siskou</i>	
The Dissemination and Communication Plan and Activities of the CrowdHEALTH Project: "Collective Wisdom Driving Public Health Policies"	445
<i>Andriana Magdalinou, John Mantas, Patrick Weber, Parisi Gallos and Lydia Montandon</i>	
Determining and Evaluating the Dissemination and Exploitation Plans and Activities for the CrowdHEALTH Project: The Role of the Impact Creation Board	449
<i>John Mantas, Andriana Magdalinou, Patrick Weber, Parisi Gallos and Lydia Montandon</i>	
Understanding the Food Habits and Physical Activities of Diabetes Cohort in Qatar	453
<i>Anjanarani Nazeemudeen, Hamada R.H. Al-Absi, Mahmoud Ahmed Refaee, Mowafa Househ, Zubair Shah and Tanvir Alam</i>	
An Efficient Method to Predict Pneumonia from Chest X-Rays Using Deep Learning Approach	457
<i>Uzair Shah, Alaa Abd-Alrazeq, Tanvir Alam, Mowafa Househ and Zubair Shah</i>	

Semantic Reconciliation of Standard and Localized Medical Terminologies for Knowledge Interoperability	461
<i>Taqdir Ali, Mowafa Househ, Tanvir Alam, Sungyoung Lee and Zubair Shah</i>	
Cardiovascular Diseases in Qatar: Smoking, Food Habits and Physical Activities Perspectives	465
<i>Hamada R.H. Al-Absi, Mahmoud Ahmed Refaee, Anjanarani Nazeemudeen, Mowafa Househ, Zubair Shah and Tanvir Alam</i>	
The Impact of Clinical Decision Support Systems (CDSS) on Physicians: A Scoping Review	470
<i>Raghad Muhiyaddin, Alaa A. Abd-Alrazaq, Mowafa Househ, Tanvir Alam and Zubair Shah</i>	
Health Informatics Association of Qatar (HIAQ): Building a Digital Health Ecosystem	474
<i>Farahnaz Yousif, Hessa Almulla, Raghad Muhiyaddin, Dena A. Althani, Zubair Shah, Tanvir Alam and Mowafa Househ</i>	
Machine Learning Models Reveal the Importance of Clinical Biomarkers for the Diagnosis of Alzheimer's Disease	478
<i>Mahmoud Ahmed Refaee, Amal Awadalla Mohamed Ali, Asma Hamid Elfadl, Maha F.A. Abujazar, Mohammad Tariqul Islam, Ferdaus Ahmed Kawsar, Mowafa Househ, Zubair Shah and Tanvir Alam</i>	
The European Educational Programs in Biomedical and Health Informatics	482
<i>John Mantas</i>	
The Accreditation Procedure Ensures Quality of Education in Biomedical and Health Informatics	484
<i>John Mantas</i>	
The Importance of Health Informatics in Public Health During the COVID-19 Pandemic	487
<i>John Mantas</i>	
Subject Index	489
Author Index	495

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Unsupervised Machine Learning for the Discovery of Latent Clusters in COVID-19 Patients Using Electronic Health Records

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Abstract. The goal of this paper was to apply unsupervised machine learning techniques towards the discovery of latent clusters in COVID-19 patients. Over 6,000 adult patients tested positive for the SARS-CoV-2 infection at the Mount Sinai Health System in New York, USA met the inclusion criteria for analysis. Patients' diagnoses were mapped onto chronicity and one of the 18 body systems, and the optimal number of clusters was determined using K-means algorithm and the elbow method. 4 clusters were identified; the most frequently associated comorbidities involved infectious, respiratory, cardiovascular, endocrine, and genitourinary disorders, as well as socioeconomic factors that influence health status and contact with health services. These results offer a strong direction for future research and more granular analysis.

Keywords. Big Data Analytics, Unsupervised Machine Learning

1. Introduction

Coronavirus Disease (COVID-19) has spread rapidly throughout North America, and so observations and data about this illness on the American population are now available. New York, in particular, has become the largest single focus of confirmed cases in the USA [1], and it is effectively the American epicenter of the pandemic since March 2020. The large, high-density population of NY has led to the growth of an even larger medical record dataset, which must be methodically analyzed to produce actionable information. Early efforts to find patient characteristics and risk factors are already underway; one case series recently demonstrated that hypertension, obesity, and diabetes are the most frequent comorbidities found in laboratory confirmed COVID patients that require hospitalization [2]. However, a broad approach to discover *latent* clusters is critical for a comprehensive understanding of the course of illness. The goal of this paper is to identify these latent clusters of patient characteristics by using an unsupervised machine learning approach.

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2. Methods

The dataset was pulled from Epic, an electronic health record at Mount Sinai Health System between January 2020 and April 2020, and de-identified for further analysis. This analysis aimed to identify latent clusters from patients who contracted coronavirus, and thus only records of patients who tested positive for SARS-CoV-2 were included. The initial analytical dataset comprised 6220 eligible patients. After deletion of records with missing values the final dataset included 6101 patients.

Since each patient could have multiple underlying comorbidities, we mapped diagnoses into chronicity indicator and one of the 18 body systems, based on ICD-10 codes [3]. If patients had more than one diagnosis, chronicity and body systems would be the aggregated information of all diagnoses. Chronicity was positive if one or more chronic diseases were detected and negative if no chronic diseases were detected. The same rule applied to all 18 body systems. In addition, the age-adjusted comorbidity index was calculated using patient’s age and ICD-10 code of diagnoses [4]. In the end, age, comorbidity, ICU status, alive, sex, race, ethnicity, chronicity and body systems were the variables we used for clustering analysis. All numerical variables were normalized between 0 and 1; and all categorical variables were changed into dummy variables. We performed PCA to address the multi-collinearity issues between variables. 15 components were selected, as they explained over 80% of variance. Important variables were chronicity, body systems (3, 7, 10, and 18), age and race. K-means algorithm was used for clustering and the elbow method was used to determine optimal number of clusters. All analyses were performed in Anaconda Jupyter Notebook, using Python 3.7.3. T-test, proportion testing were used. All tests were two-sided, with $p<0.05$ being considered statistically significant.

3. Results

4 clusters were identified (Figure 1). Clusters 0 and 2 constituted patients who were sicker and had more conditions (Table 1). Clusters 1 and 3, constituted patients with less comorbidities. Over 97% of patients in clusters 0 and 2 had one or more chronic diseases. In contrast, only 15% of patients from cluster 1 and 3 had chronic diseases. The average ages of clusters 0 and 2 were 10 years older than clusters 1 and 3. In addition, patients from cluster 2 had a 20% death rate, whereas the death rate of cluster 3 was around 5%. Race was also an important factor in forming the clusters.

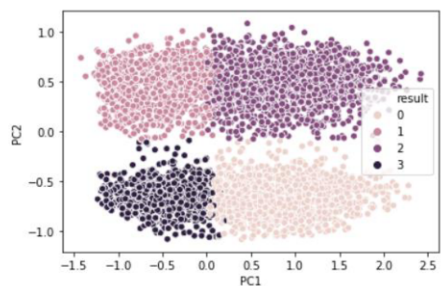


Figure 1. Visualization of the 4 clusters based on the first 2 principle components

Age and comorbidity index were significantly different between clusters 0, 2 and 1; but not between clusters 1 and 3. ICU length of stay were all significantly different across all four clusters. Patients in clusters 0 and 2 had high comorbidity index, whereas patients in cluster 1 and 3 had low comorbidity index. Although patients in cluster 2 had a shorter ICU length of stay and percentage use of ventilators, comparing to cluster 0, these patients had higher comorbidity index and had 3% higher death rate.

Table 1. Descriptive statistics of clusters (SD - standard deviation)

Clusters	0	1	2	3
count	1153	1959	1572	1417
Numeric Variables				
Age				
Mean	64.54	51.51	67.95	50.29
SD	15.62	17.97	14.68	17.20
Comorbidity				
Mean	3.12	1.20	3.45	1.09
SD	2.17	1.43	2.12	1.34
ICU Length				
Mean	1.73	0.15	1.34	0.38
SD	3.79	1.03	3.36	1.54
Categorical Variables				
STATUS				
Alive	82.74%	94.38%	79.71%	94.71%
Deceased	17.26%	5.62%	20.29%	5.29%
SEX				
Female	44.32%	49.52%	44.59%	42.48%
Male	55.68%	50.48%	55.41%	57.52%
RACE				
American Indian or Alaskan	0.00%	0.05%	0.13%	0.00%
Asian	0.69%	7.55%	7.25%	0.85%
Black	0.00%	38.74%	44.78%	0.00%
Pacific Islander	0.26%	6.43%	4.45%	0.14%
Other	99.05%	0.00%	0.00%	99.01%
White	0.00%	47.22%	43.38%	0.00%
ETHNICITY				
Hispanic	3.56%	0.05%	0.25%	0.71%
Not Hispanic	96.44%	99.95%	99.75%	99.29%
On Ventilator	16.22%	1.79%	10.50%	3.53%
ICU	31.40%	4.44%	23.47%	10.16%
Chronicity	96.96%	14.04%	97.77%	15.74%

In terms of body systems, all patients had relatively higher proportion of heath conditions in body systems 1, 8, 16 and 18 (Table 2). However, patients from cluster 0 and 2 exhibited higher proportion of conditions in body systems 3, 7, 10 and 18. There were significant differences between cluster 0 and cluster 2 in representation of health conditions in body systems3, 16 and body system "none."

Table 2. Percentage affected of body systems

	Cluster			
Body System	0	1	2	3
1. Infectious and parasitic disease	74.41%	40.07%	75.51%	46.93%
2.Neoplasms	12.40%	2.65%	11.83%	1.62%
3. Endocrine, nutritional, and metabolic diseases and immunity disorders	70.42%	3.52%	66.28%	4.80%
4. Diseases of blood and blood-forming organs	20.21%	1.28%	18.70%	1.91%
5. Mental disorders	13.79%	2.76%	15.20%	2.54%

6. Diseases of the nervous system and sense	30.27%	2.19%	29.01%	2.33%
7. Diseases of the circulatory system	65.05%	1.53%	68.19%	2.40%
8. Diseases of the respiratory system	83.87%	57.58%	85.05%	60.69%
9. Diseases of the digestive system	20.03%	3.06%	18.26%	3.60%
10. Diseases of the genitourinary system	47.88%	5.00%	45.29%	4.45%
11. Complications of pregnancy, childbirth, and the puerperium	0.43%	3.62%	0.57%	2.12%
12. Diseases of the skin and subcutaneous	6.68%	1.53%	7.32%	1.13%
13. Diseases of the musculoskeletal system	20.21%	4.34%	20.99%	4.16%
14. Congenital anomalies	1.39%	0.05%	1.46%	0.07%
15. Certain conditions originating in the	0.17%	0.26%	0.13%	0.00%
16. Symptoms, signs, and ill-defined conditions	87.94%	54.77%	90.71%	59.14%
17. Injury and poisoning	12.75%	2.40%	12.53%	2.33%
18. Factors influencing health status and contact with health services	48.40%	21.34%	46.31%	16.51%
Body System "None"	2.17%	0.92%	3.94%	0.21%

4. Discussion

The majority of patients who tested positive for COVID-19 had respiratory symptoms. Patients with high comorbidity scores and chronic diseases were affected most by COVID-19. Age was also an important factor, but it is highly correlated to comorbidity and chronicity. In addition, patients with a history of metabolic diseases and immune system disorders, or medical conditions in the circulatory system or genitourinary system were more susceptible to serious complications when infected.

The discovery of these 4 clusters represents an important milestone towards understanding the course of illness, and subsequently optimizing disease prevention and patient care. Future investigations and a more granular analysis should be directed towards these clusters.

5. Conclusions

4 clusters were identified. Clusters 0 and 2 contained patients with the most serious conditions. Age, comorbidity index, chronicity, race and body systems (3, 7, 10 and 18) were important variables in separating these clusters.

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Application of Social Network Analysis of COVID-19 Related Tweets Mentioning Cannabis and Opioids to Gain Insights for Drug Abuse Research

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Abstract. We applied social network analysis (SNA) to Tweets mentioning cannabis or opioid-related terms to publicly available COVID-19 related Tweets collected from Jan 21st to May 3rd, 2020 (n= 2,558,474 Tweets). We randomly extracted 16,154 Tweets mentioning cannabis and 4,670 Tweets mentioning opioids from the COVID-19 Tweet corpora for our analysis. The cannabis related Tweets created by 6,144 users were disseminated to 280,042,783 users and retweeted 11 times the number of original messages while opioid-related Tweets created by 3,412 users were disseminated to smaller number of users. The opioids Twitter network showed more cohesive online group activities and a cleaner online environment with less disinformation. The cannabis Twitter network showed a less desirable online environment with more disinformation (false information to mislead the public) and stakeholders lacking strong science knowledge. Application of SNA to Tweets provides insights for future online-based drug abuse research during the outbreak.

Keywords. social media, pandemic, cannabis, opioids, drug abuse

1. Introduction

One in nine Americans use illicit drugs. Approximately \$740 billion are estimated for cost related to illicit drug abuse in the U.S [1]. Illicit drugs such as marijuana or cocaine stimulate or inhibit the central nervous system to cause hallucinogenic effects. Although the FDA has not approved a marketing application for cannabis for the treatment of any

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disease or condition except one, where its use is strictly controlled, there are products available on the market [2]. Drug abuse behavior is associated with stress, poor mental health status, poor ability to relate to others and poor social support [1]. Drug abuse behaviors are likely to be worsening during the COVID-19 pandemic [3]. Network analysis, based on the formalism of graph theory, is commonly used to characterize and understand relational data in a variety of scientific fields [4]. When applied to Tweet data, social network analysis may be used to identify key Twitter users and Tweets, as well as the relations between them, based on the structure (topology) of networks of Tweets and retweets [5]. In the context of a global pandemic, several measures of network centrality, including degree (the entities with the most links to other entities) and betweenness centrality (a broker of indirect connections among all others, a gatekeeper of information flow) may be particularly useful in detecting the spread of information or disinformation (disinformation/inaccurate information is shared deliberately while misinformation is shared accidentally) on illicit drugs. The purpose of the study was to apply social network analysis on COVID-19 related Tweets mentioning cannabis and opioids to gain insights for future Twitter-based illicit drug abuse intervention and development of algorithms during the pandemic.

2. Methods

We applied SNA techniques on a publicly available Tweet corpus mentioning COVID-19 (keywords: covid19, Covid, covid-19, COVID, corona, coronavirus). We used the Twitter API, ORA and a Terremoto High Performance Computing Cluster. We extracted publicly available Tweets mentioning COVID-19 related terms ($n=2,558,474$ Tweets) from Tweet corpora collected daily using an API from Jan 21st to May 3rd, 2020. First, mental health and behavioral science experts and clinicians in our team randomly extracted 16,154 Tweets mentioning cannabis (keywords: cannabis, marijuana, #CBD, weed, hemp, CBDoil) and 4,670 Tweets mentioning opioids (keywords: morphine, heroin, oxycodone/OxyContin/Percocet, hydrocodone/Vicodin, Norco, codeine, fentanyl, methadone, buprenorphine, Probuphine) from the initial COVID-19 Tweet corpora for our analysis to assess information or disinformation dissemination online behavior on cannabis during the COVID-19 pandemic [1]. Second, we applied SNA to Tweets mentioning cannabis and opioids to automatically detect the similar groups and to identify stakeholders on the topics within Twitter [4,5]. Girvan-Newman algorithm was selected after evaluating the utility of four clustering algorithms (Concor, Newman, Principal Component, and Louvain). The algorithms were considered less effective for the following reasons: 1) Concor: subjectivity and inefficiency of parameter settings as applied to the clustering process; 2) Principal Component: results included a large cluster consisting of 1662 users, which was less meaningful for clinical interpretability; 3) Louvain: modularity score was similar to Newman's algorithm, yet it included more clusters with only two users. Network measures to characterize the networks including density, size, and centralities of top stakeholders were computed using ORA. Third, we visualized the detected groups using a network diagram. Lastly, mental health and behavioral science experts and clinicians interpreted the results as disinformation (inaccurate information deliberately shared by the stakeholders) or as information (accurate information) according to clinical meaningfulness for use in future online interventions.

3. Results

The cannabis related Tweets created by 6,144 users were disseminated to 280,042,783 users and retweeted by 11 times the number of original messages. Similarly opioids related Tweets created by 3,412 users were disseminated to 496,010 users and retweeted 106 times the number of original messages. The top 10 stakeholders who disseminated information and disinformation about cannabis and opioids during the COVID-19, were identified as the media (CNN, Financial Times, High Times Magazine), actors, lobbyists, one individual, and organizations (a private funding agency, a football association) in the cannabis Tweet corpora ; and a journal (Nature), the media (AP, CNN, PBS), individuals and a sportsman in the opioids Tweet corpora (Table 1).

Table 1. Top 10 stakeholders in COVID-19 related publicly available Tweets mentioning cannabis and opioids (unit: 10⁵)

Rank	Cannabis	Centrality	Opioids	Centrality
1	CNN	16.28	nature	300
2	FinancialTimes	9.24	Individual 3	19.05
3	rainnwilson	9.16	morphine_prince	18.45
4	Individual 1	8.14	Individual 4	14.66
5	Individual 2	8.14	jr_heroin	14.66
6	ACLU	5.62	CNN	14.1
7	goal	5.17	detroitnews	7.848
8	HIGH_TIMES_Mag	3.46	AP	4.142
9	NORML	1.95	Individual 5	2.25
10	Weed Investor	1.59	ThaiPBS	1.684

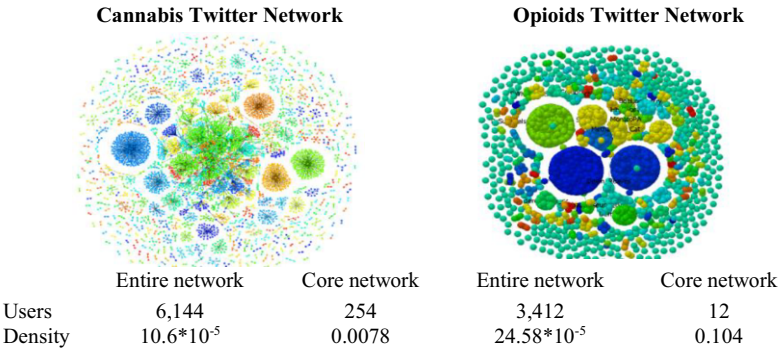


Figure 1. Social networks on COVID-19 Tweets mentioning cannabis and opioids

A total of 622 distinct groups (n=6,144 users) was detected in the cannabis Tweet corpora (Newman modularity 0.89) and a total of 161 distinct groups (n=3,412) was detected in the opioids Tweet corpora (Newman modularity 0.34). The cannabis Tweet network contained 80% small subgroups (498 subgroups) and 5% large subgroups (32 subgroups). Similarly, the opioids Tweet network contained 88% small subgroups (141 subgroups) and 7% large subgroups (11 subgroups) (Figure 1). Topics detected within the cannabis Tweets include disinformation on COVID prevention or cures, promoting cannabis use behavior, buying, and delivery methods such as vaping or eating. Topics discussed within the opioids Tweets include the opioids crisis, fake cures, addiction on morphine, methadone and oxycontin, criminal justice, drug trafficking, and fentanyl shortage during the COVID-19 pandemic.

4. Discussion and Conclusions

This study found that information or disinformation (inaccurate information is shared deliberately) regarding cannabis created by 6,144 users were disseminated to 280,042,783 users and retweeted an average of 11 times the number of original messages ($n=16,154$) in Twitter during the outbreak. On the contrary, less number of the members ($n= 3,412$ users) disseminated information and disinformation regarding opioids to 496,010 Twitter users. Although the opioid Twitter network included a lower number of users reaching out a smaller number of audience Twitter users, the opioids Twitter network showed greater online group cohesiveness with higher activity within the network. The opioids Twitter network reflected a cleaner online environment with less disinformation than the cannabis Twitter network. To date, with the exception of one cannabis-derived drug product, the FDA has not approved a marketing or the use of cannabis for the treatment of any disease or condition. This exception is strictly controlled requiring a prescription from a licensed healthcare provider [2]. Yet the cannabis Twitter network were filled with disinformation including the use of cannabis for COVID prevention and treatment. The cleaner and healthier network environment with less disinformation of the opioid Twitter network could be explained by the characteristics of the top stakeholders of the network. Whereas both networks contained similar amount of regular individuals who constantly disseminated disinformation, the opioid Twitter network included a top stakeholder grounded in sound scientific foundation (Nature). Unlike the opioids Twitter network, the cannabis Twitter network included a top stakeholder as an entity with less scientific foundation (CNN). Further, the cleaner environment of the opioid network maybe explained by users' adherence behavior on the Twitter rules and policies. The authors suggest that the scientific entities grounded with evidence and rigorous methods are strongly encouraged elevating their social media presence during the pandemic. This study found that the betweenness centrality algorithm was able to detect more hidden gatekeepers of information and disinformation on illicit drug use during the COVID-19 than degree centrality algorithm. Betweenness centrality algorithm calculates the shortest path between every pair of nodes in a connected graphs and entities with high betweenness centrality are able to connect different groups [4]. The authors suggest that SNA with degree and betweenness centrality calculation methods would be beneficial to intervene information and disinformation for future online-based illicit drug use research during the outbreak [4].

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E-Health in Norway Before and During the Initial Phase of the Covid-19 Pandemic

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Abstract. The use of e-health services has for many years gradually increased in Norway as in most European countries. Searching for information about health and illness has previously by far been the most popular service. In this study, we review the literature with the aim of examining any changes in e-health use during the Covid-19 pandemic. We find that there has been a marked change in Norway, with an extreme increase in video consultations, especially in primary care and in the mental health field. The government has also released an app for tracking the illness, which so far has been downloaded by approximately 1/4 of the population. These changes are likely to impact the use of e-health also after the pandemic.

Keywords. E-health, Telemedicine, Norway, Covid-19

1. Introduction

For many years, the use of e-health has gradually increased in Norway as it has in Europe in general [1-4]. In a population-based representative study of people aged 40 and above conducted in Norway in 2015-2016, with more than 18,000 respondents, 52.7% had used e-health services in the last year [5,6]. While the availability of video consultations, health apps, and other services has improved, until recently, by far the most utilized e-health service was searching for information about health and illness online [6,7].

The Covid-19 pandemic has impacted society as well as the health services in many ways, and we wanted to examine which changes in e-health use the pandemic has resulted in so far in Norway.

2. Methods

We performed a narrative search of the literature for empirical studies presenting data on e-health use in Norway during the Covid-19 pandemic, restricted to studies dating from March and April 2020.

We searched PubMed and Google Scholar, using variations of the following search terms in different combinations: 'Covid-19', 'Corona virus', 'e-health use', 'video consultation', 'app' and 'Norway' in Norwegian and English.

Given the short time the illness has been observed in Norway, we also searched for relevant 'grey literature', including newspaper articles, websites with relevant

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information, official documents, etc., describing the use of e-health during the initial phase of the Covid-19 pandemic in Norway.

3. Results

We were unable to identify any relevant peer-reviewed publications, probably due to the recency of the topic. However, there were several reports of changes in e-health use during the pandemic and the ensuing shutdown (i.e. mass quarantine) from 13th of March, 2020. One Regional Health Authority reported a 350% increase in video consultations in March [8] and one Mental Health and Substance Use Clinic increased its use of video consultations from zero to 250 consultations in 12 days [9].

A one-day count performed on the 16th of March, 2020, found that there had been approximately 11,000 video consultations involving general practitioners and municipal-level mental health services [10]. 80% to 90% of the general practitioners in Norway were technically able to provide video consultations in the third week of March [10].

This great increase in video consultations appeared to be driven by necessity. The Norwegian Directorate of Health recommended, when possible, to use e-health services (including video consultations) to reduce the risk of contagion [11]. Some health providers, such as most private practice clinical psychologists, were forced to close their offices for a period of several weeks by the authorities and could only provide remote/e-health services [12].

While the shift to e-health during the initial phase of the pandemic appeared to be seen as acceptable or even welcomed [8-10], some voiced concerns that the lack of traditional services was challenging particularly for some patient groups, such as severely mentally ill patients or patients with severe substance use problems [13]. During the epidemic, some patients might not receive timely physical examinations and other procedures that necessitate physical consultations, while others may not be able to fully benefit from the provider-patient relationship without physical face-to-face encounters [7,14-16].

Another possibly landmark shift in the use of e-health occurred with the introduction of the app 'Smittestopp' ('Stop the infection'). The app was developed by the Norwegian Institute of Public Health and Simula and its purpose is to aid the health authorities in limiting the transmission of coronavirus [17]. The app transmits information obtained through Bluetooth and GPS about the user's position, movements and physical proximity to other app users to a central database.

In a first phase, anonymous data about movement patterns obtained from the app will be used in fighting the pandemic. In a second phase, data from the Norwegian Surveillance System for Communicable Diseases will be combined with data obtained from app to warn the user if he or she has come into contact with someone who is infected and therefore needs to take appropriate action, including self-quarantining [17].

In the period from 16th of April to the 29th of April, 1.45 million Norwegians had downloaded the app [18], which amounts to approximately 27% of the total population of Norway. It is expected that more people will download the app as its functionalities come into use and its usability is proven to the population, although some have voiced privacy concerns [18]. On Iceland, a Covid-19 tracking app was by the end of April downloaded by approximately 40% of the population [18].

4. Discussion

While e-health uptake has been steadily increasing for a long period, spurred on by an increase in new technologies such as mobile apps [1-7], the Covid-19 pandemic has resulted in very fast changes in the use of e-health in Norway. A rapidly spreading virus and an ensuing mass quarantine lead the authorities to enforce social distancing measures and recommend the use of e-health services whenever possible [11].

Many Norwegian hospitals and clinicians have previously been slow in providing remote consultations and other e-health services [4,7]. The pandemic changed the situation rapidly, leading to a very fast increase in the use of video consultations. During the Covid-19 pandemic there appears to have been an explosion in the number of clinicians offering e-health services, and in particular video consultations [8-10]. This change appears to have been particularly great within the field of mental health services [9,10], which lends itself especially well to video consultations and other e-health tools, as it usually does not typically depend on regular face-to-face interactions and physical examinations (with the possible exception of the most severely ill patients) [13].

More than a quarter of the total population downloaded a Covid-19 tracking health app to their smartphones within less than 2 weeks [18]. This massive roll-out of a government-sponsored health app is likely to change attitudes and further the use of new e-health tools such as health apps into mainstream Norwegian healthcare.

We do not know how the epidemic will develop in Norway or around the world and how it will impact the population and the health service as it unfolds. However, it seems likely that the high interest in e-health today might be conducive to a permanent strengthening of the role of e-health in the health services in Norway. Many hospitals and clinicians have started to routinely use e-health tools, and it is likely that -while the services have their limitations- many will experience that these tools can work well in a range of situations, increase access and save travel time [19], which may encourage the use of e-health services also after the pandemic.

This paper draws on a narrative review methodology, which has limitations. The literature search was not systematic and we were unable to identify any relevant peer-reviewed publications, probably because of the recency of the topic.

5. Conclusions

The Covid-19 pandemic has, during its first six weeks, resulted in major changes in the use of e-health in Norway. Little is known about how the pandemic will develop in Norway and in other countries, but it is likely that the uptake of e-health will remain at a higher level than before the pandemic. Many providers, patients, and other users are getting introduced to and accustomed to different e-health services and are discovering the many benefits as well as the limitations of these services.

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Setting up an Easy-to-Use Machine Learning Pipeline for Medical Decision Support: A Case Study for COVID-19 Diagnosis Based on Deep Learning with CT Scans

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Abstract. Coronavirus disease (COVID-19) constitutes an ongoing global health problem with significant morbidity and mortality. It usually presents characteristic findings on a chest CT scan, which may lead to early detection of the disease. A timely and accurate diagnosis of COVID-19 is the cornerstone for the prompt management of the patients. The aim of the present study was to evaluate the performance of an automated machine learning algorithm in the diagnosis of Covid-19 pneumonia using chest CT scans. Diagnostic performance was assessed by the area under the receiver operating characteristic curve (AUC), sensitivity, and positive predictive value. The method's average precision was 0.932. We suggest that auto-ML platforms help users with limited ML expertise train image recognition models by only uploading the examined dataset and performing some basic settings. Such methods could deliver significant potential benefits for patients in the future by allowing for earlier disease detection and care.

Keywords. Artificial intelligence, automated machine learning, AutoML Vision, COVID-19, chest CT scan, image classification, coronavirus disease

1. Introduction and background

Coronavirus disease 2019 (COVID-19) constitutes an ongoing global health problem with significant morbidity and mortality that has emerged in China in December 2019. Due to its rapid dissemination, the World Health Organization (WHO) declared the novel coronavirus outbreak as a pandemic on March 11, 2020. The clinical course of the disease varies and, in severe cases, may lead to acute respiratory distress syndrome

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and/or multiple organ failure. Timely and accurate diagnosis of COVID-19 is of utmost importance for the prompt treatment of the patients and their isolation. The diagnosis is confirmed by reverse-transcription polymerase chain reaction (RT-PCR). According to several reports, the sensitivity of RT-PCR might not be high enough to rapidly recognize infected patients. Computed tomography (CT) of the chest can detect quite early after the onset of symptoms, certain features of lung infection associated with COVID-19. CT could, therefore, serve as a useful tool for the early detection of COVID-19 lung involvement. The National Health Commission of the People’s Republic of China has initially proposed screening, based only on clinical and chest CT findings [1].

Applications of artificial intelligence (AI) are rapidly entering health care and are being used for a wide range of health care and research purposes, including, for example, disease detection [2], empirical therapy selection [3], and drug discovery [4], among others. The complexity and the growing volumes of data in health care suggest that AI techniques will increasingly be applied in almost every medical field in the upcoming years. Recent studies have demonstrated that AI using deep learning models may prove extremely helpful in the medical imaging domain due to its high capability in identifying specific disease patterns.

Automated deep learning may provide an opportunity to considerably expand the use of AI in health care. This will encourage medical professionals who are not AI experts to experiment with AI algorithms, allowing them to explore a much wider range of applications [5]. Such methods could deliver significant potential benefits for patients in the future by allowing for earlier disease detection and care. The aim of the present study was to evaluate the performance of an automated machine learning algorithm in the diagnosis of COVID-19 pneumonia using chest CT scans.

2. Methods and Materials

We analyzed a dataset that contains 349 COVID-19 and 397 non-COVID-19 CT scan images, which were captured by patients with any lung diseases, not associated with COVID-19. These images were gathered from COVID-19 articles on medRxiv and bioRxiv. The procedure of the collection of these CTs images is described in detail in [6, 7], and the dataset is available for research purposes [8]. For our experiment, we chose to utilize the Google AutoML Cloud Vision for model design, training, validation, and testing. Neural Architecture Search (NAS) [9] is the underlying framework that supports this platform to find the best way to train deep learning models. AutoML platforms can assist users with limited ML expertise in developing image recognition models by only uploading the examined dataset and performing some basic configuration settings. The number of CTs images that were used in every stage of the model’s creation procedure are shown in the following table (Table 1).

Table 1. Number of images that have been assigned to the Train, Validation and Test sets

Label	Train	Validation	Test	Total
COVID-19	279	34	36	349
Non-COVID-19	317	39	41	397
Total	596	73	77	746

3. Results

The AutoML Cloud Vision performance metrics are recall, precision, and average precision. The average precision measures how well the deep learning model performs across all score thresholds and is the area under the precision-recall curve. The closer this score is to 1.0, the better the model performs on the test set. In our case, the average precision’s value is 0.932. The recall (sensitivity) is 0.8831, and precision (positive predictive value) is 0.8831 for a given score threshold.

The score threshold, in our example, was set 0.5, allows us to explore how this value affects the precision and recall of our model, and the corresponding tradeoff curve (Figure 1). This can help us find a good balance between false positives and false negatives. In our case, by having set the score threshold 0.5, the precision and recall both have the same value (=0.8831), which leads to an F1 measure equals to 0.8831.

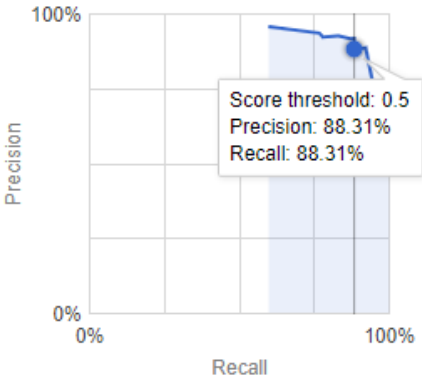


Figure 1. Precision-Recall tradeoff curve

Additionally, the confusion matrix for the deep learning model is shown below (Table 2), which represents the cross-tabulating ground truth labels versus the labels predicted by the model.

Table 2. Confusion Matrix of 77 test CTs images

True Label	Predicted Label	
	COVID-19	Non-COVID-19
COVID-19	31	5
Non-COVID-19	4	37

4. Discussion

Current literature suggests that lung imaging may play a pivotal role in screening and in the rapid diagnosis of COVID-19 disease, in symptomatic patients, pending confirmation by molecular tests [10-12]. In this study, we evaluated the performance of an AutoML Cloud Vision model with promising results in terms of accuracy in detecting patients infected with COVID-19 using CT lung scans. Our results obtained by using AutoML are comparable with the performance ($F1 = 0.85$ and $AUC = 0.94$) of classic deep

learning models developed using traditional non-autoML techniques [7] applied to the same dataset. Despite the high positive predictive value of lung CT findings in coronavirus disease, certain limitations exist. COVID-19 pneumonia shares common imaging characteristics with other viral pneumonias or non-infectious lung diseases. Moreover, in the early stages of the disease or in asymptomatic patients, a CT scan may be negative. Therefore, a multidisciplinary approach to diagnosis is essential.

5. Conclusions

There are several constraints that limit the development and widespread adoption of AI methods in clinical practice, with the major concern being the lack of open datasets to train AI models. Collaborative projects which gather and share big data may contribute to the fight against this new pandemic. AutoML platforms may help users with limited ML expertise train image recognition models by only uploading the examined dataset and performing some basic settings. This could prove a substantial tool in the quest of the medical profession to understand and treat the disease, eventually delivering significant potential benefits for patients in the future.

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Evidence-Based Health Intelligence with Globally Localized Epidemic Knowledge Base: Merging Pathological Data, Socio-Environmental Data and Intervention Knowledge Data

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Abstract. The increased prevalence and frequency of infectious diseases are alarming with respect to the disproportionate fatalities across different regions, socio-economic conditions, and demographic groups. Combining pathological data, socio-environmental data, and extracted knowledge from white papers, we proposed a Globally Localized Epidemic Knowledge base (GLEK) that can be utilized for efficient and optimal epidemic surveillance. GLEK merges social, environmental, pathological, and governmental intervention data to provide efficient advice for epidemic control and intervention. Heuristically utilizing multi-locus data sources, GLEK can identify the best tailored intervention.

Keywords. Epidemic, Infectious Disease, Applied Text Analysis, Relational Epidemic Surveillance, Population Health, Health Informatics, SARS, H1N1, MERS

1. Introduction

The unprecedented COVID-19 pandemic, which has reached 213 countries as of May 20, 2020 [1-3], highlights the increased and urgent need for proper epidemic surveillance and management systems. The main challenge of modern epidemics is their multiplexity. Throughout history, pandemics have had significant impacts on human society [4], but the complexity introduced by globalized dynamics imposes new constraints on conventional quarantine methods. The main issue encountered when dealing with the estimation of risk of a new virus based on the simulation of previously observed curves is that those curves in a novel case vary depending on the social conditions and compositions of the various infected sites. We need a better platform on which to assemble systematically our experience and data regarding various pandemic episodes. A globalized data collection and white paper knowledge integration for epidemic surveillance, which is not only lucrative but also needed, can be made at two levels: the local and global. In this work, by combining socio-environmental data, pathological data,

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and knowledge extracted from white papers and commission reports, we proposed a Globally Localized Epidemic Knowledge base (GLEK) system that can be utilized for efficient and optimal epidemic surveillance.

2. Multilayered Knowledge Base for Epidemic Surveillance

Health outcomes are social products [5], and epidemics demonstrate the importance of social determinants of health [6]. Fatality of infectious diseases varies greatly across different geographical regions and demographic segments, as well as social groups [7-9]. There are wide variations in a country as well as extended heterogeneity across border lines. Depending on social conditions, the fatality of a virus may be enhanced and diminished. Reactions to the epidemic differ greatly across regions and social and demographic groups. Infectious diseases are inevitably social. The social components of epidemics are closely related to the local context but vulnerable to the global dynamics. Along with pathological knowledge, government attitude, past experiences, social diversity, and the level of public sanitation are equally important for efficient pandemic control. Both pathological data for epidemic surveillance and locally customized reports, such as white papers and social data, are crucial components in explaining differential pandemic spread patterns. Owing to the high uncertainty, every new epidemic episode challenges the health practitioners and policy makers.

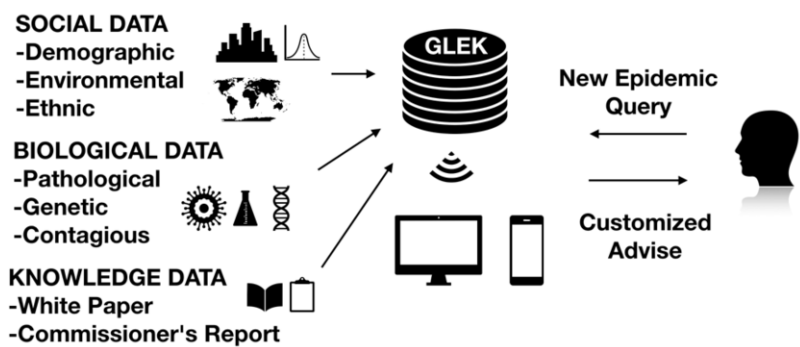
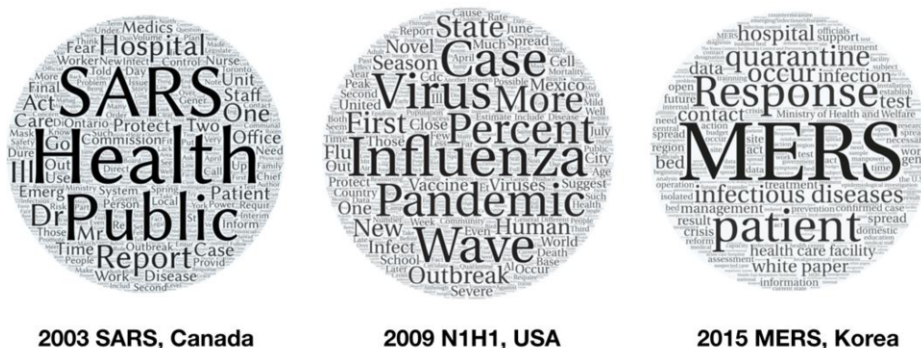


Figure 1. Globally Localized Epidemic Knowledge-base (GLEK)

A knowledge-based framework can be useful for formulating recommendations [10, 11]. GLEK combines a database system and a knowledge base system. The database component collects and stores empirical (both pathogenic and social) and knowledge data (both governmental and scholarly) related to any epidemic case on a cloud space. The knowledge base component provides a query engine to suggest an optimal matching epidemic intervention and thus improves and updates the sophistication of the epidemic knowledge relevance. To achieve these, GLEK implements a matching mechanism that covers both pathological similarities and social contexts. As shown in Figure 1, GLEK can provide the best matching epidemic cases regarding multiple categories and automatically extract knowledge from the white papers and governmental reports from socially and pathologically similar cases. To demonstrate the optimization strategy, we summarized three different epidemic episodes in different countries in Table 1. Figure 2 shows the different focuses and key words from the case reports [12-18].

Table 1. Three Cases of Different Epidemic Unfolding

	SARS (2003, Canada)	H1N1 (2009, U.S.)	MERS (2015, Korea)
Cumulative number of cases	375	6,800,000	186
Number of deaths	44	12,469	39
Case fatality rate (%)	11.73	0.18	20.97
Direct spread	Possible	Possible	Possible
Indirect spread	Not Certain	Possible	Conditional

**Figure 2.** Epidemic White Paper Contents Analysis Using Top 100 Keywords

GLEK will recommend socially similar cases for the optimal intervention or quarantine strategies that are extracted from white papers or official reports. When MERS 2015 broke out in South Korea, it would have been more relevant to look at the SARS 2003 case in Canada than the H1N1 2009 outbreak in South Korea or the H1N1 2009 outbreak in the United States. Matching starts with an infection reproduction power (which can be measured by R_0 , the expected number of secondary cases produced by a single infected individual) [19], an infection speed, and other pathogenic similarities. In this case, both infectious diseases (SARS and MERS) refer to respiratory syndromes caused by infection with a coronavirus variant. The number of infected and fatality rate, confirmed in the termination phase of the two epidemics, were relatively similar, as shown in Table 1. There are many similarities in the paths of transmission of the two epidemics and the response of health authorities. SARS 2003 in Canada happened in a slightly denser population environment (local context: MERS 1,096/km² and SARS 4,457 /km²). Both SARS 2003 in Canada and MERS 2015 in Korea were evaluated as successfully controlled in that the epidemic did not significantly spread to neighboring cities or countries [16, 17]. The Canadian authorities implemented social quarantine early compared with the MERS 2015 case in Korea.

3. Conclusions

The increased prevalence and frequency of infectious diseases are alarming, causing disproportionate fatalities across different regions, socio-economic conditions, and demographic groups. Hence, it is necessary to create a globally connected but simultaneously localized database that can account for differences between countries or cases. Traditional epidemic surveillance systems have been specialized for specific symptoms or locations. Hence, they exclusively and independently focus on the

prevalence of a single infectious disease. A possible shortcoming of such specialization is the increased probability of underestimating, if not neglecting, the complication and co-prevalence of multiple epidemic cases over diverse localities. This approach can be particularly problematic given the fact that modern infectious diseases are not constrained to one domestic region. Therefore, epidemic surveillance is inevitably and simultaneously related to the local sentiments and global dynamics. To avoid this preventable pitfall, we advise widening our surveillance scope to a landscape of global infectious diseases and customizing it to the local needs. The best tailored intervention could be efficiently identified by heuristically utilizing multi-locus data sources.

Acknowledgments

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Epidemiological Analysis of the Covid-19 Epidemic in Greece

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Abstract. During the last months the Coronavirus disease 2019 (COVID-2019) has been recognized as a global threat. Transmission of the infection has rapidly increased in Europe as well as in Greece, living behind a huge number of deaths. During this situation an analysis of the spread of the disease must be undertaken and characteristics of the virus must be recognized. For the analysis of the impact of the disease in the population during this time period, epidemiological indexes have been introduced.

Keywords: infection COVID-19, epidemiological indexes, virus, infection disease

1. Introduction

The global impact of COVID-19 has been profound, and the public health threat it represents is considered as the most serious one caused by an RNA virus since the 1918 H1N1 influenza pandemic. The increase in mortality is due to diverse brands of the virus, on the genetic characteristics of the virus circulating and on the existing degree of immunity and the dynamic potential of the immune system appearing in different age groups of the population. If these changes are profound, and since there is no immunity in the population, this RNA virus can cause a pandemic [1,2].

2. Methods

In the case of a pandemic, the spreading of the disease is intense and fast encompassing a large number of the population. This means that a large number of people can get sick at the same time, many of them seriously, a situation that creates serious health problems with various implications economical and societal and a huge burden on the healthcare systems around the world [1, 3]. For this reason, an effort has been made to inspect the degree of the spread of the virus using epidemiological indexes [2, 3, 4]. The outbreak of the Coronavirus COVID-19 has taken the lives of several thousands of people worldwide and locked-down many countries and regions, with yet unpredictable global consequences [6-10].

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In the analysis, different time periods of the recorded collected data would be considered, in particular 4.4.2020, 10.4.2020 and 24.4.2020. During the 4.4.2020, in Greece, 69 new cases have been recorded, 9 new deaths and 91persons were intubated in the intensive care units around the country [11].

In total 68 deaths and 1613 cases. Prevalence (P) [5] is defined as the number of persons with a disease or unhealthy condition in a particular period in the general population. Sometimes is referred as point prevalence and expressed as a proportion or probability. Based on that definition during the previous period, the prevalence (P) for the infected patients is $(68/1613)100\%=4.21\%$. The corresponding percentage (probability) for the patients who have been reported dead is $(9/68)100\%=13.23\%$.

During the 10.4.2020, in Greece, 54 new cases have been recorded, 4 new deaths and 77 intubated in ICU [11]. In total 90 deaths and 2009 cases. Based on that definition during the previous period, the prevalence (P) for the infected patients is $(54/2009)100\%=2.88\%$. The corresponding percentage (probability) for the patients who have been reported dead is $(4/90)100\%=4.44\%$.

During the 24.4.2020, in Greece, 7 new cases have been recorded, 0 new deaths and 55 intubated in ICU [11]. In total 121 deaths and 2408 cases. Based on that definition during the previous period, the prevalence (P) for the infected patients is $(7/2408)100\%=0.29\%$. The corresponding percentage (probability) for the patients who have been reported dead is $(0/121)100\%=0\%$. A map of geographic spreading of the disease in Greece, for 4.4.2020, 10.4.2020 and 24.4.2020 (respectively) is given in Figure 1.

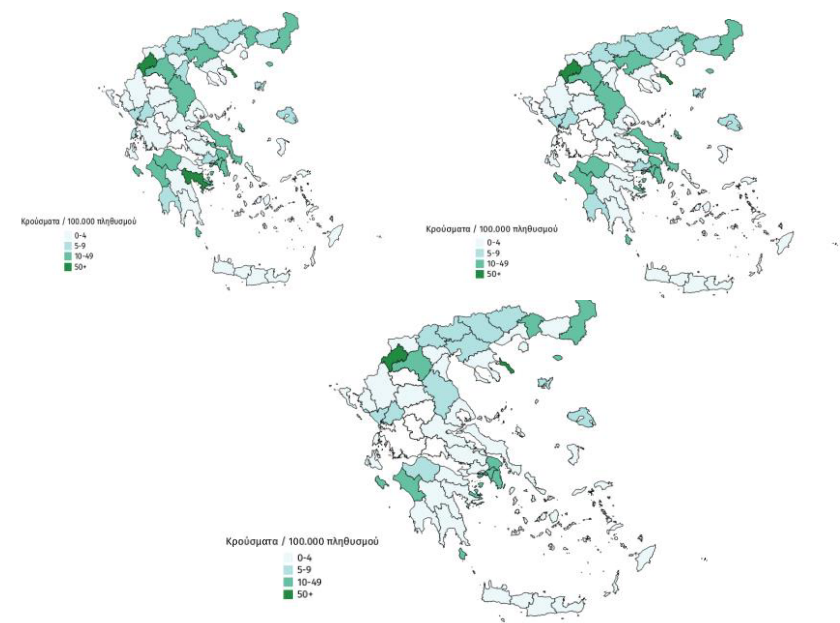


Figure 1. Maps of Greece for different days of Covid-19 spread

3. Results

From the early March of 2020, strict measures have been enforced in the general population to protect all the public from the COVID-19 Infection. The country has been under lockdown for several weeks, where schools and universities were closed, the means of transportation were stopped and only a few of them were functioning. Banks and commercial shops and malls were closed. The highest percentage of the population complied with these measures enforced fearing the strong pathogenicity of the virus. Due to these implemented measures, the epidemic was engulfed and we had very few new cases of the disease, in comparison with other European countries (Italy, Spain, Germany, UK and France) and definitely with the US, where the new cases of the epidemic amounted in several thousands of carriers and victims. It is wishful to expect this epidemiological situation of the spread of the covid-19 virus in Greece will remain stable and only few new cases will appear in the «epidemiological map» of the country in the near future.

4. Conclusions

In this analysis, an introduction of the spreading COVID-19 virus is given and the measurement of the epidemiological indexes is applied. Based on the results, there is a profound increase in the recorded new cases in the general population as well as in the cases where deaths have been recorded.

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Application of Topic Modeling to Tweets as the Foundation for Health Disparity Research for COVID-19

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Abstract. We randomly extracted publicly available Tweets mentioning COVID-19 related terms (n=2,558,474 Tweets) from Tweet corpora collected daily using an API from Jan 21st to May 3rd, 2020. We applied a clustering algorithm to publicly available Tweets authored by African Americans (n=1,763) to detect topics and sentiment applying natural language processing (NLP). We visualized fifteen topics (four themes) using network diagrams (Newman modularity 0.74). Compared to the COVID-19 related Tweets authored by others, positive sentiments, cohesively encouraging online discussions (e.g., Black strong 27.1%, growing up Blacks 22.8%, support Black business 17.0%, how to build resilience 7.8%), and COVID - 19 prevention behaviors (e.g., masks 4.7%, encouraging social distancing 9.4%) were uniquely observed in African American Twitter communities. Application of topic modeling techniques to streaming social media Twitter provides the foundation for research team insights regarding information and future virtual based intervention and social media based health disparity research for COVID-19.

Keywords. social media, pandemic, virtual intervention, health disparities

1. Introduction

To date, a total of 3,525,116 confirmed COVID-19 cases and 243,540 deaths have been reported worldwide. While there are several ongoing clinical trials, there are no medicines that have been shown to prevent or cure the disease. Notably, African Americans are disproportionately affected by Covid-19 [1]. Topic modeling applies statistical analyses to counts of words or word groups that co-occur within text documents in order to reveal latent word groupings with potential semantic significance

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across a collection of documents. Compared to manual reading and keyword/key phrase extraction algorithms (TF-IDF, TextRank), topic modeling offers the ability to find semantically meaningful groupings of multiple words across very large document collections, even in cases when all of the words do not appear together within any single document or section [2]. Topic modeling is typically applied in health science to facilitate meta-analyses of large collections of research publications, or for generating high-level summaries of discussions (e.g., on social media) among groups of interest. The purpose of the study was to apply topic modeling techniques to Tweets as the foundation to inform designs of culturally sensitive interventions targeting African Americans on virtual platforms for COVID-19.

2. Methods

We applied topic modeling and sentiment analysis for content mining of publicly available Tweet corpus mentioning COVID-19 (keywords: covid19, Covid, covid-19, COVID, corona, coronavirus). We used NCapture, ORA and a Terremoto High Performance Computing Cluster (<https://cuit.columbia.edu/shared-research-computing-facility>). We randomly extracted publicly available Tweets mentioning COVID-19 related terms (n=2,558,474 Tweets) from Tweet corpora collected daily using an API (https://osf.io/qruf3/?view_only=08302960d9f4486083e82971a1eda125) from Jan 21st to May 3rd, 2020. First, 327 XML files were merged using Perl regular expression commands and shell scripting on the Terremoto cluster. Second, we randomly extracted Covid-19 related Tweets using publicly open African American Twitter community hashtags (#blacktwitter, #staywoke, #blacklivesmatter). Third, we applied NLP and a clustering Newman algorithm to the publicly available Tweet corpus. The relative frequency of 55,035 n-grams from both corpora were compared using Chi-square in order to identify n-grams uniquely occurring in Tweets authored by public African American Twitter communities. Next, we visualized 15 topics using a network diagram (Newman modularity 0.74). Lastly, experts in African American culture studies, public health, nursing and behavioral science performed qualitative thematic analysis on the detected topics. The larger study was approved by the Institutional Review Board (IRB).

3. Results

Positive sentiments, cohesively encouraging online discussions (e.g., Black strong 27.1%, growing up black 22.8%, support black business 17.0%, how to build resilience 7.8%) , and COVID-19 prevention behaviors (e.g., masks 4.7%, encouraging social distancing 9.4%) were uniquely observed in Tweet corpus authored by African Americans. Top 50 unique n-grams in COVID-19 related Tweets authored by African Americans and their frequencies are summarized in **Table 1** (χ^2 p-value < 2.2e-16).

Table 1. Top unique n-grams in COVID-19 related public Tweets within African American Communities

n gram	frequency	n gram	frequency
African Americans	40.72%	stylist	6.26%
xcellence	32.66%	Monday motivation	6.04%
black strong	27.07%	woo young (k-pop singer)	6.04%
growing up black	22.82%	calling	5.82%
support black business	17.00%	quarantine	5.82%
warriors	16.11%	hospitals	5.59%
died (deaths, dying)	13.20%	mortalities	5.37%

doctors	12.30%	patients	5.15%
lock down hustle	11.63%	wards	5.15%
black girl magic	10.07%	blue lives matter	4.92%
cases	10.07%	essential not expendable	4.92%
Michigan protest	9.84%	gentiles	4.92%
communities	9.17%	Hebrew Israelites (Black group)	4.92%
white privilege	8.28%	essential workers	4.70%
how to build resilience	7.83%	hypocrites	4.70%
black girls rock	7.61%	masks	4.70%
artvsartist	7.38%	china lied	4.47%
stay home save lives	7.38%	minimum wage	4.47%
hand wara	7.16%	real relief now	4.47%
nurses	7.16%	star wars	4.47%
caucus	6.94%	Wisconsin	4.47%
families	6.71%	women matter	4.47%
stocks	6.49%	businesses	4.25%
humors	6.26%	disparities	4.25%
schooling	6.26%	end times	4.25%

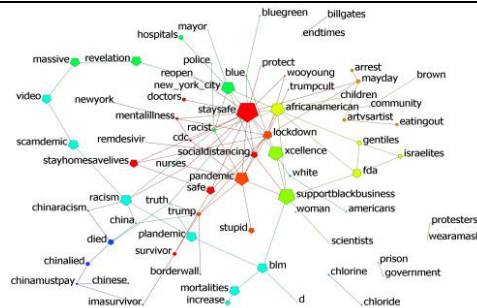


Figure 1. Semantic visualization of topic modeling on COVID-19 Tweets authored by African Americans
Fifteen topics (four themes) were identified in 1,763 publicly available COVID-19 related Tweets within African American Twitter communities (Newman modularity 0.74). Four main themes include: 1) Symptom and Transmission Patterns- cure, case, patient, death; 2) Treatments, Prophylaxis and Cures- data, CDC, mortality, rate; 3) Effectiveness/Impact of Interventions by Health Authorities and Other Institutions– day of lockdown, quarantine, covid safe, crisis, impact, free food; 4) Fear –protect, help, new, African American community, black, isolation, quarantinelife, school, foodshortage.

4. Discussion

We detected fifteen topics in publicly available Tweets by African Americans applying topic and further categorized those topics into four main themes including symptoms/transmission patters, treatment, implementation of interventions, and fear. Social media has become important in the global discussion of the science behind the pandemic. Understanding the spread of the virus is critical because of its deadly nature. Yet, several hundred new studies arise daily. The global scientific community is cooperating in ways never seen before in order to ensure vaccine and treatment development are guided by the most accurate findings [3]. In a study comparing COVID-19 knowledge by misinformation source found that social media respondents were unconvinced handwashing or social distancing was valuable. In fact, tremendous distrust from the CDC emerged as social network respondents believed the COVID-19 threat was a politically motivated hoax from the CDC, the virus is man made in China and Vitamin C is a secret cure [4,5]. Inaccurate information spread on social networks

generally includes the impact from COVID-19 is not real including the death toll is a lie. Medical professionals are bombarded dispelling myths during care visits which is beginning to take a toll on their well-being [6]. Fear is evidence by people not seeking care when COVID-19 symptoms exist, the drinking of bleach indicating we are not doing a good job in protecting the public from inaccurate information. Yet, in the recent weeks social networks have taken a variety of steps to dispel myths including the addition of a portal to vet information from public officials and banning conspiracy theory content, which drives fear. Some public figures with popular social media platforms have been observed to use fear and chaos to drive their agendas and recruit people for their causes. They often spread distrust of the government and the information in the news about the virus, treatments and death. Follower with inaccurate information are often times confused leading to adverse effects including the ignoring of stay-at-home orders. The US media system supports disinformation, racism and hate as it drives up the ratings and advertising revenue, making dispelling such myths even more difficult. In March, however, Twitter set out to ban inaccurate information and to remove such influencers like Fox news hosts as it listened to civil rights organizations to tack these actions [6,7]. The generalizability of this study is limited by using the control, which did not exclude Tweets written by African American individuals. A few recent classifiers have been developed to detect demographic information in Twitter; however, they were either unavailable or in a form that is not easily applicable. As a result, some important topics uniquely discussed by African American Twitter communities may have been excluded.

5. Conclusions

Our topic modeling detected information, rumors, positive sentiments, cohesively encouraging online discussions (e.g., Black strong 27.1%, growing up Blacks 22.8%, support Black business 17.0%, how to build resilience 7.8%), and COVID -19 prevention behaviors (e.g., masks 4.7%, encouraging social distancing 9.4%) as unique culture within African American Twitter communities. This new knowledge adds insights regarding future virtual based intervention and social media based health disparity research for COVID-19.

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200 Years Since the Birth of Nursing Informatics?

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Abstract. It is 200 years since the birth of Florence Nightingale. This keynote paper reviews some of her work relating to health statistics and outlines its continuing legacy to nursing informatics around the world and especially in poorer countries, like South Africa, in the 21st century.

Keywords. Florence Nightingale, Uniform Classification, Hospital Statistical Form, Mortality

1. Introduction

Florence Nightingale was born in Florence, Italy, on 12 May 1820, and grew up at Embley, East Wellow, England, the family home, with her older sister, Parthenope, where they were initially educated by a governess (1,2). Then their father continued their home education himself because he believed that women should be educated. Nightingale thrived in her studies. Statistics became a tool that she used in many of the reports she wrote post the Crimean War. Some scholars regard Nightingale as a great statistician, rather than the founder of modern nursing (3,4).

2. 1820: the early years

The sisters were educated for a life in society. Embley provided the perfect setting for Mrs Nightingale to entertain some of England's foremost personalities including Charles Babbage, who originated the concept of a digital programmable computer and was the founder of the London Statistical Society. Nightingale records in 1867 (1,2) that God called her to His service on 7 February 1837, aged 16 years, at Embley, but she did not know what she was to do. Her life at home was miserable; her sister repeatedly reproached her, and she disliked the dull routine of Victorian home life. In December 1845, Nightingale asked her parents if she might go to Salisbury Infirmary for three months to observe. An argument followed. Her mother was worried about the offensive language Nightingale might hear in a hospital and the embarrassment she would bring on her family (2,5). Her father went to London to get away from the tension and spoke

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to friends about hospital nursing. Most held the established opinion that a gentlewoman could find herself in “unpleasant surroundings” should she become a nurse (1).

3. 1837: Her Craving to Work

Nightingale only enjoyed domestic responsibilities was when she was asked to give someone nursing care or there was a need for a temporary housekeeper. In January 1837 there was an outbreak of influenza and Nightingale, her cousin and the cook did not catch it. Nightingale spent the month acting as “nurse, governess, assistant curate and doctor while continuing with her studies” (6) and admitted in a letter to Parthenope “At all events, I have killed no patients, though I have cured few” (6). Parthenope was unwell and she and her mother planned to visit Carlsbad in the summer of 1851. Nightingale demanded to go with her mother and sister to spend time at Kaiserswerth, Germany. Pastor Theodor Fliedner had founded an order of deaconesses where spinsters could work within the confines of a religious community. Nightingale arrived in early July and stayed three months. The routine at Kaiserswerth was strict but she returned home feeling more peaceful, although still resolved to take control of her life and follow her own path. In April 1853 Nightingale became the Superintendent at the Institution for the Care of Sick Gentlewomen in Distressed Circumstances in London. Her father’s one positive move was to give Nightingale a generous £500 a year allowance, equal to approximately 75,000 euros today. The following year the British were at war in the Crimea and the war correspondent William Howard Russell sent news back of the fighting there in October 1854. On 21 October Nightingale and a group of nurses set sail for Constantinople. Nightingale was mentally burdened by her experiences in Scutari and began to statistically analyse the causes and rates of death of the soldiers with the help of Dr William Farr. The Government attributed the huge death rate to malnourishment and hypothermia on the front line. Small (7) undertook an in-depth exploration, including formerly unused letters, of “Nightingale’s own claim that while she was Superintendent of Nursing in the hospitals of the Crimea War 14,000 soldiers died in hospital because she and the medical staff neglected elementary sanitary precautions” (7). Nightingale and Farr showed that it was the unhygienic hospital conditions, particularly overcrowding, that precipitated the soldiers’ deaths. Small confirmed that the Army’s neglect of the soldiers in the trenches was not the cause “as everyone believed. It had been primarily caused by bad hygiene. The worst of these, where 5,000 men died in the winter of 1854/5, was Florence Nightingale’s own base hospital at Scutari” (7), in Constantinople. Cook (1) stated that Nightingale recognised that the majority of soldiers need not have died. She devised the coxcomb, a statistical figure, to illustrate the causes and rates of death during the war, where the statistic being represented is proportional to the area of a wedge in a circular diagram (8,9). Small reasoned that Nightingale’s logical thought processes brought her to the conclusion that her inexperience and pride had led to the death of thousands of soldiers and that the remainder of her life was focussed on trying to redress her guilty feelings.

4. 1858: Collaboration with Dr. Farr on Uniform Classification and Model Forms

Dr. William Farr was a prominent epidemiologist who was appointed in 1838 to the General Register Office of England and Wales. In his first Annual Report Farr strongly

recommended the implementation of a uniform classification. The tenet of organising diseases by anatomical site as suggested by Farr, was the foundation of the International List of Causes of Death. His nomenclature and classification of disease, endures as the foundation for the International Classification of Diseases, now in its 11th revision (10). As a fellow member of the Statistical Society Farr knew Nightingale and worked with her on several statistical projects. In 1859 she was examining hospital statistics in London and found that each hospital used its own nomenclature and classification of diseases and there was no consistent methodology for data collection. Several willing hospital doctors and Farr assisted her to prepare a standard list of diseases and a model Hospital Statistical Form was designed. The forms were printed in 1859 and four London hospitals agreed to use them. Nightingale and Farr studied the results which showed that a large field of statistical analysis would be available if all hospitals adopted the forms. On 21 June 1861 at a meeting at Guy's Hospital it was agreed that the Metropolitan Hospitals should implement a standardised system of Registration of Patients, that each hospital should publish its statistics annually and that Nightingale's Model Forms be embraced as much as possible. Cook suggested that the scheme was abandoned because the data collection and checking was laborious and costly to ensure it was uniform and accurate. This then impinged on the validity of the conclusions drawn from the statistical analysis (1). Undeterred and with the help of Farr and Sir James Paget from St Bartholomew's Hospital, Nightingale then created forms for collecting surgical patient data. The Royal College of Surgeons studied the results but reported negatively (1,11). No information is given for the reason for the negative report and this lack of evidence suggests that the surgical Hospital Model Forms also fell into disuse.

5. 1871: Notes on Lying-in Institutions

Nightingale wrote *Notes on Lying-in Institutions* in 1871 (12). She collected English and European statistics on maternal mortality. It began with a brief preface on the rise in maternal deaths at the Kings College Hospital Midwifery School, which started in 1862. It closed five years later because nine women had died that year following 125 deliveries. Later in the treatise (12) Nightingale turned her attention to deaths in lying-in institutions. She maintained that puerperal fever was the primary cause of death across Europe and that lying-in hospitals and lying-in wards in general hospitals should be closed. Maternal mortality is still excessively high. About 295,000 women died during and following pregnancy and childbirth in 2017 (13). 86% occurred in Sub-Saharan Africa and Southern Asia. As with women in 19th century Europe, poorer women have, on average, many more pregnancies than more wealthy women and hence their risk of death is higher. Puerperal sepsis, haemorrhage and toxemia (eclampsia) still feature at the top of the list of causes of death. The key reasons which prevent women from obtaining health care are: poverty, distance to facilities, lack of information, inadequate and poor quality services and cultural beliefs and practices. This leads one to reflect that some poorer countries of the world have not developed beyond the level of 19th century Europe.

6. Nightingale's Legacy to the Poorer Countries of the World

The majority of the African continent is rated by the world bank as low income countries, with a few rated as middle income. Africa's 54 countries have several large cities that can be compared to large cities around the world but the majority of the people living in the rural areas have a very different view of the world. It is reasonable to compare major South African cities to European cities that have every technological convenience, for example; Durban, Pretoria, Johannesburg, Cape Town and Port Elizabeth. However, South Africa also has 27% of its population unemployed and low paid workers living on less the 150 euros a month. The larger part of South Africa and indeed Africa as a continent, is similar to Europe in the 19th century. "Around 640 million people currently live without electricity in Africa – 210 millions of which are in fragile and conflict-affected countries" (14). Technology is hard to sell where there is no electricity and the majority of people still cook on open fires. In South Africa the current poor doctor patient ratios and the difficulties of attracting doctors to rural areas, means nurses are providing most Primary Health Care (PHC) services in some 4,000 nurse-led clinics predominately in rural areas together with a growing number of mobile clinics. Their role includes the collection of data to support programmes of care often in conjunction with the Centre for Disease Control, CDC Africa. Many African countries use paper-based recording systems to collect data handwritten in registers, similar to Nightingale's Model Hospital Forms, to support the administrative purposes of public health programmes. Programmes of care have defined clinical guidelines which require nurses to record the patient's visit in one of many registers. Each programme of care has its own register, for example for HIV, Diabetes, Asthma, Hypertension, Tuberculosis (TB) and Antenatal care. Difficulty occurs when a patient has more than one disease, for example Tuberculosis and HIV, into which register should the patient be entered? For registers to be of any value, they should be written contemporaneously, however in the rural clinics the volume of patients waiting to be seen negates this possibility. Registers are often written up at the end of the day or week and therefore the accuracy of the data is suspect. This data is then hand aggregated for submission to the District Health Information System (DHIS) in the form of ICD codes.

7. Conclusions

"Nursing Informatics science and practice integrates nursing, its information and knowledge and their management with information and communication technologies to promote the health of people, families and communities world-wide." (15). This is the definition that the IMIA Nursing Special Interest Group asks that members of the IMIA family use. It links the need for information management to support the health of people. It includes information processing and communication technologies but does not specify any particular technology. The management of information by nurses for the advancement of healthcare is pivotal to a 21st century definition of nursing informatics. The tools and technologies that are used are secondary. Nightingale, today would probably use a laptop, smart phone or tablet computer and be an expert spreadsheet guru with varying scenarios that forecast death rates and mortality, depending on the validity of the data collected. She would still be influential with national and international decision makers concerning the inequalities still to be addressed in the world.

Nightingale's unique contributions to nursing administration and management confirmed her as a pioneer nursing informatician. Her broad education prepared her to research meticulously, document in detail and think creatively. She was a thorough researcher and her data led approach, with illustrations, so that others might understand, indicated her drive to improve care. Nightingale would approve of IMIA's definition of Nursing Informatics because its purpose is "to promote the health of people, families and communities world-wide" (15) which is the critical component of the duties of 21st century nurses in their care of the sick around the world. Nightingale died peacefully 13 August 2010 and would be delighted in the way that healthcare, especially nursing, has developed over the past 200 years. Her statistical work has influenced health care management including the development of world health monitoring of diseases and epidemiology. However, she would be saddened that the world still has a long way to go to reach health equality for all to a 21st century standard.

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Remote Monitoring of Patients in Quarantine in the Era of SARS-CoV-2 Pandemic

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Abstract. The aim of our study is to propose a remote patient monitoring solution through a smart phone application (Smart Patient) collecting health data to support diagnosis, monitoring and predicting poor outcome in asymptomatic/mild cases of COVID-19, including signs and symptoms, risk factors, comorbidities, medications and vital signs such as body temperature, respiratory rate, heart rate and oxygen saturation. By continuous daily recording of suspected cases and patients, family doctors in the community will be able to follow up cases and intervene promptly when deterioration in vital signs and symptoms takes place referring the patient to the hospital.

Keywords. Monitoring, public health, SARS-CoV-2, smart phone

1. Introduction

Coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2 has provoked a significant threat to global health [1]. Those diagnosed with COVID-19 or suspect infection are advised by the CDC/WHO to stay home, unless they need urgent medical care. With quarantines to contain the spread of the pandemic, governments and healthcare providers must utilize solutions to monitor COVID-19 patients who are asymptomatic or present mild symptoms and are confined at home. To assure patients' monitoring, the Greek National Public Health Organization (NPHO) has implemented a system for telephone counseling and referral of patients to specific health structures for screening and/or hospitalization [2, 3]. Mobile Health and home monitoring technologies comprise rapidly evolving fields using various apps and sensors aiming at monitoring and management of chronic diseases with promising results [4-6]. The aim of our study is to propose a remote patient monitoring solution (Smart Patient) through

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a mobile smart phone application collecting important medical health data, relevant to COVID-19.

2. Methods

We propose a COVID-19 remote patient monitoring mobile application for the recording of two separate groups of clinical information: (1) patient-reported data (clinical signs and symptoms, medical history and medications) through completion of a basic screening diagnostic digital questionnaire for COVID-19 signs and symptoms as well as important health data for risk assessment, and (2) vital signs data (body temperature, heart rate, respiratory rate and oxygen saturation) generated by the smart phone or other wearable sensors communicating with the smart phone through Bluetooth technology. Once on the smart phone, the sensor data can be displayed in the respective app of the sensor and at the same time, all data (sensor and patient-reported) can be sent to a secure cloud storage and on a SSL encrypted website accessible to the physician. The proposed mobile application may be compatible with iOS and Android systems and the user may download it from App Store and Google Play.

3. Discussion

The “Smart Patient” monitoring solution for COVID-19 data reporting and patients’ follow up could be utilized by family doctors and other physicians in their area of responsibility. Through continuous daily recording of suspected cases and patients, physicians may intervene timely in cases of deterioration in vital signs and symptoms referring the patient to the regional hospital. Additionally, the implementation of remote monitoring of patients throughout the country could be a valuable tool for epidemiological surveillance of the pandemic, through central reporting of suspected and confirmed COVID-19 cases. However, implementation of the “Smart Patient” monitoring solution depends on health policy makers, and many challenges including patients’ cooperation and training, logistics and legal implications have to be considered. To address data privacy issues, further developments may include a secure messaging system with end-to-end encryption and APIs to connect with popular health apps like Apple Health.

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Safety Justification of Healthcare Applications Using Synthetic Datasets

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Abstract. *Background:* Increasing numbers of intelligent healthcare applications are developed by analysing big data, on which they are trained. It is necessary to assure that such applications will be safe for patients; this entails validation against datasets. But datasets cannot be shared easily, due to privacy, and consent issues, resulting in delaying innovation. Realistic Synthetic Datasets (RSDs), equivalent to the real datasets, are seen as a solution to this. *Objective:* To develop the outline for safety justification of an application, validated with an RSD, and identify the safety evidence the RSD developers will need to generate. *Method:* Assurance case argument development approaches were used, including high level data related risk identification. *Result:* An outline of the justification of such applications, focusing on the contribution of the RSD. *Conclusions:* Use of RSD will require specific arguments and evidence, which will affect the adopted methods. Mutually supporting arguments can result in a compelling justification.

Keywords. Safety, assurance, realistic synthetic dataset, clinical decision support

1. Introduction

Advances in technologies have resulted in numerous intelligent healthcare applications, providing advice, support as well as diagnosis. Failures in their operation may cause harm to patients, by offering incorrect advice, or by making the wrong diagnosis. This is increasingly recognised in regulation and standards, where they are seen as medical devices [1], [2], in need of safety assurance [3]. Developers are often asked to articulate the justification of their application's safety, known as an assurance case (e.g., UK NHS DCB0160 and DCB0129). Assurance cases provide a means of explaining how evidence created during development and validation, can allow to claim that an application is acceptably safe. Effective assurance of intelligent applications will require validation, by testing the application using datasets, representative of the clinical scenarios in which they are used. However, datasets cannot be freely used for validation, as they may result in compromising the privacy of patients. The use of Realistic Synthetic Datasets (RSDs) is seen as a way to overcome this and encourage innovation [4], [5]. The paper presents the outline of an assurance justification of an intelligent application, using the RSD based approach. The assurance framework provides the aspects that need to be justified, and expected types of evidence, in order for an RSD based approach to be used confidently

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for the validation of intelligent applications. The framework was used to elicit requirements for appropriate statistical evidence for the use of RSD, in a proof of concept project on generating realistic synthetic datasets for application validation.

2. Safety Justification of the of the Synthetic Dataset

Figure 1 shows the identified assurance justification outline, for of an intelligent healthcare application following the process in [6]. Claims are expressed as post conditions [7], supported by a series of further claims, until they can be supported by evidence.

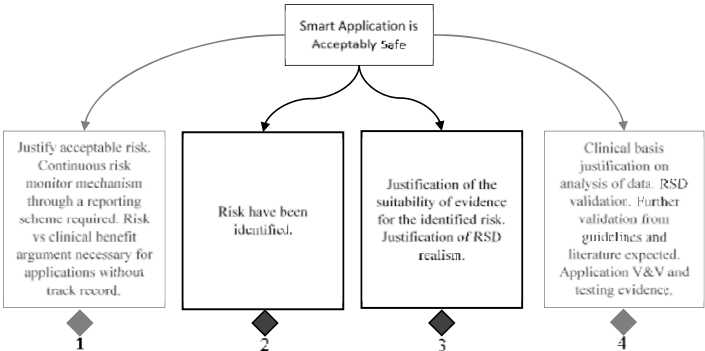


Figure 1. Justification outline (claim and supporting arguments) for an intelligent healthcare application (arguments #2 and #3 are relevant to RSD), loosely using the Goal Structuring Notation that is common in safety cases. Diamonds denote that the argument need to be further developed.

A high level claim about assurance is supported by four arguments : a) description of the acceptable residual risk, which will eventually need to be balanced against expected clinical benefit (arg. #1); b) justification of correctness of the application, including testing results, and validation against the RSD (arg. #4); c) justification placing our confidence in the claim made by argument #4 (arg. #3); and d) justification that the application risks have been identified, including the risks of using an RSD (arg. #2).

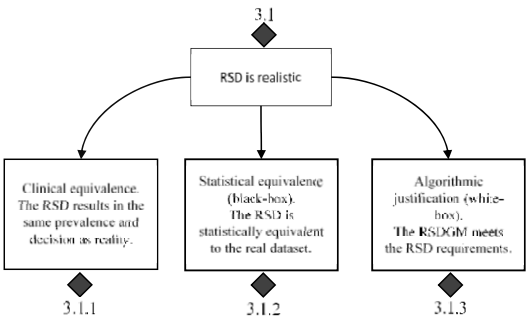


Figure 2. Justification for the realism of the Realistic Synthetic Dataset (RSD).

Figure 2 illustrates the expected arguments of the justification for claiming that the RSD is realistic. There are three arguments identified: a) the RSD results in a dataset that represents realistically clinical knowledge (e.g., prevalence of a disease), as well as outliers; b) statistical equivalence of the real and the synthetic datasets; and c) the employed generation methods are fit to satisfy the RSD usage requirements. The

statistical equivalence looks at the approach as being a black box, only comparing the resultant RSD with the real dataset. However, applications that may be highly critical (e.g., secondary care CDS, or large numbers of patients exposed to the risk), a justification of the RSDGM itself may be necessary to provide sufficient assurance. Tolerance of difference between the two datasets will need justification in the context of specific applications.

3. Establishing the Risk of using the Synthetic Dataset

Risk identifies the safety significance of failures that may affect the users of a service. A safety analysis process will aim to eliminate, or reduce their risk to acceptable levels. Achieving this requires identification of the failures, and their likelihood and severity. Table 1 summarizes a top-down identification of failures that may be caused due to the RSD [8], which are expected to be found in argument #2.

Table 1. Failure modes applying the RSD, to be considered when using the RSD for application validation.

RSD Failure Modes	Description
Unrealistic	The resultant dataset contains data, based on which, any inferences would be wrong or beyond a certain tolerance when compared to reality.
Coverage	RSD does not detect inferences for border cases and outliers.
Underrepresent	Minority populations not sufficiently represented in the synthetic dataset.
Unwarranted	The resultant dataset creates inferences unwarranted in the real data.

In the context of validating a healthcare application (figure 1), failure modes may: a) detect a wrong recommendation (undetected error); b) suggest a false negative on a recommendation by the application (undetected inference); c) provide false assurance that a minority population is covered; and d) falsely suggest that the application should have provided a recommendation (unwarranted inference).

4. Evidence Supporting Assurance of the Synthetic Dataset

The arguments supporting the claim about the realism of the RSD, will require different types of evidence (Table 2).

Table 2. Potential evidence suitable to support the arguments for the realism of the RSD (Figure 2)

Argument	Evidence
3.1.1 – Clinical equivalence	Expert clinical review, comparison with literature, coverage and quality of the real data, persona-based testing, outlier testing.
3.1.2 – Statistical equivalence	Divergence metrics for probability distributions, cross-correlation matrix between the two datasets, non-parametric statistical significance,
3.1.3 – Algorithmic justification	Hyperparameter configuration, probability graphs, divergence metrics minmax proof.

The clinical equivalence argument (3.1.1) is expected to provide independent support to the other branches, by not only focusing on comparison of the two datasets, but comparing the RSD with reality. This way we can identify problems that the two other arguments may not reveal. It will also encourage identification of counter evidence, overcoming potential confirmation bias. Persona-based scenarios allow testing for outliers and minority representation, based on experts’ knowledge and literature. The statistical equivalence argument (3.1.2) focuses on evidence of suitability of the RSD to be used in lieu of the real dataset. This can be challenging, as the purpose of the RSD is to diverge from the real dataset, in order to preserve privacy. Finally, the algorithmic

argument (3.1.3) offers evidence about the RSDGM. This is the branch that is most dependent on the adopted method. Methods, such as probabilistic graphs, offer more visibility than neural network approaches (e.g., Generative Adversarial Networks).

5. Conclusions

Realistic synthetic datasets are a promising approach, for validation and safety assurance of intelligent healthcare applications. This will overcome barriers of using real datasets due to privacy concerns, enabling development of applications that may increase patient benefit. The paper presented an outline for the justification of such an application, validated specifically with an RSD. This allows the RSD developers to understand the implications of assurance on the generation process. The framework allowed to identify design and validation requirements, for an RSD generation method, in a proof of concept project.

Acknowledgements & Notes

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Lessons Learned: Implementation of a Nationwide Innovative E-Learning Module for Health Enabling Technologies

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Abstract. E-learning enables students to participate in online courses across universities. As a part of the HiGHmed joint teaching and training program, we developed an e-learning module entitled *Health Enabling Technologies and Data* based on the Gilly Salmon 5 stage model didactic concept. This course was implemented at a German Technical University in the winter semester 2019/20 and evaluated by the students after completion. Student evaluation indicates good teaching presence but improvable social presence. From the perspective of the lecturers, we have learned that interactivity should be enhanced to improve the students' engagement, and incentives shall be established to foster students' active participation. Therefore, we will revise the course for the next term by (i) web conferences, (ii) assessment of interactivity, and (iii) clear "take-home" messages.

Keywords. e-learning, health enabling technologies, lessons learned

1. Introduction

Educating students is a key responsibility of universities [1]. E-learning allows students to learn independently of time and place [2]. In light of the current situation regarding the coronavirus disease (COVID-19) pandemic and the restrictions on contact, online-based courses may allow to bridge this crisis.

To guarantee the qualified handling of data in health care and research by future researchers, the implementation of new e-learning modules is on demand [3]. The HiGHmed consortium brings together outstanding competencies in teaching and training in medical informatics and is part of the medical informatics initiative in Germany. In this context, we developed an e-learning module entitled *Health Enabling Technologies and Data* and implemented it in the winter semester 2019/20 at the TU Braunschweig [4]. Health enabling technologies (HET) can continuously monitor vital parameters, which supports physicians in detecting diseases. HET worn on a human body to measure cardiac activity, generate data that may be superimposed by artifacts, such as movement artifacts and recording gaps. Hence, HET imposes challenges in signal processing as well as semantic integration of this data in electronic health records which need to be addressed in the curricula of medical informatics students.

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Therefore, we implemented this e-learning course to cover HET data management from a comprehensive perspective, starting with data generation, followed by its recording, storing, and ending with its analysis. In this work, we want to share our experience and the lessons learned from the lecturers' perspective when implementing this e-learning module. Additionally, we analyze the students' feedback obtained using evaluation sheets from the first roll-out of our online module.

2. Method

2.1. Didactic Concept

An appropriate didactic concept builds the foundation of an online course. The concept has to fulfill four criteria: (i) *Implementable* with existing learn management systems (LMS) available at all academic partners, e.g. ILIAS, Moodle, and Stud.IP; (ii) *Reproducible* structure, which ensures the comparability of courses and enables a consistent evaluation; (iii) *Enable* various learning outcomes for different target groups; (iv) *Adaptable* for academic, applied, or clinical practice for each target group.

As the didactic concept of the proposed e-learning course, we chose on the Gilly Salmon 5 stage model: (1) access and motivation, (2) online socialization, (3) information exchange, (4) knowledge construction and (5) development fulfill the addressed criteria [5]. We implemented this model as follows: All teaching material is online accessible. An e-moderator sets tasks, provide teaching material, clarify open questions of students, sensitizes for learning difficulties, and moderates the learning process [6]. During the course, the learners have to solve online interactive tasks, i.e., e-tivities [7]. The e-tivities are structured as purpose, task, and response [7]. To fit the four criteria given at the beginning of this chapter, this concept can be implemented in different LMS using open-source software such as ILIAS, Moodle, or Stud.IP and the concept also has a reproducible structure. This enables a comparative evaluation of all courses and ensures a certain level of quality. Furthermore, it is possible to allow different learning outcomes for the different target groups and to address various levels of practice. Because everyone can learn at their own pace and has the opportunity to deepen certain topics of particular interest.

2.2. Course Structure

The course has four main subject areas (i) introduction, (ii) processing of HET signals, (iii) data analytics and (iv) data integration and is structured in eleven chapters: (1) HET environment, (2) Sensors for HET environment, (3) Sensor integration, (4) Data recorded in HET environments, (5) Quality of recorded data, (6) Signal enhancement, (7) Feature-based signal analysis, (8) Signal analysis using deep learning, (9) Interoperability, (10) Semantic interoperability standards, and (11) HiGHmed use case cardiology and ethics.

To implement this course we used the Stud.IP system with the plugin Courseware. The students tested the plugin before the course started and were offered introductory documents for using it. 59 teaching videos are produced with the software Camtasia by qualified teachers as well as a domain expert. Each video has a minimum length of 5 minutes and a maximum length of 15 minutes. The average duration of all videos is 12.1 minutes and the total length of all teaching videos is 11 hours 58 minutes. For each chapter, the students have to solve e-tivities. An example is shown in [Figure 1](#).

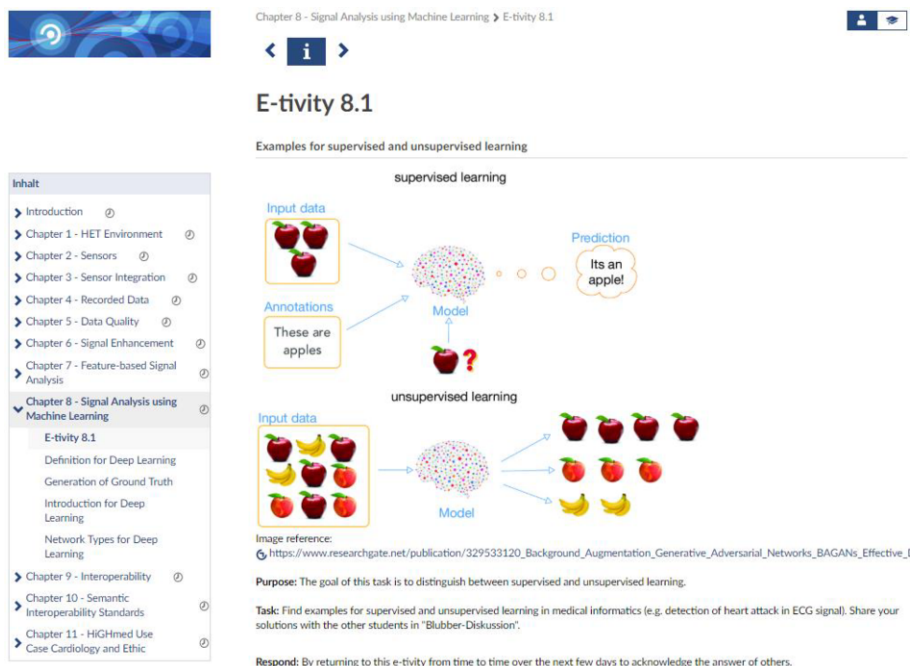


Figure 1. Screenshot of the course structure in Stud.IP with the plugin Courseware.

2.3. Evaluation

Eleven students successfully finished the module *Health Enabling Technologies and Data* and six of them filled out the evaluation sheet. The questions were designed based on the Community of Inquiry (CoI) method [8] and the roll-out was executed with the evaluation system EvaSys. Each student received a link with a TAN number by e-mail so that one student can only evaluate once. The evaluation used a 5-point Likert scale, where 5 indicates the best performance.

3. Results

The evaluation sheet contains questions regarding (1) quality of LMS, (2) teaching presence (3) social presence, and (4) cognitive presence. In the evaluation, the quality of the LMS used (Stud.IP) achieved the highest value with a mean value of 4.5 (Figure 2). Moreover, this category has the lowest standard deviation with 0.5.

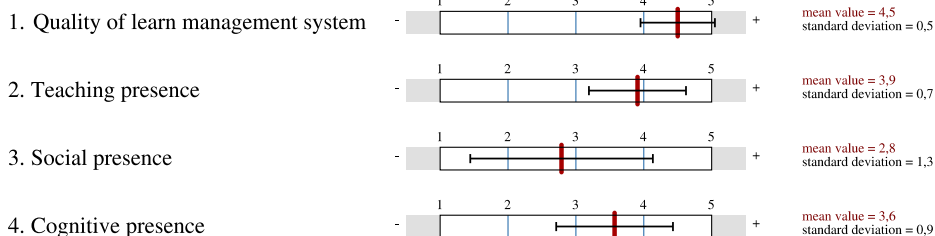


Figure 2. Boxplot of the global evaluation results regarding the four categories.

The teaching presence achieves a mean value of 3.9, which includes the communication of clear course objectives, quality of feedback, and motivation support of students. The lowest mean value is 2.8 for social presence. This category contains group cohesion. The cognitive presence has a mean value of 3.6 and covers the quality of discussions as well as knowledge development.

4. Discussion

This was our first e-learning course and no member of the teaching group moderated any online course before. We learned several remarkable lessons during the execution of the course and from our students' feedback. The small group of participants in the evaluation allows limited statements. However, the evaluation does indicate a direction. In the beginning, our focus was on the production of high-quality teaching videos and less on online socialization, resulting in relatively little student participation. The low interactivity has probably led to a weak sense of group belonging [7]. Besides, the incentive for the students was small, as they only received a grade for the written exam at the end of the course, and the participation in e-tivities was not included in the final grade. In the semester 2020/21, health care professionals and students from other nationwide academic partners will also participate in the online course, allowing us to revise the course and consider the following points: (1) each student will undergo a technical pretest before the course starts; (2) an incentive will be established for solving the e-tivities. Therefore, the solution of e-tivities, will be included in the final grade next to the final examination; (3) to increase the feeling of belonging to a group, every user will be asked to add a profile photo, we will also use web conferences between the e-moderator and the groups and online consultation hours; (4) the videos should include clearly defined learning objectives and "take-home" messages. The International Medical Informatics Association on education in biomedical and health informatics published recommendations to provide an appropriate level for teaching [9]. These recommendations are also transferable to e-learning.

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The Mishandling of Anonymity in Terms of Medical Research Within the General Data Protection Regulation

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Abstract One of the major regulatory factors for health informatics is data privacy protection. In the European Union, a shared set of laws has been implemented – the General Data Protection Regulation. While this set of rules aims at harmonizing the European data privacy protection standards, it fails in properly detailing the handling of anonymized data. This is a problem, as, for example many current research initiatives aim at reusing patient data collected within primary care, but lack a patient consent, hence, might rely on anonymized data as being the only alternative. Within this work, we detail different aspects why the concept of anonymity is wrongly handled within the GDPR and give suggestions how the laws could be adapted.

Keywords. GDPR, anonymization, data privacy protection

1. Introduction

The GDPR [1] is the European Union's approach to harmonize the laws of privacy protection of its participating nations. One of its goals was to create a regulatory toolset [2] against large data gathering cooperations. While it is doubtful that this goal was achieved [3,4], we can see some harmful effects of the GDPR on medical research [5].

This work is about a problem which impacts a subset of projects which want to work with routinely collected patient data, but lack a patient consent. As an example, this can be an issue for large scale approaches like the medical informatics initiative in Germany which would like to reuse most of a hospital's patient data, but due to missing consent cannot use any data retrospectively [6]. Without further ado, the contents within these valuable datasets are lost and have to remain unused. Though, there might be one alternative to this problem, which would be anonymization of the given data [7,8]. Unfortunately, as we will show within the section of methods, the GDPR does not value to detail the handling of anonymization and offers nearly no information concerning this important issue (GDPR: Recital 26). In combination with more severe punishment (GDPR: Article 83) academically this data is in danger to remain irrelevant, hence, as stated before, harming progress in terms of medical research.

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2. Methods

Within the section of methods of this work we tried to identify the most problematic aspects of the GDPR in terms of anonymization. We list these aspects within the section of results and attempt at presenting a solution how the GDPR could be adapted to better support the option of academically working with anonymized patient data.

3. Results

Aspect 1 – Underrepresentation: The GDPR basically ignores the handling of anonymous data. The category has been represented solely within recital 26 which states that anonymous data is not person identifying, hence, does not need to be discussed within the GDPR: “[...] *This Regulation [GDPR] does not therefore concern the processing of such anonymous information [...]*”

Aspect 2 – Responsibility: The GDPR’s handling of anonymized data would make sense if data could easily be turned into fully anonymous data. That is not the case. With enough background information non-directly identifying data fields (MDAT) could be used to identify a patient whose IDAT (directly identifying data) had been removed (formal anonymization) [7,8]. Hence, patient records have to be altered in a way that they are not easily re-identifiable while conserving as much medical information as possible. Usually the most we can reach is factual anonymity [7] which can be achieved by e.g. altering or generalizing the so called quasi identifiers (typically fields containing dates or locations) [9,10] but with a potential risk of re-identification remaining [11]. Technologies like k-Anonymity aim at grouping individual patient tracks into similar groups of a specific size (k) [8]. Still, there remain ways to also foil this concept as the harsher concepts of l-diversity and t-closeness demonstrate [12,13]. In general, aside from identifying patients based on their individual features, they could potentially be identified just based on their treatment patterns. Working with factual anonymity is theoretically accepted and even supported by the GDPR. The GDPR states: “*To determine whether a natural person is identifiable, account should be taken of all the means reasonably likely to be used, such as singling out, either by the controller or by another person to identify the natural person directly or indirectly (4).*” The problem about this section is, that it is absolutely unclear how to proof that data has been adapted adequately and who bears the responsibility about this decision.

Aspect 3 – Unregulated publication: As has been stated, the GDPR works for full anonymity. An example for that is aggregated data but we usually do not see individual anonymized patient tracks within publications as it is intuitive and has been shown before that even with high efforts they could potentially be re-identified. The question has to be raised: Should there really not be a difference in regulating factual anonymized data and fully anonymized data? At the moment the GDPR allows to treat both factual and fully anonymized data the same way: Hence, factual anonymous data which is, as shown before, potentially re-identifiable, could be under current laws published to the whole world, drastically increasing the possibilities of attack scenarios.

Aspect 4 – Technical challenges: As we have shown truly effective factual anonymity is hard to accomplish. Effective factual anonymity needs well trained informatics specialists. There might be tools like ARX which could help to set up e.g. k-anonymity [14], but as has been shown, depending on the project k-anonymity might not be sufficient. The competence to technically create factual anonymity and the skills

to proof that the risk of identifying is diminishingly low is something only distinct expert groups, not available for most academic projects, could supply.

Aspect 5 – Contradiction: The biggest issue about the GDPR might be, that the GDPR contradicts itself. We can deduce that within the GDPR it is accepted that factual anonymity is not full anonymity. While full anonymity cannot lead to re-identification, factual anonymity could potentially be broken (else it would be full anonymity). Now, if data can, even if there is a diminishingly low chance, be re-identified, it is potentially person identifying and should, hence, be part of the GDPR. As recital 26 states, this is not the case, thus, the GDPR contradicts itself.

4. Discussion

The GDPR currently has no sound concept in terms of anonymity. It circumnavigates this shortcoming by claiming: Anonymous data is not person identifying (*see aspect 1*). We showed that this is not a good solution for medical research arising from the 5 presented aspects. With anonymity being the main option to having no patient consent, the resulting effect is often the loss of relevance for retrospective medical datasets without a consent. Applying factual anonymity under current legislation is not a real option as it can potentially, with enough effort and information, be broken (*see aspect 3*). If the threat of re-identifying factual anonymity cannot be excluded, factual anonymity should be seen as at least potentially person identifying (*see aspect 5*).

A solution could be: Within the GDPR fully anonymous data (usually aggregated data) should remain the class of data which cannot be re-identified and which can be used and published without any regulations. Aggregated data though, is not something academic projects usually utilize in the first place. Scientists need to work with microdata (e.g. individual patient tracks), with aggregated data (fully anonymous) being at the end of the chain of work, not at the start. Thus, a new class of data could be introduced: Rule based anonymous data. It would be a sub-class of factual anonymity, but not with the aim of providing maximal security against re-identification, but instead giving a strict ruleset which increases the security level significantly, but is easy to apply and understand (*see aspect 4*) without the unrealistic demand of creating nearly unbreakable factual anonymity if no consent is available. This approach would also supersede thinking about responsibility (*see aspect 2*), because the law would not be under arbitrary discretion but based on strict rules. Since rule-based anonymity would potentially be person identifying, the GDPR would have to be extended by rules for this class. All laws of the GDPR at the same time would apply for this class, hence a free and completely unregulated upload of this kind of data into e.g. the internet would not be an option. The use of rule-based anonymity should then be regulated: Examples could be, that persons working with this data must be specified, the circle of persons working with this data must be kept as small as possible and so forth. Most important regulation could be the purpose which could be interconnected with already existing recitals like considering a legitimate (GDPR: Recital 47) or public interest (GDPR: Recital 54). More general this could be an option for research projects with a direct benefit for society. We can only echo the conclusion of Mostert et. Al [15] that there should be research exemptions in data protection law.

This work is not about the formulation of such a ruleset – but it could in theory look something like the following: Appliance of a one way encryption on IDAT, identifiers and locations, date fields being trimmed to year, grouping of all data fields

containing biometrical data like eye color or size. We have to stress that this is only a naive suggestion for a possible ruleset, but we believe that the concept of rule-based anonymization would be a better alternative than what we currently find within the GDPR. At the moment, the need of a consent without any real options within GDPR appears to be too heavily weighted. Richter et. Al showed within their study, that most patients within their survey would even be willing to abolish a consent completely if their data would be used for beneficial research [16]. In that regard, our call for a new class of anonymity and better handling within the GDPR seems to be modest.

5. Conclusions

As long as the GDPR is not reworked scientist will struggle to use anonymity as a serious alternative to a patient consent. Hence, retrospective data lose their value and their potential to be used as a source for science and research. While this work tries to shed light on the mishandling of anonymity within the GDPR it can only offer possible suggestions how this problem could be solved.

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Legal Challenges for IT Service Providers in Pharmacogenomics

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Abstract. IT providers offering services based on genetic data face serious challenges in managing health data in compliance with the General Data Protection Regulation (GDPR). Based on a literature research and our experiences, an overview of GDPR compliant processing of sensitive data is given. The GDPR requirements for processing sensitive data were specified for a use case concerning a service provider of a pharmacogenomic decision support system. Start-ups who want to enter into the health market also have to comply with the Medical Device Regulation (MDR). The associated efforts for legal compliance constitute an impediment for many start-ups. We created a comprehensive overview, which aligned the requirements of the GDPR with the life-cycle of a medical device. This overview shall help start-ups to grasp and overcome the regulatory hurdles faster.

Keywords. general data protection regulation, GDPR, data management, sensitive data, genetic data

1. Introduction

Pharmacogenomics (PGx) deals with genetic effects on the metabolic pathways of drugs [1]. Even though, clear targets are defined in guidelines [2], there is a lack of PGx testing, especially due to paucity of knowledge and implementation know-how. This explains the existence of IT service providers in this domain, offering, for example, workflows for PGx clinical decision support. However, such providers are facing serious challenges with respect to health data management, which can lead to sub-optimal service delivery.

Here, we describe challenges posed by the General Data Protection Regulation (GDPR) with the aim to comprehensively guide IT providers offering services based on sensitive and in particular genetic/genomics data. Especially, GDPR compliant storage and transfer of sensitive data are central issues that will be addressed. In addition to that, we will also discuss implications of the Medical Device Regulation (MDR) and ways to integrate its requirements into an overall perspective.

2. Methods

Information on the GDPR and its references to genetic data was obtained with a PubMed research using the MeSH terms (GDPR[Title/Abstract]) AND (genomic[Title/Abstract])

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OR genetic[Title/Abstract] OR sensitive[Title/Abstract]). The resulting articles were analyzed and categorized according to their relevance. We relied on PubMed rather than legal databases as our focus was on practical approaches to establish conformance with the GDPR. The analysis was enriched by considering additional challenges implied by the MDR and our own experiences at the intersection between research and the market.

3. Results

3.1. GDPR Compliant Processing of Sensitive Data

Our PubMed research led to 17 articles, including four relevant articles for our purpose to provide some guidance for the practice [3–6]. Sariyar et al. [7] discuss GDPR related issues around different types of genetic data. They emphasize that the GDPR is demanding higher protection and stricter requirements for genetic data than for other sorts of personal data, as genetic data may contain sensitive information about the data subject and their blood relatives [8]. However, there are no additional data protection implications related to genetic data compared to other forms of sensitive data such as data concerning health, sexuality or sexual orientation.

The GDPR also defines fundamental rights of the data subject (defined as 'identified or identifiable natural person' (Art. 4) from which data is being collected, held or processed). The controller, defined as 'natural or legal person (...) which (...) determines the purposes and means of the processing of personal data' (Art. 4), is obliged to provide information such as the purposes of the processing for which the personal data are intended as well as the legal basis for the processing (Art. 13 (1) lit c). Moreover, the controller is responsible for the implementation of appropriate technical and organizational measures to ensure data processing according to the regulation (Art. 24 (1)). Organizational measures are, for example, the provision of explicit consent forms to the users, the assignment of roles for access control and the carrying out of a Data Protection Impact Assessment (DPIA). The technical measures include implementation such as authentication (Recital 57) and access control (Recital 39), encryption (Recital 83), pseudonymization (Recital 78) etc. The stored data must be provided in a structured, commonly used and machine-readable format (Art. 20 (1)). As the data subject has the right to rectification (Art. 16), to erasure (Art. 17 (1)) and/or to restriction of processing (Art. 18 (1)) the data, the data controller must be able to carry out these tasks.

Besides the data controller, the GDPR also defines the role of a data processor, which processes personal data on behalf of the controller (Art. 4). Processing by a processor is governed by a contract or other legal act that is binding on the processor with regard to the controller (Art. 28 (3)). From the GDPR perspective, the data processor is primarily responsible for applying technical measures described above. In addition to data controller and data processor, further roles such as data protection officer have to be assigned as well under certain conditions (Art. 37 (1)).

3.2. Scenario: PGx Service in an B2B Environment

In the following, we concretize how the regulatory requirements can be fulfilled based on the use case of an PGx CDSS service provided for health professionals. Four roles have to be differentiated in such a setting:

1. Patient (Data subject): the person whose personal data is being collected.
2. Health Organization (Data controller): a laboratory or hospital performing gene sequencing & analysis and storing the corresponding data.
3. Health Professional (Data processor): a physician or other professionals working in a health organization.
4. Service provider (Data processor): a company offering the PGx service.

Figure 1 shows the central processes: 1) The patient gives his explicit consent by signing the corresponding form provided by the health organization, 2) his blood sample is taken by the health professional and 3) analyzed & stored by the health organization. 4) The related pseudonymized data is transmitted to the service provider 5), where it is stored. 6) During drug prescription, the drug information and the present medication of a patient together with its pseudonym is sent to the software provider, which infers PGx information. 7) This information is provided to the physician in order to ensure 8) a PGx safe drug therapy. Central tasks of the health organization are pseudonymization prior to transmission to the software provider, assigning roles, access control, and carrying out an DPIA. The software provider is responsible for fulfilling further requirements of the GDPR, e.g. providing the functionality for erasure (Art. 17 (1)), provide data in machine-readable format (Art. 20 (1)) etc.

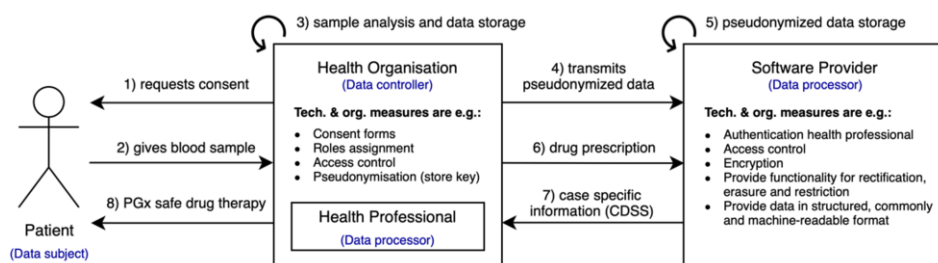


Figure 1. Processes in the PGx service scenario, listing some technical and organizational measures for the data controller and data processor.

3.3. Considering the MDR for an Overall Perspective

Processing of genetic data for research purposes is mainly regulated by the GDPR. However, companies operating in the health sector need also to be compliant with the MDR and acquire a corresponding medical device certification. The associated efforts constitute one central reason why many start-ups shy away from entering into the market and prolong their time within the research environment. With the MDR, further requirements, such as a comprehensive quality management system (QMS) according to ISO 13485, have to be met. Table 1 summarizes the main regulatory requirements that need to be considered by a health IT service provider in each phase of its product cycle, from the product idea to post-market surveillance (PMS).

Table 1. Actions to fulfill GDPR and MDR requirements along the product life-cycle.

	MDR	GDPR
Idea	Define intended purpose. Classify product (MDR Annex VIII). Implement QMS (ISO 13485).	Identify collected data and requirements.
Design	Consider risk management measures (ISO 14971).	Consider security, privacy and compliance requirements.
Development	Develop the product and document the development process (MDR Annex II).	Add supporting tools (Consent tracking, access control etc.).
Audit	Proof the conformity with the regulations. If necessary, audit with notified body.	Data privacy certification (voluntary, see Art. 42 (3)).
Release	UDI registration (MDR Art. 29) and CE marking (MDR Art. 20).	-
PMS	Surveillance and monitoring (MDR Art. 83 seq.).	Ensure data security, consent tracking etc.

4. Discussion/Conclusions

The main goal of the GDPR is to enhance effectiveness and harmonization of data protection in the EU; however, deviations from it are existent in several countries. In Switzerland, for example, the data subjects’ rights are different and not defined in the corresponding Federal Act of Data Protection, but regulated by other regulations within the Swiss legal system, e.g. the Federal Act on Human Genetic Testing HGTA (abbreviated as GUMG in German). It is important to take such deviations into consideration, when providing services throughout Europe. For the MDR, no such deviations are to be expected. However, for countries like Switzerland an authorized representative has to be established within one of the EU 27 member states.

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Comparison of Machine Learning Algorithms for Classifying Adverse-Event Related 30-Day Hospital Readmissions: Potential Implications for Patient Safety

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Abstract. Studies in the last decade have focused on identifying patients at risk of readmission using predictive models, in an objective to decrease costs to the healthcare system. However, real-time models specifically identifying readmissions related to hospital adverse-events are still to be elaborated. A supervised learning approach was adopted using different machine learning algorithms based on features available directly from the hospital information system and on a validated dataset elaborated by a multidisciplinary expert consensus panel. Accuracy results upon testing were in line with comparable studies, and variable across algorithms, with the highest prediction given by Artificial Neuron Networks. Features importances relative to the prediction were identified, in order to provide better representation and interpretation of results. Such a model can pave the way to predictive models for readmissions related to patient harm, the establishment of a learning platform for clinical quality measurement and improvement, and in some cases for an improved clinical management of readmitted patients.

Keywords. Readmissions, adverse events, classification, patient safety, machine learning, artificial intelligence

1. Introduction

Nearly one in five patients is re-hospitalized within 30 days of discharge [1], incurring significant costs to the healthcare system [2]. Therefore, minimizing post-discharge adverse events has become a priority for many health care systems around the globe. Many studies in the last decade have focused on identifying patients at risk of readmission using predictive models [3][4]. However, few attempts have been made to identify potentially preventable readmissions [5], and, to the best of our knowledge, no studies have explored models to predict or identify readmissions related to hospital adverse-events. Moreover, study review highlights the need to use more standardized hospital information system (HIS) data related to the readmission (eg. biological, radiological, billing and administrative data) instead of institution-specific or clinical judgement based data, for an earlier and more benchmarkable prediction. The main objective of the study was to construct a model, based on routinely available data from the HIS, that could determine, on a near real time basis, if the patient readmission within

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30 days was associated with a hospital acquired adverse event that occurred in the previous admission (response variable).

2. Materials and Methods

The dataset used for training and testing of algorithms was built using the gold-standard approach, by a multidisciplinary consensus panel (internal medicine physician, radiologist, nurse, and patient safety professionals), expanded when needed to include physicians from specialized disciplines. The panel analyzed and classified 307 patient readmissions (within 30 days) extracted from the HIS from October 2019 till March 2020 (excluding readmissions of oncology patients and elective readmissions) that occurred in a 250 beds university hospital in Beirut, Lebanon where the study took place. On average, 30 min were required for every case preparation, and 25 min for the panel discussion and classification of each medical case. 46 of these cases were labeled as related to adverse events, to which 47 cases non related to adverse events were randomly chosen from the remaining dataset, to define a final balanced dataset of 93 cases, containing almost equal cases for each of the two classification classes: “Readmission related to adverse event”, and “Readmissions not related to adverse events”. 23 features (explanatory variables) were identified by the panel based on previous research results accomplished on this subject [6] and were extracted from the HIS. The features consist of both binary and continuous variables corresponding to the readmission and the previous admission cases. A supervised learning approach was adopted using different machine learning algorithms: Random Forests (RF), Decision Tree (DT), Boosting (BT), Artificial Neural Networks (ANN) and Logistic Regression (LR). Cross-validation of the model generated by each algorithm was performed using established methods (K-Folds=5 and Leave-One-Out) to avoid the results being influenced by the partitioning of the original dataset. Results of the different algorithms were reported and compared using model classification accuracy, based on the information entropy. Variable importance was determined by calculating the relative influence of each feature on the classification (except for ANN where this method is complex and not standard). This study was submitted to the hospital’s institutional review board (IRB) and was exempt from further review since it does not directly involve human subjects.

3. Results

All algorithms showed good accuracy (>0.85) in the model training phase, which underlines their ability to fit data to a theoretical model using the proposed features. Table 1 shows the accuracy obtained from different algorithms when the predictions of the generated models were compared against the test dataset. Among the different algorithms, ANN showed to be the most predictive (0.88), followed respectively by LR (0.62), RF (0.62), DT (0.60), and BT (0.55). Table 2 shows the features’ different weight importance, when this option was possible by the type of algorithm used, and highlights the features with significant weight (>5%).

Table 1. Accuracy result on evaluation for algorithms tested, with chosen algorithm parameters

Algorithm	Mean accuracy	StdDev accuracy	Parameters (algorithm-specific function arguments used for result optimization, as per SKLEARN and KERAS libraries definitions)
ANN	0.88	0.07	24/6/4/1 architecture, optimizer RMSprop, lr=0.0001, epochs=10000, batch size=30

LR	0.62	0.10	<i>penalty='l2', dual=False, tol=0.0001, C=1, fit_intercept=False, intercept_scaling=1, class_weight='balanced', solver='lbfgs', max_iter=30000</i>
RF	0.62	0.06	<i>n_estimators = 30, criterion="entropy", max_depth=8, min_samples_leaf=2, min_samples_split=4, max_leaf_nodes=15, bootstrap=False</i>
DT	0.60	0.06	<i>criterion='entropy', max_depth=8, min_samples_leaf=2, min_samples_split=4</i>
BT	0.55	0.07	<i>XGBClassifier, max_depth= 8, learning_rate = 0.001, gamma = 1, n_estimators=200</i>

Table 2. Feature importance by model (highlighted are those with mean importance ≥ 0.05)

Feature	RF	DT	BT	LR	Mean
Days since last discharge	0.15	0.15	0.25	0.01	0.14
White Blood Cells (WBC) value upon readmission	0.08	0.05	0.06	0	0.0475
Microbiological culture ordered in first 48h of readmission	0.03	0.1	0.08	0.07	0.07
C-Reactive Protein (CRP) value upon readmission	0.04	0	0.11	0	0.0375
Creatinine serum differential ratio	0.05	0.04	0.13	0.06	0.07
Potassium level differential	0.05	0	0.05	0	0.025
White Blood Cells (WBC) level differential	0.05	0.08	0.07	0	0.05
C-Reactive Protein (CRP) level differential	0.1	0.11	0	0	0.0525
Combined WBC-CRP levels	0	0	0	0.11	0.0275
Hemoglobin differential ratio	0.05	0.17	0.04	0.01	0.0675
Calcium level differential	0.03	0	0.06	0.01	0.025
Patient age	0.06	0.08	0	0.04	0.045
Patient sex	0.08	0	0.08	0	0.04
Paracetamol use on readmission	0	0	0	0.09	0.0225
Number of biological exams ordered in first 24h of readmission	0.07	0	0.04	0.01	0.03
Number of radiological exams ordered in first 24h of readmission	0.04	0	0.04	0.01	0.0225
Remarks in radiological requests ordered in first 24h of readmission	0.01	0	0	0.12	0.0325
Number of different types of medication during previous admission	0.06	0.06	0.05	0	0.0425
International Normalized Ratio (INR) raise	0.1	0.12	0	0.12	0.085
Number of surgical procedures performed in previous admission	0.04	0	0.11	0.04	0.0475
Cerebral CT-Scan performed on readmission	0	0	0	0.07	0.0175
Abdominal CT-Scan performed on readmission	0	0	0	0.06	0.015
Thoracic CT-Scan performed on readmission	0.03	0.06	0	0.11	0.05
Readmission type (Inpatient/ Outpatient)	0	0	0	0.08	0.02

4. Discussion and Conclusions

Predictive performance of the different algorithms: While accuracy levels across different algorithms seem to be moderate to low, they remain comparable to studies in the literature on 30-days readmissions [3][7]. However, the significance of the features adopted in this study versus other models in the literature is that they permit a near real-time computation of the classification as soon as the patient is readmitted, thus allowing the possibility for immediate proactive administrative and/or clinical interventions to reduce the risk of any preventable adverse event. A few factors could potentially explain and lead to improving this result. First, the sample size can be improved with additional expert time and resources. Another factor is inherent to the nature of the classification outcome variable itself which can only be built on expert opinion and thus contains,

despite all methods used to lower the risk of judgement bias, a residual level of uncertainty. The high number of harm categories in the medical field [8], and patient-specific influencing factors that should be taken into consideration, induce a need for a high number of features to encompass this domain's complexity.

Feature importance and possible interpretations: In contrast with other similar studies, the features were chosen in this study to be all directly extractable from a basic HIS, and not needing human intervention for data aggregation or interpretation. This choice is in line with the need to standardize such tools and benchmark results across different healthcare systems. In the majority of tested models, the features impacting most of the results are: Days since last discharge, respective differential of CRP/WBC/INR/Creatinine serum, hemoglobin differential ratio, Thoracic CT-Scanner and Microbiological Cultures performed upon readmission. This result can be intuitively interpreted as a higher sensitivity towards detection of infections, hemorrhages and acute kidney injury cases. Interestingly, from the results obtained, the models insinuate also that readmissions occurring within 12 days of previous discharge are more prone to be associated with patient harm.

Potential practical implications for patient safety: Validating automated models for classifying 30-day readmissions can have some important implications for patient safety efforts in hospitals. Firstly, through correctly estimating the true level of nosocomial harm relative to readmissions, and using this information to analyze and improve clinical practices, hospitals will be able to measure the impact of deployed patient safety efforts over time. Secondly, permitting a proactive management of such cases as soon as they enter the hospital, can help prevent any further harm and address any implications that may arise. Finally, the results can pave the way to more proactive models that can predict risks of preventable readmissions due to adverse-events before patients are physically discharged from the hospital, or identify the patients "at risk" and follow up with them by phone before they actually return to the hospital, thus preventing extra costs for the healthcare system and third-party payers. Given the time and effort that was needed to construct a training and testing dataset on this domain, the validated sample size used in this study was relatively small. Also, some specific data (such as radiology reports, medical notes) could not be extracted from the HIS at this point of the system's integration. These limitations will be taken into consideration in future studies to improve outcomes.

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Semiautomated Approach for Muscle Weakness Detection in Clinical Texts

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Abstract. The automated detection of adverse events in medical records might be a cost-effective solution for patient safety management or pharmacovigilance. Our group proposed an information extraction algorithm (IEA) for detecting adverse events in neurosurgery using documents written in a natural rich-in-morphology language. In this paper, we challenge to optimize and evaluate its performance for the detection of any extremity muscle weakness in clinical texts. Our algorithm shows the accuracy of 0.96 and ROC AUC = 0.96 and might be easily implemented in other medical domains.

Keywords. Natural Language Processing, Adverse Events, Neurosurgery, Annotation

1. Introduction

The narrative clinical text contains a lot of useful yet unstructured information that is difficult to be extracted or classified straightaway. Natural language processing combined with supervised machine learning might be a promising solution when automation of information extraction or document classification is demanded. E.g., automated detection of adverse events in medical records might be a cost-effective solution for patient safety management or pharmacovigilance [1]. However, most of the clinical texts in electronic health records are inappropriate for supervised machine learning, in other words, they require annotation or labeling, which is a time-consuming and subjective process. Recently, our group proposed an information extraction algorithm (IEA) for detecting adverse events in neurosurgery using documents written in a natural rich-in-morphology language [2]. This research aimed to optimize and evaluate our algorithm for muscle weakness (paresis) detection.

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2. Methods

The dataset for our research was initially prepared in a project on muscle strength prediction by deep learning with medical images (supported by the Russian Foundation for Basic Research (RFBR) grant 19-29-01154). The task in our study was to classify patients as having any extremity weakness (paresis) or not by medical texts. The preoperative textual data and the sections of discharge summaries referring to the preoperative period were obtained for a cohort of 1167 patients (average age 39.7 ± 17.8 y.o., 578 (49.5%) males) who underwent glial tumor resection at N.N. Burdenko National Medical Research Center of Neurosurgery in a period between 2009 and 2018. The dataset was scored and manually labeled (0 – no paresis, 1 - any paresis) by two independent experts, the third independent expert resolved all discrepancies. The labeled dataset was used in testing our algorithm's performance in slight modifications. All the data extracted from electronic health records (EHR) were processed and analyzed within the R programming environment (version 3.5.0) in RStudio Server IDE (version 1.2.519) using *rsample*, *drlib*, *broom*, *yardstick*, *glmnet*, *doMC*, *dplyr*, *tidyr*, *stringr*, *tidytext*, *tidyverse*, *quanteda*, *qdapRegex*, *tm*, *scales*, and *cutpointr* packages.

2.1. Paresis detection in EHR

We preprocessed all the source text documents related to neurological examination upon admission to build the initial corpus:

- words transformed to lower case;
- all the characters except for alphanumeric symbols and single spaces removed;
- texts tokenized with a space separator;
- stop-words and meaningless words (single letters, artifacts, etc.) removed;
- spelling corrected and tokens lemmatized.

The unique lemmas were screened by an expert to select those likely related to or certainly used in the paresis description (first step). The context of each selected term was defined from n-grams containing it (second step). We found 5-grams sufficient considering the importance of prepositions in the Russian language. Those 5-grams were rated by 0.5 (if indicating any paresis with uncertainty), 1 (if indicating any paresis obviously), or 0 (if no paresis was mentioned) by the expert. We tested two modes of using the scores to decide whether muscle weakness is present in the source documents containing the rated 5-grams. The first option considered paresis in only those medical records in which at least one 5-gram received 1 point (IEA1, “utmost confident algorithm”). In the second mode, the presence of paresis was decided considering the sum of scores for all rated 5-grams found in each case history based on an optimal cutpoint (IEA2, “highly suspicious algorithm”).

2.2. Performance evaluation

The quality of the IEA1 and IEA2 was evaluated using ROC-analysis. The sensitivity (SENS, also referred to as recall), specificity (SPEC), accuracy (ACC), positive predictive value (PPV, also referred to as precision), negative predicted value (NPV), F-measure (F), cutoff value (COV) and area under ROC-curve (AUC) were computed for all methods. The bounds of 95% AUC confidence interval were calculated using

bootstrapping. The cutoff point was chosen to maximize the sum of sensitivity and specificity for every algorithm.

3. Results

We observed high inter-rater reliability (Cohen’s Kappa = 0.852) between experts annotating the dataset, however, correction by the third expert was required. The initial vocabulary of 9932 words was screened to select 738 words related to paresis description (first step), which were found in 7413 5-grams to be labeled by the expert on the second step. The whole process required at least 13 working hours.

The quality of IEA1 in detecting paresis was better than IEA2 (Table 1).

Table 1. The quality metrics of information extraction algorithms.

Method	COV*	SENS	SPEC	ACC	PPV	NPV	F	ROC AUC [95% CI]
IEA1	1	0.947	0.965	0.961	0.905	0.981	0.926	0.956 [0.941; 0.969]
IEA2	2.5	0.911	0.912	0.912	0.784	0.967	0.843	0.962 [0.951; 0.972]
IEA1 nouns	1	0.944	0.965	0.960	0.905	0.980	0.924	0.954 [0.938; 0.969]
IEA 2 nouns	2	0.927	0.916	0.919	0.794	0.973	0.855	0.970 [0.958; 0.980]

* for all algorithms, ‘paresis’ cases were considered when output ≥ cutoff point

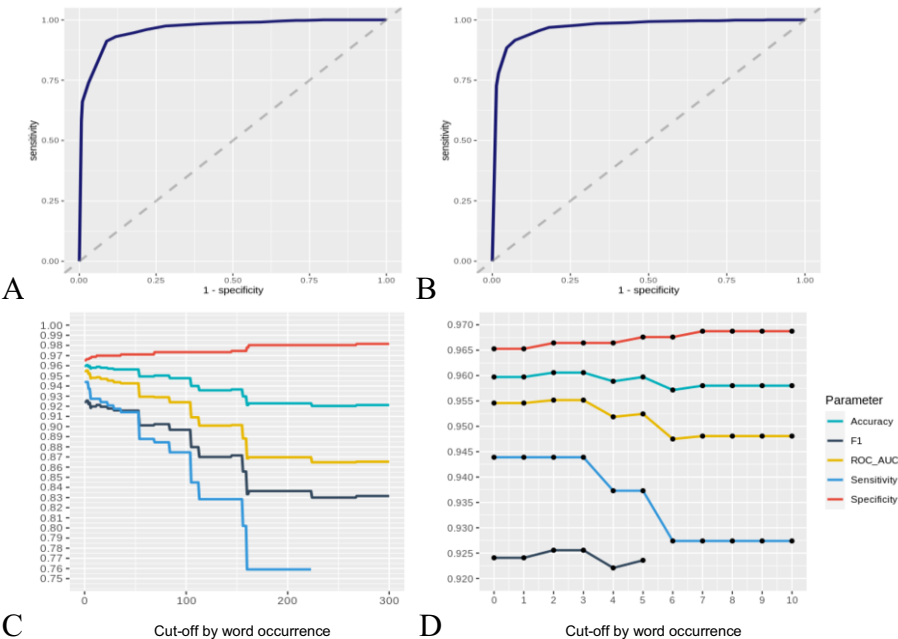


Figure 1. A - ROC curve for IEA2, B – ROC-curve for IEA2 using nouns only, C – the quality metrics of “IEA1 nouns” changing with the cutoff (number of word occurrences), D – changes in “IEA1 nouns” quality dependent on the word occurrence cutoff in a range of 0-10.

Since the workflow for that type of text labeling was time-consuming, our approach required optimization to reduce the workload. We hypothesized that the initial vocabulary may be redundant for paresis detection and can be reduced with minimal loss in algorithm quality. Thus, we tested our algorithms using only nouns ($n = 4061$; 320 words selected) for the first and corresponding 4885 5-grams for the second steps (Table 1, “IEA1 nouns” and “IEA2 nouns”). “IEA2 nouns” modification appeared to perform slightly better than IEA2 by all parameters (Table 1, Figure 1 A, B). Finally, the words which occurred less than 4 times in all texts were filtered leading to the reduction of initial vocabulary (down to 2376 words with 152 nouns selected) and 5-grams (down to 4663) to be labeled without any loss in quality of paresis detection (Figure 1 C, D). The total time of pure expert work was reduced to 6 hours.

4. Discussion

Learning from adverse events in medicine may improve patient safety [1]. Information extraction from and classification of clinical texts is challenged in various medical domains (e.g., infections or drug trials) and with natural language processing (e.g., word embeddings, neural networks, etc.) [3]. However, these technologies have been occasionally applied in neurosurgical adverse events detection [4]–[6]. We proposed and tested the algorithm (different from rule-based methods), which might be feasible in clinical text annotation and adverse events detection as a first step to automate this process with machine learning. We managed to reduce the expert workload with our algorithm by ~50%, keeping the quality of paresis detection at the same high level.

5. Conclusion

Our semiautomated algorithm of adverse event identification in clinical text showed the accuracy of 0.96 in paresis detection and may be easily implemented in other medical domains. *This project was supported by the RFBR grant 18-29-22085. The extraction of data for glial tumors was also supported by the RFBR grant 18-29-01052.*

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Confirmatory Factors to Nursing Practice for Patient Safety of Nurses in Kalasin Hospital, Kalasin Province, Thailand

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Abstract. This cross-sectional research aimed to explore the associated factors with nursing practice for patient safety of nurses in Kalasin Hospital, Kalasin Province, Thailand. The 245 samples were randomized which using created questionnaires which was applied to collect their opinion. The results showed that level of nursing practice for patient safety was moderate level (average = 3.55, S.D. = 0.89) in addition to their experience in patient care, knowledge patient safety and safety culture skills was a significant relationship to practice of nursing professional skills with statistical significance ($r = 0.625$, $p\text{-value} = 0.001$). It was revealed that supporting system and resources sufficient for the top administrative level in hospital were significantly related to nursing practice and patient safety. Policy direction of the hospitals is becoming aware of the importance of transforming organizational culture in order to improve patient safety and nursing practice toward to safety culture as quality awareness in the organization.

Keywords. Confirmatory Factors of nursing, Nursing practice, Patient safety

1. Introduction

Patient safety is an important that affects the health care service in the health services community worldwide. Since that is the quality of service in the public health system. From the data of the World Health Organization were found 18 percent to be in an adverse events and found more than 2500,000 deaths.[1] In case of Thailand found the rate of adverse events 9.1 percent. Which is caused by the system and service process including data communication and drug error. These various faults can be prevented from operating system.[2] From such importance, Thailand has been introduced A Patient Safety Goal-PSG which such as set a ultimate goal in care for the safety of the patients.[3] The hospital, which implement an important role in patient care. And having experienced problems in the past adverse events occurred from the operation of personnel in hospital. Especially nurses, which have the highest number of personnel and must carry out work regular patient care.[4] From the literature review found that, there are many factors that affect the nurse's work performance provide security.[5] Age, place of operation that is a factor related to the nurse's work performance [6]. In addition, expertise, work

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experience, awareness and receiving training on patient safety had affecting operations the efficacy of patient safety [7].

Kalasin Hospital is a public hospital as a general hospital providing services to people in Kalasin Province, in Thailand. This was a place which found incidence of adverse events of patient due to nursing practice. Including pressure ulcers were found 3.56 percent, medication administration error 36.23 percent of all error in hospital and the patient falls and falls 24 times per year [8]. Form advert events is mistake that can be prevented from both individuals and work systems. Therefore, the researcher is interested in studying factors affecting nursing practice of nurse for the patient safety of professional nurses. To apply the knowledge gained as a basis for development and improvement nursing practice guidelines for patient safety in the organization.

2. Methods

This cross-sectional study was conducted in Kalasin Hospital, Kalasin Province, Thailand during January to March 2020 The units for this study were drawn from 7 sector of patient care units of hospital.

The population of this study was the nurse working in patient care units of Kalasin hospital. Including was 852 cases. Sample size calculated using the sample size calculation formula to estimate the average population. The 245 samples were systematically randomized to the number of desired results.

The questionnaire was used as the research tool. The reliability of the questionnaire was declared by using Cronbach's alpha coefficient which was 0.92 was applied as the research tool. The questionnaire was divided to 4 domains.

Collect data was conducted by using online questionnaire via the QR code scan by smart phone distributed to the randomized subjects. This research was conducted with permission from the Research Ethics Committee, Kalasin Hospital.

Quantitative data analysis was applied by using a computer package program. Descriptive statistics were included frequency distribution, percentage, mean, standard deviation inferential deviation including inferential including Pearson correlation were analysed and presented at a previous descriptively.

3. Results

Table 1. Nurse Characteristic each department and outcomes patient safety in 7 sector of Kalasin Hospital.

Nurse Characteristic	Medication	Surgery	Pediatric	Obstetrics	Orthopedic	Eye ears throat nose	Psychiatry
RN age	41.91	38.89	42.95	40.70	39.21	42.60	44.43
Experience	19.25	18.72	18.63	17.63	19.88	16.59	18.15
RNs pass training	76.12	82.16	76.36	78.96	80.23	79.36	83.99
Report mediation	286	290	320	132	126	99	56
Report falls	8	5	0	2	5	0	6
Response rate	50%	64.35	56.97	59.1%	64.09%	52.97%	66.78%

Table 2. Perception safety culture of nurse personals and patient safety knowledge score of nurse personals Kalasin Hospital, Kalasin Province

Hospital Safety Survey	average	S.D.	Level
Overall perception of patient safety nurse personals	3.52	0.86	Most
Overall patient safety knowledge score nurse personals	3.45	0.89	Moderate
Total	3.48	0.87	Moderate

Table 3 Patient Safety Operation score of nurse personals Kalasin Hospital, Kalasin Province

Operation patient safety	average	S.D.	Level operation
Infection control	3.39	0.95	Moderate
Drug safety	3.29	0.91	Moderate
Care process	3.59	0.94	Most
Emergency response	3.93	0.74	Most
Total	3.55	0.89	Most

Table 4. Results of relationship analysis of age, Experience in patient care, Knowledge patient safety and Safety culture with Nursing practice for patient safety of Kalasin Hospital, Kalasin Province

Factors	Nursing practice for patient safety of Kalasin Hospital		
	Peason's coefficient of correlation	p-value	Level correlation
Experience in patient care	0.611	0.00*	High
Knowledge patient safety	0.625	0.00*	High
Safety culture	0.610	0.00*	High
Total	0.625	0.00*	High

Result of the overall factors has a relationship high level positive with Nursing practice for patient safety of Kalasin Hospital with statistical significance at the level 0.001 (r=0.625).

4. Discussion of results

From the results of the study, it was found that in general information of nurse professional in Kalasin hospital had experience in patient care (average 18.40 years) to have skills in nursing practice and had the most operation nursing, good resulting This finding is correspond with Kaewsomsee Siwaporn (2017) [9].They found that the nursing experience patient care in patient care (average 15.80 years) had operation nursing the most level and the nurse professional, them received training patient safety.

For the level of safety culture of the nursing professionals, the overall is at a high level of perception safety culture. Which when considering each aspect founded Communication openness and staffing had moderate level. Which communication is important and staffing inappropriate causing nurse to work hard, then found advert event in patient. Recipients in accordance with the previous report of Timothy and Kathleen (2007) [10]. As for the patient safety knowledge score of nurse personals has a moderate level. From the analysis, it was found that personnel still lacked understanding, There for the hospital administrators should supporting training knowledge patient safety. This finding is correspond with the Sara Singer (2012). [11] that has studied Workforce Perception of Hospital Safety Culture: Development and Validation of the Patient Safety Climate in Healthcare Organizations Survey.

Finally, experience patient care knowledge and safety culture as a whole has high level of positive relationships. The operation nursing practice of nursing professionals with statistical significance (r = 0.625, p-value = 0.001) which is consistent with the study of Thongthip & Chalongsuk (2014) [12] who reported the operation nursing practice has a high level of positive relationship with the Knowledge patient safety and

Safety culture. This finding could be explained that support from the organization of administrative resources sufficient and appropriate will allow personnel nursing in Kalasin Hospital to safety culture in activities with the high-quality development resulting in good results for nursing practice the organization and the continuous development.

5. Conclusions

To sum up, confirmatory factor for patient safety comprised with their experience on patient care skills and safety culture which awareness in quality improvement were significantly important for nursing practice with requires organization support and training to be the professional manner in a hospital.

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Patient Awareness of the Severity of Their Information and Medication Management-Related Adverse Events

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Abstract. Adverse events (AEs) in healthcare are commonly reported internationally. However, the structure of event reporting varies based on the healthcare service system, legislation, and the safety culture among service providers. Based on several studies, medication management-related errors have a long history of being reported. However, there is evidence that information management-related errors increase workload, costs, and patient suffering. This study focuses on AEs reported in the categories of medication and information management in a national reporting system. Our aim was to determine whether patients were informed about these errors and whether there were any relationships between the severity of these errors and the disclosure to patients. Based on the results, almost all errors in both categories without any harm to patients were disclosed to patients. Patients were not informed about 40% of information management-related AEs that caused severe harm.

Keywords. safety, incident reporting, medication error, information management, disclosure

1. Introduction

Adverse event (AE) reporting systems are important tools to monitor both safety hazards and quality concerns in care delivery. Various means are used both at a hospital and national level to report the status of patient safety. Based on the results of a survey, AE reporting systems and technologies vary among countries, and reporting practices within a hospital are distinct [1]. Depending on tools and instructions, AE reporting is often voluntary, which causes a lack of trust in the statistics due to the presumption of underreporting. In hospitals, 10% of AEs are detected by reporting systems, which is a major barrier to understanding errors and preventing harm [2]. Another often-discussed barrier to reporting is the fear of blame, which is associated with a blame culture instead of a safety culture. Blame has commonly been associated with events where a complaint was anticipated. Blame is also allocated easier when equipment or patient factors are considered to have caused AEs [3].

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Previous studies indicate that it is difficult for healthcare professionals to discuss safety events with patients, especially when using words like “error” or “mistake” [2,3]. Reason describes in his Swiss cheese model how AEs are frequently the result of multiple smaller errors within a failed system; it is not important whose fault the error was but why and how defenses failed [4]. AEs mostly occur as a consequence of latent errors in the system that lead to unsafe clinical practices [5]. The prevalence of disclosure seems to be higher in the United States and Europe than in other regions. The reported frequency of disclosure of patient safety incidents (DPSIs) among the general public is relatively lower than the frequency of DPSIs reported by medical professionals. Furthermore, patients emphasized the key elements of DPSIs, such as an apology, explanation, and promising to avoid its recurrence, but these essential elements were often missing [5-6]. Of patients who reported harm, 11.4% received an apology from the clinician or medical organization. In addition, most of the general public has little experience with full disclosure [6].

Medication errors (MEs) are the most often reported AEs [1,6]. Factors contributing to MEs can be classified as failures in prescribing, failures in medication review process, or failures in drug administration. The classification used in this study in AE reporting often overlaps with events classified in the category of information management, which includes failures in the coordination of care, documentation, and communication as subcategories that cause distraction and interruptions in information flow. Whether classified as a medication management-related or an information management-related AE, MEs are surprisingly more often regarded as severe AEs due to the possibility of fatal consequences [6].

The purpose of this study was to describe the severity of AEs and analyze whether patients were informed about the events. The study aimed to answer the following questions: What kind of relationship exists between the severity of events and the type of event, and what kind of relationship exist between the severity of events and disclosure to patients?

2. Materials and methods

The data consists of AE reports from 44 public and 3 private healthcare organizations in Finland that are considered to have harmed the reputation of the organization. The AE reports were collected from the years 2007-2016 [7]. From all the data we collected, reports were classified either as information management-related or medication management-related events. Data on the severity of harm and the potential disclosure to patients were collected for both error categories. The data were analyzed using cross-tabulation and chi-squared tests.

3. Results

The total number of AE reports was 99512. The number of medication management-related errors was 49935 (50.2%), and the number of information management-related errors was 18891 (19.0%). The prevalence of information management-related and medication management-related events from 2007-2016 show that the number of these two AEs have been the same during these years.

The severity of events and the type of events demonstrated that information management-related and medication management-related AEs caused mainly no harm or minimal harm. The most severe errors occurred in emergency care and in intensive care units, and the most frequent severity of all events was minimal harm. The most serious events involved only a single AE type.

The distribution of medication management-related and information management-related errors that caused harm slightly differed (Table 1).

Table 1. Medication management-related and information management-related errors and their severity

	No harm	Minimal harm	Moderate harm	Severe harm	Total
Medication-related	24966	13842	2248	180	41236
	60.5%	33.6%	5.5%	0.4%	100.0%
Information-related	8904	5328	1513	145	15890
	56.0%	33.5%	9.5%	0.9%	100.0%
Total	33870	19170	3761	325	57126
	59.3%	33.6%	6.6%	0.6%	100.0%

Figure 1 shows the rates of AE disclosure by the degree of harm caused to patients. When the event did not harm patients, patients were often informed (96% and 90% for medication management-related and information management-related errors, respectively). Minimal, moderate, and severe harm caused by information management-related AEs were disclosed in more than half of the cases (58%, 62%, and 58%, respectively). Medication management-related AEs were disclosed more often than information management-related errors.

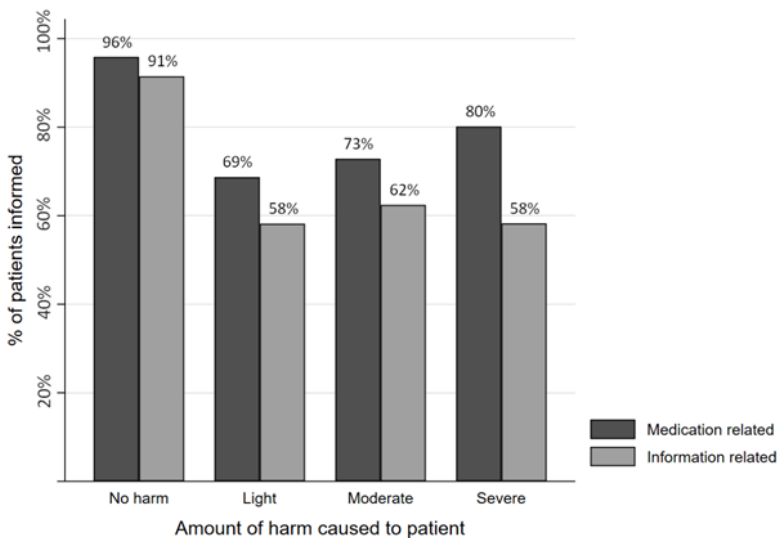


Figure 1. The rate of error disclosure by the degree of harm caused to patients.

We examined this relationship further with a chi-squared test, which indicated a significant difference in disclosure between categories of harm ($\chi^2(3) = 2145.14$, $p < 0.001$).

4. Discussion and Conclusions

The number of medication- and information management-related events reported remained almost constant. Studies have also confirmed the problem of categories with overlapping subcategories [1-2]. In our study, AEs classified as information management AEs included failures in the coordination of care, documentation, and communication as the subcategories that caused distraction and interruptions in information flow.

The severity of AEs illustrated that the most serious events were infrequent. The mean of the severity of events demonstrated that AEs caused mostly minimal or no harm. This study confirms the findings of previous studies that minor events are often disclosed to patients [3] and medication management-related AEs are disclosed to patients more often than information management-related AEs [6]. In terms of event disclosure, minor harm caused to a patient seemed to reduce the frequency of disclosure to the patient [3]. This tendency can be observed throughout our data and all types of AEs. The frequency of disclosures of medication management-related events increased as the severity of the event increased from minimal to severe. The frequency of information management-related event disclosure seemed to be lower than that of medication management-related event disclosure. A proportion of 80% of medication management-related and 60% of information management-related AEs that caused severe harm were disclosed to patients. These proportions are higher than those in previous studies [3,5], in which 65% of AEs were disclosed. Almost all AEs in both categories without harm to patients were disclosed to patients.

Further research will clarify the reason the disclosure of severe AEs was lower than that of events with no harm. Furthermore, more information on why disclosures did not increase when the severity of information management-related AEs increased is needed.

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The Quality Improvement Information System for Surveillance and Monitoring for Patient Safety and Personal Safety in Kalasin Hospital, Kalasin Province, Thailand

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Abstract. This mixed-method research aimed to evaluate in need assessments and develop an intervention model for quality improvement information system-QIIS for surveillance and monitoring Patient safety and Personals safety in Kalasin Hospital, Thailand. The process was divided into 3 phases, 1) Studies on needs assessments of patients and hospital staff-2P, 2) Develop the program and assessment 3) Program implementation and evaluation. The 245 participants were participated during October 2019 - Februarys 2020. A questionnaire and semi-structure interview by content analysis were applied to investigate on needs assessments and intervention evaluation were using checklist for observation. The results revealed that information alert from supportive technology especially in real-time were sophisticated improving and significantly increasing with the positively and satisfaction levels of the staff increasingly particularly in pre and post observation (p-value <0.05). The key success of QIIS was comprised as suddenly response and information alert system, for this reason their staff could be immediately responsive to problems as much as they affords.

Keywords. Quality improvement, Information surveillance, information alert

1. Introduction

The Safety system is necessary goal of the health service system and it is significant foundation for organization quality management [1]. The Ministry of Public Health-MOPH of Thailand has announced policy direction to Hospital patient safety and personal safety in all level off care [2]. The both, patient safety and personal safety has founded an adverse incident. There were a tendency to increase in the hospital [1]. Kalasin hospital, Kalasin province is a public general hospital under control of MOPH, has embraced the top policy and they endeavored to attempt in participation of patient safety and personal safety criterion into practice by defining the strategic direction to

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focus on becoming the 2P Safety hospital [3].The ultimate goal is the 2P Safety hospital has the patient and personal in the hospital safety [4].

However, previously, patient safety and personal process were difficult to access their information. In order to the reasons of prevent, reduce the severity of incidents and surveillance that may occur. In addition, it was found that the factors related to the obstacles to reporting adverse events were lack of time, fatigue, poor reporting tools and corporate culture.[6].These sophisticate reasons have must be developed to access information system that is sustainable, appropriate and maintain of surveillance and monitoring systems.[7]. Thus, in this research were employed the mixed method both action research framework to implement intervention. This was evidence-based finding develop the quality of the organization which participated in the development, engaging supportive technology. It was according to policy from the top level to encourage the Smart hospital Thailand 4.0 through, 2P safety strategy [5].

2. Methods

This mixed methods study was conducted in Kalasin Hospital, Kalasin Province, Thailand during October 2019 to February 2020. The units for this study were drawn from 7 sector of patient care units of hospital.

The population of this study was working in patient care units of Kalasin hospital. It was included as 962 cases. The number of sample size was calculated by using the sample size calculation formula to estimate the average population. The 245 samples were systematically randomized to the number of desired results.

The created questionnaire and semi-structured interview were applied as the research tool. The questionnaire was divided to 2 domains. First domain inquired about professionals information. Second domain queried their satisfactions information were applied from Opas [6] had Cronbach alpha 0.78.

Collect data was conducted by using online questionnaire via the QR code scan by smart phone distributed to the randomized subjects. And, quantitative data has been collected from Incident report of patient safety and personals safety in Program “Polang” Report. This research was conducted with permission from the Research Ethics Committee, Kalasin Hospital.

Qualitative data had been approached with an critical analysis by content analysis. Descriptive statistics were included as frequency distribution, percentage, mean, standard deviation, Inferential statistics, such as Independent t-test.

3. Results

Phase 1 Show that general information of professional in Kalasin Hospital, Kalasin province.



Figure 1. Health care position of studied subjects

The result data of information system needs for supporting surveillance and monitoring 2P Safety nurse by content analysis founded 1. Need a system that is easy to use 2. Have a secure system for patient and personal information 3. The menu of all process are simply 4. There is a notification system when a report occurs 5. The system can save historical data.6.The system has a date for revisions, And has notification system 7. The department can view the report 8. Fast system.

Phase 2, the intervention has been introduced the supportive information system requirements to develop information system. To surveillance and monitor the safety of patient and personals. According the program was employed a framework of System Development Life Cycle: SDLC [9] Which has function consisting of,1. The system logs in the system according to the user rights. 2.Risk incident the reporting system for 2P Safety then after report has Line alert at system and Mobile phone. 3. Review tracking system and collect the incident of risk. 4.Report and processing system

Table 1. The result of the information system user satisfaction rating, Surveillance and tracking patient safety and personal safety .Kalasin hospital, Kalasin province (Phase 3)

	average	Pre - Intervention S.D.	Level- Satisfaction	Post average Intervention Satisfaction	Level S.D.	
Functional Requirement Test	3.39	0.95	Moderate	4.62	0.52	Most
Functional Test	3.49	0.80	Moderate	4.83	0.82	Most
Usability Test	3.55	0.49	Moderate	4.73	0.49	Most
Security Test	4.53	0.57	Most	4.53	0.57	Most
Total	3.74	0.70	Moderate	4.67	0.60	Most

Table 2. The result of satisfaction and Risk incident rate and indicator of SIMPLE patient and personal in Kalasin Hospital average , dependent t test

	average	S.D.	t	p-value
Satisfaction				
Pre development	2.55	1.87	8.77	< 0.005*
Post development	3.14	2.24		
Risk incident rate were be fixed in 24 hours				
Pre development	2.45	1.24	9.65	< 0.005*
Post development	4.04	2.31		
Indicator of SIMPLE patient and personal safety				
Pre development	2.39	1.95	7.39	< 0.005*
Post development	3.52	1.76		

The result were showed Satisfaction scores, Risk incident rate were be fixed in 24 hours and Indicator of SIMPLE patient and personal safety had Significant at 0.005 level when compare with pre-post development.

4. Discussion of results

From the results of the study, **First** it was found that in general information of health professions of Kalasin hospital the largest number are nursing profession. This finding is correspond with reality of the hospital context in Thailand that nurses are forceful group of people who are involved in hospital patient and personal safety current results is agreed with Kaew somsri siwaporn reported [7].

For the information system needs for supporting surveillance and monitoring 2P safety by content analysis founded has intelligence technology support with team

development systems. Associated with Jingxuan Li [8] report. He founded user needs information system that is easy to use has notification system.

The Second phase, that were implementation program Polang surveillance report of 2P Safety when has incident and report for prevention harm with alert Line. More ever the system showed data real time for administrator. And there were rapid management incident and harm of 2P safety in hospital. Found that overall height level satisfaction. With agree was Pawat logawit (2013) [9]. They found that satisfaction of informatics system for risk management it height level with compare pre and post development program. **The last phase** result the all satisfaction and Risk incident rate, Including Indicator of SIMPLE 2P safety had Significant at 0.005 level when compare with pre-post development. Accordance with the previous report of Watcharee Sangmanee (2018) [10]. A study of Incident Reporting in Songklanagarind Hospital. found that Satisfaction had Significant at 0.005 level.

5. Conclusions

In conclusion, the QIIS was suddenly response and information alert system via supportive technology and social network connection, so that their staff could be immediately responsive to problems from frontline station. This was improving model for the surveillance and monitoring in 2P safety were significantly important and success for quality awareness and quality control in the organization.

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Iconic Visualization of Sickle Cell Patients Current and Past Health Status

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Abstract. Rapid access to patient overall health status is essential for a physician during a medical consultation. The use of a HIS for the management of neonatal screening and follow-up of sickle cell disease patients at CERPAD in the Saint-Louis region of Senegal leads the patient electronic records growing in volume and complexity. To facilitate access to relevant information and shortens the time required to analyze and understand these clinical data, an original solution is to set up a data visualization system. In this article, we propose the integration of two iconic visualization tools into the SIMENS-CERPAD module designed for sickle cell screening and healthcare. The two tools use the VCM iconic language and consist of a simplified anatomical schema showing the current health status of the patient and a timeline to visualize its temporal evolution.

Keywords. Visualization, VCM Icons, Timeline, Sickle Cell Disease, Computer Graphics, Nonverbal Communication

1. Introduction

The amount of medical data in health facilities is increasing, in Senegal as in the rest of the world. This data includes, on the one hand, the patient records from consultations carried out by doctors and on the other hand, the results of biological and radiological analyses. Thus, physicians are faced with an increasingly complex medical history with extensive data, on the basis of which they must make critical diagnostic and therapeutic decisions. Thus, it is easy to miss important information [1]. In the laboratory, one of the main challenges for biologists is to take advantage of the flood of data without being overwhelmed by it [2]. A possible solution would be the visualization of this medical data.

Visualization tools facilitate the medical decision-making process by reducing the time required to analyze and understand clinical data despite their complexity [3]. In biology, visualization allows a better understanding of biological processes and facilitates the interpretation of a biological examination [2, 4].

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In Senegal, the integration of a medical knowledge visualization system into a Health Information System (HIS) represents a new innovative scientific dimension in local medical practice. An example of initiatives is the National Medical Information System for Senegal (SIMENS) project [5], a modular HIS, initially designed for the medical services of level 3 health facilities in Senegal's health pyramid [6].

In this article, we propose the use of the VCM iconic language (Visualization of Medical Concepts) [7] for facilitating the access to the information in patient records. We integrated VCM into the SIMENS module designed for the Center for Research and Ambulatory Care of the Sickle cell disease (CERPAD) in the Saint-Louis region of Senegal. CERPAD systematically screens newborns in maternity hospitals in the region, and ensures early follow-up and management of sickle cell disease adapted to the Senegalese public health system [8]. We also demonstrate the use of VCM for monitoring sickle cell disease in Senegal on real data.

2. Material and Methods

VCM is an iconic language for medical concepts [9]. It allows representing with icons the main concepts (clinical conditions, pathologies, treatments, monitoring ...) found in medical records. These icons can be used to identify the excerpts of interest in a medical document; they are not intended to replace the text but rather to help find more quickly the excerpts that interest the physician and those that do not, especially during the consultation. Mr. VCM is an anatomical schema that allows summarizing a set of VCM icons [7] on a small visual interface.

We used VCM icons to visualize the sickle cell patient's medical problems contained in the results of biological analyses carried out in the laboratory and those contained in the conclusion (such as diagnosis) of consultations carried out in the medical service. In the SIMENS-CERPAD database, we identified the actual terms used in the conclusion of laboratory tests and consultations that were useful to visualize. In a second step, we manually made a correspondence between these terms and VCM icons. Similar terms (e.g. lab tests evaluating the same physiologic function) were mapped to the same icons. In order to facilitate the identification of the important points in a patient record, we retained only the icons for the lab tests associated with non-normal results (e.g. glycemia above 1 g/l).

We combined two icon-based visual approaches: an "instantaneous" anatomical approach with Mr. VCM showing the current state of the patient, and temporal approach with a timeline to visualize its historical evolution.

We collected the opinions of users using a questionnaire with four questions regarding their overall satisfaction with the use of Mr. VCM, the performance of the tool, the quality of the icons displayed and the quality of the information provided by the icons. Among these users, we have the biologists for the interpretation of new test results and the doctors for diagnosis and therapeutic decision-making. For each question, they could express a positive or negative opinion, with the opportunity to add free comments.

3. Results

We identified 76 terms in the CERPAD database, that were candidates for iconization, and we mapped them to 20 different VCM icons. Figure 1 shows a screenshot of the

integration of Mr. VCM into the SIMENS-CERPAD module showing the current status of the patient. In this example, icon #1 represents red blood cells, with a combination of two disorders: anemia and malaria, as shown by the popup tooltip. Information on anemia is obtained from the patient's latest blood count and information on malaria is obtained from the thick drop analysis. Icon #2 represents parasitic infections (here, in blood cells, i.e. malaria). Icon #3 shows that the patient suffers from an inflammation, but the location is unknown; it corresponds to a high value of C-reactive protein (CRP), a biological marker of inflammation. Other anatomic pictograms on Mr. VCM are grayed, indicating at a glance that there are no abnormalities observed for these organs (e.g. heart, liver and kidney): either there is no available lab test, or their results are normal.

Figure 1 also shows the timeline, featuring VCM icons and textual labels. To open it, click on the button circled in red on the left of the interface. It shows the icons of the disorders from which the patient has suffered from birth to the current date. It is also possible to visualize the evolution of a given disorder by filtering the icon of the chosen disorder in the legend panel on the right. Icon #4 shows a risk of rhythm disorder in February 2015 (orange color representing risk disorder in VCM). Cardiac pathology was finally diagnosed in November 2017 (icon #5, red color representing current disorder in VCM). A zoom allows the user extending or shrinking the timeline, and permits obtaining more accurate information about the exact date where the diagnosis was made. By clicking on the icon, text information is displayed in a tooltip with more details: biologist's conclusion and/or doctor's diagnosis. It is also possible to get details on the entire results of the laboratory tests or the consultations from which the information comes from.



Figure 1. Visualization of a patient record with Mr. VCM and with the iconic timeline.

All 6 (six) users questioned gave a positive opinion on their overall satisfaction with the use of the icons, the performance of the tools (VCM and timeline) and the quality of the icons displayed. They find that the icons provide reliable and sure information. They think that icons make it easier to interpret data by reducing the time required to analyze and understand the data.

4. Discussion and Conclusions

Many medical data visualization tools exist [2], and timeline is a common approach for visualizing patient records. On the contrary, the use of icons and iconic summaries like

Mr. VCM is innovative, especially for visualizing sickle cell disease specialized health records. Moreover, timeline and icons can be combined together, as we propose here. We have integrated two visualization tools and applied them to the follow-up of sickle cell patients. This approach can be used to monitor sickle cell disease in sub-Saharan Africa.

Thanks to the icons, VCM brings out information that might otherwise go unnoticed in the text data. It enables the biologist to identify in a temporal and instantaneous manner the relevant information that facilitates his tasks when interpreting and writing the conclusion of the results of lab tests. Similarly, the doctor can visualize Mr. VCM and immediately get an idea of the patient's health state and his main disorders.

The timeline provides a very intuitive representation that gives a quick and general overview of the patient's state of health. It makes it possible to present the data from medical records in an iconic and chronological format that meets the expectations of biologists and physicians who want a flexible access to all possible information within a given period of time.

In conclusion, the proposed visual approaches allow biologists and doctors obtaining quick information on the history, pathologies, symptoms, treatments, monitoring... for a given patient. The anatomical schema and the timeline are complementary, but both use the same icons. Our perspectives include a more comprehensive evaluation of this approach, and its extension in other SIMENS modules, beyond sickle cell disease.

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Using Machine Learning Algorithms to Predict Antimicrobial Resistance and Assist Empirical Treatment

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Abstract. Multi-drug-resistant (MDR) infections and their devastating consequences constitute a global problem and a constant threat to public health with immense costs for their treatment. Early identification of the pathogen and its antibiotic resistance profile is crucial for a favorable outcome. Given the fact that more than 24 hours are usually required to perform common antibiotic resistance tests after the sample collection, the implementation of machine learning methods could be of significant help in selecting empirical antibiotic treatment based only on the sample type, Gram stain, and patient's basic characteristics. In this paper, five machine learning (ML) algorithms have been tested to determine antibiotic susceptibility predictions using simple demographic data of the patients, as well as culture results and antibiotic susceptibility tests. Implementing ML algorithms to antimicrobial susceptibility data may offer insightful antibiotic susceptibility predictions to assist clinicians in decision-making regarding empirical treatment.

Keywords. Antibiotic resistance, AMR, Machine Learning

1. Introduction and Background

Fast spreading antimicrobial resistance in healthcare facilities constitutes a global concern with serious public health and economic implications. Over the past two decades, antimicrobial resistance (AMR) has been a significant threat to public health systems worldwide. Antibiotic resistance occurs naturally, but the misuse of antibiotics in veterinary and human medicine has intensified the growing AMR trend. Health care

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costs for patients with AMR infections are higher than care patients with non- AMR infections because of more extended periods of sickness, more testing, and the use of more costly medicines.

We recently published [1] the resistance rates of MDR isolates of the intensive care unit and other hospital wards, in a Greek public healthcare institution. Using the same microbiological dataset, we presented a methodology [2] that assists physicians in selecting the most suitable antibiotic treatment based on local antibiotic resistance patterns.

Artificial Intelligence (AI) innovations have changed the healthcare innovation environment, leading to improved patient outcomes while reducing healthcare costs. AI is now facing challenges that were previously considered as not feasible in healthcare. Digitalizing health records makes it possible to perform data mining in non-structured medical data, and clinicians can easily take various evidence-based decisions with this.

Several recent investigational studies advocate the use of ML algorithms in the healthcare domain, with a special interest in antibiotic resistance [3–5]. In the present study, we suggest the implementation of ML techniques to forecast antibiotic resistance using data from the Microbiology lab, available in the hospital information system (HIS), such as the type of sample, bacteria classification according to staining procedure (Gram stain), antibiotic susceptibility testing and simple patient data (age/gender). We explicitly limit our study to easily obtainable data to motivate the need to investigate the cost-effectiveness of applied data science proposals.

2. Methods and Materials

Data from Microbiology Laboratory patients hospitalized in two Departments of Internal Medicine at a Greek public tertiary hospital were analyzed over the one-semester (2nd semester 2018). The 5,590-instance dataset contains the attributes of age (numerical), gender (binary), Gram stain (binary), sample type (categorical), antibiotics (categorical), and the binary class attribute (antimicrobial susceptibility). In this study, we selected to use the WEKA framework, an ML software written in Java [6].

To evaluate final model performance [7], a part of the dataset is not used during training and is only for testing purposes. Cross-validation is a resampling method used on a small dataset to validate ML models. The method has a single parameter called k that corresponds to the number of equal-sized sets of instances to be divided into. This technique is also called k -fold cross-validation. Cross-validation is used in applied ML to estimate a model's skills on unseen data. That is, using a small sample to evaluate how the model is supposed to behave when used to predict data not used in the model training process. In our experiments, we compare the following five classifiers following a 10-fold cross-validation approach:

- The J48 algorithm, the implementation of the C4.5 algorithm [8]
- A random forest machine learner [9]
- A Multinomial logistic regression model with a ridge estimator [10]
- The k -nearest neighbors (kNN) algorithm [11, 12]
- A multi-layer perceptron (MLP) [6, 7]

To find the best classifier, we consider some key metrics, as TP Rate, FP Rate, Precision, Recall, F-Measure, MMC, Area under the Receiver Operating Characteristics (ROC) curve (AUC) and the Precision-Recall Plot (PRC).

3. Results

The results of applying the aforementioned techniques are shown in Table 1. The best results achieve an F-measure of 0.724 with the k -nearest neighbors (k NN) algorithm and a ROC area of 0.758, with the Multinomial logistic regression model. The experimental results suggest that the Multilayer perceptron classifier could serve as a suitable model for Internal Medicine Departments' antimicrobial susceptibility data sets, taking into account the evaluation of both F-Measure (0.721) and ROC Area (0.746) results.

Table 1. Weighted average measures by classifier (10-fold cross-validation)

Classifier	TP Rate	FP Rate	Precision	Recall	F-Measure	MCC	ROC Area	PRC Area
J48	0.739	0.467	0.720	0.739	0.722	0.311	0.722	0.740
Random Forest	0.717	0.435	0.708	0.717	0.712	0.292	0.721	0.747
Logistic	0.731	0.514	0.706	0.731	0.704	0.267	0.758	0.780
kNN	0.733	0.439	0.719	0.733	0.724	0.316	0.727	0.739
Multilayer Perceptron	0.735	0.457	0.718	0.735	0.721	0.309	0.746	0.766

4. Discussion

After having tested different ML models, a ROC area of 0.758 represented the best performance achieved, which means that our model is capable of distinguishing between the two classes of antibiotic susceptibility with an accuracy of 75.8%, based exclusively on the type of the examined sample, the Gram stain classification of the pathogen, and prior antibiotic susceptibility results.

The ML techniques presented in this article permit us to anticipate the sensitivity results from the Microbiology Lab. The early detection of patients at high risk for resistance to certain antibiotics, it could yield useful information for the clinician in prescribing empiric therapy based on the local antibiotic resistance pattern. Implementation of such prescribing practices may have significant implications for antibiotic stewardship.

Certainly, the models' prediction performance will be significantly improved once the patient's clinical characteristics are also included in the antimicrobial susceptibility dataset. Still, any inclusion of such information must incur the cost of retrieving the relevant data, and this may be an exercise that will involve a variety of hospital departments, thus elevating the costs of communication as well as complicating the need to align protocols which may operate across different departments. After paying that cost, one would also need to review the extent to which the extra information gained (in terms of, for example, improved accuracy metrics) can be effectively incorporated into the practice of the hospital physicians, who may need to rethink the way they review their decisions in the light of confirming or opposing recommendations from a decision support system. This does not only refer to the actual attitude of physicians who may need to consider modifying their practice but also to the extent to which such considerations may also be triggered by a change in protocols or the extent to which such recommendations can be made within the prescribed time limits. All in all, we consider

this study as a point in the spectrum of cost-effectiveness investigations that the ML techniques are bound to trigger in the healthcare sector.

5. Conclusion

In this article, we evaluated five ML models on two Internal Medicine Departments' antimicrobial susceptibility dataset. Examining different models, even in these limited data sets, offers the option of choosing the best possible model. Even a small increase in the accuracy of a model, especially in this medical field, can have a significant effect on the doctor's decision to choose the appropriate empirical treatment. Although there are certain limitations in the present study, our main end-point was to design an additional low-cost tool to identify antibiotic-resistant infections and guide appropriate empirical treatment, especially in situations where an urgent decision needs to be taken before the completion of standard antimicrobial susceptibility testing. In future work, we plan to enrich our datasets with clinical attributes and also to investigate the experimental configurations, which would possibly improve the algorithms' performance.

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Process Coverage and Use Case Support of Health Registry Software in Germany

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Abstract. Registries usually operate an IT-infrastructure supporting at least data management as one of the business processes. Several activities in Germany between 2007 and 2018 surveyed the market of respective software products. Combining a survey with representatives of software products with a workshop protocol of software demonstrations, a detailed insight into the market of IT-components arose. A comparison between 2015 and 2018 revealed little progress. The focus is still electronic data capture functionality. With the presented activities, rich material is available to assist registry developers in the planning of their IT-infrastructure and the selection of software products.

Keywords. Data management, electronic data capture, infrastructure, registry

1. Introduction

The Agency for Healthcare Research and Quality (AHRQ) defined a registry as an “organized system” [1]. That means that a couple of resources along with core business and supplementing processes constitute a registry. The AHRQ distinguished between the registry as a system and the registry database as “a file (or files) derived from the registry” being part of the IT-infrastructure. Core processes are data management, data analysis, management of participants, and management of study sites [2]. From the point of view of health services research, registries could be seen as an observational method used to study health care practice in a controlled setting [3]. Focusing on the IT-infrastructure, the range of commercial products was unclear in Germany. Furthermore, the required functionality was not well described in the past.

The TMF - Technology, Methods, and Infrastructure for Networked Medical Research is the umbrella organization for networked medical research in Germany (cf. <http://www.tmf-ev.de/>). The TMF is the platform for interdisciplinary exchange as well as cross-project and cross-location cooperation in order to identify and solve organizational, legal/ethical and technological issues. Several members of TMF operate registries as their main task. Therefore, registries received major attention within

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working groups, projects and initiatives within the TMF and with participation of the TMF office. Starting with a survey in 2007, components of a registry's IT-infrastructure were examined several times. In the following, findings will be reported along with a roundup of the current state.

2. Methods

This paper comprises activities between 2007 and 2018 concerning the IT-infrastructure of registries. In 2007, eleven from 55 TMF members submitted information covering 14 registries answering a questionnaire. Subsequently, a convenient sample of 10 registry owners was interviewed in 2009 extending the topics of 2007 [4]. The interview included three additional modules together with the questionnaire from 2007: about technical aspects, related to the registry's service management, and a definitional one. The survey led to the recommendation of a distributed, level-oriented organizational concept for the registry's IT-infrastructure. As part of a so-called IT-report of the TMF, a second survey about registries was undertaken in 2012. Twenty-seven from 88 members offered information about 31 registries or cohorts. Ten of the registries reported in-house development based on open source software, eight used three different commercial systems for electronic data capture (13 without information).

In 2014, commercial and non-commercial software products for registries were presented in a workshop. This workshop initiated a survey inviting vendors, suppliers and in case of non-commercial products experts for providing information. Beneath general information about their software, the participants were asked to classify their software products according to top-level-tasks from an exhaustive requirements catalogue (KoRegIT, [2]). Four inclusion criteria were defined: the software is specifically designed for registries or cohorts, the software covers the data management process at least, the software is available under a commercial or open license, and at least one application exists independently from the developers' institution. Information about 13 software products could be presented in the TMF's IT-report 2015. In 2018, 12 software products were presented in a workshop for 16 projects that intended to establish a registry for health services research [5]. The presentation followed a pre-defined agenda covering several use cases within the top-level-tasks introduced before. A member of the organizing team recorded the availability of the functionality needed to support the use cases. Some representatives of the software products additionally delivered the information of the survey from 2015.

As a summary of the activities introduced before, the coverage of registries' business processes will be presented for each software product. Additionally, the use case support will be compared between 2015 and 2018.

3. Results

Table 1 shows the coverage of registries' business processes by 20 software products. Due to the inclusion criteria, all software products support the data management, e.g. the recording of data, the presentation of summaries, or central monitoring. Generalists support other business processes of registries as well, specialists focus on data management alone. Some software products stem from the field of clinical trials as

secuTrial and REDCap3. Others were primarily developed for registries as the solutions of the Gesundheitsforen and NTD. The comparison between 2015 and 2018 revealed that there is little progress in the support of top-level-tasks and use cases of registries by the software market (table 2). The focus is still on basic electronic data capture.

Table 1. Software products for registries and cohorts (Statement by vendors, suppliers, or experts; 2015 or 2018). German users contributed information concerning OpenClinica and RedCap.

Name	Start	License	DM	RD	PM	CRM	ANAL	ARCH
Adjumed.net	2007	com.	~	~	-	~	+	+
asthesis	2010	com.	+	+	+	+	+	+
BRT	2012	com.	+	~	+	+	+	+
CentraXX	2010	com.						
Clinspire	2015	com.	+	+	~	~	~	~
FORGA-DB	2007	com.	+	~	~	+	~	~
genomatch.register	2014	com.						
Gesundheitsforen	2011	com.	+	+	~	~	~	~
iO study office edc 6.0	1994	com.	+	+	~	~	~	-
Marvin	2003	com.	+	+	+	+	-	+
OpenClinica3	2006	LGPL	+	~	+~	+~	~	~
OSSE	2012	AGPLv3	+	~	+~	~	~	-
NTD registry database	2008	com.						
ProMISe	1995	ASP	+	+	+	+	+	~
REDCap3	2008	no charge	+	~	~	-	~	~
secuTrial	2000	com.	+	~	+~	+	+	+
Smart Reporting	2016	com.	+	~	~	~	~	~
tripletrax	2015	com.	+	~	~	+	~	+
VRI	2007	com.	~	~	+~	~	~	+~
Webspirit EDC	2004	com.	+	+	~	~	~	+~

Note: DM = data management, RD = registry development, PM = management of participants, CRM = management of study sites, ANAL = data analysis or data utilization, ARCH = archiving, ASP = Application Service Providing, LGPL = GNU Lesser General Public License, AGPL = GNU Affero General Public License; categories of support: “+” = complete, “~” = partial, “-” = none, “+~” = available through other modules or software products; details are missing for three software products.

4. Conclusions

The market of software products for registries focusing on data management is still growing. Listing 13 offers in 2015, the list includes 20 offers now. However, important use cases such as central monitoring and data provision are still not addressed by all software products. The same is true for the support of the development phase of a registry. Business processes beside data management could be handled using one of the generalists. On the other hand, special solutions are available to implement the relationship to study sites or to manage participants. Therefore, the conflict between a best-of-breed collection and an all-in-one solution exists also for the components of the IT-infrastructure of registries. Moreover, model kits promise to combine the advantages of both concepts, providing highly integrated but separated components. Because migration of the business components of a registry’s IT-infrastructure is a complex task, the choice of software products should be based on a thorough analysis of requirements and an unambiguous agreement of priorities between all stakeholders. The presented activities could be a valuable contribution to the planning of a registries’ IT-infrastructure and the selection of software products.

Table 2. Coverage of top-level-tasks (TL, 2015) and use cases (UC, 2018). Structure taken from KoRegIT [2]. (2015: statement by vendors, suppliers, or experts; 2018: protocol; 12 software products each year).

Phase	Top-level-task (2015) /use case (2018)	used/ available	partial available	in development	planned	not planned/ not available	unclear
Development/Preparation							
	Preparation of data acquisition and data recording (TL)	9	1			2	
	<i>Creation of case report forms (UC)</i>	12					
	Development and implementation of the authorization scheme (TL)	9	2			1	
	<i>Implementation of the authorization scheme (UC)</i>	12					
	User data and master data management (TL)	10	1	1			
	<i>Management of users, rights and roles (UC)</i>	9	1				2
Operation/Implementation							
	Data acquisition and data recording (TL)	11	1				
	<i>Registration of participants (UC)</i>	12					
	<i>Editing of a record (UC)</i>	12					
	<i>Visit presentation (UC)</i>	12					
	<i>Visit creation (UC)</i>	12					
	<i>Record deactivation/blocking (UC)</i>	9					3
	Monitoring (TL)	9	1	1		1	
	<i>Central monitoring execution/support (UC)</i>	9	3				
	Provision of information related to a participant (TL)	4		1	1	6	
	<i>Generation of a findings record (UC)</i>	5	1			5	1
	Data management (organization and maintenance of data) (TL)	11	1				
	<i>Central monitoring execution/support (UC)</i>	9	3				
	<i>Data export and data provision (UC)</i>	9				2	1

Note: The phases development/planning, operation/usage, operation/enhancements and closing were not addressed in 2018. The use cases “central monitoring execution/support” are intentionally combined and listed twice.

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Enhancing Medical Education with Data-Driven Software: The TrainCoMorb App

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Abstract. Medical education can take advantage of big data to enhance the learning experience of students. This paper describes the development of TrainCoMorb, an online, data-driven application for medical students who can practice recognizing comorbidities and their attributable risk for negative outcomes. Trainees access TrainCoMorb to create scenarios of comorbidities, step-by-step, and see snapshots of the risk for inpatient death, hospital septicemia and the projected length of stay. The study utilized an enormous claims dataset (N=11m.). A dynamic Bayesian algorithm was developed, which calculates and updates conditional probabilities for the outcomes under study in each phase of an ongoing scenario. The trainee initiates a scenario by selecting demographics and a principal diagnosis, then adds chronic and hospital-acquired conditions to see a summary of the attributable risk in each phase. TrainCoMorb is anticipated to assist medical students gain a better understanding of comorbidities and their impact on clinical outcomes.

Keywords. Medical education, Bayesian methods, Comorbidities

1. Introduction

A comorbidity is the presence of one or more diseases co-occurring with a principal diagnosis (D_x) [1]. Comorbidities are related to adverse outcomes [2], complications, and hospital readmissions [3]. In today's health systems, physicians are challenged to manage complex patient comorbidities and should therefore develop skills to recognize comorbidity profiles and assess their risk for adverse outcomes. Unsuspected comorbidities worsen a situation since treatment for the first condition may conflict with the second and therefore early detection of subsequent conditions will enable adjustments to the treatment plan. All the above motivate researchers to study the impact of comorbidities on clinical outcomes [4]. While most research approaches study a narrowed down disease domain, to facilitate decisions for a wide spectrum of patients, use of advanced data analytics is imperative, although underexplored [5].

Medical education recently started to take advantage of new technologies. The American Medical Association funded medical schools to find creative ways to prepare medical students, giving them access to large clinical data sets, which have the potential to simulate patterns of patient care [6]. Adding interactive, data-driven tools to medical education is therefore anticipated to enhance the clinical decision-making capacity and the overall learning experience [7]. With data-driven medical education systems, the trainee can exercise in a realistic, consequence-free simulation environment.

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The objective of this work is to develop and evaluate *TrainCoMorb* (*Training with Comorbidities*), an online data-driven training application for medical students and residents who can practice recognizing comorbidities and their attributable risk for negative outcomes. Trainees can use the app to create scenarios of comorbidities in a computer assisted manner, to have at their disposal dynamically updated realistic snapshots of patient safety outcomes (hospital mortality, hospital acquired conditions) and the length of stay. This is a joint work between the College of Health Sciences and College of Medicine, at the Central Michigan University (CMU).

2. Methods

2.1. Data Sources

The study utilized a large Limited Data Set (LDS) from the Centers for Medicare and Medicaid Services (CMS) with 11,264,189 records. The dataset includes patient admission information, the principal, secondary, and hospital acquired diagnoses in ICD-10-CM format, medical procedures, and, finally, discharge, and patient disposition information. The entire dataset was used for the purpose of this study. To reduce dimensionality, the ICD-10-CM codes were transformed to Clinical Classification Software (CCS) codes, a well-known clinical diagnosis classification (with an ICD to CCS mapping), for a meaningful and compact clinical representation of diagnoses.

2.2. Approach

The backend of *TrainCoMorb* is based on cross-sectional data analysis. A dynamic Bayesian algorithm calculates conditional probabilities for inpatient death, and hospital-acquired septicemia as well as the mean length of stay, any time the user updates their scenario. The trainee initiates a patient scenario by selecting patient demographics and the principal D_x . Next, the user is directed to select any chronic conditions for the patient under investigation, and finally, is given the option to add any hospital-acquired conditions. In each step, updated risk estimations become available to the trainee.

Since the *TrainCoMorb* app metrics are based on conditional probabilities, the app provides to the trainee direct estimations based on exact cases from the 11-million-record LDS dataset of the system backend. During the construction of the scenario, on each step, the system filters out the database and calculates conditional probabilities for the outcome of inpatient mortality and hospital septicemia, and the mean value for the length of stay. For a collection of n diagnoses, the probability is calculated with formula (1):

$$P(death|Dx1 \dots n) = P(Dx1 \dots n \text{ and death}) / P(Dx1 \dots n) \tag{1}$$

With the step-by-step calculation of the risk, the system calculates the attributable risk for death, of some newly added diagnosis D_{x2} , with formula (2):

$$AR(Dx2) = P(death|Dx1, Dx2) - P(death|Dx1) \tag{2}$$

The algorithm has two consequent linear probability estimations, where the trainee selects, in order, the demographics and principal D_x and then the preexisting chronic

conditions. Then a user feedback loop is initiated where the trainee can add hospital acquired conditions to the scenario, one by one, and to see updated risk estimations. The loop can be interrupted by the trainee at any point, to end the scenario. Figure 1 shows the system workflow and the user-system interaction.

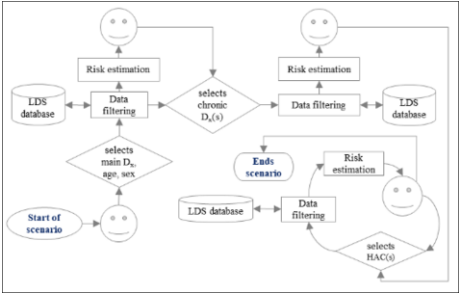


Figure 1. Diagrammatic representation of the workflow of a typical *TrainCoMorb* session

3. Results

Trainees can use *TrainCoMorb* to create clinical scenarios of comorbidities in a computer-assisted manner and have at their disposal dynamic realistic risk snapshots. As an example, a trainee initiates a scenario of a female, 75-79-year-old patient, admitted to the hospital with pneumonia. Then the trainee added the chronic condition Congestive Heart Failure (CHF). Finally, after selecting fluid-disorders as a hospital-acquired condition, the trainee decided to end the scenario, to see a summary of the decisions, step by step, with the attributable risk estimations for each step (Fig. 2). Characteristically, in this scenario, the risk for death was doubled when CHF and fluid disorders were added to the clinical scenario.

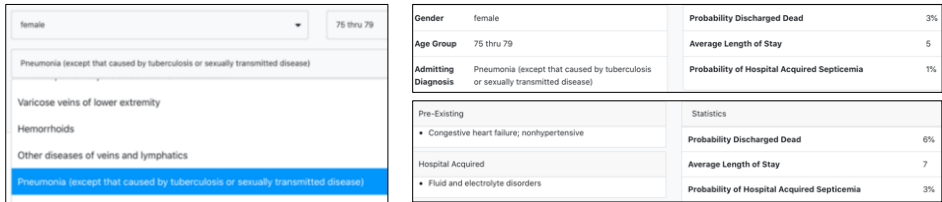


Figure 2: The trainee initiates a scenario (left). The system estimates P(death), P(septicemia), & LOS (top right). Then the trainee adds chronic & hospital acquired conditions to see the updated risk (bottom right).

Table 1 shows a summary of five example scenarios that were created with the app. Every completed scenario is stored into a ‘comorbidity database’ which can be accessed by the trainee who can review risk estimations for previously created scenarios.

Table 1. Five example scenarios generated by the *TrainCoMorb* application

Base scenario	Risk indicators [P(d), LOS]	Added Chronic	Added Hospital Acquired	Updated risk
Female, 65-69yrs, Non-Hodgkin's	6%, 11d	Essential HT	UTI	6%, 16d
Male, 70-74yrs, Prostate Cancer	1%, 2d	Diabetes	Anemia	5%, 5d
Female, 70-74yrs, COPD	1%, 5d	Diabetes	Pneumonia	2%, 6d
Female, 75-79yrs, Pneumonia	3%, 5d	CHF	Fluid disorders	6%, 7d
Male, 80-84yrs, Septicemia	13%, 7d	Kidney Disease	Aspir. Pneumonit.	22%, 10d

4. Evaluation

A panel of experts was formed with two physicians, two medical residents from the CMU College of Medicine, and two CMU College of Health Professions faculty, with expertise in health informatics, and nursing. The members were granted access to *TrainCoMorb* for two weeks and were asked to complete predefined scenarios and to create their own scenarios. Then they provided feedback via an open-ended survey. In summary, the panel suggested the following enhancements to improve the app: (1) in each scenario step, recommend comorbidities that the trainee could add, (2) do not show risk estimations when <30 records are matched, (3) evaluate the correctness of trainee decisions based on conditional probability comparisons of other alternative paths.

5. Conclusions

TrainCoMorb is anticipated to assist medical students and residents gain a better understanding of inpatient comorbidities and their impact on clinical outcomes, and ultimately make proactive clinical decisions. The researchers plan to recommend *TrainCoMorb* as a supplementary tool into the medical curricula of CMU. The system will be useful for medical residents to practice recognizing comorbidities and learn their risk for negative outcomes. Health systems quality assurance trainees and hospital administrators can also use the app to study the effect of frequent case mix profiles on negative outcomes and develop plans tailored to high-risk patient case-mixes.

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Evaluating the Students' View of Medical and Paramedical Sciences About Perceived Benefits and Barriers of Virtual Social Networks for Learning Purposes

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Abstract. Social networks are new technologies that facilitate the sharing and exchange of information and knowledge as well as the communication between students and professors. The purpose of this study was to investigate views of medical and paramedical sciences students about benefits and barriers of virtual social networks for learning purposes. A cross-sectional study was carried out in 2017 and the research tool was a researcher-made questionnaire based on a literature review. The majority of students (medical= 93% and paramedical sciences= 84.7%) tended to use social networks for learning purposes. Also, the results showed that “sending and receiving educational videos” and “sending and receiving educational texts, posts and contents” was the highest priority for medical and paramedical sciences students for using social networks. Overall, the results of our study showed that the social networks can play an effective role in educating medical students and improve students' motivation for learning. However, the use of these technologies also brings problems and challenges.

Keywords. Social networks, Students views, e-Learning, Benefits, Barriers

1. Introduction

In the 21st century, learning has become as an exciting activity by the use of tools such as the internet and social networks. Social networks are considered as economical and convenient tools for people to cooperate nationally and internationally [1]. Also, they can play an important role in educational programs and help students to interact with professors and other students [2]. Social networks can also bring challenges despite having many benefits in the field of education and learning [3, 4, 5]. This study investigated the views of medical and paramedical sciences students about benefits and barriers of virtual social networks for learning purposes.

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2. Methods

A cross-sectional study was conducted between May to July 2017 in Mashhad University of Medical Sciences (northeastern Iran). The research population consisted of all students of the school of medicine and school of paramedical sciences in Mashhad University of Medical Sciences (n= 480). The sample size was determined based on Cochran formula with 95% confidence interval. The only inclusion criterion was that all students should study at the time of this research. The exclusion criteria were: a) transfer students and guest students from other universities; b) students who were on leave at the time of the study; c) foreign students. Data was collected using a researcher-made questionnaire based on a literature review [6-8]. The questionnaire included questions about: a) demographic information (age, gender, level of education, field of study); b) Students' attitudes towards social networking applications in learning (6 questions); c) Students' attitude toward the benefits and barriers of social networks (13 questions) on a five-choice Likert scale (Strongly Disagree= 1 to Strongly Agree= 5); d) Priority of using social networks for learning purposes (6 questions: last priority= 1 to first priority= 6). The questions were evaluated by two health information management and two medical informatics specialists for content validity. As a result, vague questions were reviewed and corrected. The reliability was assessed using the test-retest method ($r= 0.79$). The data were analyzed using the SPSS version 16.0.

3. Results

In this study, the majority of participants were female (71.3%) and single (80.2%), with an average age of 21 years old. The results showed that most medical students (34.8%) used social networks 11-20 times and most paramedical students (41.1%) used it 1-10 times per day. Also, the majority of medical (32.2%) and paramedical (22%) students stated that they use social networks between 2-3 hours per day. The majority of medical students (38.9%) stated that their attitudes toward using social networks for learning purposes were slightly more positive in the last two years, while the majority of paramedical students (36%) stated that their attitudes have not changed. The majority of students (medical sciences= 93% and paramedical sciences= 84.7%) tended to use social networks for learning purposes. According to Table 1, most of the medical students describe that “using social networks in the classroom for non-educational purposes has made me loose the benefits of the classroom” (mean= 3.95 ± 0.76 of 5). From the perspective of paramedical sciences students, facilitation of university projects and researches (3.79 ± 0.85) is the most important benefit of social networks.

Table 1. Students' attitude toward the benefits and barriers of social networks

Students' attitudes	Schools	Mean $\pm$ SD	Total
Using social networks in the classroom for non-educational purposes has made me lose the benefits of the classroom.	Medicine	3.95 $\pm$ 0.76	3.63 $\pm$ 0.97
	Paramedical Sciences	3.29 $\pm$ 1.04	
The use of social networks facilitates the conduct of academic projects and research.	Medicine	3.75 $\pm$ 0.74	3.77 $\pm$ 0.80
	Paramedical Sciences	3.79 $\pm$ 0.85	
I find many resources, links and educational topics using social networks.	Medicine	3.80 $\pm$ 0.85	3.75 $\pm$ 0.88
	Paramedical Sciences	3.70 $\pm$ 0.92	
Social networks motivates better learning than traditional teaching methods.	Medicine	3.59 $\pm$ 0.92	3.45 $\pm$ 0.94
	Paramedical Sciences	3.29 $\pm$ 0.93	
	Medicine	3.44 $\pm$ 1.05	3.51 $\pm$ 0.98

Social networks help in collaborative and collective learning.	Paramedical Sciences	3.58±0.91	
In my country, social networks play an important role in scientific progress.	Medicine	3.34±1.13	3.05±1.13
Using social networks could integrate curriculum and instruction.	Paramedical Sciences	2.76±1.07	
In my opinion, communicating with classmates through social networks is useful for educational purposes.	Medicine	3.53±0.96	3.34±1.01
Communicating with professors through social networks will provide me with good learning experiences.	Paramedical Sciences	3.15±1.03	
I need experience to be proficient in using social networks for educational purposes.	Medicine	3.57±0.97	3.65±0.95
Many of my friends recommend using social networks for educational purposes.	Paramedical Sciences	3.73±0.93	
My professors believe that using social networks is important for educational purposes.	Medicine	3.44±0.94	
I have enough experience to use different social networks for educational purposes.	Paramedical Sciences	3.22±1.02	3.33±0.99
	Medicine	3.44±1.02	3.41±0.99
	Paramedical Sciences	3.39±0.95	
	Medicine	3.53±0.95	3.30±1.02
	Paramedical Sciences	3.06±1.04	
	Medicine	3.44±0.95	3.21±0.99
	Paramedical Sciences	2.97±0.97	
	Medicine	3.54±0.99	3.37±1.02
	Paramedical Sciences	3.19±1.01	

The results showed that “sending and receiving educational videos” (4.14±1.74) and “sending and receiving educational texts, posts and contents” (3.94±1.69) were the highest priority for students who use social networks. (Table 2).

Table 2. Students' attitudes about priorities the use of social networks in learning purposes (last priority=1 up to first priority=6)

Priority (Mean ± SD)	Schools	1st N (%)	2nd N (%)	3th N (%)	4th N (%)	5th N (%)	6th N (%)	Mean ± SD
Sending and receiving educational videos (4.14±1.74)	Medicine	92 (37.7)	34 (13.9)	31 (12.7)	29 (11.9)	22 (9.0)	36 (14.8)	4.15± 1.85
	Paramedical Sciences	61 (25.8)	52 (22.0)	51 (21.6)	24 (10.2)	26 (11.0)	22 (9.3)	4.14± 1.62
Sending and receiving text educational posts and content (3.94±1.69)	Medicine	43 (17.6)	74 (30.3)	21 (8.6)	33 (13.5)	30 (12.3)	43 (17.6)	3.75± 1.78
	Paramedical Sciences	48 (20.3)	77 (32.6)	39 (16.5)	28 (11.9)	22 (9.3)	22 (9.3)	4.15± 1.56
Curriculum planning with classmates (3.80±1.56)	Medicine	22 (9.0)	59 (24.2)	75 (30.7)	32 (13.1)	37 (15.2)	19 (7.8)	3.75± 1.41
	Paramedical Sciences	62 (26.3)	28 (11.9)	49 (20.8)	37 (15.7)	31 (13.1)	29 (12.3)	3.86± 1.71
Communicating with experts in other universities for educational purposes (2.97±1.44)	Medicine	10 (4.1)	29 (11.9)	51 (20.9)	80 (32.8)	57 (23.4)	17 (7.0)	3.20± 1.23
	Paramedical Sciences	18 (7.6)	24 (10.2)	26 (11.0)	50 (21.2)	46 (19.5)	72 (30.5)	2.74± 1.60
Lesson counseling with professors (3.17±1.66)	Medicine	42 (17.2)	25 (10.2)	44 (18.0)	39 (16.0)	58 (23.8)	36 (14.8)	3.37± 1.68
	Paramedical Sciences	25 (10.6)	23 (9.7)	32 (13.6)	45 (19.1)	61 (25.8)	50 (21.2)	2.97± 1.61
Make connections for research projects (3.00±1.73)	Medicine	37 (15.2)	23 (9.4)	23 (9.4)	32 (13.1)	38 (15.6)	91 (37.3)	2.84± 1.86
	Paramedical Sciences	24 (10.2)	31 (13.1)	38 (16.1)	51 (21.6)	50 (21.2)	42 (17.8)	3.16± 1.58

4. Discussion

The findings showed that most of the students tended to use social networks for learning purposes. Maloney et al., in their study about identifying students' use and behaviors 'of social networks in the health area found that the majority of students use social networks for specialized educational and learning purposes [9]. Alsuraihi et al., in their study about the use of social media in medical education in Saudi Arabia, found that 95.8% of medical students found social media useful and tended to use it in education. Also, 87.7% of them stated that they use social media for their educational purposes [10], which is consistent with the present study. The findings showed that in terms of students' views, ability to send and receive educational videos is the most important use of social networks among the educational purposes. Previous studies have also shown that the ability to send and receive videos, images, and educational texts to assist medical students' educational goals is one of the most important features of social networks [11, 12]. However, sending and receiving educational videos and pictures is usually costly and time-consuming due to the large size of files. This is challenging in developing countries such as Iran, where the Internet speed is low [13] and costs are high, so easy and extensive use of social networks is challenging. Overall, the results of our study showed that the social networks can play an effective role in educating medical students and improve students' motivation for learning. However, the use of these technologies also brings problems and challenges such as the privacy of students and professors, internet costs, high dependency of the students on social networks, redundancy of unrelated information to non-educational purposes.

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Visualization of Potential Drug Synergies

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Abstract. Drug synergy must be taken into account when prescribing several drugs for treating the same disorder. Synergies are sometimes known from clinical trials, but they are not systematically studied. In this paper, we present a visual approach for identifying and explaining the potential synergies between the 2-15 drugs available for a given disorder. It is based on the chaining of two bioinformatics databases, Drug Bank and Signor, and relies on set visualization with rainbow boxes. We apply this approach to antihypertensive drugs, and show that some European recommendations can be visually deduced and explained.

Keywords. Drug synergy, Hypertension, Visual analytics, Visualization, Non-verbal communication

1. Introduction

For many disorders, several drug treatments are available and can be prescribed. In patients with advanced forms of the disease, it is sometimes possible to associate several drugs or active principles (*i.e.* a bitherapy or tritherapy), in order to obtain a synergy in their beneficial effects. However, this synergy is not systematic and depends on the mechanisms of action of the drugs involved: in some cases, no benefit is obtained by combining several drugs. Moreover, when prescribing several drugs, the risk of adverse effects may be increased.

In clinical practice, the decision to prescribe a drug association is made on the basis of recommendations given in clinical practice guidelines. The guidelines themselves rely on clinical trial results and/or professional expertise when no medical evidence is available. Nevertheless, it would be of particular interest to be able to predict the potential synergy between the drugs available for a given disorder, especially when guidelines are not available, or in order to confirm and strengthen the existing guidelines. In the literature, several systems were proposed for predicting drug synergies [6-7]. However, these systems focused on automatic prediction, while a visual approach would be interesting for presenting the pharmacological data available to experts and clinicians, and for explaining why a synergy exists between two drugs.

In this paper, we present a preliminary study aimed at visualizing, identifying and explaining the potential synergies between the main antihypertensive drug classes, by

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chaining two bioinformatics databases, Drug Bank and Signor, and applying a set visualization technique, rainbow boxes.

2. Methods

We used two bioinformatics databases. First, Drug Bank 5.0 [1] was used to extract the therapeutic and non-therapeutic targets of each drug. Since most targets are proteins, we also used Signor 2.0 [2], which describes up- and down-regulation between proteins in Human. Both data sources were integrated in an OWL ontology using ontology-oriented programming [3], and relations present in Signor were chained, in order to obtain, for each drug, the list of protein targets that the drug activates and inhibits, directly but also indirectly (using simple Boolean rules such as if drug D activates protein P1 that inhibits protein P2, then drug D indirectly inhibits protein P2).

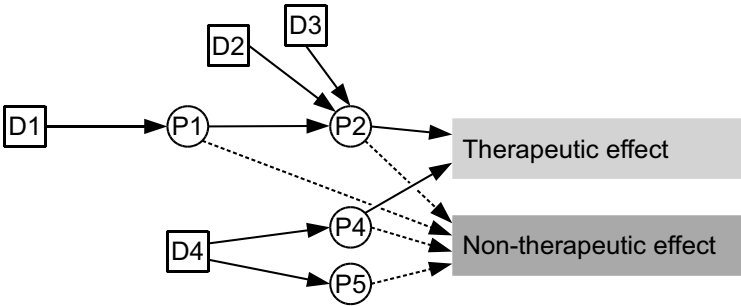


Figure 1. Simple example of drug and protein regulation pathway (D: drug, P: protein / target).

Regarding the underlying mechanism for drug synergy, our hypotheses are the following: (a) Non-therapeutic targets (*e.g.* P5) may cause undesired effects, including adverse effects. (b) No synergy is expected between two drugs that have the same target. In this case, it is probably better to prescribe only one drug, with an increased dose. For example, in Figure 1, no synergy is expected between D2 and D3. (c) No synergy is expected between two drugs when the target of one drug is located upstream the regulation flow of the target of the other drug (*e.g.* in Figure 1, between D1 and D2, or D1 and D3). In addition, drugs acting upstream are expected to have more adverse effects, *e.g.* here D1 may cause more adverse effects than D2 and D3 because P1 may have additional undesired effects. (d) On the contrary, a synergy is expected between drugs having distinct unrelated targets (*e.g.* in Figure 1, between D1 and D4, D2 and D4, or D3 and D4). (e) When drugs have more than one therapeutic target, we expect a higher synergy when their targets differ and are not located upstream one of each other.

To facilitate the identification of drugs having similar or different targets, we used visual analytics and set visualization with rainbow boxes [4]. Each drug can be considered as an element, and each protein can be modeled as the set of all drugs acting on that protein (directly or indirectly). The nature of the drug targets are indicated using colors, and we add hatches to indicate indirect targets.

3. Results

We applied our approach to antihypertensive drugs. Existing synergies between these drugs are well-known and described in guidelines. This allows the validation of our approach. Five main antihypertensive drug classes exist: Betablocking agents (*e.g.* acebutolol), Angiotensin-Converting Enzyme (ACE) inhibitors (*e.g.* captopril), Angiotensin II receptor blockers (ARB, *e.g.* irbesartan), Thiazide diuretics (*e.g.* hydrochlorothiazide) and Calcium channel blockers (CCB, *e.g.* diltiazem).

Figure 2 shows the resulting visualization with rainbow boxes. Drug classes are shown in columns, and target proteins in colored boxes. Boxes cover one or more column, corresponding to the drug that acts on this target, *e.g.* only Betablocking agents act on the “Beta-1 adrenergic receptor” target, while Betablocking agents, ARB and ACE inhibitors act on the “Beta-2 adrenergic receptor” target. Columns were ordered according to box similarity, as usually done with rainbow boxes.

Box color indicates the nature of the target: red for non-therapeutic targets, yellow for therapeutic targets located upstream another therapeutic target (*e.g.* P1 in Figure 1), green for other therapeutic targets (*e.g.* P2 and P4 in Figure 1). White hatches indicate indirect targets, *e.g.* for ACE inhibitors, their action on “Type-1 angiotensin II receptor” is indirect, and results from their action on “Angiotensin-converting enzyme”. Drug synergy is expected to occur between columns having different green boxes.

Calcium channel blockers	Betablocking agent	Angiotensin II receptor blocker	ACE inhibitor	Thiazide diuretic
			Leukotriene A-4 hydrolase	
			Angiotensin-converting enzyme	
			B1 bradykinin receptor	
	Beta-1 adrenergic receptor	Type-1 angiotensin II receptor		
	Beta-2 adrenergic receptor			
	72 kDa type IV collagenase			Carbonic anhydrase 1
	Matrix metalloproteinase-9			Carbonic anhydrase 2
Voltage-dependent calcium channel gamma-1 subunit	Transcription factor AP-1			
	Calcium-activated potassium channel subunit alpha-1			
	Solute carrier family 12 member 3			
Voltage-dependent L-type calcium channel subunit alpha-1C				

Figure 2. Rainbow boxes showing the direct and indirect targets of the five main antihypertensive classes.

Several information regarding drug synergy can be obtained from Figure 2: (1) Betablocking agents, ARB and ACE inhibitors have the same “downstream” therapeutic targets. Consequently, there is no expected synergy between these drugs (hypothesis c above). (2) In addition, ACE inhibitors have more non-therapeutic targets that ARB. Thus they are expected to cause more adverse drug events. (3) Drug synergy is expected between CCB and one of Betablocking agents, ARB, ACE inhibitors or Thiazide diuretics. The European Society of Cardiology (ESC) and the European

Society of Hypertension (ESH) guidelines [5] recommend for uncomplicated hypertension one of the following four associations: ACE inhibitor + CCB, ACE inhibitor + diuretic, ARB + CCB, ARB + diuretic. This recommendation is partly concordant with the synergy expected from Figure 2, however, our approach allows explaining why a synergy is expected or not between some drugs. In addition, the same guidelines explicitly mention the absence of synergy between ACE inhibitors, and also mention that ARB cause fewer adverse drug events. On the contrary, our approach found no synergy between diuretics and ACE, ARB or Betablocking agents.

4. Discussion and Conclusions

In this paper, we proposed a visual approach for identifying and explaining the potential synergies between the drugs available in a given indication, on the basis of the data present in bioinformatics databases. We tested this approach in hypertension, a domain in which drug synergies are known from clinical trials, and detailed in guidelines. Our approach allowed identifying some already known synergies in this context. In the literature, few works focused on drug synergy. Protein-protein interaction networks are classically used for identifying synergies [6], as we did here. D. Chen *et al.* [7] used pathway-pathway interactions in addition to drug targets and showed that pathway-pathway interactions increased predicting performances. However, existing approaches do not propose a visual overview of the drug targets, as we did here with rainbow boxes. The perspective of this work are: (1) To improve the proposed approach by considering additional bioinformatics databases and by using more sophisticated rules for chaining regulation interactions between proteins, for example considering weighted interactions between proteins. (2) To apply the proposed approach to more complex domains, such as oncology, in which drug treatments are complex and often associated. In addition, new oncologic treatments are regularly marketed, and their synergy with previous treatments remain unknown at the beginning. (3) To extend our approach for supporting personalized medicine. For example, if the patient does not express a given receptor, the corresponding box can be hidden in rainbow boxes, adapting the visualization to the patient.

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Use of Natural Language Processing for Precise Retrieval of Key Elements of Health IT Evaluation Studies

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Abstract. Having precise information about health IT evaluation studies is important for evidence-based decisions in medical informatics. In a former feasibility study, we used a faceted search based on ontological modeling of key elements of studies to retrieve precisely described health IT evaluation studies. However, extracting the key elements manually for the modeling of the ontology was time and resource-intensive. We now aimed at applying natural language processing to substitute manual data extraction by automatic data extraction. Four methods (Named Entity Recognition, Bag-of-Words, Term-Frequency-Inverse-Document-Frequency, and Latent Dirichlet Allocation Topic Modeling) were applied to 24 health IT evaluation studies. We evaluated which of these methods was best suited for extracting key elements of each study. As gold standard, we used results from manual extraction. As a result, Named Entity Recognition is promising but needs to be adapted to the existing study context. After the adaption, key elements of studies could be collected in a more feasible, time- and resource-saving way.

Keywords. health IT, evaluation studies, natural language processing

1. Introduction

The search and retrieval of health IT evaluation studies via PubMed just by using MeSH terms can be challenging due to lack of precise MeSH terms in the field of health IT evaluation [1]. Having precise information about health IT evaluation studies is important for evidence-based decisions in medical informatics. To solve this issue, in an earlier study, we have used a faceted search based on ontological modeling of key elements of studies to retrieve precisely described health IT evaluation studies [2]. However, retrieving the key elements for the faceted search manually was time and resource-intensive. To solve this issue, we now aimed at applying natural language processing based on the ontology population approach to substitute manual data extraction by retrieving the key elements of the studies by automatic extraction [3]. The

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aim of this paper is to compare four methods for automatic data extraction with regard to their effectiveness.

2. Methods

We compared four natural language processing methods: Bag-of-Words (BoW), Term-Frequency-Inverse-Document-Frequency (TFIDF), Latent Dirichlet Allocation (LDA) Topic Modeling and Named Entity Recognition (NER). We applied each of them to 24 health IT evaluation studies after generating text corpora and pre-processing of the studies. We aimed at extracting the following key elements of health IT evaluation studies: evaluated application system, features of the evaluated application system, organizational unit and users of the evaluated application system, and software product name. Furthermore, we focused on the author of the study, the used study method and the outcome criteria of the study. The programming language Python and the Integrated Development Environment (IDE) PyCharm were used. We utilized the following Python libraries: gensim, NLTK, pandas, pyLDAvis, python-docx, scikit-learn, scispacy and spacy [4]. The detailed information of the experiment and code can be found on the github repository of this study [5]. We compared the effectiveness of the methods by comparing the extracted key elements with the outcome from manual data extraction. The efficiency was measured by observing the coding task due to complexity of the code and the reusability of the Python code.

3. Results

The three statistical-based natural language processing methods Bag-of-Words (BoW), Term-Frequency-Inverse-Document-Frequency (TFIDF) and Latent Dirichlet Allocation (LDA) Topic Modeling were not helpful to extract key elements of the studies. The results of the three methods mostly present single words. Table 1 illustrates one example for each of these 3 methods for the key elements evaluated application system and outcome criteria of the study².

Table 1. Examples for the statistical-based natural language processing methods a) Bag-of-Words (BoW), b) Term-Frequency-Inverse-Document-Frequency (TFIDF) and Latent Dirichlet Allocation (LDA) Topic Modeling.

Method	Extracted key element of the study	Results with the natural language processing method	Results with manual data extraction
BoW	Application System	nursing system	nursing information system
	Outcome Criteria	users satisfaction	user interaction satisfaction
TFIDF	Application System	information nursing systems	see above

² J. Liaskos, and J. Mantas, Measuring the user acceptance of a Web-based nursing documentation system., *Methods Inf. Med.* **45** (2006) 116–20.

	Outcome Criteria	satisfaction user	see above
LDA TM	Application System	nursing system information	see above
	Outcome Criteria	user satisfaction	see above

The rule-based natural language processing method Named Entity Recognition (NER) showed more promising results. Table 2 illustrates this with one example of the same study.

Table 2. Example result for the rule-based natural language processing method Named Entity Recognition (NER)

Method	The extracted element of the study	Results with the natural language processing method	Result with manual data extraction
NER	Application System	nursing information system	nursing information system
	Outcome Criteria	user interface satisfaction	user interaction satisfaction

Overall, 19 of 24 evaluated application systems, 14 of 15 software product names and 5 of 24 outcome criteria could be extracted correctly with Named Entity Recognition (NER). All four natural language processing methods were efficiently usable due to high code reusability within each method.

4. Discussion

Named Entity Recognition (NER) is promising for the retrieval of four key elements of health IT evaluation studies: the evaluated application system, the software product name, seldom the outcome criteria of the study and mostly all authors and co-authors. To increase the probability to retrieve also other key elements and so improve the effectiveness of the method, the Named Entity Recognition (NER) method needs to be adapted. Here, so-called entity lists, usable in the Python library spacy [6], could be used. The entity lists could be generated based on the already existing terms of the ontology. By using these entity lists, already known modeled key elements could be detected in a time- and resource-saving task. These entity lists could also serve in the future as a general speech model in the field of medical informatics within several natural language processing applications. Such a general speech model is currently missing in the field of medical informatics. The challenge for our use case is still the unsolved procedure of handling not yet known key elements of health IT evaluation studies. Here, we aim at investigating machine learning methods with parts of active learning, where the person who extracts the key elements of a study can intervene constantly and actively in the machine learning process [7].

The other investigated natural language processing methods Bag-of-Words (BoW), Term-Frequency-Inverse-Document-Frequency (TFIDF) and Latent Dirichlet Allocation (LDA) Topic Modeling as used were not useful for our context. As observed,

they only extract single words, which were not sufficiently similar to the manually extracted key elements. However, Topic Modeling with n-grams could be investigated more due to the possibility to detect more word phrases in this way [8].

Nevertheless, a further limitation of all four methods is the missing context, which is not visible in the results of the analyses, and the reader normally gains while reading an article. Here wrong assumptions on the significance of results to be indeed the right key element are possible. Due to this circumstance, natural language processing methods and here mostly Named Entity Recognition (NER) are only helpful for a semi-automatic data extraction of key elements of studies.

5. Conclusions

The investigated natural language processing methods Bag-of-Words (BoW), Term-Frequency-Inverse-Document-Frequency (TFIDF), Latent Dirichlet Allocation (LDA) Topic Modeling and Named Entity Recognition (NER) cannot substitute the manual extraction of key elements of health IT evaluation studies. However, the Named Entity Recognition (NER) method is promising for semi-automatic data extraction but needs to be adapted. After this adaption, a general speech model for several applications of natural language processing in the field of medical informatics could be gained.

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Local Distortion Hiding Algorithm in Medical Data: A Case Study Using CART

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Abstract. Data sharing has become an increasingly common process among health organizations, but any organization will most likely try to hide some sensitive patterns before sharing its data with others. Local Distortion Hiding (LDH), a recently proposed algorithm, has been evaluated only on the assumption of an opponent using the J48 (C4.5) classification algorithm. We now extend the basic approach, and we present a medical dataset hiding case study of a processed by LDH and attacked with the CART algorithm.

Keywords. Privacy-preserving, hiding decision tree rules, medical data privacy

1. Introduction and background

Data privacy is important in health informatics, especially when it comes to analyzing large datasets collected from various sources like health care providers, insurance companies, pharmacies, and research institutions. Information in health care is considered sensitive, and its protection is a major concern when examining the patient's personal health care data for research purposes. Privacy-preserving data mining [1,2] is a research area designed to alleviate issues arising from the use of data mining on data collection, information or knowledge contained in data collections, and the confidentiality of the subjects recorded in them. In our previously published articles [3,4], we suggested a set of techniques to effectively protect against the disclosure of sensitive patterns of information in mining classification rules. We aim to conceal sensitive rules without compromising the information integrity of the entire dataset. The class labels at the tree node corresponding to the tail of the sensitive pattern are changed after an expert selects the sensitive rules to remove the gain achieved by the metric, which causes the split. In the articles [5,6], we expand the above work by formulating a generic look ahead technique that takes into account the structure of the decision tree (DT) from an affected leaf to the root.

LDH (Local Distortion Hiding) algorithm [7] can be used to protect sensitive patterns that result from the use of data mining techniques. In our previous work [8], we presented an application of LDH in an educational dataset and in [9] we applied our technique in a medical dataset that did not, as our previous techniques did, affect the class labels of sensitive instances, but rather modified the values of the attributes of these specific instances. In the proposed approach, we first identify the instances that lead to the development of a particular rule, and then effectively mask this rule with minimal

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effect on the rest of the DT by appropriately modifying attribute values. This technique is based on gain ratio, which is the standard metric of C4.5 classifier [10], and it has been tested in different datasets by only using *J48*, the implementation of C4.5 in WEKA [11]. In this paper, we apply LDH algorithm to the same medical dataset as in [9] and test if the under consideration rule is also be hidden by using another classifier than *J48*, to investigate the resilience of the underlying technique to a variety of attacking opponents.

2. Applying Local Distortion Hashing for Leaf Hiding

In order to hide minimally by modifying the original dataset, we can interpret "minimal" changes in datasets by evaluating if the sanitized DT created by hiding is syntactically identical to the original with minimal modification of the initial dataset. In our example, after the proposed modification, we use the kappa statistic to compare the efficiency of the deduced DT with the original one. The information gain metric is used to select the test attribute at each node of the DT, much like ID3, one of the earliest DT induction algorithms [12], while its successor, C4.5 [10], uses the gain ratio metric, which is an improvement of the information gain. The attribute with the highest gain ratio is chosen as the splitting attribute. Therefore, if we want to suppress a specific attribute test at a node, it would be a reasonable heuristic to seek to change the values of the instances that would enter that node. By this change, the resulting information gain (due to that attribute) will be decreased and being equal to zero where possible. The algorithm LDH locates the parent node of the leaf to be hidden and ensures that the attribute tested at that node will not generate a splitting, which would allow that leaf to re-emerge. CART (Classification And Regression Trees) [13] is a rather common DT classification algorithm based on Gini's impurity index as a splitting criterion.

3. Applying LDH to a medical dataset

We show an example in this section regarding a binary medical dataset from the UC Irvine Machine Learning Repository [14] (SPECT). The SPECT Heart [15] training dataset is based on data from cardiac Single Proton Emission Computed Tomography (SPECT) images. Any patient is grouped into one of two categories, normal or abnormal. SPECT is a good dataset used to check Machine Learning algorithms; it has 187 instances that are described by 23 binary attributes (A1–A22, Class). The binary values for the attributes (A1–A22) are true (t) or false (f), and the values for the Class could be positive (p) or negative (n). We chose for our experiments to use the WEKA [11] framework, an ML software written in Java, and, more specifically, the *J48* and *SimpleCART*, which are the implementations of the C4.5 and CART algorithms, respectively. Both C4.5 and CART algorithms are widely used because of their quick classification and high precision. In our example, we try to hide the terminal node *attr15*, which is shown in the Figures 1 and 2. In this way, we managed to eliminate the node's contribution *attr15* below its parent *attr5*, and the result is shown in Figures 3 and 4. Since the size of the aforementioned DT is too big to fit into a single page, only the section of the DT rules is displayed around the critical node.

<pre>attr13 = t attr22 = t: p (66.0) attr22 != t attr10 = t: p (20.0) attr10 != t attr5 = t attr15 = t: n (1.0) attr15 != t: p (1.0) attr5 != t attr21 = t attr3 = t attr12 = t: p (2.0) attr12 != t: n (1.0) attr3 != t: p (2.0) attr21 != t: p (11.0)</pre>	<pre>attr13!=(f) attr22=(f) attr10=(f) attr5=(t) attr15=(t): n(1.0/0.0) attr15!=(t): p(1.0/0.0) attr5!=(t) attr21=(t) attr3=(t) attr12=(f): n(1.0/0.0) attr12!=(f): p(2.0/0.0) attr3!=(t): p(2.0/0.0) attr21!=(t): p(11.0/0.0) attr10!=(f): p(20.0/0.0) attr22!=(f): p(66.0/0.0)</pre>
Figure 1. Original DT with the node <i>attr15</i> .(J48)	Figure 2. Original DT with the node <i>attr15</i> .(CART)

All dataset files (.arff), before and after hiding has been applied, and the corresponding outputs of both classifiers are available at the website [16].

<pre>attr13 = t attr22 = t: p (66.0) attr22 != t attr10 = t: p (20.0) attr10 != t attr5 = t: p (2.0/1.0) attr5 != t attr21 = t attr3 = t attr12 = t: p (2.0) attr12 != t: n (1.0) attr3 != t: p (2.0) attr21 != t: p (11.0)</pre>	<pre>attr13!=(f) attr22=(f) attr10=(f) attr5=(t): p(1.0/1.0) attr5!=(t) attr21=(t) attr3=(t) attr12=(f): n(1.0/0.0) attr12!=(f): p(2.0/0.0) attr3!=(t): p(2.0/0.0) attr21!=(t): p(11.0/0.0) attr10!=(f): p(20.0/0.0) attr22!=(f): p(66.0/0.0)</pre>
Figure 3. Final DT without the node <i>attr15</i> . (J48)	Figure 4. Final DT without the node <i>attr15</i> . (CART)

The kappa statistic adjusts precision by taking into account by chance alone the possibility of a correct prediction.

Table 1. WEKA output for the J48 and CART classifiers on original and modified datasets.

	Original		Modified	
	J48	CART	J48	CART
Correctly Classified Instances	182	182	181	181
Incorrectly Classified Instances	5	5	6	6
Kappa statistic	0.834	0.834	0.795	0.795
Mean absolute error	0.0352	0.0326	0.0406	0.0379
Root-mean-squared error	0.1328	0.1276	0.1425	0.1377
Relative absolute error	29.296%	21.529%	26.831%	25.064%
Root relative squared error	48.866%	46.976%	52.442%	50.686%

The kappa statistic values corresponding to both classifiers (J48, CART) on original and modified datasets are exactly the same, 0.834 and 0.795, respectively. From all other WEKA statistics presented in Table 1, we can also conclude that the node *attr15* was successfully hidden without significantly affecting the effectiveness of the resulting DT.

The under investigation part of the DT induced by the modified dataset produced by LDH algorithm is the same as the original one without the node *attr15* for both classifiers.

4. Conclusions

Our methodology (LDH algorithm) enables one to determine which DT leaves should be hidden in the original dataset, and then to adjust those attribute values in specific instances. Even though LDH algorithm is based on gain ratio metric - the one that is used by C4.5 - in this work, we presented a case study by testing the resulting dataset in another classifier (CART), which is based on another metric (Gini). We observed that the under consideration decision rule in this medical dataset was successfully hidden on both classifiers without compromising the information value in rest classification rules. We expect LDH to demonstrate similar resilience to any DT induction algorithm, which uses information-based splitting criteria, and we plan to confirm this expectation by experimentation.

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Development of a Presentation Interface for Seismo- and Ballistocardiographic Data

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Abstract. Ballistocardiography is a method to gain detailed information about body movements imparted by the ballistic forces associated with cardiac contraction. We measured using different setups and sensor positions to gain information of a reference signal of healthy adults. We used two resting state recordings and two recordings under physical stress (ergometer and treadmill) with stepwise increasing load. Data was gathered from 34 subjects, which results in 72 data sets, overall, more than 18h of signal data. With these data we have created a first database for BCG reference. We started data analysis and created a first naive data representation prototype. Using this naive attempt, we created a user interface for the intuitive representation of live data as well as retrospective data.

Keywords. User Interface, Ballistocardiography, Seismocardiography, Data Management, Big Data

1. Introduction

Ballistocardiography (BCG) is a method to gain detailed information about body movements imparted by the ballistic forces associated with cardiac contraction and ejection of blood and with the deceleration of blood flow through the large blood vessels (see NLM Definition [1]). These heart-related movements are translated by a sensor device into an electrical potential which is suitably amplified and recorded (see [2]). Detailed information on cardiac physiology, for example on valve closures, primarily of the left atrium and ventricle, is measured using the special form of BCG, seismocardiography (SCG), on the thorax. The use of BCG technology can additionally, in combination with other non-invasive, diagnostic methods, such as pulse oximetry, determine the blood pressure over the pulse transit time (PTT) [3].

2. Method

In order to collect a first basic set of data from healthy subjects, we first measured 34 subjects ($m = 21$, $w = 13$), within different setups (M1-4), including two different

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accelerometer positions. For M1/M2, the tri-axe acceleration sensors (Kionix KX123-1022) are placed at positions on the sternum, the apex of the heart and the spine. For the measurements M3/M4, two positions on larger vessels (temple, wrist), for a BCG setup, plus cardiac apex were used. This should allow comprehensive PTT investigations.

M1/M3 are resting state recordings, while M2/M4 are conducted under physical stress. M2 is recorded while using an ergometer (2 min at 40-60 W, 1 min at 70-100 W, 30sec at ≥ 110 W). M4 is measured while using a treadmill (2 min at 5 km/h, 1 min at 10 km/h, 30 sec at 15 km/h). For the data recording, we used a new, highly synchronous, scalable, modular measuring system with a Field-Programmable-Gate-Array (FPGA) core, some kind of a modular processor, and three tri-axial acceleration sensors, as well as a 6-channel ECG as a reference. The data output rate for the accelerometers was at 17.2 kHz and for the reference ECG at 12.4 kHz, as a result of the more complex communication [4]. We used split and compress methods to store the signal data within the database, every measurement was stored in four parts. Including meta data we stored about 800 GB for about 18 h of measurement signal data.

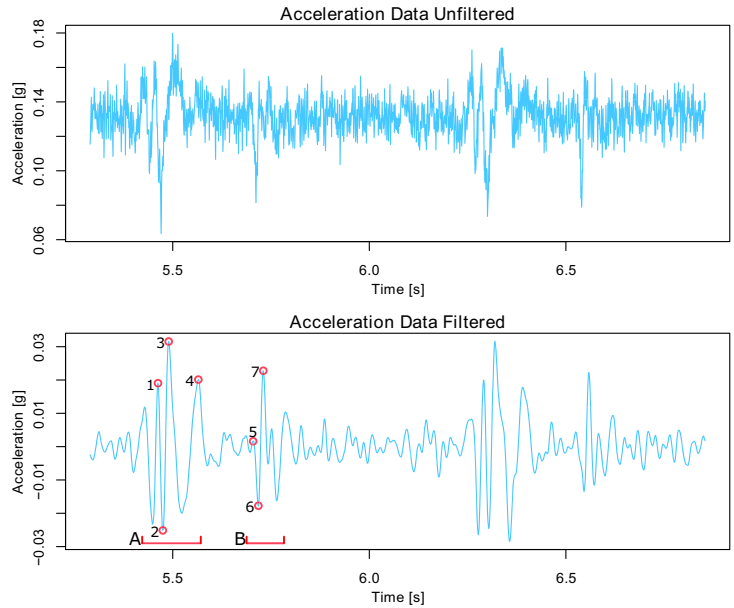


Figure 1. Presentation of the raw output date (top) of the measurement M1 (cardiac apex z-axis) and the first filtered data stream (bottom)

In **Figure 1** two heartbeats can be seen in a raw calibrated acceleration data view, as well as in a first filtered and calibrated acceleration data stream. For the filtering we selected a third-order Butterworth bandpass filter with the limits 7 Hz and 40 Hz. In the bottom view we have annotated some features of the SCG signal. First, there are two intervals (A and B). Interval A represents the expulsion phase (contraction phase or systole) of the blood into the body circulation and B (relaxation phase or diastole) the refilling of the left ventricle. Basically, the left side cardiac physiology processes can be mapped with the SCG (see [5]). Interval A comprises four features, starting with the mitral valve closing (1), the isolating valve from the left atrium into the left ventricle, followed by the isovolumetric contraction (2). The isovolumetric contraction is the atrial systolic contraction. If the left chamber is filled, the aortic valve opens (3) and thus the

path into the body circulation, the ventricular systole starts, represented by the rapid ejection (4) of the blood into the vascular tree. In B you can see the features aortic valve closing (5) and thus the start of heart's refilling, as well as the rapid filling (6). After the heart is refilled, the mitral valve opens (7) and thus the preparation for a new systole [5].

3. Results

As can be seen from the illustration in [Figure 1](#), the evaluation of, e.g. the real-time display for medical diagnostics, is a challenge. For this reason, we decided to develop a first display version in the form of a serial data stream display, as shown in [Figure 2](#).

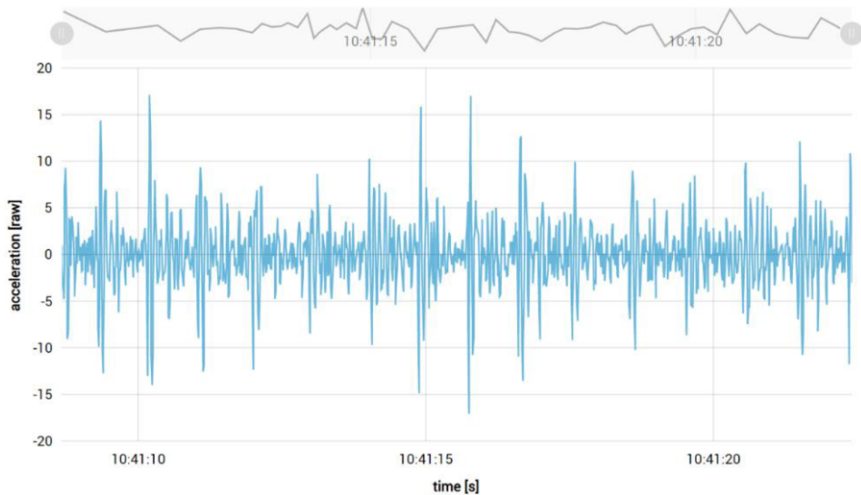


Figure 2. First visual representation attempt for the SCG live data

With this display prototype, we first implemented the option of the zoom function within the time axis (gray bar at the top of the figure). This attempt shows the common visualization. However, this form of presentation has proven to be unsuitable, since it is only possible to limited compare a small selection of heartbeats that are strongly dependent on time. Furthermore, no parameters or aggregations are used for visualization in this version. After consulting user interface (UI) experts, we developed the second concept prototype (see [Figure 3](#)). With this graphical UI, the last ten heartbeats can be displayed in filtered and calibrated form in an overlay with newest first, as well as the averaged signal curve. In addition, after consulting with medical experts, we also represented breathing as a separate signal feature of the SCG measurement in the lower area of the surface as a serial data stream over the entire measurement period. In addition, a selection of parameters (last pulse rate, mean time interval between heartbeats and last respiration rate) was shown on the right.

4. Conclusions

The current UI concept shows a first attempt for live BCG and SCG data visualization for upcoming diagnostic purpose. The layout, as well as the feature presentation will be

improved and further reviewed by medical experts. For the usage of the interface for the presentation of retrospective data the inclusion of meta data, as well as an advanced use of feature knowledge, for example by using box plot on several signal spots (e. g. SCG signal features), can be imagined. By providing a proper UI a further step to a diagnostic use of BCG and SCG and thus a practical benefit for medicine is made.

The collected data will be usable as open data soon and can be extended by research groups, e.g. data from sickened patients.

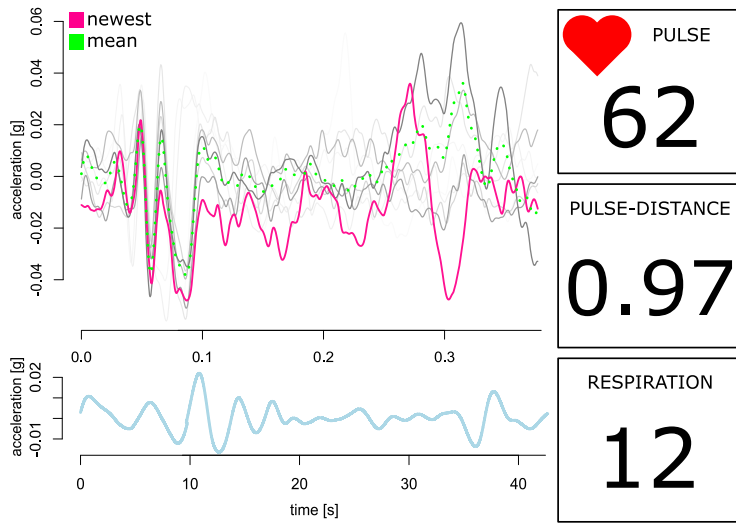


Figure 3. Advanced UI concept of SCG data of ten heartbeats in overlay on mitral closing point as anchor

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At this point we would like to thank *User Interface Design* for the support in the creation of the concept and the UI.

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Visualization of Drug Interactions for Supporting Medication Review

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Abstract. The number of elderly patients with multimorbidities has considerably increased since recent years. These patients are often polymedicated and at higher risk of safety incidents due to polypharmacy. To reduce polypharmacy, one solution is Medication review (MR). MR aimed at optimizing drug treatments, is unfortunately not very frequent in practice. Indeed, consulting the properties of 5-20 drugs in parallel is a cognitively complex task. It is therefore necessary to develop software for supporting MR. The existing tools only list alerts concerning drugs and their interactions. The objective of our work is to facilitate the pharmacist's access to the medical knowledge necessary for drug interactions. Using visual analytics, we propose an interactive tool that synthesizes information on drug interactions. It shows an overview of drug treatment and make it visually accessible by the pharmacist to facilitate MR.

Keywords. Visual analytic, Medication review, Drug interactions

1. Introduction

The number of elderly patients with multimorbidities has considerably increased since recent years. These patients are often polymedicated (*i.e.* they receive 5 drugs or more) and are consequently at higher risk of safety incidents due to polypharmacy. Polypharmacy is both a public health and an economic issue.

To reduce polypharmacy, one solution is medication reviews (MR). A MR is “a structured interview with the patient, carried out by the pharmacist in collaboration with the general practitioner (GP) with the aim of optimizing patient care” [2]. In many countries, including France, MR is reimbursed by health insurances.

However, the simultaneous consultation of the properties of 5-20 drugs is a long, difficult and cognitively complex task. This often discourages pharmacists, and in

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practice few MR are performed. It is therefore necessary to develop software for supporting MR.

Current systems for MR display a flat list of all drug interactions; when interactions are numerous, the list occupies multiple pages and it is tedious to read and to summarize because the user has to scroll continuously. Other systems offer a table-based approach to summarize drug information [3], but it becomes visually less readable as the number of drugs and drug properties increases. In a previous work [4], we showed that visual analytics can help to present drug properties when comparing similar drugs.

The objective of this work is to propose an interactive tool relying on visual analytics for providing an at-a-glance overview of all interactions of the drugs taken by a given patient, in order to facilitate the pharmacist's access to the necessary medical knowledge during MR.

2. Method

To carry out this project, we exploited the Thériaque drug database (<http://www.theriaque.org/>), one of the four accredited databases in France, to extract drug interactions and contraindications. In our approach, we were inspired by the approach of A. Galopin for the medication management of poly-pathological patients [5]. In the context of prescription support, the method he proposed consisted in representing recommended drug association using “therapeutic circles”: candidate drugs are represented by small circles, organized in a large circle. Then, recommended bitherapies are represented by edges connecting two drugs. We adapted this idea by presenting the drugs taken by the patient, with edges representing the drug-drug interactions. In addition, we represented drug-disease interactions by the color of the drug circles.

For implementation, we worked with Python and the Django framework for the development of a web application. We generated vector images (SVG) for the visualization of the analysis of drug interactions.

3. Results

Figure 1 shows the proposed interface showing drug-drug and drug-disease interactions.

First, the drugs are represented by small circles. The first letters of the drug name are displayed in the circle; the full name appears by moving the mouse over the drug. The system detects interactions between the patient's condition and the drug. According to the level of risk, it colors the circles of the drugs according to a gradient of color ranging from yellow for the drugs presenting a minor risk to red for the contraindicated drugs. The other circles are green.

Second, the system detects all drug-drug interactions and represents each interaction by an edge connecting the two drugs involved. These edges are colored according to the four levels of interaction with a gradient of colors ranging from yellow (for minor interactions) to red (for major interactions).

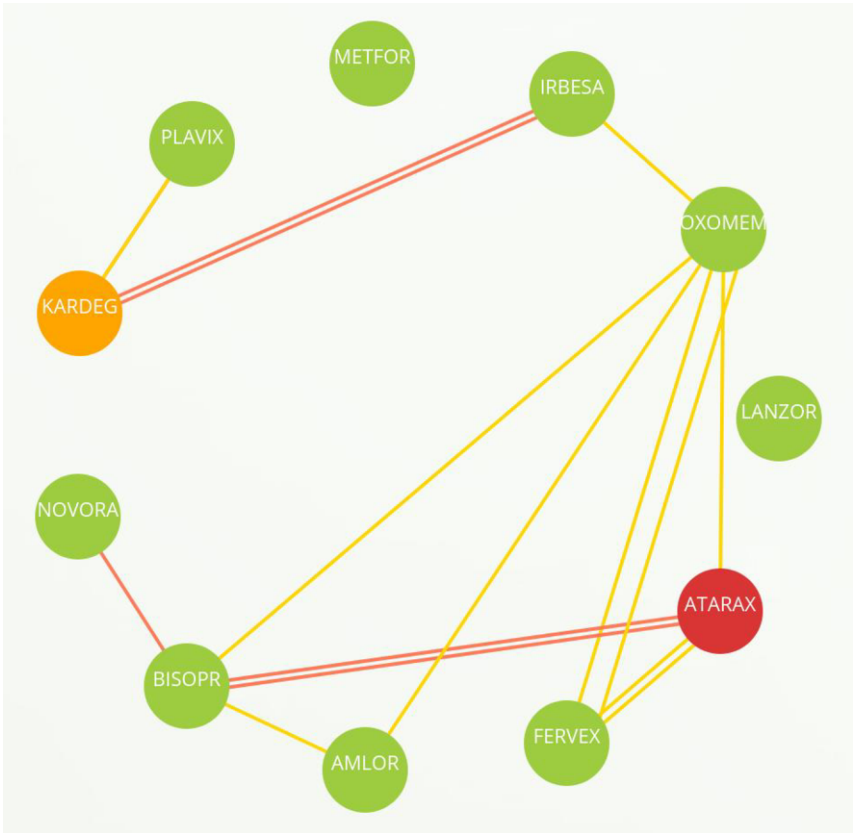


Figure 1. Screenshot of the proposed visual interface showing 11 drugs, 2 drug-disease interactions and 15 drug-drug interactions.

In addition, the system offers the user the possibility of accessing the explanatory text of interactions and contraindications in an interactive way by clicking on the segment representing the interaction or on the drug presenting an alert.

In Figure 1, one can immediately identify two drug-disease interactions, and see that there are many (15) drug-drug interactions, 5 of them being of moderate seriousness. The visualization allows identifying at a glance the drugs with the highest number of interactions (here, Oxomemazine) and those involved in the most serious interactions (Bisoprolol). The pharmacist may decide to reevaluate the risk-benefit balance of these drugs, and suggest to stop them or reduce their posology.

4. Discussion and conclusions

The system we propose provides an at-a-glance overview of drug-drug and drug-disease interactions of all drug in a given drug order. It allows information to be accessed quickly in a concise and efficient manner.

This type of representation in a circle has the advantage of synthesizing interactions well. It is effective in displaying all interactions and thus makes it possible to visually detect the most risky and potentially dangerous drugs, *e.g.* those with the

highest number of interactions and the most severe ones. In some circumstances, the drug database detects interactions that are not relevant, for example: (a) the interaction is linked to the dose while this dose is not reached (e.g. aspirin – furosemide); (b) the interaction is limited to a clinical condition that the patient does not have (such as pregnancy); (c) the contraindications are purposely violated by the prescribers for very specific reasons. However, these problems are well-known in drug alert systems, and are not specific to the proposed visual tool.

In the future, the proposed interface could be improved as follows: (a) Drugs could be grouped or arranged according to their indication or their prescriber (e.g. cardiologist, endocrinologist, *etc.*), this will make it possible to detect interactions between drugs from different prescribers. (b) Interactions could be grouped according to the potential risk for facilitating the risk assessment. (c) Interactions could be filtered to keep only the most relevant according to the patient profile and the dose of the drugs. (d) Drugs could be ordered in order to avoid intersecting edges. (e) The system can be enriched with proposals of therapeutic alternatives. (f) The visualization could also list the foods that may interact with the treatment. (g) Inappropriate medicines for the elderly could also be detected and highlighted in the interface.

Another perspective of this work is the evaluation of the proposed interface in controlled and/or clinical conditions with pharmacists.

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Determining Role of Social Factors in Adoption of Electronic Health Records by Nurses

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Abstract. This paper explored social factors influencing Electronic Health Records (EHR) adoption by Nurses at Moi Teaching and Referral Hospital (MTRH), Eldoret, Kenya. Correlation analysis showed that there existed an affirmative, strong and statistically substantial link between the social factors and EHR adoption, $r(279) = 0.591$, $p < 0.05$. Linear regression analysis disclosed that there existed a statistical and significant linear association between social factors and EHR adoption, $F(1, 277) = 148.721$, $p < 0.01$ and that social factors can statistically and significantly affect / predict EHR adoption, $\beta_2 = 0.615$, $t(279) = 12.195$, $p < 0.01$. The study concludes that training nurses to rely upon EHRs and their decision support instruments can solely work to speed up all-round EHR uptake. It is recommended that nursing schools should incorporate informatics into their program of studies to ensure that future nursing students are equipped with skills that can help drive healthcare's application of technologies such as EHRs.

Keywords. Social Factors, Adoption, Electronic Health Records, Nurses

1. Introduction

An Electronic Health Record (EHR) is “a digital version of a patient’s paper chart” [1]. EHRs are official, secured health documents available on real-time electronically. Adopting this system has inference for the social transformation within the health sector. EHRs have the potential to address the health needs of society and subsequently contribute to health funding and policy formulation [2]. For instance, Katurura and Cilliers [3] identified social factors: user training, skills and commitment as vital to the success of EHR deployment in South Africa’s healthcare system. Omary et al. [4] blames the low uptake of eHealth in developing states on lack of technical know-how amongst the providers. Social impact and attitude to use have been identified as major factors affecting adoption of technology in healthcare [5]. Prior studies have produced mixed results on major predictors of computer attitudes [6]. A number of studies have found age [7], computer experience [8] and practice site [9] to be precise predictors, whereas other writings have not. Literacy in computers, training on systems, clinical specialty, profession and job contentment are some of the variables that relate mutually with attitudes [8]. This study looked at how social factors: technical skills and attitudes towards EHR use affect the adoption of EHRs by Nurses at MTRH.

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2. Methods

Descriptive cross-sectional survey design was adopted for this inquiry. A list of all 926 Nurses in MTRH was prepared and computer randomization program was used to select a proportion of 279 random numbers between 1 and 926. Hence the study proportion target was one-third of all the Nurses. The Nurses’ sample size was arrived at by applying Yamane’s procedure [10]. The study used 95% confidence interval and allowed a margin of error of 5% as shown below where: n = Sample Size, N = Population Size, e = Sampling Error

$$n = \frac{N}{1 + N(e)^2} \qquad n = \frac{926}{1 + 926(0.05)^2} = 279.34$$

(1)

Quantitative primary data was collected using five close ended questionnaire scale items for social factors and five scale items for EHR Adoption [5,11]. Response to statements were scored with the most favorable dimension given the highest score of 5 and the most unfavorable dimension given the lowest score of 1.

3. Results

Research findings revealed that there is management commitment to EHR implementation (Mean = 4.17). All the studied factors summed up to a mean of 4.01, standard deviation of 0.63, skewness -0.63 and kurtosis of 0.72. Since the values of skewness were tending to zero then there was a relatively normal distribution of the responses. All the items in kurtosis ranged from -3 to 3, as shown in Table 1 below.

Table 1. Social Factors Descriptives

Item	Mean	Std. Dev.	Skewness	Kurtosis
There is training for healthcare staff on EHR usage.	4.007	0.897	-1.126	1.193
There is further follow-up training after the first formal training of EHR usage.	4.111	0.771	-1.187	2.145
My EHR system promotes doctor-patient relationship.	3.892	0.934	-0.876	0.265
My EHR is designed for all levels of users in MTRH.	3.878	0.959	-0.960	0.470
There is management commitment to EHR implementation.	4.168	0.727	-1.117	2.400
Social Factors	4.012	0.628	-0.630	0.722

Correlation analysis revealed an affirmative, strong and statistically meaningful link between social factors and EHR adoption, $r(279) = 0.591, p < 0.01$ as shown in Table 2 below.

Table 2. Correlation Between Social Factors and EHR Adoption

		Social Factors	EHR Adoption
Social Factors	Pearson Correlation	1	0.591**
	Sig. (2-tailed)		0.000
	N	279	279
EHR Adoption	Pearson Correlation	0.591**	1
	Sig. (2-tailed)	0.000	
	N	279	279

** . Correlation is significant at the 0.01 level (2-tailed).

Based on a bivariate linear regression model, the inquiry examined the consequence of social factors on EHR adoption. The study tested the following hypothesis:

H_1 : Social factors affect electronic health records adoption by Nurses at MTRH.

From the model summary, the findings revealed that social factors explained 34.9% variation in EHR adoption, $R^2 = 0.349$. This implies that 34.9% of these factors could be explained by EHR adoption as shown in Table 3 below.

Table 3. Model Summary for Social Factors and EHR Adoption

Model Summary				
Model	R	R Square	Adjusted R Square	Std. Error of the Estimate
1	0.591 ^a	0.349	0.347	0.52860

a. Predictors: (Constant), Social Factors

The results for Analysis of Variance (ANOVA) indicate that the model was statistically significant in linking the social factors and EHR adoption, $F(1, 277) = 148.721$, $p < 0.01$, as shown in Table 4 below. Considering the value of the F-statistic, the alternate hypothesis was therefore accepted.

Table 4. ANOVA for Social Factors and EHR Adoption

ANOVA ^a					
Model	Sum of Squares	df	Mean Square	F	Sig.
Regression	41.556	1	41.556	148.721	0.000 ^b
Residual	77.399	277	0.279		
Total	118.955	278			

a. Dependent Variable: EHR Adoption

b. Predictors: (Constant), Social Factors

From the regression coefficients, the study findings indicate that social factors positively and significantly predict EHR adoption, $\beta_2 = 0.615$, $t(279) = 12.195$, $p < 0.01$, as shown in Table 5 below.

Table 5. Coefficients for Social Factors and EHR Adoption

Model	Unstandardized Coefficients		Standardized Coefficient	t	Sig.
	β_2	Std. Error	Beta		
(Constant)	1.703	0.205		8.314	0.000
Social Factors	0.615	0.050	0.591	12.195	0.000

a. Dependent Variable: EHR Adoption

4. Discussion

Descriptive analysis showed that Nurses agreed there is management commitment to EHR implementation in MTRH. That was consistent with an earlier finding which indicated that senior management backing was incontrovertibly correlated with the EMR adoption [12]. Correlational analysis demonstrated a positive, strong and statistically meaningful link between social factors and EHR adoption. Social factors accounted for 59.1% positive relationship with EHR Adoption. The findings were in line with earlier studies by Katurura and Cilliers [3] who identified such social factors as a critical success in EHR implementation of South Africa's public care. Linear regression analysis of this study revealed that social factors can statistically and significantly predict EHR adoption. This implies that these factors predict a magnitude of 61.5% on EHR adoption. These findings were consistent with those of Garavand, Mohseni, Asadi, Etemadi, Moradi-Joo and Moosavi [5] who found that social impact is effective in the uptake of health information systems.

5. Conclusion and Recommendations

The findings of the inquiry underscore that social factors do statistically and significantly predict EHR adoption at MTRH. The study concludes that training nurses to rely upon EHRs and their decision support instruments can solely work to speed up all-round EHR uptake. It is recommended that nursing schools should incorporate informatics into their program of studies to ensure that future nursing students are equipped with skills and qualifications that can help drive healthcare's application of technologies such as EHRs.

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An Approach Based on Preference Learning for Identifying Experts Reasoning in Antibiotic Treatment

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Abstract. Clinical Practice Guidelines (CPGs) aim at improving the quality of health care by providing standardized best practices for diagnosis and treatment. However, physicians have difficulties to understand the (often implicit) rationale underlying expert recommendations. The aim of this paper is to propose an approach based on preference learning for building a model that is closest to the reasoning of experts to provide recommendations. We apply this method to antibiotherapy in primary care. The preference model was learned from the recommendations and from a database describing the domain.

Keywords. Preferences learning, Experts reasoning, Clinical Practice Guidelines

1. Introduction

Clinical practice guidelines (CPGs) are textual documents written by a group of experts according to scientific evidence. They contain recommendations and their justifications. In the domain of antibiotic prescription, we analyzed these justifications and showed that experts used antibiotic properties to recommend antibiotics [1, 2]. The preference model used by experts is based on these properties, but still need to be explicitated, before to be implemented in a clinical decision support system (CDSS). Preferences can be acquired by elicitation from experts or by learning them directly from data. However, as preference elicitation is time consuming, it is more appealing to learn preferences from data, which is easy to observe and collect. The idea of preference learning [3] is to learn and construct a preference model from observed preference information. For example, in our studied problem, we hypothesize that we could learn the preference model used by experts for recommending antibiotics by extracting preference rules on the properties of antibiotics. Once the preference model

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is learnt, it could be used for various purposes (e.g. treatment predictions). Methods of preference learning can be quantitative or qualitative. Quantitative approaches [4,1] consist mainly to learn a utility function on training data. For qualitative approaches [5,6] the objective is to learn a binary preference relation that compares each pair of objects. Here, we propose a method for learning preferences of CPG experts from both recommendations and a database containing the antibiotics and their properties. We aim at building a qualitative model that is closest to the reasoning of experts to provide recommendations in the domain of antibiotherapy in primary care.

2. Methods

We used a database containing the antibiotics, their properties, and their recommendation rank as defined in CPGs. This database was validated by antibiotic experts according to a Delphi process [1]. Let P be the set of properties of antibiotics of the database D . For each property p_i in P , we denote the domain of p_i by $\text{dom}(p_i)=\{1=\text{True}, 0=\text{False}\}$. Each instance d in D has a recommendation rank. Antibiotics having $R_d=1$ are preferred to those having $R_d=2$ which are also preferred to those having $R_d=3$ which are also preferred to those having $R_d=4$. Antibiotics having $R_d=0$ are not preferred since that are not recommended. See simplified example in Table 1. We use the notation $R_i=0$ to represent $R_d=0$, $R_i=1$ to represent $R_d=1$, etc.

Table 1. Simple example of the database with 5 antibiotics (instances) and 3 properties

Instances	P ₁	P ₂	P ₃	Recommendation Rank (R _{i=0,1,2}) in CPGs
d ₁	0	0	0	0
d ₂	0	1	1	2
d ₃	1	1	0	2
d ₄	1	1	1	1
d ₅	1	0	1	1

The aim is to learn preference rules from antibiotics properties, which will allow to associate the same recommendation ranks than those defined in CPGs. Let us give the following definitions.

Definition 1 (Items) Let P be the set of antibiotics' properties,

- 1. Each element that is built on P is called a single item.
- 2. Each element that is built on the connective logic $\wedge$ and contains at most two properties p_i in P is called a conjunctive item.
- 3. Each element that is built on the disjunctive logic $\vee$ and contains at most two properties p_i in P is called a disjunctive item.

X denotes the set of items. We define $\text{Sat}(d \in D, x \in X)$ a function that returns True if instance d satisfies item x and returns false if instance d does not satisfy item x .

From Example of Table 1, we have p_1, p_2, p_3 which are single items, $(p_1 \wedge p_2), (p_1 \wedge p_3), (p_2 \wedge p_3)$ which are conjunctive items and $(p_1 \vee p_2), (p_1 \vee p_3), (p_2 \vee p_3)$ which are disjunctive items.

Definition 2 (Preference rule) A preference rule r is a partial order in the form of $x_1 > x_2 > x_3 > x_4$ where x_i is an item defined in Definition 1.

Each preference rule contains 4 items (4 corresponds to the greatest recommendation rank of the database). The aim is to define the best items. Hence, we dene in the following the support of each item regarding each recommendation rank.

Definition 3 (Support) The support of an item $x \in X$ regarding instances $d \in D$ having a recommendation rank $R_d = r$ is defined as:

$$Supp(x, r) = \frac{|\{d \mid Sat(d, x) \text{ and } R_d = r\}|}{|\{d \mid R_d = r\}|} \quad (1)$$

The support of an item x for a rank r is defined by the fraction of the number of instances d having a degree $R_d = r$ that satisfy x on the number of instances having rank r . Its interest increases with its support (ideally 1). Computing the support of each item regarding each rank allows determining which item is best for that rank.

From data of Table 1, we have $Supp(p_1 \wedge p_3, r = 1) = 1$, $Supp(p_2, r = 1) = 0.5$.

Our method is summarized as follows:

1. Generate the list of possible items X following Definition 1.
2. Compute the support of each one regarding each recommendation rank $R_i = 1 \dots 4$
3. Determine best items ($BestR_i$) for each rank $R_i = 1 \dots 4$. They are those having a support superior to a fixed minimal support (thresholdSupp is in the $]0, 1]$, it can be fixed by an expert). Given a learned preference rule $x_1 > x_2 > x_3 > x_4$,
4. the item x_1 corresponds to one of best items for $R_1 = 1$, x_2 corresponds to one of best items for $R_2 = 2$, etc. Note that it is not necessary to select the best items for $R_0 = 0$ because these items should not appear in the preference rule.
5. Each rank can have more than one best item, so different preference rules can be learned.
6. Return $\{L\} = x_1 > x_2 > x_3 > x_4$, where $x_i = 1 \dots 4 \in BestR_i = 1 \dots 4$

In order to evaluate the quality of each learned preference rule L , there is need to define a new rank associated by L for each instance in D as follows.

Definition 4 Let $L = x_1 > x_2 > x_3 > x_4$ be the learned rule. The rank inferred by L for instance d is $Inf(L, d) = k$ iff $Sat(d, x_1 \vee x_2 \vee x_3 \vee x_4)$ and $k = \min(j \text{ such that } Sat(d, x_j))$.

To explain this definition, let us consider the rule r_1 given in Table 2. Each instance that satisfies $(Proto \wedge Spect)$, its rank is 1, each instance that satisfies $(Proto \wedge SideEff)$ and falsifies $(Proto \wedge Spect)$, its rank is 2, each instance that satisfies $(Proto \wedge Efficacy)$ and falsifies $(Proto \wedge Spect)$ and $(Proto \wedge SideEff)$, its rank is 3. Finally, each instance that falsifies the three items of r_1 , its rank is 0. In addition, we introduce the accuracy measure (it measures the prediction rate of the obtained rules) as follows:

Definition 5 (Accuracy) Given a database D , a learned rule L , the accuracy of L is:

$$Accuracy(L) = \frac{|\{d \in D \mid Inf(L, d) = R_d\}|}{|D|} \quad (2)$$

Best preference rules are those having highest accuracy.

3. Experimental study

The obtained preference rules and their accuracy are given for pharyngitis in Table 2. Best items for $R_1 = 1$ are $(Proto \wedge Spect)$ and $(Proto \wedge RiskResi)$ with thresholdSupp=1. Best item for $R_2 = 2$ is $(Proto \wedge SideEff)$ with thresholdSupp= 1. Best items for $R_3 = 3$ are $(Proto \wedge Efficacy)$, $(Proto \vee Taste)$ and $Proto$ with thresholdSupp= 1. These results highlight that experts prefer to recommend (i) in rank 1 the antibiotics having short

duration protocol (Proto), and with either narrow spectrum (Spect) or low risk of ecological adverse effects (RiskResi), (ii) in rank 2, the antibiotics having short duration protocol (Proto) and low risk of side effects (SideEff), (iii) in rank 3 the antibiotics with short duration treatment (Proto) alone or with [high efficacy (Efficacy) or good taste (Taste)]. Finally, each antibiotic that do not verify all items of each rule has rank 0. The highest accuracy is 0.91. This explains that the formalization of CPGs by preferences leads us to suspect inconsistencies in the guidelines [1].

Table 2. The preference model in pharyngitis. Note that in this case, the greatest recommendation rank is equal to 3. So, the length of the obtained preference rules is equal to 3.

Preference Rules	Accuracy
$r_1=(Proto \wedge Spect) \succ (Proto \wedge SideEff) \succ (Proto \wedge Efficacy)$	0.91 (91% of instances are well classified)
$r_2=(Proto \wedge RiskResi) \succ (Proto \wedge SideEff) \succ (Proto \wedge Efficacy)$	0.91 (91% of instances are well classified)
$r_3=(Proto \wedge Spect) \succ (Proto \wedge SideEff) \succ (Proto)$	0.91 (91% of instances are well classified)
$r_4(Proto \wedge Spect) \succ (Proto \wedge SideEff) \succ (Proto \vee Taste)$	0.91 (91% of instances are well classified)
$r_5=(Proto \wedge RiskResi) \succ (Proto \wedge SideEff) \succ (Proto)$	0.91 (91% of instances are well classified)
$r_6=(Proto \wedge RiskResi) \succ (Proto \wedge SideEff) \succ (Proto \vee Taste)$	0.91 (91% of instances are well classified)

4. Conclusions

This paper proposes a method for learning preferences of CPG experts from both recommendations and a database containing the antibiotics and their properties. The aim of this paper is to propose an approach based on preference learning for building a model that is closest to the reasoning of experts to provide recommendations. In the future, we aim at validating our approach in other clinical situations, and then implementing the preferences rules in AntibioHelpR a CDSS for antibiotic prescription in primary care.

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eHealth Literacy Training Among Carers of Older People and People with Dementia: A Modified Delphi Survey

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Abstract. New web-based services emerge to support carers in their role, but little is known regarding the way that carers use the internet or any related services. In an effort, to improve the health-related digital skills of carers aiming to support their caring role, we have developed eHealth Literacy Learning Skills among Carers of People with Dementia, the eLILY project. This paper presents the findings of a modified Delphi survey planned and delivered in the framework of the project as an effort to integrate stakeholders' knowledge and expertise in the proposed curriculum.

Keywords. eHealth, caregivers, aging, literacy, dementia

1. Introduction

Carers are defined as people, family or friends “that provide mostly unpaid care to frail seniors” [1] and considered to be a vulnerable population with a high risk of anxiety, depression, use of antidepressants and high morbidity [2–4]. New web-based services emerge to support carers, but little is known regarding the way they use the internet or related services (forums, telehealth, telemedicine, platforms). Even if research has shown that carers are positive to use technology, they may not be aware of the existing services, lack the skills to use them, or the services may no longer be available or updated [5].

To improve the health-related digital skills of carers, we have developed the eLILY project with the coordination of the Polish partner and the participation of partners from Cyprus, Greece, Bulgaria and Italy. The eLILY Erasmus+ project is a 2-year funded project, aiming to provide a blended training program (class sessions and eLearning courses) for carers of frail older people and people with dementia (PwD) based on the Lily theory model developed by Norman and Skinner [6], integrating dimensions presented by Chan & Kaufman [7], Gilstad [8] and adapted to fit the web 2.0 technology requirements. The Cyprus University of Technology was responsible for the

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methodology of the face to face training curriculum development and piloting. The proposed curriculum for carers included six (6) modules: a) Digital Literacy (3 hours), b) Communication skills (2 hours), c) Health Literacy (HL) and eHealth Literacy (eHL) (2 hours), d) Media Literacy 1 (2 hours), e) Media Literacy 2 (2 hours), f) Interactive services (2 hours). The survey aimed to assess the appropriacy and adequacy of the proposed curriculum and to receive qualitative feedback from Health Care Professionals (HCPs) and carers.

2. Method

The methodology used for the curriculum development included nine (9) core steps: Brief survey on HL and eHL policies and related projects in all partners' countries, development of the curriculum, implementation of the Delphi survey among HCPs and carers in every country, finalisation of the curriculum, development of the contents and trainers' manual in English and partners' languages, pilot testing of the curriculum, analysis, reporting and fine-tuning. A modified version of the Delphi method is presented, in which the research team provided the questionnaire and invited the HCPs and carers to provide their feedback. Adaptation of the modules was based on the first-round results, followed by assessment and degree of agreement, reaching consensus by the research team, in the second round of the Delphi. The data collection lasted one month (April 2019).

2.1 Participants

In total, 58 HCPs and 39 carers participated in the survey. Being a HCP working in the field of dementia or working with older people or being a carer of an older person or a PwD were the inclusion criteria. HCPs and carers were included as both would use the curriculum, carers as learners and HCPs as trainers.

2.2 Questions used in the Survey

Based on previous Delphi surveys, the partnership developed the following set of questions:

- closed questions to evaluate the appropriacy and adequacy of the modules, using a 5 point-Likert scale. Modules and sections could be considered as appropriate, if they met the needs for eHealth literacy training among carers and adequate, considering duration and number of steps of every module. Replies 4 and 5 of the 5 point-Likert scale were considered as an agreement in favour of the statement,
- open questions on the number, the duration and the steps of the modules in every section (combination, addition and modification of modules or sections of the modules).

2.3 Adapted Second Round

A second round was organised based on the percentages of agreement and the qualitative information of the first round. An updated version of the training was presented to a smaller group of the research team.

3. Results

For the majority of the countries, the HCPs, were middle-aged (mean age= 34-38 years), with tertiary education. In Bulgaria, the HCPs were older (mean age = 55 years), and in 6 cases, HCPs reported below secondary education, depicting the social situation for this profession working with older people.

The youngest carers were in Cyprus (mean age = 41 years) and Poland (mean age =47 years) compared to the other three countries: Bulgaria (mean age =66 years), Greece (mean age = 66 years), and Italy (mean age =54 years). Children caring for their older parents were the majority of the carers. In Poland, we encounter the highest education among the sample of carers and the highest participation rate (12/15 tertiary education) of all partners. In both cases, women were the majority of the sample (HCPs: 48/58, carers: 23/39).

All modules had a high percentage of agreement in the case of HCPs (appropriacy mean score over 80% and adequacy over 76%) and the carers (appropriacy and adequacy mean score over 80%). Therefore, the modules with the lowest percentage were reviewed. Regarding HCPs, we encounter the lowest percentage of agreement in the appropriacy dimension for Module 6 (81.1%), followed by Module 2 (87%) and 3 (87%). Concerning the adequacy questions, we encounter high percentages of agreement in all countries except for Bulgaria. Module 6 is the module with the lowest percentage of agreement regarding the adequacy (76.5%). Carers provided low scores for appropriacy in case of Module 6 (81.6%) and 1 (84.4%) and adequacy in Modules 5 (82%) and 1 (80.4%).

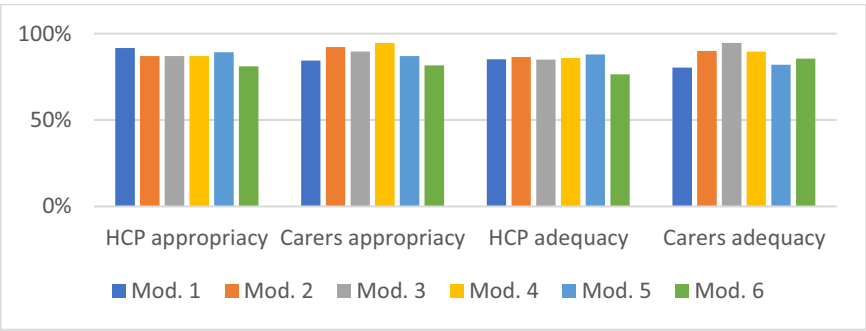


Figure 1. HCP and Carers' appropriacy and adequacy agreement scores

3.1 Qualitative Results

The most relevant information was derived from the comments received with the main topics of the discussion: a) duration of the course, in which participants suggested a possible combination of the modules, c) management of emotionality, d) access to online

self-help groups, e) Internet security issues, f) focus on dementia issues g) basic digital skills training.

3.2 Results of the Adapted Second Round among the Partnership

A smaller group of 11 members of the partnership assessed the percentage of agreement from round one and reached a consensus on the proposed curriculum. The research team worked during the 2nd transnational meeting in Limassol, Cyprus, on 16-17th May 2019 into small working groups to combine the sections in 4 modules based on the consensus (Figure 2).



Figure 2. Carers eHealth Literacy Training Version 2.0.

4. Discussion

This study has both strengths and limitations. The initial modules were proposed directly by the research team and not as part of the Delphi round 1 and the results were not combined with qualitative focus group results following a mixed method design. Apart from these limitations, all partners integrated the qualitative and quantitative results into the final curriculum. This final curriculum aims to integrate HCPs and carers knowledge on the training needs of eHL and HL. Even if HL and eHL are part of our everyday life, we may overlook their importance. Carers are positive towards an eHealth Literacy training that is short, deals with emotionality issues and enhances their basic digital skills and privacy issues. Carers usually search for information to assist their care-recipients and could benefit from the training course by enhancing their skills of finding, understanding, assessing and applying online information [9].

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Innovation in Cancer Treatment: The Impacts of Robotic-Assisted Surgery Adoption at the Brazilian National Cancer Institute

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Abstract. Robotic-assisted surgery has been actively applied in several fields of minimally invasive surgery, and its use in cancer treatment is increasing. This technology has diffused rapidly, despite high costs and limited reimbursement. Studies have proven the positive results of robotic surgery for patients' quality of life. The objective of this article is to describe the impacts of robotic-assisted cancer surgery adoption at the Brazilian National Cancer Institute. A single qualitative case study was conducted with a descriptive approach, and to have triangulation, data were collected from 3 different sources – participant observation, technical reviews, and seven semi-structured interviews with the main actors involved in the case – and analyzed through content analysis. Despite the considerable costs associated with robotic surgery, this innovation dramatically decreases the length of hospital stay and reduces complications and rehabilitates the patient in a much faster way.

Keywords. Medical Robotics, Innovation, Cancer Treatment. INCA, Case Study

1. Introduction

In the last years, there has been a growing trend towards the use of minimally invasive procedures in oncological surgical procedures. The purpose has been to the reduction of

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morbidity related to such surgeries while keeping the best cancer treatment. Various researches have analyzed the viability and treatment results of the conventional laparoscopic approach and indicated that the outcomes were similar to the open technique with fewer morbidity [1].

Although the clinical evidence is incipient, Robotic surgery is considered an innovation in the process of laparoscopic surgery in which the surgeon controls sitting on a console the arms of a robot to operate the surgical instruments. With the three-dimensional vision of the surgical field, the surgeon gets better visualization and accuracy. The procedures are not performed by a robot, but by the surgeon who has specialized training on how to use this innovation. The technology offers better visualization and dexterity. The robot is computer controlled to eliminate any tremors and allow precise movements [2].

The innovations that have arisen over the last decades have brought a great revolution in the field of surgery. Robotic-assisted surgery has been actively applied in several areas of minimally invasive surgery, and its use in cancer treatment is increasing. Viability and safety have been the focus of the studies, but an analysis of the cost involved is also of great relevance [3].

Robotic technology has diffused fast, despite elevated costs and limited reimbursement. Studies have proven the positive results of robotic surgery for patients' quality of life with an emphasis on i) reduction of blood loss; ii) shorter hospitalization time; iii) minor scars; iv) reduction of pain and the need for prolonged medication; v) faster recovery; vi) lower the risk of infection; (vii) reduction of the need for additional procedures [4].

Surgical innovation generates enhancements in healthcare, but it as well brings up ethical issues, including risks of injury to patients, conflicts of interest, and unfairness in access to health services. Patients can be subject to unacceptable risks during the implementation of new procedures; conflicts of interest can influence clinical decision making, and innovation may lead to imbalances where patients who are already better condition have greater access to innovative treatments [5, 6].

The number of empirical researches on health innovations has increased in recent years, evidencing the existence of a positive relationship between the use of innovative technologies and reduction of mortality rates, decrease in costs and increase of productivity [7].

This study is about healthcare innovation management and will extend this field of knowledge through the analysis of the adoption of robotic surgery in the treatment of cancer. The objective of this article is to describe the impacts of robotic-assisted cancer surgery adoption at the Brazilian National Cancer Institute (INCA).

2. Methods

The research portrayed in this article has a qualitative approach and is descriptive. The study adopts the method of a single case study, with the forms of data collection being participant observation, technical reviews, and seven semi-structured interviews with the main actors involved in the case. The choice of the institution as a single case is justified by the relevance of INCA at the Brazilian Health System.

The interviews were conducted in the second half of 2019 and were supported by a script with open questions. The answers obtained were treated by the method of content analysis of the categorical type, and the categories of research were defined from the

literature review. The unit of analysis was the processes and structures changed by the introduction of the robotic system.

3. INCA Case Study

Brazilian National Cancer Institute (INCA) was the first Brazilian public institution in the medical field to have a surgical robot. The Da Vinci Surgical System began to be used at the Institute in March 2012, from that date until July 2018 has performed 782 robotic surgeries.

The implementation of new technology, such as robotic surgery, has introduced new challenges to training physicians and residents at the Brazilian National Cancer Institute. For medical experts, all with a high reputation in their fields, the introduction of robotic surgery at INCA has been considered as a unique opportunity to learn new technologies.

Business intelligence applications were developed for the management of robotic surgery at INCA. The economic issues identified in this case study involved operating room time, hospital stay, and total costs.

The robotic surgery dramatically decreases the length of hospital stay, reduces complications, and rehabilitates the patient in a much faster way, as shown in the following dashboard, Figure 1.

However, robotic surgery certainly is more expensive if the purchase and maintenance of the robot system are included in the total costs.

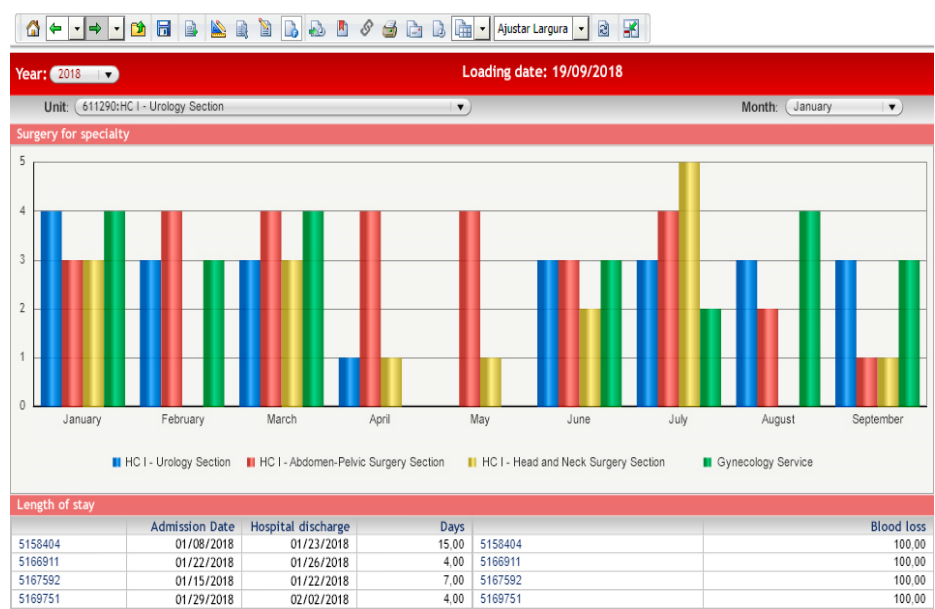


Figure 1. Length of Hospital Stay After Robotic Surgery

The higher costs of robotic surgery were observed principally due to the elevated purchase and maintenance costs for the robot and to the longer operating room time. However, new evidence has demonstrated that operating room time reduces with experience in the use of the robot.

4. Conclusions

Although robotic systems such as the da Vinci surgical system provide innovative tools and imaging, one constraint of the robot-assisted laparoscopy implementation is related to costs increase. Once robotics is applied to cancer treatment, costs rise exponentially and become one of the most significant obstacles to this kind of cancer surgery innovation diffusion.

These innovations have brought an extraordinary revolution in the field of cancer treatment. The main reason that the majority of Brazilian hospitals have not already implemented this system is related to the costs that may be bigger than some institutions' budgets can afford. There are considerable costs associated with robotic surgery. Therefore, the implementation of these kinds of robotics systems needs to improve efficiency and cost-effectiveness to consolidate this innovation. The robotic and telesurgery technology may further improve patient outcomes while presenting new options for the minimally invasive treatment of cancer in the future.

The most critical logistic issues raised in this research were related to the chronic dependence of international manufacturers of robotic surgical systems and their peripherals, whose practices tend to the concentration of market aggravated by the difficulties of imports of equipment and supplies for the Brazilian health industrial complex.

Change management strategies should be used to implement innovative processes. To roll out this kind of innovation effectively, the robotic surgery project managers should maintain a positive relationship with physicians and residents and engage them in extensive information sharing across organizational levels. Future research must explore the use of artificial intelligence in Robotic-Assisted Surgery. The next generation of surgical systems should increase the ability to view and analyze images. Evidence of the efficacy and safety of robotic surgery and its associated costs should be evaluated in a wide range of procedures. New systems must reduce training costs, and the learning curve of physicians and new projects should prioritize the reuse of supplies.

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The Confirmatory Factor Analysis of Quality Assurances Among Medical Laboratory in the Primary Care Units: Roi - Et, Thailand

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Abstract. The purpose of this research was to examine determinants factors of medical Laboratory Accreditation in the Primary Care Units (LA-PCUs): Roi-Et province, Thailand. 550 cases were sampled using stratified random sampling, which questionnaires were qualified by previously validated scales. Data analyses were approached with descriptive statistic and confirmatory factor analysis were employed to standardization. The results found that the LA – PCUs model comprised of 7 sub-components. It was revealed to have significant within internal consistency. Each of the sub-component had a standard component weight. Between 0.94 - 0.99, each metric of the domain had the components weight value the standard is between 0.72 - 0.88. Evidences has approved that the models have been developed to evaluate the fitness properties and was found to be valid to provide a measurement of quality assurances of the medical laboratory in the PCUs confirmed by the empirical data.

Keywords. Quality Assurances, Medical Laboratory, Primary Care Units.

1. Introduction

Medical Laboratory in the Primary Care Units (PCUs) was the early diagnosis and screening test for the high-risk groups, monitor the symptoms and progression of disease among patients such as blood glucose testing, protein in urine, sugar in urine, pregnancy test and hematocrit test. [1] Most importantly, the collection of specimens and transported to the laboratory hospital that had the potential for more accurate analysis according to academic principles in which the test item. The person performing for analysis testing must understand the test methods, as well as the need to control the quality of the analytical standards to be able to provide health services to people with efficiency and effectiveness in the future [2]. Accreditation was a procedure by which an authoritative body gives formal recognition that an organization was competent to carry

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out specific tasks. [3] As a result of effecting, it expands services to continue, increased attention to quality, efficiency, and cost-effectiveness was paramount. The researcher, therefore, studied the components and developed the quality indicators, laboratory standards in PCUs. To develop the indicators and criteria for quality assessment of medical and public health laboratories in PCUs will be useful to get indicators that can indicate. Additionally, how it reflects the quality assurance and sustainability of the primary level laboratory. [4] The purpose of this research was to examine determinants factors of medical laboratory accreditation in the PCUs (LA-PCUs): Roi-Et province, Thailand, and empirical data.

2. Material and Methods

This research was a part of a Dr.P.H. thesis. The Institutional Review Board of Mahasarakham University approved the research protocols (Approval No: 011/2018). A quantitative survey was conducted in April and July 2018. Second-order confirmatory factor analysis model to examine the goodness of fit index of the quality assurance for medical and public health laboratories in PCUs. Roi-Et Thailand of public health workers and empirical data there were methods of researching as follows.

2.1. Population and sample

This research was conducted with a sample group consisting of 229 health promotion hospitals where sub-unit of PCUs in Roi-Et province. 550 public health care workers who performed laboratory analysis in the PCUs and selected by using the stratified random sampling.

2.2. Research instruments

The questionnaire with 5 level rating scale consisting developed from the International Organization for Standard (ISO 15189: 2012) of medical laboratories [5] which was synthesized together with the standard of Medical Technology 2017 of Thailand. (Laboratory Accreditation: LA 2017) [6] by synthesizing into Laboratory Accreditation in the Primary Care Units model (LA – PCUs) had 7 sub-components were 1) Organization, 2) Environmental conditions, 3) Laboratory material, 4) Pre-analytical process, 5) Analytical process, 6) Internal Quality Control and 7) Post-analytical process. The answers were recorded on a 5-point scale (coded from 1 to 5). The content validity of the questionnaire in the current study was 0.925, and the reliability was 0.79. The correlation item-total score range was 0.76 to 0.92. Data analyses were approached with descriptive statistic and confirmatory factor analysis were employed to standardization.

3. Result

3.1. Construct validity

The preliminary examination found that the 7 sub-components of the self-compassionate kindness matrix were not identity matrices. It shows that all 7 sub-components were

sufficiently relevant to be able to analyze them further (Bartlett's Test: $\chi^2 = 4216.485$ $df = 21$ $p < .000$). The consider each component was found that the Kaiser-Mayor-Olkin (KMO), that was the components of self-compassion studied were sufficiently correlated to further analysis as shown in table 1.

Table 1. Inter-correlations of LA-PCUs dimensions (N = 550)

	POS	QC	ANA	PRE	EQU	ENV	ORG
POS	1						
QC	0.823	1					
ANA	0.741	0.769	1				
PRE	0.767	0.796	0.868	1			
EQU	0.711	0.737	0.759	0.786	1		
ENV	0.686	0.734	0.732	0.758	0.86	1	
ORG	0.687	0.713	0.734	0.76	0.809	0.843	1
Mean	3.681	3.707	3.595	3.636	3.870	3.771	3.755
SD.	0.722	0.752	0.785	0.781	0.718	0.723	0.720

Bartlett's Test: $\chi^2 = 4216.485$ $df = 21$ $p < .000$ KMO = .918

All coefficients were significant at the $P < 0.0001$ level.

Note: Organization (ORG), Environmental conditions (ENV), Laboratory material (EQU), Pre-analytical process (PRE), Analytical process (ANA), Internal Quality Control (QC) and Post-analytical process (POS)

Therefore, each sub-component in the LA - PCUs Model was related to each other. This relationship was caused by the relationship between the variance and the covariance of the sub-components s adjusted to standard values. It can be concluded that the LA - PCUs Model was appropriate and blends with the empirical data from the sample a hierarchical factor structure was also hypothesized and tested. Results of the hypothesized second-order factorial structure were presented in Figure 1.

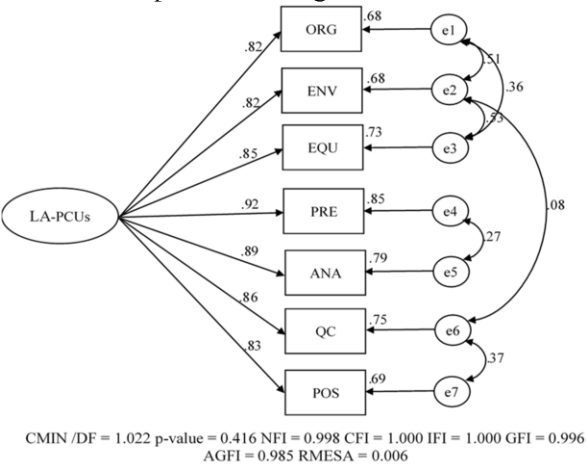


Figure1. A Second-Order Confirmatory Factor for LA – PCUs Model

4. Discussion

The purpose of this research was to examine determinants factors of medical laboratory accreditation in the Primary Care Units (LA-PCUs): Roi-Et province, Thailand. It was

revealed to have fitness within internal consistency. Each of the sub-components had a standard component weight between 0.94 - 0.99, each metric of the domain had the components weight value the standard was between 0.72 - 0.88. Quality assurance in medical laboratories incorporates all the factors that may influence the generation of reliable results. [7] The quality assurance system is necessary in part for advanced services and professional development and the other for accountability. [8] Such systems require criteria and standards used in the assessment. But these things are not easy to create in particular in primary care units that do not have a medical technologist to analyze. According to the research the LA-PCUs model has 7 sub-components which corresponds to the ISO 15189 was the standard of choice for the accreditation of medical laboratories that recognizes world-class quality and the application of a rigorous process of quality assurance [9-10].

5. Conclusions

The findings show evidence of the correctness of the tools and therefore support the use of tools for local education. Current results also show the acceptable reliability and accuracy of the studied tools. The total alpha coefficient is equal to or greater than 0.70 for all dimensions. Confirmation factor analysis demonstrates support for LA-PUC factor validity.

Additionally, the analysis of confirmed factors to test the importance of item loading and unrelated relations, as well as the evaluation of the overall model, fit to provide evidence of the accuracy generated. In practice, all 7 sub-components of LA-PCUs have been proven to be a valuable tool for quality assurance studies in medical laboratories in PCU: Roi Et, Thailand. The data also support hierarchical models.

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Application of Geographic Information Systems (GIS) to Analyse and Detect the Risk of Chronic Diseases in the Elderly

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Abstract. The prevalence of Non-Communicable Diseases (NCDs) in older people has been concerning in several ways. This study investigated the risks of health behaviour of elderly by applying the Geographic Information System (GIS) to analyse the risk of NCDs for the elderly in Thailand. **Methods:** The survey investigated 1,006 elderly people in Chuen Chom District, Maha-Sarakham Province, Thailand. Kernel Density Estimation Surface was used for spatial analysis with 120 elderly by structured interviews concerning health behaviour to identify the risk of NCDs. **Results:** It was found that in Lhao Dok Mai many elderly people had NCDs. The behaviour of the elderly creating risks of NCDs was drinking alcohol, smoking, lack of exercise, consuming excessive food, and stress. **Conclusion:** The risk areas for NCDs among the elderly were identified by GIS, therefore, local authorities should be supporting the elderly by using GIS to prevent any further severe cases of NCDs.

Keywords. Elderly, NCDs, GIS, Health Behaviour

1. Introduction

In an aging society there are more elderly people whose physical body is in a period of deterioration. The percentage in Thailand of the elderly in the total population was expected to reach 14% in 2015, 19.8% in 2025 and nearly 30% by 2050 [1]. Most of the elderly suffer from chronic diseases such as diabetes, high blood pressure, heart disease and gout [2]. Maha Sarakham province (MSK) is a local area in the Northeast of Thailand, which has a population of about 900,000 people, of which there are approximately 90,200 elderly people [3]. Chun Chom District is a district in MSK, containing 4 sub-districts and 47 villages. The number of elderly people is 3,986, representing 14% of the population [1]. Geographic Information System (GIS) helps to analyse spatial data in conjunction with the global positioning systems (GPS) to

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ascertain the habitation of the elderly [4]. We are particularly concerned with critical issues in the health of the elderly, especially concerning non-communicable diseases (NCDs). By applying GIS we can determine the location of the elderly, while also capturing the coordinates to analyse the risk points for the elderly who are confined with NCDs, as well as the risks of health behaviour for NCDs in the elderly.

2. Methods

2.1 Data collection

The study area chosen was Chuen Chom district, Maha Sarakham province in Northeast Thailand. The Global Positioning System (GPS) of Universal Transverse Mercator (UTM) grid coordinate system from WGS 84 was used to survey the location of 1,006 elderly patients and 12 hospitals in the area. It was found that the elderly patients, consisted of 307 cases with diabetes, 443 with hypertension, and 256 with both diabetes and hypertension. Data were also collected from 120 elderly people using interviews and structured questionnaires which further investigated health behaviour [5] and included demographic data to identify their risk of NCDs. A consensus was reached by a MSU (Mahasarakham University) panel.

2.2. Data analysis

Data were collected by field work between June and July 2017 as follows: 1) Location of the elderly from coordinates of home address using GPS and Google Map. 2) Location of the 12 Hospitals using GPS and Google Map. 3) In order to aid the analysis of the distribution of the elderly, they were separated into three groups [6]: a) bedridden group, b) a home based group, and c) a socially independent group. Density analysis was obtained using the Kernel Density method and data from the interview forms included the numbers and types of elderly in each group [7, 8]. The use of mapping spatial analysis to find areas of high risk behaviour was evaluated using the mean scores of the interval scales from health behaviour questionnaires to assess the risk behaviour of the elderly by using overlay analysis to identify the factors of the health risk, which separated into four levels [9]; very high (3.26 - 4.00), high (2.51 - 3.25), moderate (1.76-2.50), and normal (1.00 - 1.75).

3. Results

3.1 The risks of food consumption and self-care behaviour in the elderly with NCDs

The results indicated that six issues of self-care behaviour of the elderly were a high risk: drinking alcohol (3.85 ± 0.31), taking sweet drinks and candies when tired (3.81 ± 0.41), smoking (3.77 ± 0.51), sleep deprivation (3.77 ± 0.51), forgetting hypertension medication (3.75 ± 2.70), adding too much salt to regular meals (3.75 ± 0.56), and using old medication instead of revisiting the doctor (3.70 ± 0.61).

3.2 The map and disease density locations

As might be expected the number of elderly people with NCDs varied according to population density. The areas with the highest elderly population density were towns (see figure 1A). The sub-district with the highest population of elderly was Lhao Dok Mai (34%), followed by Gud Pla Duk (30%), Chuen Chom (20%) and Nhong Kung (16%). The areas with a low population density of elderly were mainly farmland (see figure 1). Some hospitals were in areas of low population density and poor access.

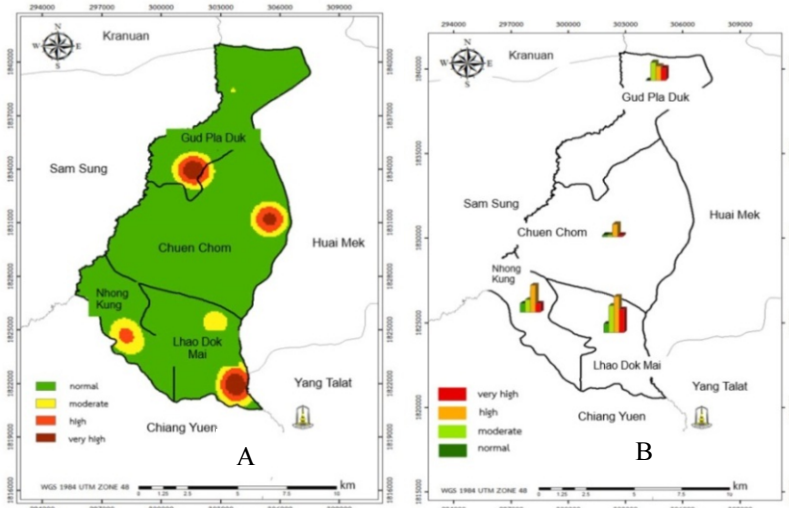


Figure 1. A: the density of elderly people with NCDs, B: the level of the risks of NCDs in Chuen Chom district.

4. Discussion

4.1 The locations of elderly people with NCDs

This is a crucial issue of concern to healthcare planning and management services, which has been discussed in several studies [10]. The government must reorganize the health system to include GIS [11], and reform planning and management to produce efficient decision-making [12].

4.2 The risk of behavioural factors affecting the health of the elderly

The behavioural factors that caused most risk of NCDs in the elderly were drinking alcohol, smoking, consuming excessive food, stress and a lack of exercise. Indeed, an active life cycle will benefit the elderly. Ichiro Tsuji studied elderly Japanese people with an active life and found they lived longer than the inactive elderly Japanese people [13]. This suggests health programmes should encourage the elderly to exercise. The overall level of food consumption behaviour was also a high risk, which indicated that nutrition can affect the health of the elderly, whose bodies are declining [14].

5. Conclusions

The GIS identified the areas at high risk of NCDs are in towns and those at low risk are in the countryside. The NCDs are caused by inappropriate life styles. The results help local authorities involved in supporting the elderly to set a plan for health promotion that prevents any serious increase of NCDs in the elderly.

Acknowledgments

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Personalized Biomechanic Models: Factors Affecting Shoulder Motion

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Abstract. The design and development of personalized prosthetics or rehabilitation treatments of extremities disorders relies on accurate mathematical models. The effect of various parameters on shoulder joint mobility was investigated in order to develop more accurate, adaptive models. Active and passive abduction at the frontal plane and active and passive flexion at the sagittal plane were studied on two different age groups. Results showed statistically significant differences in shoulder movement between the two groups. The range of movement decreased considerably in older volunteers while no significant differences were observed within the same age group. Active and passive movements differed significantly while flexion was easier to perform than abduction. Movement was independent of weight, height, BMI, gender, and handedness. Exercise had a significant positive impact on the elderly and may counterbalance age effects. Age and exercise parameters should be included in prosthetics modeling and rehabilitation to improve and personalize care.

Keywords. Abduction, flexion, shoulder-joint, statistical analysis

1. Introduction

The development of accurate and adaptive physiology models for the movement of the upper and lower extremities is critical for the design and development of personalized prosthetics and the selection of appropriate rehabilitation treatments of the disorders of these extremities. In this study, the necessary parameters for the modeling of the shoulder motion were investigated. The shoulder joint is a complex structure with a wide range of motor and functional requirements. It is a synovial ball and socket joint between the scapula and the humerus connecting the upper limb to the trunk and functionally acting as a diarthrosis and multiaxial joint [1]. It includes four joints that are responsible for any ‘normal’ movement executed by the shoulder joint, that would not compromise its stability. The types of movement performed by the shoulder joint are: i) flexion and extension in the sagittal plane, ii) abduction and adduction in the frontal plane and iii) internal and external rotation in the transverse plane [1,2]. In the literature, it has been suggested that over time the movement of the shoulder deteriorates due to a variety of reasons including age, loss of bone mass, loss of muscle mass, lack of exercise, injuries and pathologies [3]. In this work, the results of the effects of age and exercise on the motion of the shoulder are presented. In the past, we developed models for the knee joint and designed a knee replacement based on the KINECT modeling of young, healthy

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individuals [4]. The approach was successful but generated a general model that lacked adaptivity. In this paper, the hypothesis that anthropometric studies could enrich general models leading to more accurate prosthetics and rehabilitation strategies customized to the needs of the patient, was tested. Hence, the impact of age, weight, height, body-mass index (BMI), gender, handedness, and exercise on shoulder joint movement and the significant of these parameters in modeling the joint were investigated.

2. Methodology

2.1. Participants

A hundred healthy volunteers divided into two groups (A and B) participated in the study. None of them had any shoulder injuries or had undergone any surgery during the experiments or shortly before. Both groups included 25 male and 25 female volunteers (A: ages 20-25 years, body mass 72 ± 25 kg, body height 1.71 ± 0.10 m and B: ages 60-75 years, body mass 79.7 ± 25 kg, body height 1.61 ± 0.15 m). In group A, 42 volunteers had a right-hand dominance, 6 had a left-hand dominance and 2 were ambidextrous. In group B, 48 had a right-hand dominance and 2 had a left-hand dominance. All volunteers gave written informed consent before participating and no personal data was kept.

2.2. Experimental methodology

Active and passive abduction at the frontal plane as well as active and passive flexion at the sagittal plane were measured. Initially, the volunteers were asked to stand still in the anatomical position where measurements of weight (kg) and height (m) were taken. Their body-mass indexes (BMIs) were calculated using the ratio $\text{weight}/\text{height}^2$. Measurements of the range of motion on the sagittal plane were then recorded with a goniometer. The volunteers flexed and extended actively and passively their right and left shoulder. Active motion represented the volunteer's unassisted movement whereas passive motion was an assisted, by the researchers, movement with no physical pain. For flexion, zero degrees (0°) was considered the anatomical position (shoulder joint fully extended). Measurements on the frontal plane followed and the volunteers were asked to abduct their right and left shoulder actively and passively. For abduction, zero degrees (0°) was considered the anatomical position (shoulder joint fully adducted). Lastly, all volunteers described their daily exercise on a scale of 1-5 where 1 represents sedentary lifestyle and 5 daily work-out.

A repeatability analysis was performed throughout the experiments and no significant variations were observed. A reproducibility analysis was performed for randomly selected volunteers. The error of the measured position of the shoulder joint ranged between 1-3% and was considered acceptable.

3. Results

Data were recorded and analyzed using EXCEL. Statistical analysis was performed using the methods of statistical hypothesis and the linear correlation coefficient. A two-tailed t-test was applied to compare the means of two sets of values that differed with respect

to a trait [5]. Pearson correlation analysis [6] was applied to determine relationships between the different movements and the demographic parameters.

Tables 1, 2 and 3 present the mean values of all the parameters studied, the p-values for both hands for all movements, and the percentage values of the difference in the measurements of the two groups respectively. The greatest statistical differences were observed on the movements involving the right-hand side shoulders which was expected since most of the volunteers were right-handed.

Table 1. Demographics (Mean Value)

Column1	Group A	Group B
AGE (years)	22	70
BODY MASS (kg)	72	79.7
HEIGHT (m)	1.71	1.61
BMI	24.6	30.5
SEX (Female – Male)	50%-50%	50%-50%
RIGHTHANDED/LEFTHANDED	84% right-handed	95% right-handed
EXERCISE (scale 1-5)	3	2

Table 2. Significance value (p-value) for both hands and all movements on both planes.

Movements	p-value
Frontal Active Right / Left	0.000375 / 0.003576
Frontal Passive Right / Left	2.14E-05 / 9.02E-06
Sagittal Active Right / Left	0.001309 / 0.000139
Sagittal Passive Right / Left	8.96E-06 / 2.63E-05

Table 3. Percent difference in right/left movements between age groups (t-test).

Movements	Difference
Frontal Active Right / Left	4.39% / 3.11%
Frontal Passive Right / Left	4.36% / 3.28%
Sagittal Active Right / Left	3.61% / 3.60%
Sagittal Passive Right / Left	3.78% / 3.04%

Figures 1 and 2 present the mean values of the degrees of active/passive flexion and abduction respectively measured in Groups A and B for both shoulders.

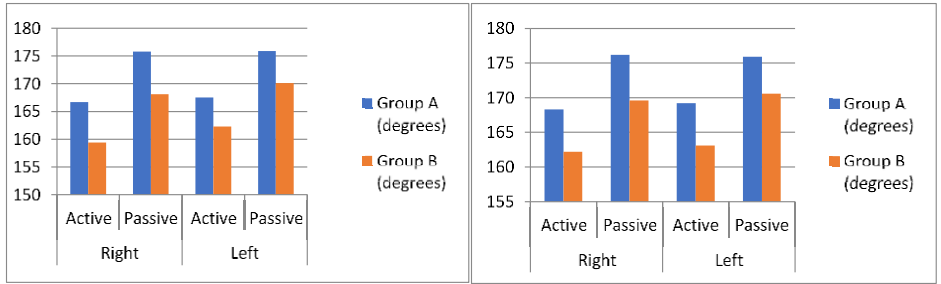


Figure 1. Flexion in the sagittal plane.

Figure 2. Abduction in the frontal plane.

4. Discussion

The purpose of this study was to determine the parameters that should be included in an adaptive model of the shoulder joint for prosthetic and rehabilitation purposes. Intra-group results showed that age had a major impact on shoulder’s range of motion.

Exercise seems to counterbalance the age-related deterioration of the movement as can be seen in Figures 3 and 4 for Group B where only 3 levels of activity were recorded.

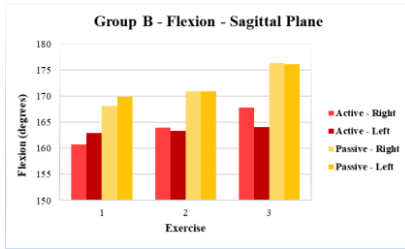


Figure 3. Flexion over Exercise for Group B.

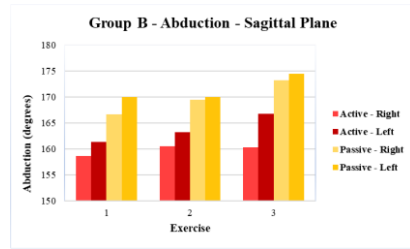


Figure 4. Abduction over Exercise for Group B.

Active movement differed significantly from passive movement. Volunteers could not achieve very high degrees in active movement possibly due to lack of training, exercise and muscle atrophy depending on the age group. In the sagittal plane, both age groups achieved greater range of motion compared to the frontal plane suggesting that flexion was an easier movement for the shoulder joint to perform than abduction.

Finally, shoulder function seemed independent of weight, height, BMI, gender and handedness, i.e., left/right hand dominance suggesting that these parameters may be of lower importance in model development.

5. Conclusions

The results of this study agreed with prior reports on the effects of age on shoulder mobility and partially for handedness [7]. Exercise seems to be a new determinant of mobility in the elderly and its effects should be further investigated in more detail. Both age and exercise should be taken into consideration when developing models of the shoulder joint for prosthetics and rehabilitation.

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DONOR-FINDER: A Web Tool for the Automatic Comparison of Genomic Profiles in ART

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Abstract. The use of genetic tests in assisted reproduction is growing fast. Among potential usages, the selection of the most suitable donor profile stands out. Being able to consider the genomic compatibility between donor and recipient is very important in order to prevent certain diseases. Nevertheless, taking this new factor into account can significantly increase the time needed for donor selection. This paper describes a web-tool designed to automatize the comparison of genomic and phenotypic profiles in assisted reproduction practices, which potentially reduces the chance of error and the time needed in donor-matching processes.

Keywords. Genomics, assisted reproductive technology (ART), web tool

1. Introduction

Infertility is a disease that currently affects between 8 and 12% of couples of reproductive age around the world [1]. As the infertility rates rise, specifically in developed countries, so does the interest in assisted reproduction technology (ART), defined by WHO as “all treatments or procedures that include the in vitro handling of both human oocytes and sperm or of embryos for the purpose of establishing a pregnancy” [2]. In some cases, ART techniques are not enough, and it is necessary to resort to donations of gametes to have a successful pregnancy.

In recent years, genomic studies have found their place in ART clinics as a resourceful tool that allow doctors to assess the genetic compatibility between two people based on their genetic profiles. These tests can detect certain mutations related to a set of disorders of interest, not only to find the reason of the reproductive problems in a couple, but also to select a donor based on genetic compatibility. Regardless of the existence of these tests, they have not reached their full potential and many clinics still rely only on phenotypic data to select donors. Also, those that do consider genetics, usually perform a manual search, a cumbersome and tiring task.

In order to cope with these limitations, the main objective of this project is to develop a tool to store phenotypic and genotypic data from patients and donors, and to compare patients and donors. DONOR-FINDER will help experts find the best match for each

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case automatically, taking every relevant phenotypical and genomic parameter into account without the burden to check every donor information by hand.

2. Results

DONOR-FINDER was developed in order to automatize the donor-matching process followed in ART clinics. Users can load phenotypic and genotypic data from patients and donors and, for each patient, automatically filter the available donors based on phenotypic features and perform a genetic comparison to find the best match.

The software was developed using Django framework and consists of three main elements: a database, a set of analytical modules and a web-based user interface (UI), all represented in Figure 1. These elements are in constant interaction in order to provide an intuitive fully working solution.

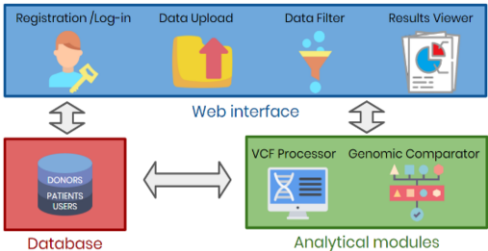


Figure 1. DONOR-FINDER Software Diagram

Information regarding (1) users, (2) patients and (3) donors was stored using PostgreSQL database, due to its compatibility with Django. Once designed, it was embedded within the web application using the Django Object-Relational-Mapper (ORM), which allows developers to define the data models using only Python logic.

Concerning data analytics, two main modules were defined (1) to process all the data, and (2) to analyze and prepare the information to be shown to the user in the web.

Genomic data needs to be prepared for comparison. The processing module takes the input variant-call-format (VCF) file and extracts all the detected single nucleotide polymorphisms (SNPs). Then, the data is annotated using the NCBI ClinVar database [3] to obtain information regarding the SNPs’ pathogenicity, diseases associated to each SNP and those associated to the genes where they are found. Finally, we select those SNPs associated to any of the 600 recessively inherited diseases² commonly considered in ART and store the annotated data in a file.

The genomic comparison module is the core of the software as it comprises all the functions needed to define the suitable donors for each patient. In short, the module receives a list of all the available donors that phenotypically match the patient of interest, compares the genetic profile of each donor with the patient and returns a weighted list with the scoring results for each donor. The first step is to compare the annotated datasets at the variant level in order to keep the variant pairs that fulfil certain conditions: different SNPs on each profile but found in the same gene, or the same SNP found in both profiles. Also, if both variants are considered “benign” with certain confidence (review status ≥ 2) the pair is ignored. This reasoning was implemented based on genetic expert criteria. Finally, the remaining pairs of variants are scored based on the criteria described in Table

² www.institutobernabeu.com/foro/wp-content/uploads/2018/04/Listado-TCG-600-enfermedades.pdf

1, where 1 correspond to the highest risk of disease; nevertheless, all the kept pairs of SNPs are associated to certain risk.

Table 1. DONOR-FINDER Scoring Criteria

Score	Condition	
1	Same SNP in both profiles	Both SNPs associated to relevant disease
2	Same SNP in both profiles	Gene associated to relevant disease
3	Both SNPs in same gene	Both SNPs associated to relevant disease
4	Both SNPs in same gene	Gene associated to relevant disease

A web-based UI was created to provide the ART experts with a tool that allow them to exploit the previously described functionalities, without needing programming skills. The tool is comprised by a set of views that will be described next:

- The registration view allows new users to create their accounts, by providing identification details, including to which of the registered centers they belong to. On the other hand, the log-in view allows already-registered users to enter the system by providing their previously defined username and password.
- Every registered user can load data from new patients or donors in the software using the donor registration and patient registration views. Both views are very similar, and ask the following details: identification details, phenotypic information (skin, hair and eye color, hair type and blood type) and genotypic information (VCF file). Phenotypic and genotypic data is required for comparison. The uploaded VCF file is processed in the first module described above, and both files are kept in the database.
- The match view (Figure 2) enables users to compare all the available donors with a patient of interest, in order to find the more suitable donor. Each user will only have access to patients and donors registered by members from the same center and only relevant data is displayed to preserve privacy.

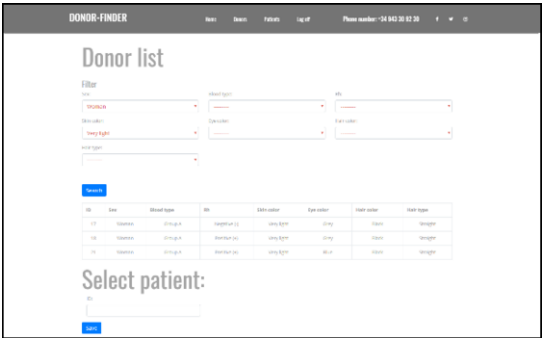


Figure 2. DONOR-FINDER Web - Match View

The user must select a patient by its ID, and afterwards the tool filters all the available donors, to only keep those that match the patient phenotypically and displays only the relevant data of filtered donors in a table. Then, the user can choose to automatically compare the chosen donors' profiles and the patients'.

The comparison results are displayed to the user in the bottom of the same view, where a pie chart (Figure 3) is shown for each evaluated donor, sorted based on their scores. The sections of the charts can have 4 different colors, each representing one of the risk scores (1-4) of the system. Also, a table summarizing the variants associated to each section in the pie chart is shown.

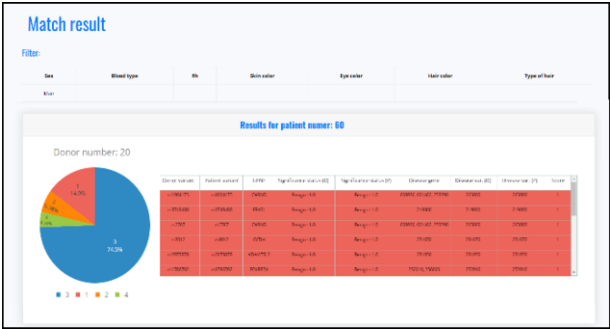


Figure 3. DONOR-FINDER Web - Results Chart

3. Discussion

The idea of developing DONOR-FINDER arises from the limited availability of similar software in the market. Different options were found that focus on physical characteristics of the subjects, but as far as we are concerned, we have not found any that also considered the genomic information for donor selection.

DONOR-FINDER is a usable tool that accurately evaluates donors' profiles in order to help finding the best donor-patient match, considering the pheno-genotypic profiles of the subjects. Automatization reduces the probability of incurring in human error, and it also potentially reduces the time needed for donor-matching processes. DONOR-FINDER compares the given patient with all the available donors, instead of the traditional method of finding the best donor by evaluating one possibility at a time.

It is important to highlight that the tool does not make decisions regarding donor-selection but provides the experts with certain recommendations and all the information they may need in order to select a donor. The advantage is that users can evaluate all the options together, and easily detect differences between donors to select the best option based on their clinical criteria.

So far, specialists in ART and genetics have shown interest in the tool and they reassure that it could be useful for them as it automatizes the donor selection process.

The validation of DONOR-FINDER will be performed with experts and three aspects will be evaluated: 1) software usability, 2) results accuracy and 3) software efficiency. Additionally, even if the tool is password protected, advanced privacy preserving issues will be handled in the future versions of the tool.

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K-Means Clustering in Monitoring Facility Reporting of HIV Indicator Data: Case of Kenya

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Abstract. Health management information systems (HMISs) in low- and middle-income countries have been used to collect large amounts of data after years of implementation, especially in support of HIV care services. National-level aggregate reporting data derived from HMISs are essential for informed decision-making. However, the optimal statistical approaches and algorithms for deriving key insights from these data are yet to be fully and adequately utilized. This paper demonstrates use of the k-means clustering algorithm as an approach in supporting monitoring of facility reporting and data-informed decision-making, using the case example of Kenya HIV national reporting data. Results reveal four homogeneous cluster categories that can be used in assessing overall facility performance and rating of that performance.

Keywords. HIV-indicator, dhis2, k-means clustering, monitoring, data-use

1. Introduction

Implementation of Health Management Information Systems (HMISs) for purposes of improving monitoring and evaluation efforts toward eradication of HIV in low- and middle-income countries has resulted in large amounts of data. Facilities using HMISs are required to submit various reports to aggregate-level HMISs[1], such as the District Health Information Software Version 2 (DHIS2) used in many countries [2]. These aggregate data are essential for program monitoring and evaluation (M&E) and for data-informed decision making (DIDM). DIDM is essential in informing policy and advocacy, and in program design, improvement, operations and management [2]. The ultimate aim of DIDM is achievement of improved health outcomes. For the submitted reports to be of best use to monitoring and evaluation (M&E) efforts, they must be complete, accurate and submitted in a timely manner. For the case of HIV, a weakness in understanding HIV information use infrequently addressed in previous studies is how M & E teams at the national level can utilize various approaches to derive insights from HIV facility reporting data aggregated in HMISs. In this study, we demonstrate use of the k-means

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clustering algorithm as an approach in supporting monitoring of facility reporting and DIDM, using the case example of Kenya HIV national reporting data.

2. Methods

A retrospective observational study was used in monitoring performance trends in HIV reporting from health facilities in Kenya. DHIS2, the national aggregate reporting system, was used in extracting facility HIV reporting completeness and timeliness data for all health facilities in all 47 counties in Kenya, for the year 2011 to 2018. Systematic procedures were used in cleaning the data prior to analysis. Facilities in this study included only those offering HIV care and treatment services. This study explored an automated approach of grouping facilities based on their reporting completeness and timeliness, as a way of determining overall facility performance in reporting. Facility reporting completeness was defined as the extent to which facilities submit the expected number of reports, and timeliness as reporting submission within the defined reporting deadline. The actual number of reports submitted by facilities are automatically calculated within DHIS2, against the expected number of reports. The k-means clustering algorithm was used in identifying homogeneous groups within the data. The average silhouette coefficient was used in measuring the quality of the selected clusters [3]. All analyses were conducted in SPSS.

3. Results

A total of 18,394 HIV care and treatment reports from a total 3,242 facilities for the period 2011-2018 were evaluated. Based on the average silhouette measures for each year (ranging from 0.58 to 0.70); the k value used was four ($k=4$), with the four homogeneous groups of facilities identified as: best performers, average performers, poor performers, and outlier performers. Figure 1 to Figure 4 illustrate the exact performance (report timeliness and completeness) over time by facilities in each of these clusters. Figure 1 illustrates results for facilities in the best performers cluster, where average percentage completeness and timeliness was high (80% and above) in the various years (2012 to 2018).

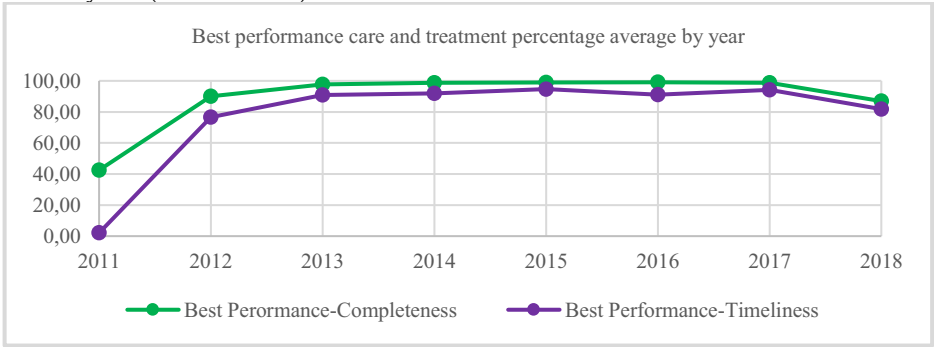


Figure 1. Care and treatment facility reporting best performance.

Figure 2 illustrates results for facilities in the average performance cluster, where percentage completeness and timeliness were lower in comparison to best performance

facilities in the various years respectively. For instance, performance in 2015 for timeliness and completeness is lower by 28.65% and 5.37% respectively compared to performance in 2015 for best performance (Figure 1.).

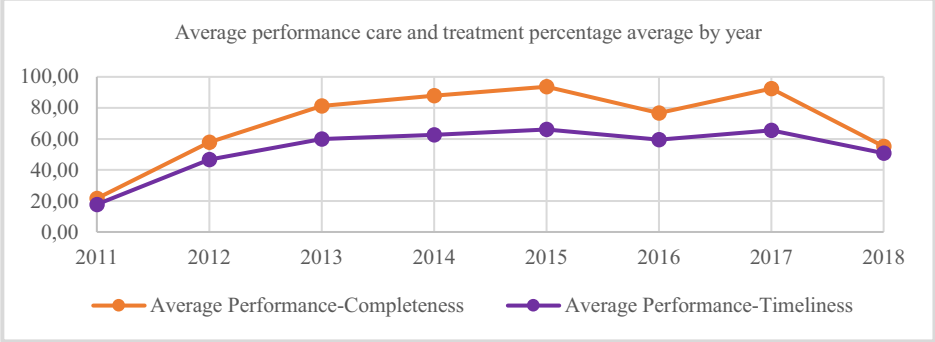


Figure 2. Care and treatment facility reporting average performance

Figure 3 illustrates results for facilities in the poor performance cluster, where percentage completeness and timeliness was low (below 50%) in the various years.

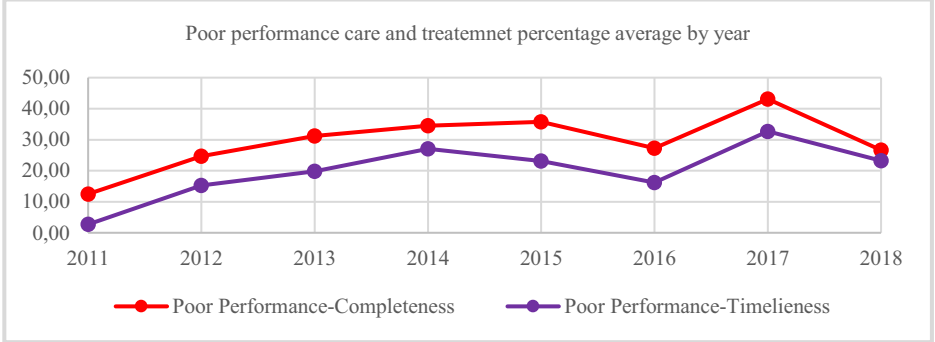


Figure 3. Care and treatment facility reporting poor performance.

Figure 4 illustrates results for facilities in the outlier performance cluster, where there was an evidently big gap between percentage completeness and timeliness in the various years. This depicts scenarios where timeliness was a problem despite good performances in completeness.

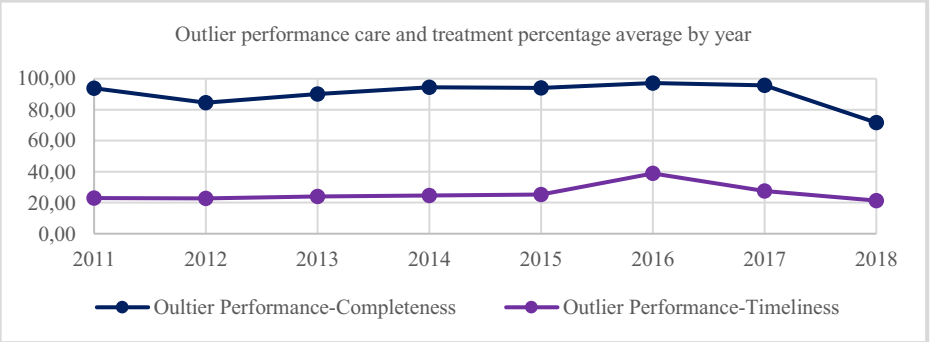


Figure 4. Care and treatment facility reporting outlier performance.

4. Discussion

In this paper we illustrate use of the k-means clustering algorithm as an approach in assessing retrospective HIV facility reporting to determine facility performance, as a way of informing reporting improvement mechanisms. These analyses provide at a glance view of various categories that emerge based on performance of facilities in meeting completeness and timeliness requirements in reporting. These results can be used by M&E teams to identify facilities whose performance is satisfactory or not, therefore providing a baseline for further evaluations and development of sustainable solutions.

Furthermore, due to the volume, velocity and veracity of health data consolidated from various sources, representing various facets of data in a way that makes sense is a challenge. In this study, we used line graphs, which are simple visualizations that can be used to represent data in a way that promotes development of insights at a glance. Figure 1 portrays an ideal situation of good facility reporting. If success is to be achieved in terms of meeting reporting requirements, then the ultimate goal for these evaluations should be to enable all facilities to attain and maintain similar results as illustrated in the best performing category. A common attribute among average, poor and outlier performance is the discrepancy between completeness and timeliness as represented by the gaps observed between them in the respective performance categories. There is therefore need for investigating issues that bring about delays more so in the outlier performance group, which has the largest gap in the completeness and timeliness measures. As the next step, we will further disaggregate the results by facility characteristics and geographic region, and also look at additional reporting domains.

5. Conclusions

The k-means clustering algorithm is essential in automatically finding homogenous groups within aggregate reporting data. This serves as a good baseline for monitoring the progression of health facility reporting performance by management and M&E teams that use large amounts of data collected from integrated data sources.

Ethical approval and Acknowledgements

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Coping with Information Technology Downtime in Hospitals: A Scoping Study

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Abstract. Downtime of information systems is a universal challenge faced by health care institutions. Regardless of whether downtime is planned or unplanned, the unavailability of essential information requires alternative solutions. In this paper, we conduct a scoping review of how hospitals deal with downtime. A total of 13 papers were included in the final analysis, and we found that coping can be grouped into three strategies; 1) Increasing communication, 2) Analog fallback, and 3) Restricted redundant systems. As the majority of coping mechanisms are related to increasing communication and analog fall back, our findings point to the importance of customizing coping mechanisms for individual healthcare institutions.

Keywords. Health Information Systems, Downtime, Coping, Failure

1. Introduction

Anecdotal stories about system breakdowns and information technology (IT) downtime are frequent in health care. We, the authors, have both been present at a large Danish hospital during such events. More investigations found that almost all healthcare institutions have experienced at least one unplanned downtime event [1]. This raises the question of how hospitals and their clinicians cope with downtime in order to ensure continued delivery of health services.

Information systems shapes work and communication [2]. However, this conjoint adaptation comes with a risk in the absence of technology. Consequently, any institution that relies on information and communication technology (ICT) seeks to ensure operational continuity through contingency planning as risk mitigation. The Safety Assurance Factors for EHR Resilience (SAFER) is one example of such work [3].

In this study, we refer to the unavailability of information systems as *downtime*. This unavailability may be planned or unplanned. Planned downtime may happen during planned actions as system updates or hardware failures. Unplanned downtime happens spontaneously. In any case, continuity of clinical services must be upheld. How the situation is handled depends on a plethora of factors; e.g., type and length of breakdown, system affected, user expertise, and experience.

We expect few experiences to be documented in literature. Thus, the aim of this work is to conduct a review of coping mechanisms for handling unexpected downtime in hospitals. We limit our focus to systems that can be fully, or partially, substituted with improvised solutions during the episodes.

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2. Method

The study was based on the recommendations of [4,5]. The search phrase was built iteratively by initial review of selected papers, and gradually adjusted as the search became more focused. The final search phrase used to include articles was ‘("technology failure" OR downtime) AND ("electronic health record" OR EHR OR "Information system" OR "electronic medical record" OR "Patient administration system" OR Paperless OR "Emergency care information systems" OR "Hospital Information Systems")'.

We searched Pubmed, Engineering Village, and Cinahl to include papers. All references were imported into Covidence, and screened by title and abstract. Following this, the full text of articles was reviewed and their findings systematized to distill key characteristics; type of study, aim, recommendations, and key coping mechanisms. Literature predating the year 2000 and those not focusing specifically on coping with downtime within the IT scope at hospitals of this study were excluded. Finally, the included literature was thematically analyzed to identify general coping categories.

3. Results

A total of 51 studies were assessed in full text, resulting in the inclusion of 13 studies for the final analysis (Figure 1). From the thematic analysis we structured the coping mechanisms into three categories: 1) *Increased communication* 2) *Analog fallback* 3) *Restricted redundant fallback*.

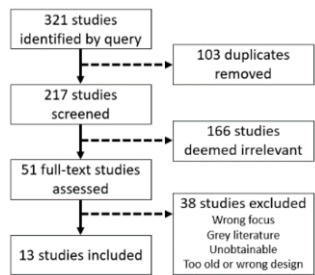


Figure 1. Inclusion of papers

Methods used to disseminate downtime ranged from case-based reporting from incidents due to natural disasters [6] and cyber-attacks [7], to aggregated narrative analysis of multiple events [8]. Observations and interviews [9], analysis of log files, to survey instruments. Likewise, the research settings varied considerably.

The findings of our analysis are distilled into Table 1 where we find confirmation in one of the key tasks of IT, namely to catalyze communication and ensure that information is made available when, and where, it is needed. In some cases institutions were aware of the growing disparity between electronic or paper-based documentation and consequently prepared an entire emergency toolkit in a storage bin containing paper forms ordered by category [6].

Table 1. Overview of results. Abbreviations used are Electronic Health Record (EHR), Care Provider Order Entry (CPOE), Clinical Decision Support System (CDSS), Laboratory Information System (LIS), Hospital Information System (HIS).

Category	Coping mechanism	Affected system	Cause
Increased communication	Phone [9–12], Alternative working procedures [7,11,13], Email [6], Command center [6],	EHR [6,7,10,13,15,16] CPOE [9]	System upgrade [10,14] System launch [11]
Analog fallback	Mass communication [14], Designated mediators [7,15,26]	LIS [12] HIS [14][11]	Hardware failure [6] Cyber-attack [7][16]
	Printed labels [8], White board [9,14], Supplementary Paper Forms [9,14,15], Notebooks [11,17],	EHR [6,8,15] CPOE [9]	System upgrade [14] System launch [11]
	Emergency Toolkit [6] [18],	CDSS [17]	Hardware failure [6]
	Printed [7,12,17], Ad-hoc logs [14]	LIS [12] HIS [7,11,14,18]	Cyber-attack [7] Natural disaster [18]
Restricted redundant systems	Use of offline computers [8], Read-only systems [6]	EHR [6] Med. Admin, [8]	Hardware failure [6]

The majority of downtime cases involve EHR or HIS systems, but also order entry systems, clinical decision support, and laboratory systems. The coping mechanisms were coupled to the type of system affected, e.g. we find that EHR downtime call for face to face communication and unstructured documentation in forms & notebooks.

4. Discussion

We strived to only include research publications. However, from our initial navigation of the field, it is evident that grey literature of all kinds actually includes a richer source of cases and experience. Analog fallbacks are the most prevalent coping mechanism. In relation to this, some of the excluded work contains useful recommendations and reflections on the interplay between backup-paper and, e.g., EHRs. Despite this, Lium et al. [19] state that EHR should not build upon a paper metaphor as this approach does not fully utilize the digital potential. We have found little to no description of if, or how, ICT systems are mimicked in their absence. This absence points to an interesting research opportunity, as we have anecdotal evidence for this happening during downtime.

Given the steady improvement of hard- and software technology, one might expect that the risk of downtime would diminish over time. Yet, as also indicated by the included studies, this is not the case. One reason is the growing connectedness and complexity of IT. Another cause is the threat of cyber-attacks of which we have seen several in the last few years. Consequently, not only should health organizations strive to boost the threat awareness and behavior of their staff, but also have clear procedures and guidelines in place given a collapse of IT systems.

5. Conclusions

The three coping strategies identified in this review, and the frequency by which they have been utilized, are indicative of the continued need for having fallback systems in place to handle lack of access to the IT systems. Although there are a number of research instruments available for gauging the impact of downtime, there is a need to harvest the experiences described in grey literature. Future work should also look at how we design IT systems that empower their end-users to deal with the lack of these same systems.

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PrositNG – A Machine Learning Supported Disease Model Generation Software

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Abstract. Decision models (DM), especially Markov Models, play an essential role in the economic evaluation of new medical interventions. The process of DM generation requires expert knowledge of the medical domain and is a time-consuming task. Therefore, the authors propose a new model generation software *PrositNG* that is connectable to database systems of real-world routine care data. The structure of the model is derived from the entries in a database system by the help of Machine Learning algorithms. The software was implemented with the programming language Java. Two data sources were successfully utilized to demonstrate the value of *PrositNG*. However, a good understanding of the local documentation routine and software is paramount to use real-world data for model generation.

Keywords. medical economics, markov processes, real-world data, machine learning, electronic health records

1. Introduction

1.1. Background

Health economic decision models (DM) play an essential role in the evaluation of new treatments, drugs or prevention programs. DMs depict the ‘typical’ progress of a disease or condition, e.g., cancer or diabetes. Markov Models (MM) are one of the most frequently used methods in the health economics domain [1]. An MM’s structure consists of several disease states $S=\{S_1,...,S_n\}$ and a maximum of n^2 transitions between them. Disease states should be defined as mutually exclusive and cumulatively exhaustive, i.e., each state should be a distinctive, well-defined step in the total disease process [2]. Trust, confidence and transparency are critical for DMs [3]. However, from a modeler’s perspective the effort to conceptualize, implement and validate a health economic model is of equal importance. Today, the process of DM generation is performed manually, supported by modeling suites such as TreeAge by TreeAge Software, Inc. [4] or general-purpose spreadsheet programs (SPM, e.g. Excel or LibreOffice Calc [5]). However, these software suites and their resulting DMs are not connected to real-world data sets or database systems, e.g., a hospital information system or a registry information system.

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Thus, medical progress has to be incorporated laboriously into a model, which leads to high development and maintenance costs.

Therefore, the authors propose a new model generation software that offers an interface to real-world medical database systems. As published previously, the structure of the model is derived from the entries in a database system by the help of unsupervised Machine Learning (ML) algorithms [2]. This DM generation software builds on the methodological groundwork of the PROSIT Online Disease Modelling Community [6], hence the name *PrositNG* (Next Generation) has been chosen.

1.2. Requirements

Persons who construct new DMs (‘modelers’) should be supported during the whole DM generation process. This includes the following steps: i) definition of disease states, ii) calculation of transition probabilities, iii) definition of cost & utility data, iv) performing the cohort simulation. Furthermore, *PrositNG* should enable modelers to ‘experiment’ with the given data, i.e., evaluate the influence of specific parameters or parameter values on the selection of patient cohorts, transition probabilities or health economic outcomes. This way, new hypotheses could be generated which can then be tested and examined in further steps or even addressed in new studies and clinical trials. Input of *PrositNG* should be configurable to support different kind of data sources or databases, e.g., CSV (comma-separated value) files, databases from disease registries, hospital information systems, etc.

2. State of the art

Today, the conceptualization of new MMs is in most cases done manually by pen and paper. SPMs can be used to implement MM calculations and cohort simulations. However, DMs built with SPMs cannot incorporate real-world patient data and are not connected to database systems from healthcare facilities. On the other hand, they are considered to be most transparent and widely available office software is sufficient when working with them. Specialized modeling software suites like TreeAge offer more features than SPMs and support additional modeling techniques, e.g., decision trees and microsimulation. TreeAge is capable to use patient data stored in an Excel/CSV file for bootstrapping and for input parameters. However, it offers no ML-based support for the selection of input parameters.

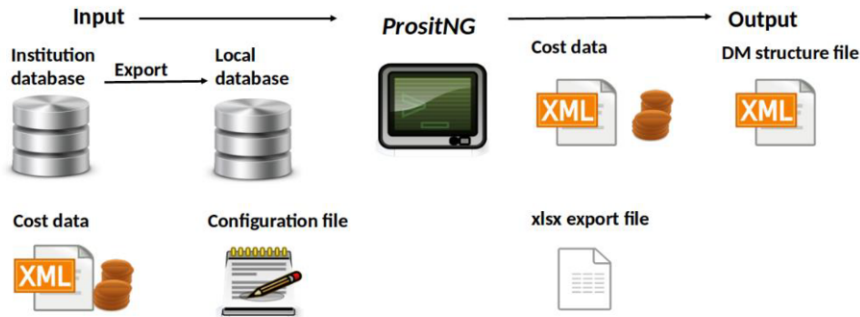


Figure 1. Input and output resources of the PrositNG modeling software suite.

3. Concept

Databases from health care providers as well as public/scientific use files should be integrated in *PrositNG*; this is achieved via a configuration file. In addition, the output of *PrositNG*, i.e., derived health economic models and results of cohort simulations should be exportable in an open, non-proprietary format (see Fig. 1). Unsupervised ML algorithms should support the construction steps of the DM: Cluster algorithms can pinpoint to meaningful combinations of parameters, i.e., valid definitions of disease states, in the real-world data set. Next, frequent combinations are used to derived transitions and their respective probabilities (details about the algorithms for model generation can be found in [2]).

4. Implementation

PrositNG was implemented with the programming language Java. PostgreSQL was chosen as local database system (see Fig. 1). The local database consists of i) a ‘flat’ primary table (one row represents exactly one case) and ii) a secondary table for progress information that is associated with a specific date field given in i). Currently, two data sources were successfully utilized: a) Local Cancer Registry [2], b) Study data from a Type 2 Diabetes screening program. The user interface is implemented with JavaFX components (see Fig. 2). We used the DBSCAN (Density-Based Spatial Clustering of Applications with Noise) implementation of the Weka collection [7] for clustering clinical parameters. DBSCAN allows for the specification of a minimum number of associated cases in a specific cluster.

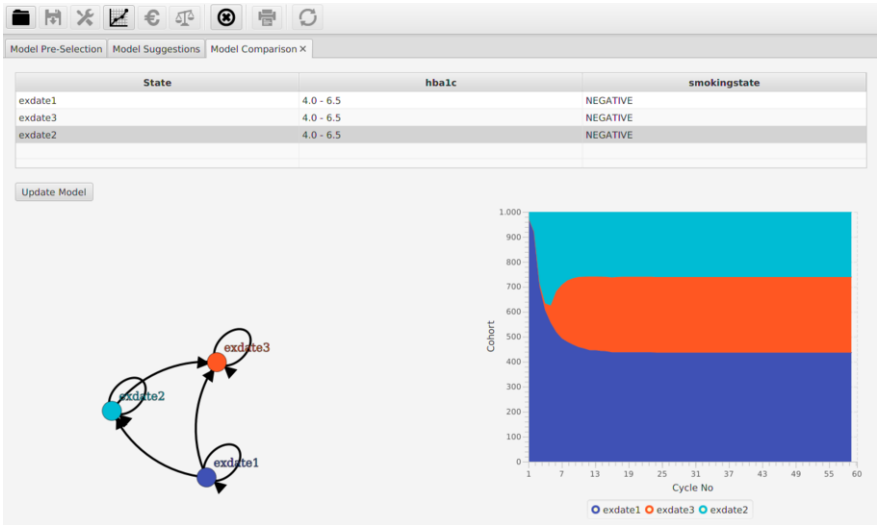


Figure 2. Screenshot of *PrositNG* – example result view: structure of 3-state DM (exdate1, exdate2, exdate3 indicate appointments for screening examinations, lower left corner), cohort simulation (x-axis: monthly cycles, y-axis: cohort members associated with a particular state; lower right corner). Data source: Type 2 Diabetes screening program.

5. Lessons learned (Discussion)

Cluster algorithms, like the used DBSCAN, can support in the selection of parameters based on frequency. Using frequent parameters could add robustness to a model or help less-experienced modelers. However, for an experienced modeler with a strong medical (documentation) background a software-generated suggestion for a cancer state like $T=3$, $N=0$, $M=0$, $surgery=true$, $radiation=false$ might be trivial as this equals well-known cancer stadium definitions. Furthermore, when relying only on frequently documented parameters *PrositNG* could not support the discovery of yet unknown correlations. This is a conflict we are still trying to solve. A good understanding of the local documentation routine and the documentation (software) system is paramount to correctly leverage real-world data for the construction of DMs. Modelers need a basic understanding of the underlying data structure and generation algorithms of *PrositNG* to evaluate the validity of the resulting models. In addition, such knowledge is needed to evaluate if and how new data sources can be leveraged for automatic model generation. Human intelligence is still indispensable.

6. Conclusions

PrositNG supports the process of automatic model generation, i.e., to construct disease states based on real-world data and to derive transitions. We could demonstrate that results of clustering can support modelers in the definition of a disease state. However, there are certain requirements for data sources that have to be met, e.g., precise date information, longitudinal data. Today, many publicly available scientific used files do not meet these criteria. Furthermore, consulting documentation staff is necessary to understand the content and meaning (semantics) of the documented data. Future work could include the development of *PrositNG* as a web-based solution as well as an online showcase for interested modelers.

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Implementation of a Secured Cross-Institutional Data Collection Infrastructure by Applying HL7 FHIR on an Existing Distributed EMR Storages

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Abstract. A secure data collection infrastructure was implemented in which Health Level-7 (HL7) Fast Healthcare Interoperative Resources (FHIR) was applied according to standardized electronic medical record (EMR) storage. This infrastructure aims to facilitate rapid secondary use of EMR data in cross-institutional analyses on the basis of the Standardized Structured Medical Information eXchange (SS-MIX), Japan's domestic standard for EMR export. Existing EMR storage comprised enormous numbers of HL7 v2 messages; therefore, the user interface and database structure are basically defined according to the HL7 v2 data types and message structures, causing difficulty in rapid extraction for researches by clinicians. To solve this problem, we are trying to enhance some user interface with HL7 FHIR, which needs SS-MIX items to be mapped through HL7 FHIR resources. We investigated definition gaps between HL7 FHIR and SS-MIX messages, and report a developed user interface with HL7 FHIR to query against existing storage.

Keywords. Privacy, Data Collection, Electronic Medical Records, HL7 FHIR

1. Introduction

Secondary use of electronic medical records (EMR) items over a public cloud is common around the world. During the process of extraction, integration, and anonymization of such data, privacy invasion is not allowed. To promote secure use of EMR items over a public cloud environment, we previously developed a cross-institutional, secure data collection system [1]. Key requirements of this system are (1) secure integration of extracted EMR items, (2) standardized EMR data sources, (3) privacy risk assessment of extracted data set, and (4) traceability of data transfer for patients. As a data source, we adopted the Standardized Structured Medical Information eXchange (SS-MIX) [2], which is the domestic standard for exporting whole EMR data to external storage in Japan. SS-MIX2, which is the next version of SS-MIX, is also based on Health Level-7 (HL7) v2 message files. This standardized storage is widely used for backing up data, regional collaboration, disease registries, and other research purposes. In this standard, we can represent definite states of 37 clinical events for each patient in a hospital,

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including admission–discharge history, medication history, and laboratory test results, using ADT/RDE/OUL HL7 v2 messages. The directory structure for stored records is based on patient ID, clinical date, and clinical event type. This structure hampers using exported data for cross-patient analyses such as epidemiological studies. Moreover, the data types and message structures are not familiar to clinical researchers, and some common model of sharing data is needed.

In view of this situation, we are trying to improve the user interface of the developed secure data collection system for querying EMR items in an SS-MIX2 storage. HL7 Fast Healthcare Interoperability Resources (FHIR) [3] is a strong candidate for building an intuitive user interface to handle the EMR items from existing EMR storage. However, at this time, sufficient materials for backward compatibility against HL7 v2 messages have not been provided, and it is difficult to apply already accumulated clinical information to this new standard. We describe the results of an investigation of EMR item mapping between SS-MIX2 and HL7 FHIR and the performance of the experimental system.

2. Methods

2.1. System Overview

Figure 1 depicts an overview of the developed system. EMR items can be exported to an SS-MIX2 storage as HL7 v2 message files according to a domestic standard. These message files are stored as blob records to the PostgreSQL v9.5 database system and converted into relational database tables in real time. By deploying a web interface that uses HL7 FHIR, queries can be processed using FHIR resources, and we tried to develop a query user interface for data collection. The web interface is implemented using HAPI FHIR Java library [4], which enables conversion of FHIR-based model objects and HL7 v2 message items.

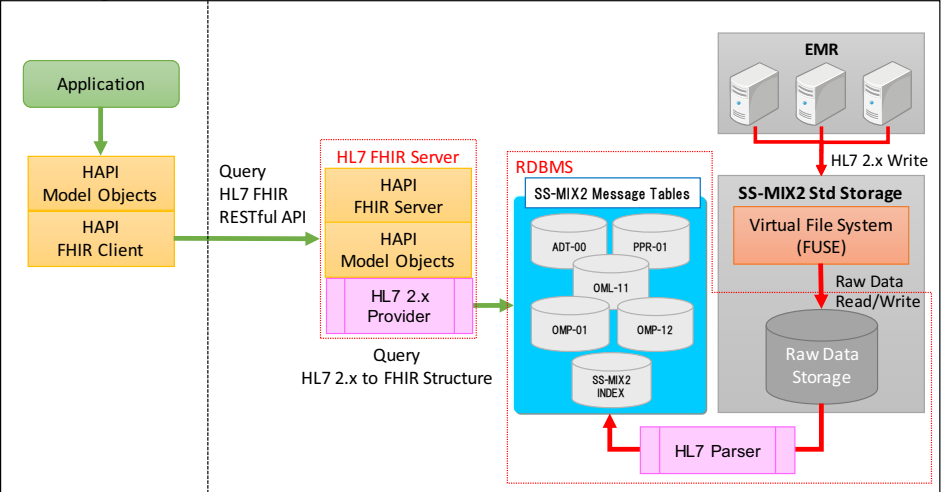


Figure 1. Overview of developed standardize storage using HL7 FHIR and SS-MIX2

Mapping EMR items between SS-MIX2 and HL7 FHIR for Intuitive User Interface HL7 FHIR is providing the resource item mappings for HL7 v2 messages on the HL7 US website. SS-MIX2 comprises 30+ HL7 v2 event messages, and the messages are

coded under the domestic standard. The FHIR mapping table has some deficiencies; some items need to be complemented by checking both coding definitions. We have performed item mapping complementation on the FHIR resources and we also developed a user interface for querying SS-MIX2 storage using HL7 FHIR resources according to the item mapping described above.

3. Results

3.1. Mapping EMR Items

There was little need to supplement the Observation resource. Table 1 shows the result of mapping ratio by FHIR resources. Although the mapping ratio scores are low, it was confirmed that this is partly due to the scattering of unused items on the SS-MIX2 side.

Table 1. Mapping Ratio of properties from FHIR Resources to SS-MIX2 Message Fields

No.	FHIR Resource	Property	Mapped	Ratio(%)
1	Patient	24	14	58%
2	Encounter	40	11	25%
3	Condition	20	12	60%
4	AllergyIntolerance	22	13	59%
5	Observation	33	20	60%
6	Specimen	27	7	25%
7	ServiceRequest	33	17	51%
8	MedicationRequest	40	20	50%
9	MedicationDispense	28	16	57%
10	Dosage	15	8	53%

3.2. User Interface

An intuitive user interface for querying existing SS-MIX2 standardized storage items have been developed. Query items can be chosen by FHIR resource vocabulary. The user interface has an area for specifying search conditions and output items, respectively.

3.3. Performance

Queries yield the expected response if the number of records is approximately 100,000. With a larger number (e.g., >10,000,000), the query response is poor owing to the database structure of the original SS-MIX2 message tables. This was caused by the database performance of joined SELECT across different segment tables.

4. Discussion

This study showed that the data extraction function for clinical research with an intuitive interface using HL7 FHIR vocabulary can be constructed with the standardized storage system widely deployed in Japan, indicating a cost-effective reconstruction of data

extraction or data exchange infrastructure without wasting previous capital investments for existing SS-MIX2 standardized storage items.

Herein, we conducted mapping of EMR items in only several HL7 FHIR resources. The remaining resources and HL7 v2 segments remain to be investigated. By nature, mapping differences persist because HL7 FHIR resources are defined according to HL7 v3 reference information model (RIM); thus, complementing the mapping gaps between HL7 v2 and v3 may remain. To achieve our minimum goal, we need to represent HL7 v2 messages as an FHIR resource, including domestic description standards and EMR item mappings for HL7 v2.

Improvement in database performance is needed when the number of data is large. Further, for our secure data collection, a system based on Bloom filter [1] needs elements of patient identification, such as insurance number, date of birth, and gender, to eliminate duplication of patient data in cross-institutional data extraction. We will continue to develop a patient deduplication mechanism. Moreover, since the developed correspondence table between SS-MIX2 and FHIR can be used for automatic generation of conversion modules, we started development of such a deployment mechanism.

5. Conclusions

This paper reports the initial performance results related to a user interface and query system with HL7 FHIR for secure data collection. We examined the mapping of EMR items between existing HL7 v2-based standardized EMR storage and HL7 FHIR definitions. We also proposed an implementation method for using existing HL7 v2-based storage and deploying HL7 FHIR message structures for the user interface.

Acknowledgments

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Towards an Architecture for the Interoperability of Hospital Information Systems in Burkina Faso

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Abstract. The successful introduction of ICTs into medical practice is a key factor in improving the performance of any health system for both patients and healthcare professionals. In Burkina Faso, many hospital information systems (HIS) have been developed and are already widely used in large health centers with proven efficiency. To improve the quality of patient care, these hospital information systems should exchange information. Interoperability is one of the privileged ways to improve the integration of different systems because nowadays a HIS is no longer just a single monolithic software system, which is run on a single machine. This paper presents a semantic interoperability architecture, which is based on a mediation approach. The mediator implements local domain ontologies for each HIS, a knowledge base, and a referential ontology which is used as a semantic repository and web services.

Keywords. Hospital information system, Interoperability, ontology, architecture

1. Introduction

Nowadays, many Hospital Information Systems (HIS) [1] are in operation in the major health centers most parts of the world, and more particularly in Burkina Faso [2,3]. Thanks to the electronic patient record, these systems, contribute to a better coordination of care, the collection of information relating to the patients and the improvement of the communication between health professionals [4]. For a better coordination of health services, most hospitals need to communicate by sharing of knowledge. Interoperability between hospital information systems is therefore an imperative. It has been defined in different ways in the literature [5], [6]. Interoperability between systems can therefore be summarized as the ability of these systems to exchange semantically consistent information and data which can be used by all. Different approaches to the interoperability of hospital information systems have been proposed in the literature. In [7], the authors have proposed an eHealth solution. However in their approaches, systems are heterogeneous and autonomously managed making it difficult to exchange information and knowledge between different information systems. As a result, health workers face an inconsistent work environment. In [8], the author offers an interoperability solution based on Web services. According to [9], Web Services do not support semantics. So in [10], the authors propose an approach based on Semantic Web tools. However, the authors

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mention some difficulties in aligning web services standards with those of the medical field. This alignment is a key factor in successful interoperability. In [11], the authors propose an interoperability solution between hospital information systems and SOA as a basis for the design, execution, deployment and invocation of services. The work of [12,13] studies the interoperability approach based on semantic services. The development of these services is also based on standards or norms in order to bring the hospital information systems into agreement with the structure of the data exchanged. There are many organizations have developed standards for medical informatics around the world. They include: HPRIM2, HL73, CEN TC2514, DICOM5 standard and the IHE6. Standard should also be noted that the XML standard is the predominant one for describing data. According to the work of [14], there are two standardisation approaches for interoperability in HIS: syntactic standards and semantic standards. The correct transmission of medical and administrative data between heterogeneous and distributed hospital information systems is based on syntactical standards [15]. These are mainly HL7 / CDA, DICOM and EDIFACT. On the other hand, semantic standards guarantee the correct interpretation of the content of the data exchanged electronically. The established standards are LOINC, SNOMED and UMLS. Unfortunately, the diversity of norms and standards poses serious problems for data integration. In this context, the authors of [16] propose that the transfer of medical data be based on international standards. A system based on IEEE 11073 for the communication of medical devices, CEN/ISO7 13606 for the modeling of health record information and then HL7 and IHE profiles for communication between hospital information systems and data storage. Furthermore, the semantic interoperability approach which is based on ontology has been studied in the work of [17]. The purpose of the semantic interoperability is to ensure that the exchanges that take place between the interconnected components retain their meaning. In our study, we propose a semantic interoperability architecture. Our approach is based on the composition and mediation of Web services. The rest of the paper is organized as follows: In section 2, we present the approach adopted as well as the architecture used by the approach. In section 3, we position our work in relation to other papers through a discussion. Finally, in section 4 we will conclude and present the prospects of our work.

2. Methods

According to [18], the composition of web services consists in combining the functionalities of several web services in a business process. Two methods of performing the composition are used: orchestration and choreography. In orchestration, a main web service takes control of the evolution of the composition and coordinates the different operations of the different web services. Choreography is not based on a main web service. Each of the services involved in the composition knows precisely what to do, when to do it and with whom to do it. Mediation is an aspect of composition [18] which is used to resolve conflicts caused by heterogeneities which may appear between web services. This is to ensure their interoperability. Mediation

² <http://www.hprim.org>

³ <https://www.hl7.org>

⁴ <http://www.cen251.org>

⁵ <https://www.dicomstandard.org>

⁶ <https://www.ihe.net>

⁷ <https://www.iso.org/obp/ui/#iso:std:iso:13606:-1:ed-1:v1:fr>

tasks can be classified into three levels of mediation: data, functionalities and business processes. Our architecture is based on a set of ontologies of domains and services. An extended description of web services is made by annotating them. The purpose of this description is to link these web services to their semantic descriptions. The heart of our architecture is a semantic mediation infrastructure, supported by a web data or process mediation service. Semantic process mediation [19] is implemented by a choreography mediation algorithm which manages the conversation between services. It uses annotated descriptions, the repository of ontologies, and uses an inference engine and a rule base. It also calls for data mediation. During this mediation several syntactic and semantic mappings are executed. Figure 1 illustrates the proposed architecture. The main components are : (i) WSDM A (Web Service of Data Mediation A): the link between HIS A and the mediation system ; (ii) WSDM B (Web Service of Data Mediation B): the link between HIS B and the mediation system; (iii) LOA (Local Ontology of A): the latter is used to enrich the requests sent by Hospital A and to make the answers more understandable by Hospital A; (iv) LOB (Local Ontology of B) is used to enrich the requests sent by Hospital B and to make the answers more understandable by Hospital B; (v) WSDM (Web Service of Data Mediation) it enriches queries using syntactic and semantic mappings across the knowledge base and referential ontology; (vi) Knowledge Base is the body of knowledge (ontologies, schema rules) in the field of health in Burkina Faso, useful for enriching requests and responses; (vii) Referential Ontology is a set of existing ontologies in the medical field; (viii) the mediator is an intermediary between the different HIS. It is a software component that solves the semantic problem.

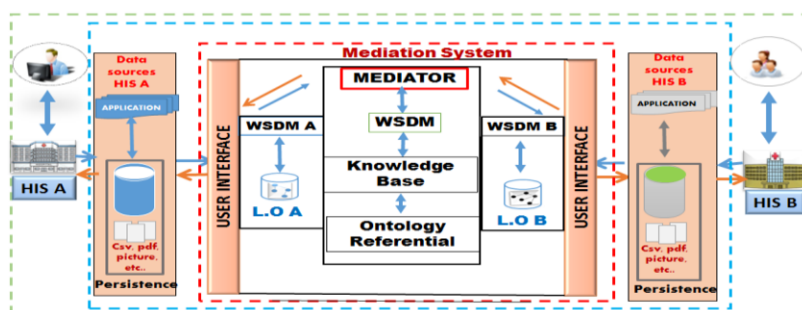


Figure 1. Architecture for the interoperability of HIS.

3. Discussion

After reading several research papers, we have distinguished two categories of approaches for the description of web services: (i) the category of approaches based on the semantic description languages which are derived from the semantic web (ii) the category of approaches which are based on annotations of descriptions of web services, which exploit the elements of existing language extensibility. The category, which is based on annotations, has more advantages than the one on the semantic description languages as long as they exploit existing standards of web services. In order to improve mediation, it is necessary to adapt the local semantic of web services to the semantics of the shared ontology. In our research, we have opted for the category based on annotations of the description of web services and a semantic model based on ontologies as well as on the notion of context. Therefore, our conceptual model allows

us to have an efficient semantic mediation because it has the following advantages: (i) there is no single representation of information (common ontology). Service providers may not be needed to adapt their local semantics (ii) semantic heterogeneities are clearly shown. They can consequently be interpreted and settled in an automatic way.

4. Conclusions and Future Work

In this paper, we have presented a classification and a comparative study of work in the field of interoperability of HIS. Following this study, we have opted for service-based approaches. Our approach is based on the annotation of the descriptions of the services by ontologies so as to propose a semantic web services-based architecture for the implementation of the interoperability mechanisms of HIS in Burkina Faso. One of the main problems encountered in the implementation of our approach is the identification of referential ontologies. In the future work, we plan to continue the implementation of the various components of the proposed architecture.

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The HiGHmed Didactical Framework for Online Learning Modules on Medical Informatics: First Experiences

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Abstract. Within the HiGHmededucation consortium various online learning modules shall be developed by members of the consortium to address the increasing need for skilled professionals in a networked and digitalized healthcare system. Transferability of these modules to other locations is one main objective for the design of online learning modules. Thus, a didactical framework for online learning modules was developed. To ensure feasibility of the framework, the participating universities were analyzed concerning availability of e-learning support structures and infrastructures including learning management systems (LMS). The analysis especially focuses on the various LMS learning tools and their suitability for the framework. The framework is the basis for 12 HiGHmededucation online learning modules of which a part has firstly been conducted in winter 2019/20 and leads to a comparable structure of the modules.

Keywords. Medical Informatics, Online Learning, Education, Health Care

1. Introduction

As part of the Medical Informatics Initiative (MI-I), the German Federal Ministry of Education and Research (BMBF) supports four consortia to develop structures and technology which meet the requirements for exchanging and analyzing data from clinical research and health care across different sites. One objective of the MI-I is the training of specialists to address the risk of an increasing shortage of skilled professionals in medical informatics (MI). In addition, health care professionals and patients need training to gain digital skills needed to face the digital transformation in health care. HiGHmed is one of the funded consortia [1]. The HiGHmededucation program aims at

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² Members can be found at <https://education.highmed.org/network/project-partner>

developing online learning modules at currently 14 universities to address the MI training needs of an increasingly networked and digitalized healthcare system. To enable the combination of these modules in a HiGHmeducation certification program and their use at different universities a common and transparent didactical framework is needed. That must consider state of the art online teaching requirements which promote communication and cooperation between learners as well as the construction of new knowledge through work tasks as the main factors for successful e-learning [2][3]. This paper presents the didactical framework that has been developed for the HiGHmeducation online modules and discusses its use for the conduction of 8 modules in the winter term 2019/2020. But besides a suitable didactical framework, creating online courses requires technological support. In order to define online tools suitable for implementing the didactical framework and to ensure feasibility of the online modules, the availability of learning management systems (LMS) and e-learning support structures at the participating universities was evaluated and an overview of available digital learning tools in current LMS was created.

2. Methods

2.1. Evaluating of available e-learning software and support structures

In a survey to gather information about utilized e-learning software at each participating university information was captured on the available LMS, the department responsible for operating the LMS as well as information on the local integration of the authentication mechanism by the German DFN AAI infrastructure [4] allowing students to use LMS at other universities.

2.2. Development of a didactical concept for online learning modules

Starting point of the development of the didactical framework is the HiGHmeducation module catalogue. This catalogue is a competence-based description of the set of modules offered by HiGHmeducation. For the development of the didactical framework, a group of experts experienced in online based teaching exchanged information with other e-learning experts, organized workshops and took part in e-learning training courses. Based on these experiences and in consideration of the already existing module catalogue, a didactical framework for the online learning modules was developed.

3. Results

3.1. Available e-learning software and support structures

When the survey was started, 11 universities were part of the consortium. Each of them has at least one and a maximum of three e-learning related service facilities. The facilities have 7.4 employees on average, while this number ranges from 3 to 15. The services of all facilities focus on the counselling and training of lecturers for the production and utilization of e-learning content and the operation of the LMS, which includes hosting and administration as well as first level support. Rare offerings are in-house development

projects and dedicated services for e-assessments. The main LMS utilized at the universities were ILIAS, Moodle and Stud.IP. Some universities utilize more than one LMS. In order to enable comparability of the different LMS, a list of available digital learning tools like wikis, blogs, forums as well as assessment tools like portfolios, tests and surveys has been created. In total, 29 different digital tools were identified. Each tool was mapped to the corresponding tool of the three LMS, if one exists. Additionally, a description of the functionality of the tools was added. The mapping shows that not all LMS offer all 29 digital learning tools. The system with the highest coverage features 97 % of the digital learning tools (see table 1).

Table 1. Coverage of the 29 digital learning tools in different learning management systems

Learning management system	Number of digital learning tools	Coverage
ILIAS 5.3.7	28	97 %
Moodle 3.5	27	96 %
Stud.IP	11	41 %

3.2. Didactical framework for design and implementation of online learning modules

The framework describes a basic didactical procedure in which each module consists of five phases (see Figure 1). These phases aim at activation of the learners, knowledge transfer, self-directed processing of learning tasks, learning success control and feedback. In each phase digital learning tools can be used to promote a sustainable learning success by motivating learners to interact with the subject matter and by enabling communication and collaboration between learners. A significant approach incorporated in phase three is the use of so called e-tivities, a concept developed by Salmon [5]. E-tivities are a special kind of exercises used in the context of online learning and collaboration.

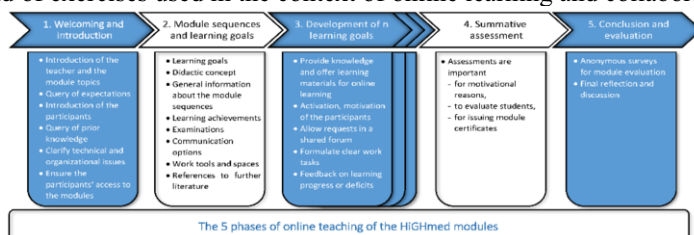


Figure 1. Phases 1 – 5 of the common didactical framework for HiGHmeducation modules

The framework was the basis for the development of 12 HiGHmeducation online modules which were conducted initially as part of a study program at one of the universities. Beginning with the next term the modules are open for interested learners in the healthcare domain of all universities of the HiGHmeducation consortium. The ECTS offered for the courses range from 1 to 6, target groups are students and scientists in the fields of medical informatics, medical information management and medicine as well as healthcare professionals [6].

4. Discussion and Conclusions

At all participating universities, LMS and support structures for the implementation of digital learning offerings are available. This corresponds to the results of Back et al. In 2013, they asked 48 medical faculties in Germany, Austria and Switzerland about their e-learning activities [7]. 34 faculties participated in the survey, 97% use at least one LMS

and each of them had support structures. The surveyed universities named the LMS Moodle, ILIAS and Stud.IP. These systems are among the most frequently used LMS in Germany, according to a survey of 204 universities in 2015 [8]. Our comparison of these LMS also shows that many different digital learning tools - in minimum 11 - are available (cf. table 1). Not all digital learning tools are available in each LMS, it is often possible to add them through plugins. Thus, the implementation of digital learning opportunities seems not to be a technical problem at any of the participating universities. In order to enable competence acquisition at a higher level not only the technical side of online learning must be taken into account. Rather, digital learning offers are necessary which enable social interaction and a constructive examination of the learning material. For Kerres and Schulmeister, communication and collaboration in digital learning processes play an important role [2][3] and Ammenwerth and Hackl [9] have shown that the use of e-tivities [5] can stimulate these communication processes. Our didactical framework, including a matrix of available digital learning tools, provides a tool to design online learning modules. Through this framework lecturers and students have a similar didactical approach to the modules, even if using different LMS. Despite the standardization, the framework offers lecturers sufficient opportunities to design their courses individually. The first conduction of online modules in 2019/2020 demonstrates the usability of the framework, but further steps are necessary to evaluate its effectiveness, to ensure inter-institutional transferability and to clarify regulatory issues. Online learning offers a variety of possibilities to support learning. A common didactical framework aims at designing online courses that follow a comparable structure. Such a framework is an important step towards the cross-location use of online learning offers.

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Assessment of HIV Data Reporting Performance by Facilities During EMR Systems Implementations in Kenya

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Abstract. There is little evidence that implementations of Electronic Medical Record Systems (EMRs) are associated with better reporting completeness and timeliness of HIV routine data to the national aggregate system. We analyzed the reporting completeness and timeliness of HIV reports to Kenya's national aggregate reporting system from District Health Information Software 2 (DHIS2) for the period 2011 to 2018. On average, reporting completeness improved to 97% whilst timeliness increased to 83% in 2017 with similar performance for the facilities under study that implemented either KenyaEMR or IQCare. However, in 2018, the reporting rates dropped by 13% for completeness and 11% for timeliness most likely due to changed reporting procedures. This suggests that besides EMRs, there are other factors influencing reporting such as reporting routines, which need to be assessed separately. Nonetheless, the EMRs have facilitated the collection of HIV data for submission to the DHIS2, which in turn facilitates the reporting process for the data officers.

Keywords. KenyaEMR, IQCare, HIV data, reporting, timeliness, completeness

1. Introduction

Many healthcare facilities in developing countries are increasingly using Electronic Medical Record Systems (EMRs) during patient care, despite challenges of unstable power supply and human capacity[1]–[3]. Mostly, the EMRs implementations in these settings are as a result of the President's Emergency Plan for AIDS Relief (PEPFAR) initiatives with a view to support HIV patient data management[4]. As such, the EMRs majorly support HIV services encompassing prevention, testing, care and treatment. Due to socio-technical challenges in developing countries, adoptions of the EMRs in the healthcare facilities differ in maturity levels. This has led to varying modes of operation with some settings using paperless, point of care approaches, retrospective data entry, or a hybrid approach[5][6]. These approaches potentially have variable impacts on the intended EMRs benefits.

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KenyaEMR and IQCare are among the major EMRs accredited to support HIV healthcare delivery services within facilities under the Ministry of Health (MoH) in Kenya[7]. On the other hand, the District Health Information Software Version 2 (DHIS2), a web-based open source system, supports collection and analysis of both routine and non-routine aggregate reporting health services data drawn from healthcare facilities countrywide [8].

With the prevalence of EMRs implementations in countries like Kenya, it remains unclear what their contribution is to quality of aggregate data in support of data-driven decision-making. This paper explores the impact of EMRs implementation efforts on quality of reporting of HIV indicators in developing countries with particular focus on completeness and timeliness of reports to DHIS2 maintained by Kenyan MoH.

2. Materials and Methods

Facilities are required by the MoH to submit HIV routine data on six programmatic areas based on a summary reporting tool for HIV referred to as MOH731 by the 15th day of every month. DHIS2 aggregate system was used to obtain HIV routine data reports for the period 2011 to 2018 on HIV counselling and testing (HTS) and care and treatment (C&T) programmatic areas for all healthcare facilities in Kenya. Systematic procedures were used to clean the data. The data sets generated and analyzed in this paper are available in the national DHIS2 online database <https://hiskenya.org/dhis-web-commons/security/login.action>. The EMRs were implemented in the facilities on varying dates from November 2012 to September 2014 for KenyaEMR and August 2012 to July 2016 for IQCare.

Descriptive analyses were conducted to compare performance in reporting completeness and timeliness by the facilities during the period 2011 to 2018. Timeliness refers to whether reporting facilities submit their reports according to the timeline set by the MoH. Completeness is the extent to which the expected reports are successfully submitted to the national reporting system. The facilities (*n*) included in the study were those which submitted MOH731 reports to DHIS2 and progressively implemented either KenyaEMR or IQCare systems. The variations in *n* was due to the establishment of new facility sites during the years under study. All analyses were conducted using SPSS.

3. Results

Table 1 shows the rates of reporting completeness and timeliness in 2011 (pre-EMRs) and in 2012-2018 when facilities progressively rolled out EMRs. There was a steady improvement of reporting timeliness and completeness across facilities with and without EMRs during the study period. In the year 2012, significant reporting rates are seen when only a few EMRs were introduced averaging around 56% and 40% in reporting completeness and timeliness respectively. On average, reporting completeness improved to 97% whilst timeliness increased to 83% by 2017 with similar performance for the facilities implemented either KenyaEMR or IQCare. However a noticeable drop in performance is seen in 2018 with an average drop of 13% in completeness and 11% in timeliness of reporting. Anecdotal evidence suggests that there was a change in reporting routines, which could have negatively affected reporting on the two programmatic areas.

Table 1. MOH 731 Reporting completeness and timeliness averages in %

Year	KenyaEMR		HTS		KenyaEMR		C&T	
	KenyaEMR		IQCare		KenyaEMR		IQCare	
	n=74		Pre-EMR Implementation		n=49		n=41	
2011			n=57					
Completeness	15.98 ± 8.71		16.95 ± 9.19		15.30 ± 7.88		17.08 ± 9.50	
Timeliness	5.96 ± 7.99		5.41 ± 6.96		5.78 ± 8.02		4.87 ± 6.98	
EMR Implementation status	With EMR	Without EMR	With EMR	Without EMR	With EMR	Without EMR	With EMR	Without EMR
	n=4	n=226	n=3	n=223	n=4	n=219	n=2	n=214
2012								
Completeness	56.25 ± 27.55	71.17 ± 25.18	58.33 ± 44.13	70.00 ± 25.10	56.18 ± 25.90	65.76 ± 25.65	70.85 ± 29.49	65.01 ± 26.05
Timeliness	41.68 ± 34.03	58.33 ± 25.15	38.9 ± 34.70	51.90 ± 25.71	33.25 ± 34.08	52.69 ± 26.05	45.85 ± 29.49	45.71 ± 23.53
2013	n=104	n=152	n=105	n=137	n=103	n=152	n=105	n=126
Completeness	92.80 ± 12.97	91.41 ± 14.35	92.31 ± 12.92	89.91 ± 16.85	91.20 ± 14.82	87.23 ± 21.06	88.74 ± 15.77	87.72 ± 19.66
Timeliness	77.65 ± 23.53	81.47 ± 19.87	76.36 ± 22.92	78.54 ± 22.88	73.23 ± 24.70	73.49 ± 27.38	64.10 ± 30.17	69.44 ± 27.71
	With EMR		n=227	n=15	With EMR		n=225	n=15
2014	n=260				n=259			
Completeness	97.44 ± 6.97		95.60 ± 8.88	97.79 ± 3.80	96.53 ± 8.87		95.45 ± 10.61	93.34 ± 17.03
Timeliness	85.90 ± 17.53		83.09 ± 19.30	75.03 ± 27.29	80.05 ± 21.30		75.44 ± 26.75	71.11 ± 27.93
2015	n=261		n=239	n=2	n=260		n=241	n=2
Completeness	99.27 ± 2.86		97.88 ± 7.03	79.15 ± 29.49	98.95 ± 3.74		97.10 ± 7.81	75.00 ± 35.36
Timeliness	90.05 ± 17.57		81.33 ± 26.11	62.50 ± 5.94	84.24 ± 22.36		78.07 ± 23.79	54.15 ± 5.87
	With EMR		n=241		n=260		With EMR	
2016	n=260				n=260		n=243	
Completeness	99.36 ± 2.43		97.76 ± 5.83		99.08 ± 3.00		98.33 ± 4.80	
Timeliness	94.12 ± 9.48		87.52 ± 14.04		83.73 ± 20.29		75.16 ± 24.87	
2017	n=260		n=243		n=259		n=244	
Completeness	98.24 ± 5.22		96.27 ± 8.68		98.75 ± 3.85		96.56 ± 9.06	
Timeliness	90.91 ± 12.72		83.17 ± 16.26		85.01 ± 19.37		73.67 ± 24.67	
2018	n=261		n=243		n=259		n=243	
Completeness	70.10 ± 23.85		66.30 ± 23.34		69.38 ± 23.96		66.48 ± 23.37	
Timeliness	67.01 ± 24.58		60.48 ± 23.99		62.47 ± 26.55		57.74 ± 26.50	

4. Discussion

The descriptive statistics concerned the two major EMRs implemented in Kenya, namely KenyaEMR and IQCare. The study looked at the two most common HIV services as required by the MoH, which are HTS and C&T. Since the systems are used at the front end of the data management, it was of interest to understand their contribution to the mandatory national monthly reporting of the HIV indicators to DHIS2 system over time. The data collected within the EMRs is not directly reported into the DHIS2 and therefore the analyzed data can only provide evidence about reporting in general terms. The

increase in reporting performance in 2013 could be attributed probably to the EMRs, but the best evidence for that would be anecdotal. Nevertheless, the inbuilt reports generation functionality in EMRs could have facilitated in the collation of HIV data, which in turn expedites the reporting process for data officers to the DHIS2. Additionally, some benefits could have arisen from the user support and e-learning resources offered by the implementing partners [9]. The method applied in this study can be replicated to data from other disease types.

The study reported here did not investigate aspects such as organizational factors, human resource, patient load factors, and financial resources. It is less clear what reporting routines were established prior to the introduction of the electronic records. However, it seems that the routines and procedures contributed to the improvement in the completeness and timeliness of reporting.

5. Conclusions

The study investigated the performance in HIV indicators reporting using descriptive statistics that included two EMRs namely; IQCare and KenyaEMR. The completeness and timeliness of reporting rate was high. However, it is easier to assume than approve that EMRs solely contribute to the success of reporting since there are other factors to consider such as organizational, human, patient load, and financial resources, which can be explored in future studies.

Ethical approval and Acknowledgements

Ethical approval was obtained from the Institutional Review and Ethics Committee in Moi University (MU/MTRH-IREC FAN:0003348). This work was supported in part by the NORHED program (Norad: Project QZA-0484). The content is solely the responsibility of the authors.

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Validation of an Automatic Wrist Blood Pressure Monitor in a Critical Care Setting

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Abstract. Invasive blood pressure (IBP) is the gold standard method for BP monitoring in critically ill patients. However, due to practical difficulties and complications, noninvasive methods may offer an alternative. We aim to evaluate an automatic oscillometry-based wrist BP monitor in critically ill patients compared to IBP. Forty five adult patients were included, and systolic, diastolic and mean BP (SBP, DBP, MBP) were simultaneously measured by IBP in the radial artery and by non-invasive blood pressure (NIBP) monitoring using the OMRON RS7 automatic wrist monitor. NIBP and IBP (mean $\pm$ SD) were: SBP 114 $\pm$ 18 vs 130 $\pm$ 18; DBP 63 $\pm$ 13 vs 63 $\pm$ 13; MBP 80 $\pm$ 13 vs 86 $\pm$ 15 mmHg. Bland-Altman analysis of the differences (NIBP-IBP) mean bias was: SBP -16; DPB 0.5 and MBP -6. The OMRON wrist monitor may not be sufficiently accurate compared to IBP in critically ill patients.

Keywords. Critically ill, noninvasive, wrist monitor, oscillometry

1. Introduction

Invasive blood pressure (IBP) monitoring is the current practice in Intensive Care Units (ICU) for continuous hemodynamic monitoring of critically ill patients and is considered to be the gold standard. However, there are often obstacles in implementation, comprising difficulties in placing of arterial catheters, catheter-related complications, as well as discomfort of the patient [1, 2]. Non-invasive monitoring is gaining ground as it is simpler, with less complications and minimal discomfort. Non-invasive blood pressure (NIBP) monitoring is a widely used method in the prehospital care, the wards, the outpatient clinics and the emergency room [3]. NIBP monitoring devices have been developed and validated mostly in stable patients in and out of the hospital [1]. The present study aims at investigating the validity of a wireless automatic wrist blood pressure monitor in the critical care setting compared to IBP.

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2. Methods

The study was conducted in an adult ICU of a tertiary teaching hospital. We included all consecutive critically ill patients, admitted to the ICU from January 15 to March 15, 2020, who already had an indwelling arterial catheter in a radial artery. We excluded patients who had arterial lines placed in other sites or did not have an arterial line. Continuous IBP was considered as the reference method. Informed consent was given by all study participants or their next of kin.

NIBP measurements were conducted using the OMRON RS7 Intelli IT HEM-6232T-E, a wireless automatic wrist BP monitor with a liquid-crystal display (LCD) screen. This is a compact device working on batteries, using a cuff oscillometry-based method of blood pressure measurement to the wrist with an electric inflation pump and a rapid automatic deflation system. It gives digital readings of systolic and diastolic BP (SBP, DBP), in a wide pressure range (0-299 mmHg) as well as a pulse rate (PR) reading (range 40-180 beats/min). It also employs Bluetooth technology for wireless connection with smart devices. The wrist cuff is eligible for BP measurements in subjects with a wrist circumference of 13.5-21.5 cm, making it suitable for obese patients as well. Position of the wrist at the level of the heart is required for a valid measurement, while a light indicator on the screen identifies the correct position. This device has been validated according to International protocols [4]. IBP measurement through a radial artery catheter utilizes an intra-arterial monitoring system comprising of the measuring apparatus (a closed tubing system filled with saline), the transducer and the monitor [5]. The transducer was calibrated at the level of the aorta and optimal damping of the system was ensured before every measurement.

We conducted one pair of simultaneous IBP and NIBP measurements in every eligible patient as follows. The wrist monitor was applied to the wrist opposite to the one with an arterial catheter. The correct position of the wrist was confirmed by the light indicator. NIBP measurement was conducted and the SBP and DBP were displayed on the screen and recorded. The mean BP (MBP) was calculated using the equation: $(SBP + 2 \times DBP) / 3$. At the same time the IBP reading (comprising SBP, DBP and MBP) was recorded from the bedside monitor. We also recorded demographic and clinical data: gender, age, SOFA severity score and the current hemodynamic status.

The correlation of paired measurements was estimated by the Pearson correlation coefficient and linear regression analysis. Bland-Altman plots were generated to test the agreement of the two methods and the mean bias and limits of agreement (LOA) were calculated. A p value <0.05 was considered significant. For clinical interpretation, BP differences ≤ 10 mm Hg were considered acceptable [6]. Statistical analysis of data was performed by the statistical package IBM SPSS® v24 for Windows.

3. Results

Forty five critically ill patients (27 male/18 female, median age 70, range 39-89 years) were enrolled. Mean SOFA score was 7 ± 2 . Regarding hemodynamics, 13 patients were stable, 13 were in shock, receiving vasopressors and 19 were hypertensive receiving antihypertensive treatment. NIBP and IBP measurements are shown in Table 1. Correlation analysis showed a strong correlation of systolic, diastolic and mean NIBP and IBP measured. Regression analysis estimated the R^2 as shown in Table 1.

The differences of BP (NIBP-IBP) expressed as mean bias $\pm$ SD (95% CI) were: SBPdif, -16.2 ± 9.6 (-19, -13.3); DBPdif, 0.5 ± 9.7 (-2.5, 3.4); MBPdif, -6 ± 8.4 (-8.6, -3.5). The bias, upper and lower limits of agreement were: SBP, -16.2 (-35, 2.6); DPB, 0.5 (-18.5, 19.5) and MBP -6 (-22.5, 10.5) (Fig.1).

Table 1. NIBP and IBP (mean $\pm$ SD, mmHg) measurements in 45 critically ill patients.

Blood Pressure	NIBP	IBP	r	p	R ²	p
SBP	114 $\pm$ 18	130 $\pm$ 18	0.861	<0.001	0.741	<0.05
DBP	63 $\pm$ 13	63 $\pm$ 13	0.709	<0.001	0.502	<0.05
MBP	80 $\pm$ 13	86 $\pm$ 15	0.838	<0.001	0.702	<0.05

SD, standard deviation; r, Pearson’s correlation coefficient; R², coefficient of determination

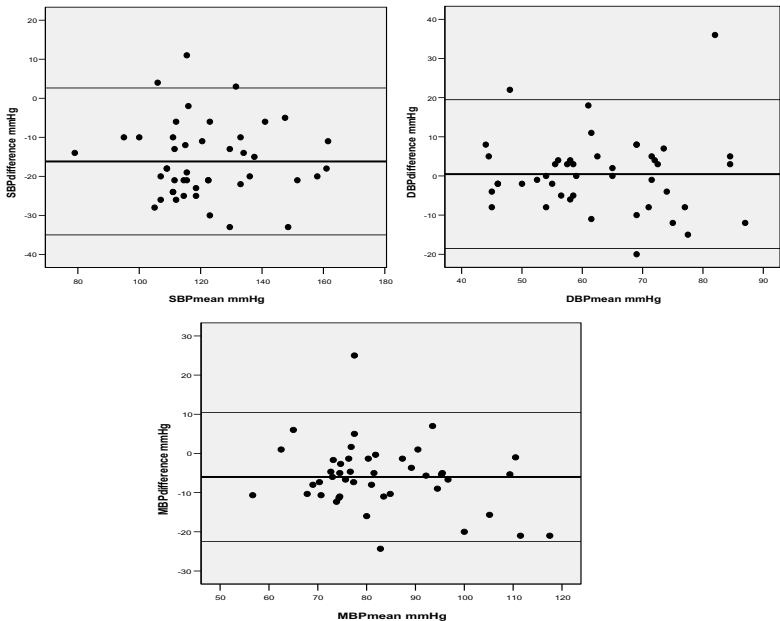


Figure 1. Bland-Altman plots for systolic (SBP), diastolic (DBP) and mean (MBP) blood pressures. The mean differences (NIBP-IBP), the upper and lower limits of agreement are denoted by the horizontal lines.

4. Discussion - Conclusions

In this study, we investigated the validity of an automatic wrist BP monitor against invasive BP measurement in a routine clinical setting in critically ill patients with a radial artery catheter. We found that although DBP and MBP measured by the OMRON device presented an acceptable bias and precision (below 10mmHg), the limits of agreement were wide. Furthermore, linear regression analysis showed that there was significant proportional bias. Overall, non-invasive SBP and MBP (but not DBP) underestimated BP compared to IBP.

This is the first study to investigate a wrist oscillometry-based BP monitor in critically ill patients. Previous studies have tested other NIBP devices in the critical care setting, showing that oscillometric and invasive BP measurement are not interchangeable, in line with our findings [7-10]. However, our study demonstrated that

NIBP monitoring using an automatic wrist BP monitor may be applied in critical care patients presenting acceptable accuracy regarding DBP and MBP. This is of particular importance during treatment of unstable patients in shock, which is titrated to a critical MBP to ensure adequate blood flow to vital organs. Thus, NIBP monitoring may be useful in a critical care setting in cases where IBP is not available or not well tolerated. Furthermore, recent studies of novel NIBP devices employing advanced technologies have shown promise [11, 12].

Our study presents some limitations including its small sample size and the heterogeneous study population (regarding the hemodynamic status and the use of vasopressors). However, this study may have some practical implications in critically ill patients, where an arterial line is not available or not well tolerated. Future larger population studies are needed to investigate the use of NIBP monitoring in critically ill patients.

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Wireless Monitoring Through Wearable Devices in the ICU: Are We Close?

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Abstract. Patients admitted to the ICU present life-threatening conditions requiring support from multidisciplinary specialists and continuous monitoring of vital signs and other parameters by a state-of-the-art medical technology. Wireless monitoring through wearable devices could be useful for hospitalized patients, particularly those who are unstable or at higher risk for serious complications such as critically ill patients. This review aims at summarizing current evidence regarding the use of wireless monitoring in the ICU setting. Relevant studies address some practical issues regarding wireless vital signs monitoring, detection of emergencies and delirium and pressure ulcer prevention. In general, wearable devices may offer multiple applications in the ICU setting. However, there are important limitations in their applicability related to high clinical requirements and patient, staff and environment related factors. Given the fast evolving field of wireless technology, more healthcare applications regarding the ICU are anticipated in the near future.

Keywords. Critical care, Intensive Care Unit, monitoring, wearable, wireless

1. Introduction

Wearable devices have been introduced in health care during the last decade [1]. Having being developed as applications for monitoring vital signs during athletic activities, they have been used initially for basic self-monitoring at home or outdoors in high risk populations as an adjunct for various activities. Soon, the medical community discovered their usefulness for wireless, remote monitoring of outpatients [2]. However, wireless monitoring through wearable devices may be useful for hospitalized patients as well, especially those who are unstable or at higher risk for serious complications such as critically ill patients hospitalized in the Intensive Care Unit (ICU) [3, 4]. This

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review aims at summarizing current evidence regarding the use of wireless monitoring in the ICU setting.

2. Methods

A search of the literature was conducted in reliable biomedical databases: MEDLINE/PubMed, Scopus and ScienceDirect. The terms used were: “wireless”, “wearable”, “monitor”, “critical care”, “critically ill” and “Intensive Care Unit” in various combinations. No language or time restrictions were applied. In order to narrow our search, we applied advanced search options requiring for the search terms to be included in the Title and Abstract. All retrieved articles (abstract and/or full text) were reviewed to document their relevance. Only studies regarding the application of wearable, wireless devices in critically ill, ICU patients of all ages were included.

3. Results

We retrieved 168 studies. After removing duplicates, reviews, experimental and animal studies, we selected 8 clinical studies regarding the use of wireless devices for monitoring critically ill patients, most of them coming from the USA and published during the last five years (Table 1). They all involved small patient cohorts ($N = 8-59$) except one ($N = 555$). A wide range of wireless devices was studied for monitoring vital signs, sleep, body position, body movement and gastric and bowel emptying.

The studies presented herein address some practical issues regarding critical care. Vital signs monitoring is of paramount importance in detection of patient deterioration. Wireless vital sign monitoring using a smart watch facilitates easy and prompt recognition of emergencies, supporting the work of the nursing staff, as demonstrated in a study from Sweden [7]. The authors used a smart phone application (Android) and Google Glass augmented-reality for real-time vital sign monitoring, threshold alarms and checklist reminders, named “The Nurse Watch”. The application was developed as a useful nurse tool and participating nurses expressed positively. A study in trauma ICU patients evaluated a miniature wireless vital signs monitor (MiniMedic, Athena GTX, Des Moines, Iowa) that was developed for battlefield trauma patient triage [8]. The study showed that the device could not accurately predict the most critical patients, but further improvements may prove beneficial in the future. A wrist fitness tracker (Fitbit Charge HR, Fitbit, San Francisco, CA, USA) was evaluated in 50 stable ICU patients for detection of activity, sleep and heart rate, in a study from Canada [9]. The researchers demonstrated that the device was well tolerated, but its sensitivity for the detection of tachycardia was moderate. Two studies addressed the monitoring of sleep cycles for detection and evaluation of delirium in ICU patients [6, 11]. The first study demonstrated a relationship between lack of REM sleep and delirium, while the second study showed that autonomous monitoring of patients (facial expressions, extremity movements and postures) and the patients’ environment (light and sound levels, visitation frequency) is feasible and the related data are associated with delirium. Another study implemented wearable position sensors on 555 ICU patients over a 5 month period, for monitoring nurse adherence with the protocol for pressure ulcers prevention involving frequent turning of patients [10]. The study demonstrated a suboptimal staff compliance with the protocol. Finally, in a recent study in a neonatal

and pediatric population, a soft skin-interfaced biosensor utilizing advanced wireless technology was evaluated for monitoring of multiple parameters in neonatal and pediatric ICUs [12]. The authors reported that vital signs measurements by this novel device presented a good agreement with the standard monitoring systems. These findings are promising and have significant clinical implications, as these innovative sensors may have various applications besides ICU monitoring, such as acute care, post-surgical monitoring, trauma emergencies, outpatients as well as chronically ill patients monitoring at home settings.

Table 1. Clinical studies of wireless monitoring devices in critically ill patients

Author, Year	Device	Study population (N)	Study focus
Rauch, 2012 [5]	Wireless motility capsule	ICU trauma (8) North American	Gastric emptying, bowel transit time
Whitcomb, 2013 [6]	Sleep monitor	ICU (7) North American	Sleep cycles in relation to delirium
Bang, 2015 [7]	Smart watch (The Nurse Watch)	ICU nursing staff (7) Swedish	Vital signs and reminder checklist to support nursing work
Meizoso, 2016 [8]	MiniMedic vital signs monitor	ICU trauma (59) North American	Vital signs for triage purposes
Kroll, 2017 [9]	Wrist fitness tracker	ICU stable (50) Canadian	Continuous data on heart rate, activity and sleep
Pickham, 2018 [10]	Position sensor	ICU (555) North American	Staff compliance for pressure ulcers prevention
Davoudi, 2019 [11]	Wearable sensor (accelerometer, light, sound, camera)	ICU surgical (22) North American	Facial expression, extremity movement and postures, and environmental factors for delirium detection
Chung, 2020 [12]	Skin-interfaced biosensor	ICU neonates and children (50) North American	Continuous vital signs, temperature, oxygenation, movement, body position and crying

4. Discussion

The clinical evidence of the application of novel wireless technology devices in the critical care setting is scarce and limited to the last few years. This finding may be explained by the fact that critically ill patients are at high risk and clinical requirements for medical devices are very strict. Thus, the deployment of wireless technology in ICUs may encounter significant difficulties. Important aspects of practical issues hindering the use of wireless technology in the ICU comprise:

1. *The patient:* As patients’ safety is of paramount importance, there is a need for stricter validation criteria for novel devices. Moreover, wireless monitors should provide high quality signals and unhindered flow of data, while being well tolerated with minimal complications.
2. *The staff:* The ICU staff is working in a stressful environment where a vast amount of data is constantly being produced by monitors, ventilators and other devices used in

the ICU. The staff has to process these data, prioritizing alarm signals during routine critical care. Wireless technology is expected to facilitate staff work, by providing filtered and processed data, and not to overwhelm the staff with even more data and workload. Moreover, trust in newer technologies has to be established in the staff.

3. *The environment:* The ICU environment poses important challenges to implementation of wireless technology, such as the presence of sensitive medical equipment continuously operating and the interference with signal transmission and acquisition due to specific construction characteristics and material properties [13]. Thus, assessment of particular characteristics of the environment is essential.

To the best of our knowledge, this is the first review study regarding wireless monitoring in the ICU. Further studies are needed for the implementation of wireless technology in the highly demanding setting of ICU. As wireless healthcare applications comprise a rapidly evolving field, advanced technology devices for medical use have much to offer [14,15]. Thus, we anticipate more clinical studies on wireless applications in the ICU in the near future.

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A Method of Justifying Confidence in the Safety of Digital Health Interventions

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Abstract. Digital health interventions (DHIs) enable improvements in health strategy and address health system challenges. The World Health Organization provides a formal classification for DHIs. However, safety claims, about such interventions, vary in quality and are often vague as to how they are communicated between technical, clinical experts and stakeholders. By combining the classifications with a method of safety analysis and justification, we postulate confidence in the safety of digital technology. Confidence is resulting from the application of the framework to the DHI, using defined health system challenges. The framework and derived safety justifications can be applied to any DHI. It can serve as guideline for health strategy, regulatory and standards based compliance.

Keywords. Digital health, safety, justification, health system, confidence, hazard analysis

1. Introduction

The lack of the adoption of the fundamental concepts of clinical risk management and safety methods, within health informatics, demonstrates safety's limited influence in the development of digital health technologies. It has been shown that the foundations of safety engineering concepts and methods can improve quality and safety [1]. The impact of digital health interventions (DHIs) on the safety of patients, and potential harm exercised by the unsafe actions of clinical users, is not documented openly. Evidence suggests a lack of rigor within the industry, where strategies for innovation to improve clinical outcomes and advance health using new technologies, overlook the principles of patient safety [2,3]. As these strategies often, see rigor as a barrier not an enabler to innovation. In contrast to the digital healthcare industry, traditional safety critical engineering industries have the capability of in-depth analysis and assessment, while they have been established over decades. Additionally, these, more open, safety cultures bring together concepts of quality, benefits and safety objectives into a more rigorous, systematic environment and innovation ready.

The World Health Organization (WHO) classification of DHIs [4], and their relationship to Health System Challenges (HSC), provides us with an opportunity to establish or affirm safety claims by the application of safety analysis methods. The HSC is a health service problem (e.g. lack of access to information or data, poor patient experience) and DHI is the class of technology intervention that aims to address the problem. This can offer insight and affirm confidence that the DHIs are safe and fit for

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purpose, by applying safety methods. The WHO classification promotes an accessible and bridging language between technical and clinical experts, aimed at simplifying dialogue and aiding digital health implementation. The classification represents discrete functionality of DHI, in order to achieve health sector objectives and meet the health system challenge (HSC), aimed at commissioners of digital services. We can apply these same classifications and challenges to identify hazards and construct a safety claim and justification. The objective of this paper is to implement the framework for the synthesis of safety justification for digitally enabled healthcare services. The ultimate aim is to apply the framework to a DHI and generate an assurance case, thereby provide a justification of safety and elicit confidence that the DHI is fit for purpose, not just to meet the health system challenge. This, in turn, will bridge the understanding of the health delivery organization and manufacturer clinical risk management processes, by way of guidance for each DHI classification. This will guide and influence the right behaviors of innovation within the boundary of good practice and safety methods.

2. Method

The aim is to identify hazards and construct a safety claim and justification. A safety claim follows an approach to safety justification that is commonly used in safety engineering industry. It is also used in traditional medical device safety assurance claims and, through graphical notation, provides a more efficient way of demonstrating safety between differing experts (technical and clinical). The method is explained below in Figure 1, and can be completed retrospectively or, ideally, in line with the requirements and definition phase of the planned DHI.

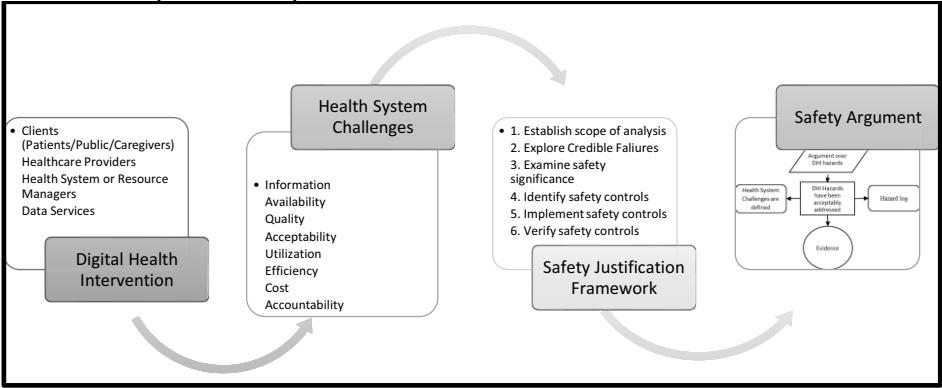


Figure 1 Method & sequence of DHI analysis

Select the DHI is a straightforward exercise, as the interventions are well defined and utilize established taxonomies, from mobile and more traditional digital health solutions. **Assess credible failures** is completed by examination of the use of the DHI and the deviation from that use. The inclusion of health system challenges provides synergy between intended operational use and the challenge faced in the health system. It is purposeful for examining the relationship between HSC, Hazard, Effect and Contribution, which is important when safety claims are made. **Examine safety significance & Identify safety controls** is where the clinical risk management methods are used – hazard analysis. An examination of DHI hazards is completed using likelihood and consequence to derive a severity level. Safety controls are identified to enable mitigation

of hazards, and this is where HSC form an important link into the framework. **Implementation and verification**, the final stage, evidences controls implemented and aligned to hazards and shape the final safety justification.

3. Results

We have applied the framework to a DHI, a self-management mobile app & web based portal for children / young people with Type 1 diabetes. The hazard assessment shows at least two health system challenges forming part of the causes to safety hazards. The framework has been applied to the DHI category of Client, Targeted Client Communication and Transmit Targeted Health Information to Client(s) Based on Health Status of Demographics. A Hazard Identification (HAZID) was undertaken to identify hazards that could cause harm to a “User” Patient. The assessment includes health system challenges in bold type as contributory causes (table 1).

Table 1 Hazard Analysis of an example Digital Health Intervention (mobile app for Diabetes Type 1)

HazID	Hazard	Clinical Safety Impact	Cause	Control
1	Mobile App and/or linked clinical website unavailable	Inability to support clinical services, stress or anxiety to service users, delayed action of treatment plans.	Unsupported mobile device configuration, Key information is not available, security issue, technical / configuration error. Lack of out of hours or system outage messages. Poor Patient Experience. Lack of access to information or data.	Care planning and intervention includes outage continuity plans. Alternative services information available through other sources. Technical assurance coverage includes mobile variants, webpage content and OS.
2	Clinical information presented is incorrect and/or misinterpreted	Reliance on information leads to inappropriate action of treatment plan or advice to manage condition.	Lack of quality/reliable data Insufficient utilization of data and information. UX issues with information presented. Out of date clinical guidelines. Lack of or inappropriate referrals.	Clinical care plans and workflows are controlled by policy and governance. Technical assurance includes UX & accessibility. Content change processes and training is implemented regularly.
3	Users rely on digital health intervention solely for care and advice and exclude care giver/clinical support	Service users/patients, care givers and health care practitioners lose confidence in the DHI. Reduced benefit of using the DHI. Patient condition may be uncontrolled and adversely impacted.	Lack of alignment with local norms. Poor adherence to guidelines. Inadequate supportive supervision. Lack of understanding of the service by users. Low technical awareness within the cohort.	Demo version of the DHI is available for training. Human factors / codesign workshop as part of the content and workflow management.

				Performance, outcomes and benefits indicators.
4	Inappropriate / incorrect implementation of DHI into health system Poor and/or declining quality of clinical information or data	Potential delay in the ongoing care of a patient, transfer or communication of critical information to support the treatment of the patient.	User(s) adopt the application informally and evolve its use into “informal” clinical care pathways. Insufficient health worker competence. Low health worker motivation. Poor adherence to guidelines. Inadequate workflow management. Poor planning and coordination.	High risk patients prioritized by local health workers. Use of recommended governance, planning and clinical engagement agreements. Use of feedback mechanisms to monitor performance and accountability.

4. Discussion and Conclusions

The exponential growth, diversity of DHIs and associated regulatory position are the biggest challenges to the industry. Policy makers, manufacturers, health organizations and digital technology users (healthcare professionals and patients) have different understandings and objectives of DHIs. The benefit for the communication between stakeholders, for safety claims aligned with the classifications of DHIs. The presented framework and associated justifications contribute to application guidance and best practice. The DHI classification scheme has been used to generate guidance on effectiveness for DHIs [5]. The results of this work indicate that the domains of security, safety and effectiveness can be correlated. The use of taxonomies, synonyms and ontologies, with established graphical notation methods, allow us to automate, predefine and guide through case studies. Further work is needed, in order to demonstrate this method and build the guidance across the DHI classification scheme. The implementation and verification of DHIs, justified this way, will provide a direct correlation to the health system challenge.

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Integrating Socially Assistive Robots into Japanese Nursing Care

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Abstract. This paper presents experiences of integrating assistive robots in Japanese nursing care through semi-structured interviews and site observations at three nursing homes in Japan during the year 2019. The study looked at experiences with the robots *Paro*, *Pepper*, and *Qoobo*. The goal was to investigate and evaluate the current state of using robots within the nursing care context, which involved: firsthand experiences with intended and real users; and response from the elderly, and nursing staff. The qualitative analysis results pointed out user satisfaction, adjusted purpose, therapeutic and entertaining effects. The potentials of using robots to assist in elderly care has been evident. Limitations currently relate to the lack of ways to fully utilize and integrate robots.

Keywords. Assistive robots, nursing-care, human-robot-interaction, impact on care

1. Introduction

According to the United Nations (UN) demographic statistics, Japan's population has decreased since 2009, holding about 128,500,000 residents at the time. As at 2019, Japan's population was about 126,800,000, but the forecast is that, the number will fall down to 108,800,000 by 2050 [1]. Moreover, Japan currently holds the world's largest population of elderly per capita with about 27% of Japan's population being 65 years or older. This means about 35 million people are over the age of retirement (65 years). Some countries argue that immigration might be the solution to this problem, while Japan has decided to invest in alternative futuristic ways of coping with its changing demographics. A proportionally large elderly population, in combination with a limited population growth, puts a higher demand on nursing care given the shortage of health care staff. Innovations have the potential to provide solutions that reduce the need for more human workers and promoting the elderly to be independent.

The Japanese government has presented six priority areas collectively, which consist of 13 areas in nursing care that require introduction of robot technology. These include namely: lifting aids, mobility aids, toilets, monitoring and communication systems, as

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well as bathing and nursing-care services [2]. Communication robots were introduced as the government's priority areas in 2014 and their development is supported since 2017.

The attitude towards robots is complex. The European Commission published a report in 2012, investigating it's at-the-time 27 member states' "public attitudes towards robots" [8]. A total of 26,751 participants responded to the survey; 87% of them had no personal experience with robots, but 70% had a positive view towards them. When asked about areas of which robots should be banned from, "on average, 86% would feel 'uncomfortable' about having their children or elderly parents minded by a robot (in fact, 66% chose point 1 'totally uncomfortable' on the scale)" [3].

Two studies from 2008 [4] and 2014 [5] revealed that people would prefer robots to perform tasks like vacuum cleaning, lawn mowing, watching over the house and so on than babysit, play with children or take care of animals. However, the Japanese Cabinet Office survey [6] with 1842 respondents has found that that 65.1% of the participants wanted to use robots in nursing care. Important points in choosing nursing care robots considered by respondents include: "easy to use" (74.4%), followed by "reasonable price" (68.6%), and "safety license" (54.6%). Only 6.4% responded that the robot having a "nice design" was important.

2. Material and Methods

A qualitative study was conducted, which involved use of semi-structured interviews and observation. We visited three different Japanese nursing facilities chosen as the study sites from a public list of nursing facilities, which use the robot *Paro*. The two nursing homes were in Hyogo prefecture, and the daycare center for elderly was in Kyoto, all close to the Ritsumeikan University Biwako Campus. The interviews were primarily held with the three facilities' managers and nursing staff. Questions directed to the nursing staff comprised of; the type of robots used, areas of use, negative and positive experiences encountered, and future considerations of robot use. On the other hand, questions directed to the site managers comprised of; reasons for investing in robots, and experiences encountered. Patients were also observed using the robots. Two of the interviews were conducted in Japanese and one in English. All interviews were transcribed; two of them were translated into English.

Content analysis was conducted to elicit and categorize information about the usage of the robots and impact they made on nursing care.

3. Results

Results from the interviews and observations gave an insight into the role and impact robots have on Japanese nursing care.

The interviews suggested that these kinds of robots all work with the mind and the mental wellbeing of the patients. Patients suffering with dementia often believed *Paro* to be a dog or even a human baby, thus treating and interacting with it accordingly. Patients often cared and worried for *Paro*, asking if it was properly fed or whether it got enough sleep, thus indicating that there was a relationship established. Consequently, caregivers were advised to avoid letting the patients use *Paro* during their meal and snack times as they might be tempted to feed it, which had occasionally happened. It was reported that interacting with *Paro* evoked memories from the past for patients, which

often made them happy. Using *Paro* in therapy also depended on the nursing staff attitude. For example, not everyone liked *Paro*, or animals in general. In addition, the staff had already busy schedules, which left them little time to deal with *Paro*. One caretaker stated that “*sometimes you have patients who take their wheelchairs and want to go somewhere, not knowing where to, which puts pressure on caretakers to keep eyes on the patients and keep them in their chairs*”. The challenge they have is to keep patients engaged and motivated. One staff member said “*I am constantly speaking to people who don’t speak back to me, but at some point if they have Paro, they make a sound or say ‘KAWAII’; so something is coming out, even if it is just a small sound, this is enough reaction for me because they don’t speak anymore*”. This caretaker clearly valued *Paro*’s curative effect.

It was noticed that the staff’s enthusiasm in using robots might induce the enthusiasm in the patients. Moreover, patients that are cognitively more capable might find *Paro* less interesting. It was observed that *Paro* was effective on both male and female patients provided they liked animals. *Qoobo* was mostly used by one patient that did not like interacting with other people.

The qualitative analysis produced several categories relating to the assistive robots’ role in care and their impact on patients and staff as presented in Table 1.

Table 1. Key findings regarding the role and impact robots have on nursing care collected from three different Japanese nursing facilities.

Robot	Role in Care	Impact/Effect on	
		Patient	Staff
<i>Paro</i>	Therapy. Indicated for patients with dementia. Pet, Baby, Robot.	Slows down dementia. Brings back old memories, emotions and stories. Lessens feeling of emptiness. Changes the patient’s mood. Provokes speech in the patients. Improves communication between patients. Helps heal patient mentally. Improves facial expression. Substitutes animal therapy. Calming effect. Could exhaust/tire patients (negative).	Distracts patients in order to enable staff do other tasks. Cheaper, easier and safer than real animals. Way of connecting and taking care of patient. Makes job easier by: Calming patients down. Making patients happy instantly. Conversation starter/talking topic. Demands time and additional effort from staff – in some cases there is no time to spare (negative).
<i>Pepper</i>	Recreation. Taiso (Exercise/stretching) Substitute for professional. Staff, Robot, Alien, Child.	Entertainment. Smile. Helps heals patient mentally.	Reception greeter. Way of connecting and taking care of patient. Smile.
<i>Qoobo</i>	Therapy. Pet, Robot.	Calming effect. Happiness.	Easier to take care of patient.
Robots in General	Robots are more than tools.	Patients do not have to hesitate. Can maintain the patient’s self-esteem. Reduces the mental burden the patient feels towards the worker.	Thinking about how to use robots effectively increases the staff’s motivation and communication. More people have visited the nursing home which allows acquiring new information.

4. Discussion

The use of robots instead of toys, dolls or animals was based on the reason that therapeutic aids should be safe and have demonstrable therapeutic effects. Animals can get stressed and behave unpredictably. Robots like *Paro* are designed to have a therapeutic effect and can work as an alternative to pet/animal therapy without the risk of allergy, bites, scratches, infections or even stress for the animal itself. In addition, robots can be cheaper than keeping pets such as dogs and demand less maintenance. Even though *Paro* is designed to resemble a baby harp seal, patients often confuse *Paro* with their own pets. What differentiates *Paro* from a stuffed animal is the motions and reactions to its environment. Still, some people dislike certain animals which makes them skeptical to animal-type robots as well. Furthermore, the interaction time and enthusiasm depend on patients' mood; typical interaction time was 30 minutes daily.

Pepper is seen more as a staff member and is mostly used to entertain patients. It was also being used for Taiso, the daily Japanese stretching. It is placed in the center to lead the show, while the staff member encourages from the side, thus the need for human workers is not eliminated. Both *Pepper* and *Paro* can be used by the patients alone. Nonetheless, they are often used together with the nursing staff. The interest of both patients and staff members also determines the use of the robots. Ultimately, consensus was found that these robots were not thought to be better than humans but are used to assist and relieve the humans from work overload. As one of the interview subjects stated *"When looking at the value of an industrial robot, the productivity is visible, but in the case of a nursing robots, we should see the number of staff halved, or more nursing care performed at the same time. However, the effect is more on patients' mentality which might not be as visible"*. Introverted patients, not interacting with others, were seen smiling and talking to the robots. Additional positive effects comprised of increased interest of groups and grandchildren to visit nursing homes and learn more about robots.

5. Conclusions

All nursing facilities were positive towards robots due to their beneficial effects such as patient satisfaction and increase in social activities. Robots like *Pepper* allow for easy updates which promote development of rehabilitation programs. Further studies are needed to generalize these initial insights into acceptance of robots into the nursing care.

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A Comparative Study of the Arden Syntax and GDL Clinical Knowledge Representation Languages

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Abstract. The expressiveness of a medical knowledge representation language has significant impact on the effectiveness of a knowledge-based clinical decision support system. We assess the expressiveness of two such languages, Arden Syntax and the Guideline Definition Language. Using data extracted from both languages' specifications, we quantify expressiveness by means of language syntax and the number of supported operators. Preliminary results show that Arden Syntax is a more dynamic standard, having better readability and a higher number and more diverse operators than GDL. In contrast, GDL is a more rigid language that utilizes an underlying data model specification in the openEHR framework.

Keywords. Decision Support Systems, Clinical; Arden Syntax; Guideline Definition Language

1. Introduction

With knowledge-based clinical decision support (CDS) approaches, knowledge is implemented through the extraction and translation of medical knowledge sources using a knowledge representation language. The expressiveness of the knowledge representation language, i.e., the variety and quantity of logics, ideas and rules that it can express, thereby has significant impact on the effectiveness of CDS systems.

The aim of this paper is to present preliminary results on a study to assess and compare the expressive power of knowledge representation languages for knowledge-based CDS systems. At present, two such languages are commonly used, the Arden Syntax for Medical Logic Modules (Arden Syntax for short) [1] and the Guideline Definition Language (GDL) [2] of the openEHR framework.

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2. Methods

We performed a comparative study of the expressiveness of knowledge representation languages for CDS systems, Arden Syntax and GDL. Both languages have an open specification, are still further developed in workgroups, have reference implementations available and have been used for the implementation and publication of CDS systems [3–6].

2.1. The Arden Syntax

Arden Syntax is a standard for the representation and processing of clinical and scientific knowledge managed by Health Level Seven (HL7) International, a non-profit ANSI-accredited standards development organization for health data interoperability [1].

Meant to be a standard for use in the medical domain, the Arden Syntax offers data types and constructs tailored to the need of medical documentation and decision making, e.g., time series and duration. Moreover, Arden Syntax resembles natural language, which improves its readability and understandability.

In Arden Syntax, each knowledge base is partitioned into medical logic modules (MLMs), which are independent units that contain enough knowledge to compute at least one medical decision. Each MLM is divided into four categories that contain maintenance information, links to other sources of knowledge, and logic to make a health decision, and optional localization for return messages.

2.2. openEHR and the Guideline Definition Language

openEHR is an open standard for the storage, retrieval, management and exchange of health data in electronic health records (EHRs) [7]. Within the openEHR program, specifications of formal models and languages for the definition of the openEHR technical platform are generated, clinical models are created for re-usable clinical content, and software is created that implement open source tools and EHR information content.

GDL [2] is a formal language for expressing decision support logic in openEHR. It is designed to be agnostic to natural languages and references terminologies by leveraging openEHR foundation types and formalisms. The standard was developed by Cambio Healthcare Systems and was later adopted by the openEHR Foundation.

Knowledge-based CDS applications created with GDL have a specific object model that consists of a resource description, terminology definitions and bindings, and the rules that define its functionality. Only the resource description and the terminology definition parts contain labels in natural language. The terminology definition part of the guideline acts as an “interface” between natural language and the purely coded CDS rules.

2.3. Study Flow & Outcome Measures

We first established comparison criteria for selected knowledge representation languages. Then, we collected general information on these languages. Information on Arden Syntax was collected from the latest specification and implementation guide [1,8]; information on GDL was collected from the openEHR GDL specification site [2] and the project website [9]. Finally, we extracted information on selected comparison criteria from these information sources.

As outcome measures, we discuss language syntax and the number of operators supported by the language. Although to the authors' knowledge a formal comparison framework does not exist, discussing these aspects will give a quantitative indication of language expressiveness.

3. Results

A comparison of syntax attributes between Arden Syntax and GDL is shown in Table 1. Arden Syntax is designed with readability in mind and its syntax resembles that of modern object-oriented programming languages. In contrast, GDL is designed to be language-agnostic, and its syntax resembles that of markup languages such as XML.

Table 1. Syntax attributes for Arden Syntax and the Guideline Definition Language.

Attribute	Arden Syntax	Guideline Definition Language
Readability	Based on English natural language, readable for technical and nontechnical users.	Language-agnostic, hardly involves any natural language.
Syntax	Resembling functional and object-oriented programming languages.	Resembling XML markup languages.
Keywords	Some reserved keywords, variable and parameter names can be chosen freely otherwise.	Variables and parameters bound to data points with an archetype.

With respect to the types and number of available operators (Table 2), Arden Syntax shows more diversity than GDL; the Arden Syntax supports both Boolean and fuzzy logics and supports 176 operators. In comparison, GDL defines a total of 28 operators in its specification.

Table 2. Operators for the Arden Syntax and the Guideline Definition Language specified by operator categories.

Operator category	Arden Syntax	Guideline Definition Language
Logical Operators	3	3
Comparison Operators*	44	6
Arithmetic Operators	7	6
Function Operators**	17	11
List operators, filters, string operations, temporal operators, aggregations, transformations, object operators, fuzzy operators, type conversions	105	
Terminological reasoning operators		2
Total	176	28

* Simple comparisons, Is comparisons, and Occur comparisons for Arden Syntax

** Numeric and time functions for Arden Syntax

4. Discussion

We performed a study on language expressive power between Arden Syntax and GDL by comparing language syntax and the number of operators supported by the language. While the choice for a CDS language is not solely determined by these factors, and the purpose and context of CDS also play a significant role, this study provides a quantitative measure to support language choice.

Arden Syntax and GDL have two different philosophies, which clearly shows in their respective syntaxes. Arden Syntax is designed with readability in mind, whereas GDL is designed to be language-agnostic. This makes it easier for programmers to learn Arden Syntax, and for clinicians to verify rules expressed in MLMs. In comparison, GDL implementations are more difficult to read and understand.

The difference in available operator types and functions in the two CDS languages mirrors the more flexible approach of Arden Syntax versus the strictly standardized approach of GDL. However, it should be noted that the effects of some Arden Syntax operators can be achieved by combining GDL operators with appropriate data types.

5. Conclusions

Both Arden Syntax and GDL are languages for the creation of CDS applications. Arden Syntax is more flexible and offers more possibilities of creating complex algorithms. GDL is a more rigid standard that guarantees its function when implemented into a system that is based on the openEHR specifications.

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The Classification of Scientific Literature for Its Topical Tracking on a Small Human-Prepared Dataset

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Abstract. The number of scientific publications is constantly growing to make their processing extremely time-consuming. We hypothesized that a user-defined literature tracking may be augmented by machine learning on article summaries. A specific dataset of 671 article abstracts was obtained and nineteen binary classification options using machine learning (ML) techniques on various text representations were proposed in a pilot study. 300 tests with resamples were performed for each classification option. The best classification option demonstrated AUC = 0.78 proving the concept in general and indicating a potential for solution improvement.

Keywords. Text classification, neurosurgery, machine learning, topic modeling, natural language processing, artificial intelligence

1. Introduction

The amount of scientific literature is growing rapidly each year, making it impracticable to process the entire amount of publications even within one professional domain [1], [2]. Selecting articles related to a specific subject or more stringent inclusion criteria is the most time-consuming stage when analyzing the literature, reaching up to 1-2 years in cases of systematic reviews.

The selection of literature for a certain purpose can be addressed as a binary classification task, in which one class is represented by articles of particular interest (e.g. included in a systematic review), and the second - by papers not suitable for a specific task. The article selection principle may be strictly formalized or implicitly defined, for example, related to the scientific interest of the researcher.

Our study aimed to assess the quality of solving such a task on a small real-world human-derived dataset using traditional machine learning methods as a proof of the concept.

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2. Methods

The dataset was initially obtained from the PubMed search engine while performing a systematic review of artificial intelligence (AI) applications in neurosurgery in July 2019. We applied a broad definition of artificial intelligence in our search strategy: ("neurosurgical procedures" OR "neurosurgery") AND ("artificial intelligence" OR "machine learning" OR "natural language processing" OR "NLP" OR "text mining" OR "fuzzy logic" OR "data mining" OR "big data" OR "topic model"). The publications obtained with that query were manually divided into two classes. An article was assigned to the first class (to be included in the review) in accordance with the following criteria:

- original research peer-reviewed article;
- abstract in English was available;
- the pathology/treatments discussed in the article were directly related to neurosurgery;
- the paper reported the results of AI assessment in diagnosis, treatment, prognosis, rehabilitation, or prevention.

The second class contained all other publications, which did not meet these requirements.

We proposed 19 classification options using machine learning (ML) techniques on various text representations. A document-term matrix (DTM) derived from article abstracts was a basic data structure for learning. Thus, any document was represented as a transformed DTM-vector reflecting the quantitative distribution of each term, term frequency—inverse document frequency (TF-IDF), the quantitative distribution of character N-grams, TF-IDF transformed vector of character N-grams, normalized document vectors based on character N-grams, word2vec embedding and singular value decomposition (SVD) vectors of pointwise mutual information (PMI) representation. We used character trigrams in our experiments.

In our experiments, the training subset was randomly sampled as 80% of the initial dataset ($n = 671$), while the remaining 20% were kept as a testing subset. The data from the training subset were transformed into several vector representations and piped into the range of ML algorithms. We applied the 5-fold cross-validation (CV) for every model on the training subset. The quality of each model was finally evaluated on a testing subset. Such an experiment was repeated three hundred times to estimate the average quality of every classification approach.

We have tested the most common ML algorithms: linear support vector machine (SVM), logistic regression and random forest. Additionally, we tested the Euclidean distance between normalized character N-gram vectors and a reference vector calculated from the training vector space as a classifier.

All the calculations were performed using the Python programming language (version 3.7) with the *pandas*, *numpy*, *nlk*, *sklearn* and *spacy* libraries in Jupyter Notebook.

3. Results

A total of 671 articles were assigned to the first ($n = 364$) or second ($n = 307$) class. The results within each test series of 300 tests were averaged for each of 19 ML models. Averaged results are shown in Table 1. The tokenization and document vectorization

methods are referred to in the “token” and “vectorizer” columns, respectively. The mean accuracy of k-fold cross-validation (CV) on a training set is shown in the “CV” column. The accuracy (ACC), precision (PREC), recall (REC), F1-score, and the area under the receiver operating characteristic curve (AUC) obtained on the testing dataset are referred accordingly. The results in Table 1 are shown in AUC decreasing order.

Table 1. Classification results by different machine learning methods over various vector representations of tokens and documents averaged within each test series.

#	Method	Tokens	Vectorizer	CV	ACC	PREC	REC	F1	AUC
1	Linear SVC	Words	TF-IDF	0.78	0.78	0.78	0.78	0.78	0.78
2	Logistic Regression	Words	TF-IDF	0.78	0.78	0.78	0.78	0.78	0.78
3	Linear SVC	Char N-grams	TF-IDF	0.75	0.76	0.76	0.76	0.76	0.76
4	Random Forest	Words	Count	0.76	0.76	0.76	0.76	0.76	0.76
5	Logistic Regression	Words	Count	0.75	0.76	0.76	0.76	0.75	0.76
6	Logistic Regression	Char N-grams	TF-IDF	0.75	0.76	0.76	0.75	0.75	0.75
7	Random Forest	Words	TF-IDF	0.76	0.75	0.76	0.75	0.75	0.75
8	Random Forest	Char N-grams	TF-IDF	0.75	0.75	0.75	0.75	0.75	0.75
9	Linear SVC	Words	Count	0.73	0.74	0.73	0.73	0.73	0.73
10	Random Forest	Char N-grams	Count	0.74	0.74	0.74	0.73	0.73	0.73
11	Random Forest	Words	SVD/PMI	0.72	0.72	0.72	0.72	0.72	0.72
12	Logistic Regression	Words	SVD/PMI	0.68	0.72	0.71	0.71	0.71	0.71
13	Logistic Regression	Char N-grams	Count	0.70	0.70	0.70	0.70	0.70	0.70
14	Linear SVC	Words	SVD/PMI	0.67	0.69	0.69	0.69	0.69	0.69
15	Linear SVC	Char N-grams	Count	0.69	0.69	0.69	0.69	0.69	0.69
16	Random Forest	Words	word2vec	0.67	0.68	0.68	0.68	0.68	0.68
17	Linear SVC	Words	word2vec	0.56	0.56	0.52	0.53	0.43	0.53
18	Logistic Regression	Words	word2vec	0.55	0.56	0.61	0.52	0.41	0.52
19	Euclidean distance with reference	Char N-grams	Count	—	0.50	0.50	0.50	0.50	0.50

The best result (AUC = 0.78) was observed for a linear SVC algorithm trained on TF-IDF vector representations. However, logistic regression with word vectors (AUC = 0.78) weighted by TF-IDF and Linear SVC on character N-grams (AUC = 0.76) led to a close performance.

4. Discussion

The results of this study demonstrate that the automated separation of scientific abstracts into user-defined classes might be a technically solvable task. That type of technology might simplify tracking dedicated literature and keeping a researcher up to date, saving a considerable amount of time.

The idea of augmenting a literature search with machine learning was discussed in other papers [2]–[5]. An important benefit of such technologies may be intellectual information retrieval, the prioritization of search results while preparing a systematic review and even future trends prediction [1], [2], [6]. Such systems should be self-tuning and self-updating [7].

A crucial limitation of our work was the relatively small document sizes (article abstracts) used for classifications. Training the models on full texts would probably lead to better results, however, abstracts are incomparably better accessible and are more common for the initial screening in real-world practice [2]. This study is also limited to one user-generated class-balanced dataset, however, a spectrum of machine learning approaches provided additional evidence to support our conclusion. A further improvement of the classification might be related to automatic extraction of in-class intrinsic text features, using the latest state-of-art word embeddings and language models (e.g. BERT), applying ensemble learning and supporting the unbalanced datasets.

5. Conclusions

The classification of scientific publications by their abstracts might be to a certain extent technically solvable and provide a basis for literature tracking in user-defined tasks.

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Association Between Number of Actionable Pharmacogenetic Variants and Length of Hospital Stay

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Abstract. The goal of this study was to evaluate association between number of pharmacogenetic variants and length of hospital stay. Electronic medical records were combined with exome sequencing results in 450 hospitalized patients. De-identified data set was used to characterize urgent care utilization and to identify presence of 44 actionable pharmacogenetic variants according to the guidelines of the Clinical Pharmacogenetics Implementation Consortium. The average age was 58.03 ± 16.47 ranging from 20 to 91 years old, average number of pharmacogenetic variants was 61.22 ± 26.52 ranging from 20 to 169, and mean length of hospital stay was 6.50 ± 4.29 ranging between 1 and 42 days. After adjusting for patient socio-demographics and overall disease severity reflected by the Charlson comorbidity index, a significant association between mean length of stay and number of pharmacogenetic variants was found using generalized linear regression (p-value < 2.2e-16).

Keywords. Pharmacogenetics, allelic variation, hospitalization, electronic health record

1. Introduction

Allelic variants of the genes that affect absorption, distribution, metabolism, and elimination can significantly affect patients' response to medication regimen and consequently the effectiveness of treatment. Previous studies demonstrated that presence of pharmacogenetic variants can result in adverse drug events [1] and increase readmission rate especially in older adults with polypharmacy [2]. In acute care settings patients receive multiple medications to stabilize their condition. Patients receiving multiple medications whose genome contain higher number of pharmacogenetic variants may potentially be less responsive to their treatment and subsequently require longer length of stay to fully recover. The aim of the present study was to assess potential association between patient number of actionable variants and length of hospital stay.

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2. Methods

De-identified data from 450 patients who participated in the electronic Medical Records and Genomic (eMERGE) project [3] were used in this study. Exome sequencing data were analyzed to identify presence of 44 actionable pharmacogenetic variants according to the guidelines of the Clinical Pharmacogenetics Implementation Consortium (CPIC) [4]. Patient socio-demographics, list of comorbidities, and hospitalization history were extracted from electronic health record (EHR). The mean and standard deviation of number of inpatient visits, overall observation time, hospitalization frequency, total length of stay, monthly length of stay, mean length of stay, Charlson comorbidity score, and number of actionable pharmacogenetic variants were calculated for each patient. Generalized linear regression was used to assess significance of association between number of actionable pharmacogenes and mean length of stay after adjusting for age, sex, race, ethnicity and comorbidity score. Data were analyzed using R version 3.3.2. and generalized linear regression was performed by R package “glm”.

3. Results

The study sample comprised 48% females and 52% males. Based on patient self-report, racial composition was presented by 52.4% Whites (W), 13.0% Black (B), 4.0% Asian (A), 1.6% Pacific Islanders (P), 27.3% Unknown (U), 1.3% Declined (D), and 0.4% Others (O). The average age was 58.03 ± 16.47 ranging from 20 to 91 years old. Self-reported ethnicity comprised of 56.0% Non-Hispanics (N), 17.8% Hispanics (H), 25.1% Unknown (U), and 1.1% Declined (D). Descriptive statistics of patient hospitalization record and comorbidity score is presented in Table 1. Majority of patients were hospitalized due to chronic cardio-vascular and kidney conditions and cancer. Charlson comorbidity score used to adjust for overall patient comorbidity pattern ranged between 0 and 16 with average value of 4.74 ± 3.56 . Bivariate association between average patient length of stay and number of pharmacogenetic variants is depicted in Figure 1. Results of generalized linear regression are presented in Table 2. After adjusting for patient socio-demographics and overall disease severity reflected by the Charlson comorbidity score, a significant association between mean length of stay and number of pharmacogenetic variants was found. The goodness-of-fit statistics demonstrated good model fit (RMSE = 2.662712; R-square: 0.01336129; F test: p-value < 2.2e-16).

Table 1. Descriptive statistics of the study sample.

N=450	Mean (SD) or % (N)	Range
Inpatient visit number	3.44 ± 4.77	1 - 53
Observation time (month)	39.80 ± 68.77	0.033 – 330.27
Hospitalization frequency	3.13 ± 4.56	0.007 – 30.00
Total length of stay (day)	23.82 ± 37.94	1 - 325
Mean length of stay (day)	6.50 ± 4.29	1 - 42
Pharmacogenetic variant number	61.22 ± 26.52	20 - 169

Table 2. Results of generalized linear regression.

N = 450		Estimate	CI	P
Intercept		1.74	1.53-1.94	< 2e-16 ***
44 gene variant count	Continued variable	0.0027	0.00098-0.0044	0.00195 **
Comorbidity score	Continued variable	-0.0032	-0.013-0.007	0.54
Gender- Female	Compared to Male	-0.107	-0.18--0.03	0.00415 **
Race-Others (A,D,O,P,U)	Compared to Black	0.21	0.06- 0.35	0.00447 **
Race-White	Compared to Black	0.008	-0.13- 0.15	0.91
Ethnicity – Others (D,H,U)	Compared to Non-Hispanic	-0.11	-0.20- -0.02	0.01566 *

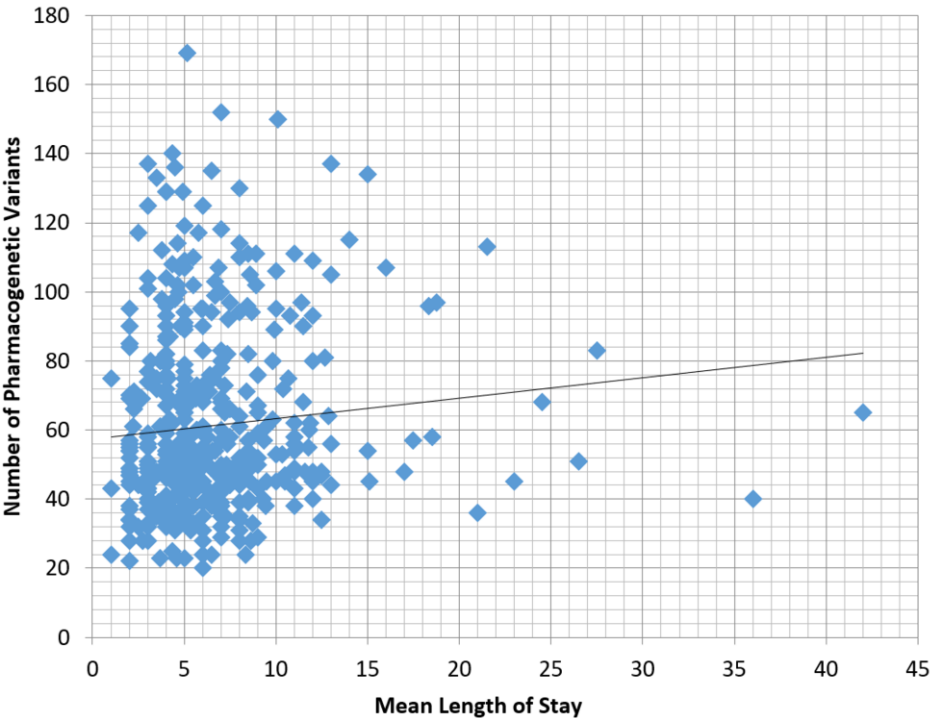


Figure 1. Relationship between number of pharmacogenetic variants and mean length of stay.

4. Discussion

For this study, we analyzed a racially heterogeneous study sample’s length of hospital stay and found that it was associated with several factors. Gender, race, and ethnicity all showed a statistically significant association with length of hospital stay. Our study also showed that having a higher number of allelic variants within the 44 CPIC-defined actionable pharmacogenes was associated with an increased length in hospital stay. This relationship remained statistically significant even after adjusting for other factors. Our study presents a novel pharmacogenetic association analysis which looks at the total number of pharmacogenetic variants as a risk factor for increased length of hospital stay. Many pharmacogenes have been identified and their risk of interactions

with certain drugs analyzed [5]. However, to date most studies have primarily examined the interactions between single genes and specific drugs [5]. Although this identifies the most significant and common gene markers, these major candidate genes only account for a fraction of the heritability of disease and disease risk [6]. It has been posited that in complex genetic traits, the cumulative effect of rare and minor alleles can play a significant role in contributing to genetic risk [7]. Our findings support this theory: within our study sample, the number of gene variations away from the major allele was found to be an independent factor which increased length of hospital stay [8].

5. Conclusions

With further exploratory studies, the implications of our study can provide a novel approach to clinical pharmacogenetics testing. Currently, pharmacogenetics testing is being implemented for a limited number of genes and drugs [9] and accounting for racial/ethnic diversity is underdeveloped [10]. This is partially due to the uncertain nature of the relationship between specific genes and risk of adverse drug reactions. Using number of pharmacogenetic variants as a different gene marker for risk of prolonged hospital stay and potential adverse events can provide a novel method of stratifying patients by risk based on their genetic profile. We recommend further studies on the relationship between number of pharmacogenetic variants, hospital stay, polypharmacy and incidence of ADRs in order to further explore this effect.

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Using Long Short-Term Memory (LSTM) Neural Networks to Predict Emergency Department Wait Time

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Abstract. Emergency Department (ED) overcrowding is a major global healthcare issue. Many research studies have been conducted to predict ED wait time using various machine learning prediction models to enhance patient experience and improve care efficiency and resource allocation. In this paper, we used Long Short-Term Memory (LSTM) recurrent neural networks to build a model to predict ED wait time in the next 2 hours using a randomly generated patient timestamp dataset of a typical patient hospital journey. Compared with Linear Regression model, the average mean absolute error for the LSTM model is decreased by 9.7% (3 minutes) ($p < 0.01$). The LSTM model statistically outperforms the LR model, however, both models could be practically useful in ED wait time prediction.

Keywords. ED overcrowding, ED wait time prediction, recurrent neural network, Long Short-Term Memory (LSTM)

1. Introduction

Emergency Department (ED) overcrowding is a complex, systemic and global healthcare issue resulting in decreased care efficiency and worsening patient outcomes [1]. Due to the aging population and the lack of inpatient capacity, admitted patients occupying ED beds create an access block for incoming emergency patients [1,2]. Hence, ED overcrowding is a problem that stems from the system as a whole rather than solely the ED [1,2].

ED wait time, defined as the time from patient arrival to physician initial assessment, can support decision making to enhance patient experience and improve hospital resource allocation [1]. Machine learning prediction models have been used to predict ED length of stay and wait time based on the patient flow in the ED [3,4]. Very limited research studies explore the use of *Long Short-Term Memory (LSTM) Recurrent Neural Networks* [5] in Emergency Medicine research, while LSTM has been commonly used in fields such as Business consistently providing more accurate sequence predictions [6]. Compared to the LSTM, *Linear Regression* (LR) [7] is a more popular method for prediction due to its easy implementation and less processing time, however, such a method may not offer accurate prediction because some complex real-world problems such as ED overcrowding may not be explainable with a linear approach.

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Therefore, the aim of this paper is to preliminarily investigate the application of the LSTM method in ED overcrowding analysis by comparing the accuracy of ED wait time prediction of an LSTM machine learning model and that of an LR model using a randomly generated patient timestamp dataset.

2. Methods

A dataset of randomly generated patient instances was created. Two models utilizing LR and LSTM methods, were created, respectively. Using K-Fold Cross Validation [8], a training-validating process followed by a training-testing process were performed to each model to predict the ED wait time. The mean absolute error of the ED wait time predicted by the model is studied by comparing to the true ED wait time. The performance of the two models are evaluated.

2.1. Patient Timestamp Dataset

A dataset was created to represent 50,000 patient instances of timestamp differences randomly generated over a pre-defined range uniformly. The use of the uniform distribution enables maximum entropy probability to ensure the consideration of all possible circumstances given the lack of clinical data [9]. A sequence of five (5) timestamp differences were used to illustrate the six (6) timestamps in a patient journey, including: patient arrival time, triage time, registered time, physician initial assessment time, ED exit time, and inpatient unit discharge time. At a specific time t , each of the five sequential timestamp differences is labelled as x_t . The ED wait time for each patient instance was calculated in minutes by adding the first 3 timestamp differences. Each patient instance contains an arrival timestamp including the month, week, day, hour and minute that was randomly generated using uniform distribution. The average ED wait time for the next 2 hours labelled as y was calculated for each patient instance by taking the average of the ED wait time of the patients arriving in the next 2 hours. The dataset was then scaled using MinMaxScaler of the Scikit-learn 0.20.1 library [10].

2.2. Linear Regression Model

Python 3.7.1 and Scikit-learn 0.20.1 were used to build an LR model with an input array of 1×5 for the 5 timestamp differences and an output array of 1×1 .

2.3. Long Short-Term Memory Model

Long Short-Term Memory (LSTM) is a type of recurrent neural network which when unfolded, contains individual identical units [5]. Each unit receives input data at each time-step of an instance in the dataset [5]. LSTM can learn long-term dependencies without the vanishing gradient problem due to its sigmoid activation function in each unit which produces an output of hidden state, h_t and cell state, c_t . Both of them depend on the input, x at time t , the previous cell state, c_{t-1} , and the previous hidden state, h_{t-1} [5]. Using Python 3.7.1 and PyTorch 1.1.0 [11], a single-layered LSTM model using 5 input units with each unit receiving an element of the patient instance sequence, x_t , as input was built. The output from the final LSTM unit passes through an LR layer with a

1 x 1 input array, which produces a 1 x 1 predicted output, $\hat{y}$, of ED wait time in the next 2 hours as illustrated in Figure 1.

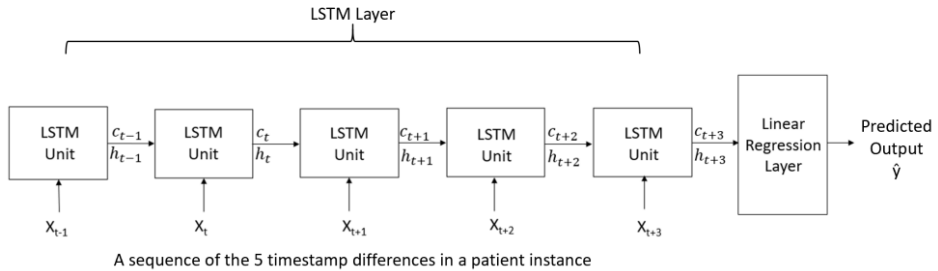


Figure 1. Single-layered LSTM model using 5 input units with a linear regression layer.

2.4. Training and Evaluation

For both the LR and LSTM model, 80% of the data was first used to train and validate the model using 100-Fold Cross-Validation for 500 epochs to observe the behavior of the hyper-parameters of the models and ensure no overfitting occurs prior to the exposure of the testing data [8]. Then, 100% of the data was used to train and test both models with 100-Fold Cross-Validation for 500 epochs. Both models include an early stopping to prevent overtraining and use mean absolute error (MAE) as loss function. The LR model was optimized using Stochastic Gradient Descent [12], while the LSTM model used ADMA, Adaptive Moment Estimation, optimization [13]. A two-sample t-test was performed on the MAE values from the testing phase in both models with a significant difference of $p < 0.01$ and 99% confidence level. The lowest MAE value for each of the models and their overall training-testing time were observed during the process.

3. Results

As shown in Table 1, the LSTM model achieved a 9.7% (3 minutes) lower average MAE ($p < 0.01$), 7.49×10^{-2} (28 minutes) compared to 8.84×10^{-2} (31 minutes) in the LR model. The minimum MAE in the LSTM model is 12% lower than in the LR model. The training-testing time of the LSTM model is 2.5 hours compared to 2.17 seconds for the LR model.

Table 1. The training-testing time (TTT), Average MAE, standard deviation (SD), 99% confidence interval (99% CI), minimum MAE (Min MAE) and p-value of the LR and LSTM in the testing phase are shown below.

Model	TTT	Average MAE (minutes) ± SD (minutes)	99% CI (minutes)	Min MAE (minutes)
LR	2.17s	8.84×10^{-2} (31) ± 6.10×10^{-3} (1.41)	$(7.27 - 10.41) \times 10^{-2}$ (27.79 – 35.05)	7.25×10^{-2} (27.75)
LSTM	2.5hr	7.49×10^{-2} (28) ± 7.43×10^{-3} (1.72)	$(5.57 - 9.40) \times 10^{-2}$ (23.87 – 32.71)	5.82×10^{-2} (24.44)
p-value	1.54×10^{-31}			

4. Discussion and Conclusions

Supported by Tax et al. 2017 [6], the LSTM model statistically outperforms the LR model due to its ability to learn the relationships between consecutive time-steps. The relatively small 3-minute prediction difference between the 2 models suggests that both models could be practically useful in wait time prediction. An important aspect of this study is the use of a complex neural network model in the ED setting to construct a wait time prediction tool. This tool serves for clinical decision support to provide patient control in ED care [14], and improves care efficiency with proactive resource allocation such as increasing the number of nurses and overflow units [1].

A major limitation of the study is the use of a randomly generated dataset without real patient flow and data quality representation. Since ED overcrowding is a system issue involving the entire hospital [1,2], it is crucial to use data that extends beyond the ED. The validity and reliability of the data may vary at hospitals which may impact the final model and its accuracy. However, incomplete patient data may offer new understanding of ED wait time. As next steps, we plan to use hospital patient timestamps as well as clinical data and explore different model architectures and accuracy evaluations.

In summary, this paper utilized the LSTM neural networks to build a model to predict the average ED wait time in the next 2 hours. Though the LSTM model statistically outperforms the LR model, both models could be practically useful in wait time prediction. Future work will include broader patient data from a hospital and variations of the model architecture.

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Automated Nerve Fibres Identification and Morphometry Analysis with Neural Network Based Tool in MATLAB

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Abstract. Analyses of nerve histology are core assays in basic and applied research and even in clinical setting. Detailed report on nerve morphology may unbiased indicate the current state of a peripheral nerve. Manual method requires trained technician and is a time-consuming procedure. Available plug-ins to well known image processors are limited in use and data outcomes. Thus, the aim of the study was to create a tool for fast and repeatable analysis of a nerve section image. As a results we get very high precision of analysis in shorter time.

Keywords. Axon evaluation, morphometric analysis

1. Introduction

Preclinical research of neuroregeneration requires assessment of nerve fibres histology. The most reliable results contain histomorphometry parameters of axons and myelin sheaths. Manual methods may vary between researchers and are time consuming. Computer-based techniques may improve the above and deliver the accuracy comparable with some manual measurements. The study aimed to prepare a neural-network MATLAB script, with a novel approach to contrast-based method used for whole nerve section analysis.

2. Materials and methods

Semithin sections of a rat sciatic nerve stained with toluidine blue were a input data. They were scanned at 40x magnifications. Firstly, the analysis includes grey-scale conversion and contrast improving modifications e.g. CLAHE. In literature we can find methods, which analyze objects after binarization. Otherwise, we worked with the

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grey-scale image. Objects found with *regionprops* function were then filtered. Our protocol offers manual verification and removal of false-positive objects. We also applied Neural Net Pattern Recognition from Matlab for filtering results. Then, a rectangle enclosing each border of an object was defined. From the centre to the edge of the acquired area line segment was lead and histogram on this length was set. The border of each axon was determined in the point of highest contrast between neighbour pixels. The borders of myelin sheaths were defined likewise. This operation was repeated 360 times, around the analyzed nerve cell (radial histogram scanning and thresholding). The method resembles manual analysis since local contrast is used to mark the axon. Finally, the main morphometric parameters may be determined. Results were compared with manual measurements of 28 random nerve images, estimated by 3 researchers in ImageJ. Comparison to manual data was shown as ratios: script: manual.

3. Results

After optimization of brightness and contrast parameters, axon area overlay at level 1,010 and 1,009 of the myelin sheaths was achieved. Paired T-test showed no significant differences between these two methods (p-value = 0,321). Use of Neural Net enables to reach 93,6% of accuracy of axons recognition versus 3 researchers. A run time of the script is about 12 times shorter than the manual method.

4. Discussion

Other similar methods consist of binarization, which doesn't allow to define borders of the nerves precisely. The script presented shows a new approach to this case. It is based on reconstructing the way of evaluation done by the scientist. Owing to this innovative idea, the higher level of accuracy of computerized evaluation is possible. The most depending factor is optimizing the differentiation between correctly and incorrectly marked borders. Further researches focus on increasing the efficiency of this protocol.

5. Conclusions

The presented script performs an accurate analysis of nerve sections on a grey-scaled image. It overcomes bias of a binarization. The method decreases time of analysis and remains repeatable.

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Using *PM-TOM* for the Minimization of Adverse Drug and Gene Interactions in Therapies for Common Multi-Diseases

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Abstract. Multiple studies show that therapies for multi-diseases can lead to dangerous reactions and high healthcare costs due to their adverse drug-drug, drug-gene, and drug-condition interactions. In this paper, we present the results of using *PM-TOM* (*Personalized Medicine Therapy Optimization Method*) for finding therapies that minimize these interactions. The testing of the method was performed on the repository of electronic medical records of the *Harvard Personal Genome Project* (*PGP*), and the public databases of the drug and genetic information: *DrugBank* and *Comprehensive Toxicogenomics Database* (*CTD*). The results presented in this paper showed a significant potential of *PM-TOM* for reducing the cumulative adverse drug interactions in therapies for common multi-diseases.

Keywords. Personalized Medicine, Clinical Decision Support Systems (*CDSS*), Multi-diseases, Polypharmacy Therapies, Electronic Medical Records (*EMR*), Adverse Drug Reactions (*ADR*), Drug-Drug Interactions (*DDI*), Drug-Gene Interactions (*DGI*), Drug-Condition Interactions (*DCI*).

1. Introduction

Polypharmacy therapies for patients with multi-diseases pose significant health risks due to the possibility of their adverse drug-drug (*DDI*) drug-gene (*DGI*) and drug-condition (*DCI*) interactions, referred to as *CADI* (cumulative adverse drug interactions).

Studies [1] and [2] found *DDIs* in 66% and 87% of polypharmacy cases and *DGIs* in 33.9% and 73% of cases, respectively. In Canada [3], drug interactions are found in 80% of patients older than 65 years admitted to the hospital. Also, the study [4] reports that in 1994 some 2 million hospitalized patients had severe Adverse Drug Reactions (*ADR*) with more than 100k fatal outcomes, making these reactions between the fourth and sixth leading causes of death in the US that year.

Our research is motivated by the necessity of finding solutions to these worrying facts. In this paper, we present the results of applying the Personalized Medicine Therapy Optimization Method (*PM-TOM*) on cases of common multi-diseases. Its formal specification can be found in the paper [5]. Section 2 of this paper presents the *PM-TOM* method, data model and algorithm. In Section 3, we show the results of testing *PM-TOM* on *EMRs* with selected common multi-diseases. An exemplary multi-disease case is discussed in Section 4, along with the conclusions.

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2. PM-TOM Data Model and Method

Figure 1 shows the **PM-TOM Data Model**. Its core entities are *Patient*, *Condition*, *Gene*, *Drug Product*, and *Drug* (main drug product ingredient), which are associated via entities *Applied Drug*, *Drug Indication*, *Patient Condition*, and *Patient Gene*. Entities *Drug-Drug Interaction*, *Drug-Gene Interaction*, and *Drug-Condition Interaction* keep information about *DDIs*, *DGIs*, and *DCIs*, including their severities.

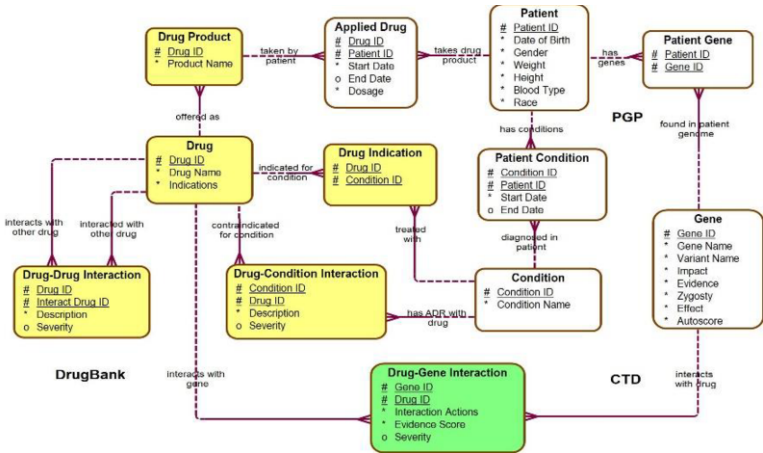


Figure 1. PM-TOM data model.

PM-TOM inputs are (i) a patient's *EMR* record, composed of the patient's conditions and genome, (ii) one or many considered drug products (*CD*) for these conditions, and (iii) the initial therapy (*IT*), composed of a single drug product for each condition.

PM-TOM outputs are (i) optimal therapy for considered drugs (*OTCD*), (ii) optimal therapy for all applicable drugs (*OTAD*), and (iii) a detailed personalized therapy report (*PTR*). *OTCD* has minimal *CADI* within the treatments formed of the considered drug products. On the other hand, *OTAD* has minimal *CADI* for therapies formulated from all medications prescribed to the patient's conditions in an *EMR* repository. *PTR* explains both optimal treatments, indicating their *CADIs*, and also describes their drug-drug, drug-gene, and drug-condition interactions. *PM-TOM* can also identify therapies with maximal *CADIs*, which suggest treatments with possible serious adverse effects.

To find *OTCD*, the **PM-TOM algorithm** [5] examines candidate therapies made from *IT* by replacing only one drug with another *CD* drug indicated for the same condition. For each candidate therapy, *PM-TOM* calculates *CADI* as a sum of its *DDIs*, *DGIs*, and *DCIs*, each interaction weighted by its severity (having values 1, 2, 3, etc.). In a special case, if the severities are not available, the *CADI* will be calculated as the sum of all *DDIs*, *DGIs*, and *DCIs*. *OTCD* is a candidate therapy with minimal *CADI*.

PM-TOM is an iterative method. In the next step, to find *OTAD*, it will examine all drugs from the *EMR* database prescribed for the patient's conditions. Instead of *IT*, the algorithm will now use its improved version, *OTCD*, created in the previous iteration. So, *PM-TOM* uses the expert knowledge of the physicians and clinical pharmacists expressed in the initial therapy, considered drugs and all prescribed drugs in *EMR*.

In the last step, *PM-TOM* generates *PTR*, which contains further details about both optimal therapies and their *CADIs*, including alternative drug products. Sample reports can be found at <https://www.abs-info-age.com/projects>.

3. Testing Results

We tested *PM-TOM* for finding treatments for common multi-diseases by using the database of the *Harvard Personal Genome Project (PGP)* [6], and public repositories *DrugBank* [7], and *Comparative Toxicogenomics Database (CTD)* [8].

In a cohort of 484 patients, we identified 16 most common diseases. Examples of these diseases are *Hypertension*, *Allergy*, *Hypercholesterolemia*, *Depression*, *Anxiety*, *Diabetes Mellitus*, *Asthma*, etc. We tested multi-disease patients that have at least three of these 16 conditions, for example: (*Allergy*, *Asthma*, *Rhinitis*) and (*Diabetes Mellitus*, *Hypercholesterolemia*, *Hypertension*, *GERD*).

Table 1 presents the testing results. Column (A) indicates categories of cases that have at least one multi-disease and the same number of all treated conditions. Column (B) shows the count of *EMRs* in each category. Column (C) displays the average number of considered drugs in each group, taken from the patient history, and column (D) the average *CADIs* of their optimal therapies for considered drugs (*OTCDs*).

The next columns show the testing results for drugs prescribed for the patient’s conditions in any *EMR*. The average count of these drugs is indicated in column (E), and the average *CADI* of their *OTAD* in column (F). In column (H), we also calculated the average *CADI* for maximum drug and gene interaction therapies for all drugs (*MITAD*). *MITAD* analysis illustrates the worst-case scenarios. Additionally, pair *OTAD* and *MITAD* show the *CADI* range for all possible treatments.

Finally, column (G) presents the *CADI* improvements between the *OTCD* and *OTAD*, which is, on average, about four times. Also, column (I) shows the ratio between the corresponding *OTAD* and *MITAD CADI*s, which come to 9 times on average.

These results suggest that various candidate multi-disease therapies show a rather large range of *CADIs* and that *CDSSs* can significantly support the physicians and clinical pharmacists to select proper treatments that minimize these interactions.

Table 1. Average *CADI* of optimal and least desirable therapies for common multi-diseases.

A	B	C	D	E	F	H	G	I
Total conditions	Patients	Considered drugs (avg.)	OTCD - CADI (avg.)	Appl. drugs (avg.)	OTAD - CADI (avg.)	MITAD CADI (avg.)	D/F CADI	H/F CADI
3	7	3.57	2.14	19.29	1	5	2.14	5
4	4	5.25	4	29.5	0.5	7.25	8	14.5
5	7	6.43	4.86	27	1.57	15	3.09	9.55
6	2	7	9	32.5	3	14.5	3	4.83
7	3	8.33	14	38.33	4	18	3.5	4.5
8	2	11.5	17.5	47.5	1.5	34.5	11.67	23
>8	3	12.67	24.33	38	9	72	3.02	8
Avg.							4.02	9.05

4. Discussion and Conclusions

As an additional illustration, we discuss the case of a male, 62 years old patient. He suffers from a complex multi-disease (*Asthma, BPH, Diabetes Mellitus, GERD, Hypertension, Hypothyroidism, Hypercholesterolemia, and Keratosis*). His genome contains pharmaco-genetic genes *ABCC6, CYP2C9, and TPMT*, and pathogenic genes *AIP, APOA5, ELAC2, HFE, KRT5, MTRR, RNASEL, SLC4A1, SP110, TGIF1*.

PM-TOM returned OTCD as *Efudex (Fluorouracil)* for *Keratosis*, *Finasteride* for *BPH*, *Flovent (Fluticasone Propionate)* for *Asthma*, *Levothyroxine (Liothyronine)* for *Hypothyroidism*, *Metformin* for *Diabetes Mellitus*, *Micardis (Telmisartan)* for *Hypertension*, *Zocor (Simvastatin)* for *Hypercholesterolemia* and *Nexium (Esomeprazole)* for *GERD*. This therapy has 19 DDIs and 7 DGIs (*CADI* = 26). Examples of these interactions are 'The metabolism of *Fluorouracil* can be decreased when combined with *Simvastatin*', and DGI 'Gene *TPMT* affects the response to *Fluorouracil*'.

After considering all applicable drugs from the PGP database, PM-TOM returned the following OTAD: *Exenatide* for *Diabetes Mellitus*, *Famotidine* for *GERD*, *Imiquimod* for *Keratosis*, *Minoxidil* for *Hypertension*, *Niacin* for *Hypercholesterolemia*, *Omalizumab* for *Asthma*, *Terazosin* for *BPH* and *Thyroid Porcine* for *Hypothyroidism*. This therapy has only 2 DDIs and no DGIs (*CADI* = 2). The complete example and its PTR can be found at <https://www.abs-info-age.com/precision-medicine-report-3>.

The above results lead to the conclusion that finding effective polypharmacy therapies for multi-diseases with minimal adverse interactions is not a simple task and that CDSSs like PM-TOM can provide significant support to the physicians and clinical pharmacists in making decisions about these therapies.

PM-TOM is an efficient iterative heuristic algorithm. Its complexity is rather low as it evaluates a small subset of all possible candidate therapies. That leaves room for its further extension with additional knowledge about the patient, such as age, gender, race, lab tests, etc.

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Students' Perceptions on Chatbots' Potential and Design Characteristics in Healthcare Education

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Abstract. Chatbots may have the potential to support healthcare education by enabling personalized learning. Trust is a pre-requisite for the users to accept the chatbots. In this study we analyzed students' assignments of the MSc course "User Needs, Requirements Engineering and Evaluation" at Karolinska Institutet, aiming to explore the chatbots' potential in healthcare education and the design characteristics of chatbots that may enhance the trust. The students identified two courses: pharmacology and medical law, that have the potential to leverage chatbots' characteristics. Our analyses on the design characteristics they suggested resulted in: recognition; visibility of system status; anthropomorphism in communication; knowledge expertise, linguistic consistency; realistic interaction. Our results are in line with previous research. Future studies could investigate the educational impact on the learning outcomes and students' satisfaction when interacting with chatbots.

Keywords. Chatbot, healthcare education, design characteristics

1. Introduction

Personalized learning has the potential to improve the decision making skills of physicians [1] by allowing greater transfer and cognitive flexibility which may be especially important for future healthcare professionals and lifelong learning [1]. As life sciences are shifting towards personalized medicine, training of healthcare professionals who enter the era of personalized medicine is of utmost importance and therefore the traditional academic setting has to adapt to include personalized healthcare education aids [3]. There is growing evidence around chatbots, understood in this context as conversational agents that they have the potential to change the way students learn and search for information. *"Chatbots are interactive, virtual agents that engage in verbal interactions with humans. This technology is an interesting case in human-machine interaction as they are designed to interact with users through the*

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usage of natural language based on formal models'' [4]. Chatbots have the potential to facilitate various processes, particularly those related to customer service and personalization because of their accessibility, scalability and relatively low cost [4].

In the context of healthcare education, chatbots may quiz existing knowledge, enable higher student engagement with a learning task or support higher-order cognitive activities [5]. Existing chatbot solutions have been studied before for their technical potential [6]. In large-scale learning activities involving a high number of students, chatbots are able to solve the problem of individual student support and contribute to personalized learning. However, limited examples of chatbots in European Healthcare Curricula have been utilized. For students but also teachers to accept and utilize the advantages of such solutions it is important to introduce trust towards the performance of a chatbot. Trust may be understood in terms of credibility and confidence in one another's judgment, as well as predictability of one's behavior [7]. There are therefore specific design characteristics of chatbots that can enhance the users' trust and therefore support chatbot's potential into healthcare education.

In this study we explored the students' perceptions on the healthcare curricula needs that the chatbots have the potential to support as well as the design characteristics of chatbots that may enhance users' trust in the identified educational domain.

2. Methods

Karolinska Institutet launches the international Master program Health Informatics. One of the courses that students have in the second semester is the "User Needs, Requirements Engineering and Evaluation". The aim of this course is to provide students tools and methods to analyze and model needs and requirements of patients, healthcare professionals and care providers, as well as to evaluate eHealth systems in different contexts [7]. The students taking this course during January 2020 were asked to identify potential application of chatbots into the healthcare curricula and to design basic paper or computerized prototypes that envision the chatbots' functionalities, focusing on the chatbots' design characteristics that have the potential to enhance the users' trust. Nine students were assigned in two different groups. They were given in total four weeks for both assignments while they were provided with feedback. We performed a thematic content analysis on the results of the students' assignments regarding the design characteristics that can benefit the end users' trust and we report on the potential of the chatbot in healthcare education as well as the envisioned prototype functionalities. This study falls outside of the vetting process of research in accordance with the Swedish Ethical Review Act (2003:460) as it does not handle sensitive personal data as defined in GDPR. Further the students were informed that the assignment could be used for research purposes and their consent was acquired.

3. Results

3.1. Potential need for chatbots in healthcare education

The students identified pharmacology and medical law as the courses that the chatbots have the potential to support. In particular the chatbots could facilitate memorizing

concepts, such as pharmacological formulas but also laws, and enable focusing on local variances in healthcare in both pharmacology and law disciplines.

3.2. *Design characteristics of chatbots in healthcare education*

Our thematic content analysis on the chatbots' design characteristics that can enhance the end users' trust resulted in the following categories:

- **Recognition:** The students designed the chatbots resembling well-known messenger applications for the purpose of enhancing the users' trust by the technical predictability. Recognition [9] with the interface is also enhanced by the fact that the students selected the chatbot's colors and interface characteristics based on the learning management system and the website of Karolinska Institutet.
- **Visibility of system status:** The students designed their chatbot including status visibility [9] so that the end users are aware about the system's operation and status by using symbols such as [Typing] [seen] [time].
- **Anthropomorphism in communication:** The students suggested that the chatbot should communicate in a human like way; understand natural language and recognize emoji's. To enhance chatbot's anthropomorphism [4] the students suggested that it should be friendly, relatable and able to joke.
- **Knowledge expertise:** To establish trust the students suggested that the chatbot shall provide precise and reliable information, including links to reliable resources and references. Moreover the students suggested that the chatbot knowledge base should be limited to the defined subjects.
- **Linguistic consistency:** The students suggested that the chatbot shall be consistent in terms of the language and terminology it is using, including standardized medical terminology.
- **Realistic interaction:** The whole process of initiating a discussion and interacting with the chatbot shall follow a realistic and logical flow, similar to real conversation in a real world.

3.3. *Chatbot prototypes' functionalities*

The students designed both low and high fidelity prototypes. The pharmacology course chatbot prototype functionalities allowed the user to log in; test and quiz knowledge; request additional information on a topic. The medical law chatbot functionalities allowed the user to log in either as a medical professional or student and request information on different medical law sub-topics or request to receive updates.

4. Discussion

The students identified two courses, the pharmacology and medical law that chatbots have the potential to support. Our thematic analyses on the students' assignments resulted in six categories summarizing the chatbots' design characteristics that have the potential to enhance the end users' trust and by that support their integration into the healthcare curricula. Our results are in line with previous research [4] regarding the anthropomorphism of chatbots having the potential to enhance the users' trust.

Moreover, Nielsen's design principles [9] were regarded by the students as applicable to the chatbot's designing process.

The students working on the assignments had mixed medical and technical backgrounds which is one of the study's strengths. However their number was limited (nine) and the results might not be generalized. Another limitation is that they received feedback during the assignments' development process that might have influenced the results. The assignments' duration was limited and did not include actual stakeholders which might influence the analysis' depth. Future studies could investigate the educational impact on the learning outcomes and students' satisfaction with chatbots.

5. Conclusion

Chatbots have the potential to support students in a personalized and interactive way. Our results provide new knowledge about the potential of chatbots in healthcare education and insights about design characteristics that may enhance the users' trust.

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Charting Early Developmental Trajectory of a Pilot Rare Disease Registry in Slovenia

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Abstract. Active surveillance of rare diseases enables evidence-informed policymaking, wide-ranging monitoring of rare disease patients, and subsequently assists progressively complex clinical and research needs. This article charts the initial steps for the development of a pilot rare disease registry in Slovenia. The research applies a case study design, while the collection of data was carried out through focus group discussions with 24 eminent experts from the field. The research results reveal the necessity for choosing an adequate development approach and point out that successful development of the national rare disease registry requires well-orchestrated efforts of all stakeholders. This inevitably includes effective preparation and implementation of the national rare disease policy, along with the divergence of clinical, organizational, and technological factors, and their integration with the long-standing public health goals.

Keywords. Rare diseases, pilot rare disease registry, case study, Slovenia

1. Introduction

In line with some indicative estimations, there are around 150,000 patients with rare diseases (RDs) in Slovenia [1]. Despite the lack of reliable epidemiological data, the abovementioned figures show that this area is of critical importance for the Slovenian healthcare system [2]. Deficient resources and knowledge in the field combined with the infrequency of RDs typically cause problems in their identification and diagnosis on one hand, while the chronicity and severity of RDs require complex and long-lasting clinical treatments on the other. Underdeveloped treatment approaches, which are often not supported by either relevant clinical evidence or appropriate medications, create additional difficulties. Insights into the problem reveal that information and communication technology (ICT) aspect in the field has been regrettably ignored, especially in terms of dedicated ICT solutions. In this context, RD registries are considered as essential tools for impartial monitoring of the prevalence and incidence of RDs, clinical studies, and can significantly assist patient treatment procedures [3]. Moreover, RD registries enable better assessment of clinical outcomes, and provide an

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applicable platform for evidence-informed policymaking. For that reason, the EU has declared the establishment of RD registries a priority in this field [4]. This is evidenced by several documents and projects [5, 6], and supported by the experience of countries that have already defined a framework for national registries and successfully implemented such initiatives [7-9]. However, despite the pressure from various national and international organizations, the Slovenian government only recently adopted the legislation requiring the mandatory establishment of the national RD registry. In view thereof, this article focuses on charting the initial steps for the development of the pilot RD registry (PRDR) in Slovenia.

2. Methods

The article applies a case study design to explore the research goals relating to the development of the PRDR in Slovenia. The collection of data was carried out through 14 focus group sessions conducted from January 2016 to February 2017.

Participants in the focus groups were selected according to their expertise and experience in the field of RDs [10]. A representativeness of the sample was ensured by a non-random stratified sampling approach. The final sample included 24 eminent experts coming from the most important institutions in the field of RDs. Conventional content analysis was used to assess the data obtained and provide the interpretation thereof, whereas the starting points for the development of the PRDR were extracted from the literature and focus group sessions.

3. Results

Planning the development of the PRDR was methodologically derived from the recommendations of the focus group participants and steps from the literature [11]:

The registry's purpose. The principal goals of the PRDR were focused on the different questions predominantly concerning the better quality treatment of the patients with RDs. Hence, the PRDR should generate reliable data regarding the incidence and prevalence, natural histories and diagnostic characteristics, and the management of RDs within the healthcare system.

Key stakeholders and the feasibility of the registry. The national project for the development of the PRDR was initiated by the leading institutions in the field related to clinical treatment of the RDs, public health, and healthcare informatics. Furthermore, registry team proposed certain regulatory amendments for the national RD registry, which were later actually introduced in the sectoral legislation.

Registry team. The team for the PRDR consisted of experts from clinical medicine, ICT/bioinformatics, genetics, and epidemiology, thus including all profiles, which are crucial for the successful development and implementation of the PRDR. The plan for actual operation of the PRDR (and forthcoming national RD registry) stipulated that registry team should contain administrative workers, health coders, and a supervisory body including patient representative.

Registry scope and data set. The PRDR should include all patients with a diagnosed RD and the pertinent OrphaCODE. The PRDR structure and suggested data set is displayed in Table 1. Patient demographic records containing personal data and vital status will be acquired from the Central Register of the Population, while the remaining

data would be provided by the reporting clinician. What is important, the data set for PRDR was adapted to ensure interoperability with the “Set of Common Data Elements for RD Registration” proposed by the European Commission’s Joint Research Centre.

Table 1. Proposed data set for the Slovenian PRDR

Data set categories and their content	
1.	Personal data: UMCN; name/surname; gender; place of birth
2.	Vital status: alive (Y/N); date and time of death
3.	Healthcare institution (of registration): name; department; date of first contact; date of registration; name of clinician
4.	Diagnostic codes (main diagnosis): OrphaCODE; ICD-10 code
5.	Characteristics (main diagnosis): description of the diagnosis; date of diagnosis; confirmed (Y/N); age at diagnosis; time of first signs/symptoms (year/antenatal/at birth/ND)
6.	Other diagnoses (all to be listed): ICD-10 code; description
7.	Genetic characteristics and biological material: HGNC code; HGVS code; OMIM number; type of biological material available; biobank name
8.	Functionality/Disability scores: result according to the ICF classification
9.	Therapeutic data: any orphan drugs (according to the EMA list)

List of abbreviations: EMA, European medicines agency; HGNC, The HUGO Gene Nomenclature Committee; HGVS, Human Genome Variation Society; ICD-10, International Classification of Diseases 10th Revision; ICF, international classification of functioning, diseases and health; N, no; ND, not determined; OMIM, Online Mendelian Inheritance in Man; UMCN, Unique Master Citizen Number; Y, yes.

Technological implementation. The activities for the design of technological solution were based on the recommendations of the focus groups and substantial outputs produced in each development step outlined above. The PRDR was constructed as a web application containing web-services, which significantly increase the functionality, simplify the use, and speed up the entire data entry/transfer process. The activities for the definition of clinical content and development of the technological solution were carried out separately. This concept allows experts to do the job as well as possible in their field; thus, clinicians can focus on defining clinical content, and ICT experts can focus on designing a technological solution. The national RD registry should have a central role in the future RD ecosystem, systematically connecting stakeholders and fragmented infrastructure, and providing required interoperability on all levels (technical, semantic, organizational, and legal). The designated institutions should form a well-organized reporting system, providing reliable data sources, standardized data formats, and high-quality data inputs for the national RD registry. Operations of the national RD registry will be conducted only in accordance with strict and predefined business rules. Compliance with the legal requirements, security policies, reporting procedures, and methodological standards should be regularly audited and prudently managed.

4. Discussion

The effective implementation of the RD registry requires a coordinated and systemic approach, along with the stakeholders’ commitment, proficient political support and adequate sourcing [4]. This includes well-defined management framework, a viable ICT solution, and necessary resources (human, material, technical, and organizational) needed for its operation. Such approach should reduce the costs and workload of healthcare providers, and accelerate the acceptance of the RD registry among clinicians. The development the PRDR was indeed a very challenging project, as the entire process had to be carried out in a sensitive healthcare milieu, and all development steps were reliant on the regulatory, clinical, ICT, and other critical elements in the field of RDs.

The planned process for the development of the national RD registry will have to be grounded in feasible project plan that precisely defines the project leaders, funding, timeline, milestones, and long-term objectives. The proposed model for the development of the RD registry does not suggest a ‘one-size-fits-all’ solution; however, the presented study could offer some starting points for further advances in the field. Given the fact that Slovenia does not have a functioning national RD registry, all its implications were theorized without empirical validation in the real healthcare surroundings. Forthcoming research attempts should be focused on in-depth exploration of the role and effects of the national RD registry, including its evaluation in the actual clinical scenarios.

5. Conclusions

Notwithstanding the identified intricacies, the establishment of the national RD registry represents a considerable opportunity that may profoundly empower stakeholders, increase the exploitation of the current healthcare system capabilities, and facilitate the better-quality treatment of the patients with RDs. Owing to latest developments in the field, including the updated legislation and development of the PRDR, the general state of affairs relating to RDs in Slovenia seems reasonably optimistic.

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Introducing DRGs into Greek National Healthcare System, in 27 Weeks

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Abstract. Experiencing a devastating and intolerable economic crisis in Greece, the National Healthcare System (GR-NHS) needed a tool to manage expenditures and quality of healthcare services. The adoption of the Australian Disease Related Group (AU-DRG) system along with the International Statistical Classification of Diseases and Related Health Problems (ICD-10) constituted the major components of the needed tool. The tool provided the means to perform the transformation of the applying reimbursement system and at the same time to monitor and control expenditures and quality of GR-NHS. The prevailing fiscal conditions urged and obliged to design and implement a project regarding the introduction of a DRG system into GR-NHS in the limiting time period of 6 months or 27 weeks. The project utilized solely the available resources of the Ministry of Health with the direct support from the largest Health Insurance Fund (IKA). The aim of the project was to enable all hospitals demanding reimbursement from Social Security to use the developed KEN-DRG system. At the same time, the Social Security would be capable of controlling and budgeting the expenditures for beneficiaries and the Ministry of Health could control and assess the expenditures and the offered quality of services using the newly developed system.

Keywords. National Healthcare System, DRGs, Hospital Information System

1. Introduction

The Greek National Health System (GR-NHS) was founded in the early 80's, and a major reform took place almost two decades later to receive its current general form [1]. The economic crisis that emerged at the end of the first decade of this millennium found the GR-NHS unprepared to handle the unreasonably rising healthcare and pharmaceuticals expenditures as the system was designed to cover different incidental needs than those present at that time. During the period of delusive prosperity up to the year of 2009, the healthcare institutions were receiving reimbursements from numerous and different Health Insurance Funds (HIF). For each provided healthcare service the private and public healthcare sectors had to submit to the corresponding HIF the entire set of treatment documents. The bureaucracy developed barriers for the controlling services and accounting departments of the numerous HIF which were employing large numbers of staff while the Ministry of Health (MoH) was receiving an outdated and blurring picture of the prevailing situation of the GR-NHS with evidence which was made available months later due to the slow-moving bureaucratic clearing procedures

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that were processing large volumes of unorganized and non-normalized data. Thus, the healthcare administrative services were incapable of applying evidence-based control and decisions processes about providing grants and funding were based on data of poor quality, short-term insecure judgments, or even worse, on arbitrary political decisions.

This paper starts with a discussion of the reform needed in GR-NHS, then it provides a brief description of the project's to introduce DRG system design, it continues with project's administration that had to achieve the set goals within the time frame of 27 weeks, and ends with the drawn perceived conclusions.

2. The Need for a GR-NHS Reform

The emerged economic crisis challenged the State with bankruptcy and emergency activities took place to control the GR-NHS performance. In order to face the pharmaceutical expenditures, the e-prescription system developed reducing the spending from a quarter of a million per month to something more than a tenth of a million on a monthly basis for the largest HIF of IKA. Also, for the suspension of expenditures, the Center for the Evaluation of Disability (KEPA) established achieving in a quarter of a year to reduce the disability factor from 15% to 8% which is the average in the European Social Security Institutions. In addition, the national information network was developed (GR-NHSnet or ESYnet) that initially operated manually and procuring its successor that it is equipped to automatically gather reliable data from each of the 131 hospitals of GR-NHS and processing the collected data to support the policy making process of the MoH. Almost a decade later ESYnet is not fully automated and the MoH is not taking full advantage of the contemporary analytics with big-data, artificial intelligence, machine learning and deep learning methods. Moreover, Quality was chosen to be the means to control the financial expenditures deciding to develop Standards of Procedures (SOPs) for GR-NHS and at the same time, develop a new reimbursement system employing Disease Related Groups (DRGs). Thus, the development of a DRG system had to be developed in a tight time-frame of 6 months or 27 weeks to face the emergency situation supporting the emergency state and meeting the fiscal obligations [2].

The reasons a DRG system was expected to act as a catalyst are given in the following three directions. First, the patients' accounts clearance added a heavy overhead for the private and public hospitals to prepare and submit on-time the full documentation of treatments to each of the almost thirty (30) HIFs. Similarly, second, the HIFs faced an analogous overhead to examine and process the received documentation to proceed with payments. Third, the efficiency measurement of healthcare services was impossible and so, it was infeasible to indirectly measure Quality and control the financial performance. In other words, prepare GR-NHS for an internal reform [2] by evolving and moving from the so called "line-item-budget" towards the "fee-for-service" [3]. Thus, the largest HIF of IKA, which supports half the nation's population, fully supported the MoH to introduce an adequately adopted reimbursement system [4, 5].

After determining the necessity of the project regarding the introduction of a DRG system, the requirements' collection for the organization of the projects followed. The delegation's trip to the German organization AOKA proved disappointing as no assistance was provided with the excuse that they did not want to jeopardize their reputation with a forthcoming failure. Thus, a project was designed based on the locally

available resources and open scientific information. The project duration should be at most 27 weeks or 6 months of time and it should cover at least the 131 Hospitals of GR-NHS and volunteering private institutions.

3. Project Design

The Australian DRG system was selected, examined, and adopted. The defined committees of medical specialists made decisions about the patients' classifications, the medical classes of diseases or groups, the levels of severity within each class, the cost related with each medical class and setting the prices related with each of the classes, and determined the holding exceptions, e.g. for oncology [5]. Two approaches were decided for pricing estimations. The first approach asked the medical specialists committees to propose prices for each class. The second approach asked for the execution of a scientific economists' study which was performed by the National School of Public Health (NSPH), the Economics department performing a relative comparison between the Greek and the Australian prices system considering and comparing the analogies of characteristic sets of economic and financial parameters. The two sets of prices defined the initial limits for the applied prices of the GR-DRG system and eventually minor adjustments on prices applied [5] including the MoH policies.

The technical development and the execution of the project plan included milestones that required attention. Coding was on top of the priorities list because it presented threefold aspects. First, the development of the DRGs coding, second, the use of the DRGs coding by 131 hospitals and third, the maintenance and promptly update of it [2]. Also, in the priorities list, it was the topic of quality measurement which had to be associated, among others, with readmissions, mortality rates, excess of hospitalization dates, and complications during treatment.

The adoption of standards and good practices included the Australian DRG system and the international classification of diseases (ICD-10). In particular, the NSPH translated ICD-10 into Greek and performed an economic study over the Australian DRG to localize and adjust its values into the Greek reality. In order to achieve standardization at the Hospitals, a set of Standards of Procedures (SOPs) submitted and followed by the Hospitals covering specific areas of everyday activities. The project was aiming at the smooth transition from the Global Budget (line-item budget) to controlled areas of Fee-For-Service [3, 5]. Thus, the Australian DRGs and ICD-10 materials were disseminated to all participants and the project relied on the process-based PRINCE2, the PERT and CPM tools, and the continuous project auditing applying Risk management (ISO 31000), Business Continuity (ISO 22301), and Quality (ISO 9001) within a cybernetic framework.

4. Project Administration

The organizational structure of the project followed the Prince2 standard. A layered organizational model adopted a Steering Committee for making high level decisions on raised issues by a Project Board Committee for resolving technical matters or escalating issues to the Steering Committee whenever necessary. Rapporteur to the Project Board was the Project Director as responsible for the project management.

The project's structure was including four additional organizational facilities. First, Project Teams which were at each of the 131 Hospitals. Second, medical specialties were setting up committees for each class or group of Medical Diagnostic Categories (MDC) to support the scientific aspects even beyond the project's life cycle. Third, for the economic scientific support it was appointed to NSPH. Forth, the project was facilitated with an adequate Help Desk communicating through multiple and specifically designed communication channels, IT Support with Wikis and cloud computing applications, and Training services employing e-learning platform. Hence, all interested parties were participating with well-determined responsibilities and adequately defined contributions.

The project's administration was characterized by three fundamental ingredients. The first characteristic ingredient was communication which was applied through the carried documentation, reporting, and weekly meetings. The second characteristic was about control which was enforced at all structured levels of the project's organization with the aims to satisfy or to propose improvements and alterations to the project plan. The third characteristic was about feedback that was received through the paper or electronic correspondence of all participants with the Help Desk of the project.

5. Conclusions

The design of the project took under consideration Cybernetic principles focusing on the reduction of the introduced system's complexity and simultaneously the increase in the project's control while keeping sustainability. The maintained sustainability forced the optimization of medical, economic, financial, administrative, operational, and technical aspects of the project. The variety of the employed concepts was thoroughly defined trying to keep low the involved entropy maintaining narrow communication channels which activate simplified administrative controlling mechanisms with rectified behavior steaming from the employed feedback.

The set objectives have been achieved within the limited available time frame and the introduced system is still in-use but without being regularly updated as it was designed for. In addition, the MoH was never took advantage of the available system, neither supported with the appropriate personnel, nor provided the technical and administrative means to keep the system alive in spite of the establishment of a relative state organization. The lack of a grouper, either developing one or supplied some commercially available system is considered as a necessity.

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Health Record Index: Secure Access of Cloud-Stored Healthcare Data

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Abstract. Healthcare 4.0 demands healthcare data to be shaped into a common standardized and interoperable format for achieving more efficient data exchange. What is also needed is for this healthcare data to be both easily stored and securely accessed from anywhere, and vice versa. Currently, this is achieved through the secure storage of the healthcare data in different cloud repositories and infrastructures, which however increase the difficulty of accessing it in emergency situations from healthcare practitioners, or even from the citizens' themselves. The latter need to have specific credentials for accessing healthcare data in private cloud repositories, which can be almost impossible in urgent situations where this data must be accessed no matter what. For that reason, in this paper we are proposing a new health record indexing methodology that facilitates the access of non-privileged users (e.g. healthcare practitioners), to the healthcare data stored in cloud repositories of citizens-in-need, under the circumstances of emergency cases.

Keywords. Healthcare, health record index, health cloud repository, HL7 FHIR

1. Introduction

Today's digital environment is characterized by a huge number of devices connected to the Internet [1], which produce and consume a large amount of data to be downloaded, evaluated, and used to trigger and activate different tasks. This data is stored either locally (on each device) or remotely (on computer clouds), with the ultimate goal of being exchanged among people who can extract additional knowledge from it, as well as analyzing or combining the extracted knowledge with other sets of information. In particular, in the field of electronic health and mostly in emergency situations, the exchange of data between citizens - patients and medical staff, is characterized of vital importance, since in this way a medical problem or solution can be identified faster, and thus improve the quality of life of the citizens [1]. After a deep research and study, it was observed that there is no standardized way to exchange healthcare data between citizens and medical staff, since more research has been attributed to the exchange of data only among the health personnel. At the same time, research was conducted on data exchange protocols, and it was observed that there is no relevant data exchange protocol that can be easily implemented and re-used simultaneously, by multiple operating systems. However, based on specific research [1][4][5][6], it was observed that what is mostly missing is the option of the citizens to store their healthcare data on cloud repositories,

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and having the ability to provide to their healthcare practitioners a mean of accessing this data without specific credentials and without providing them a direct access (i.e. link) to their cloud repository, for security reasons. Hence, the purpose of this paper is to propose an innovative proxy in the form of a Health Record Index, for informing the healthcare practitioners about the cloud location of the stored healthcare data without directly providing the data to them, in order to address emergency cases where the citizen is not able to provide her consent for third-party accessing of this healthcare data (supposing that in the past such a consent has been already approved by the citizen for granting access to the stored data to healthcare practitioners with pre-specified data access tokens).

The remainder of this paper is organized as follows. In Section 2, some data indexing techniques are illustrated in the healthcare domain, while Section 3 depicts the overall flow of the proposed Health Record index. Section 4 includes a short evaluation of the derived results, presenting our concluding remarks.

2. Indexing of Health Records

In general terms, indexing can be best described as a data structure technique that allows the quick retrieval of records from a database file [1]. In the current paper, this data structure technique will allow the retrieval of records from a cloud-based database (e.g. Dropbox [2], Google Drive [3]). In this context, several methods have been proposed, such as the work of [4] where the authors have designed a proxy architecture that enables seamless extensions by pre-processing the input text and parameters, and post-processing the annotations. The authors in [5] introduce a new algorithm with Hadoop MapReduce framework for enhancing proficiency of arbitrary reads over big dataset samples, where their proposed Hash index improves efficiency by reducing the amount of accessing data for range queries by creating buckets based on hyperplanes. What is more, the work of [6] should be mentioned where the authors present architectural best practices as lessons learned in the design and implementation of NLP-PIER (Patient Information Extraction for Research), a scalable, extensible, and secure system for processing, indexing, and searching clinical notes at the University of Minnesota. What is missing in all these research studies is that the proposed architectures are techniques that are not easily customizable and implementable in multiple domains and scenarios, since they are tailored to work under specific circumstances. Hence, what is needed and what this research adds is a standardized and easily implementable way of immediately accessing healthcare data stored on private clouds for further usage, through the indexing process.

3. Health Record Index Proposed Approach

Before referring to the importance of the current research, the following terms should be identified: “medical application of a citizen (smart Electronic Health Record application (S-EHR-app))” and “application of medical staff (Healthcare Practitioner application (HCP-app))”. A S-EHR app is any application installed on a personal mobile device that can store a user’s personal health data securely (encrypted). Such an application may contain user health information generated and signed by the healthcare provider, but may also contain data stored and produced directly by citizens or by sensors (e.g. smartwatches). An HCP-app is a software application designed to provide medical staff

with access to and use of patient data from a S-EHR app, with the goal of securely exchanging health data with any S-EHR app, using different protocols.

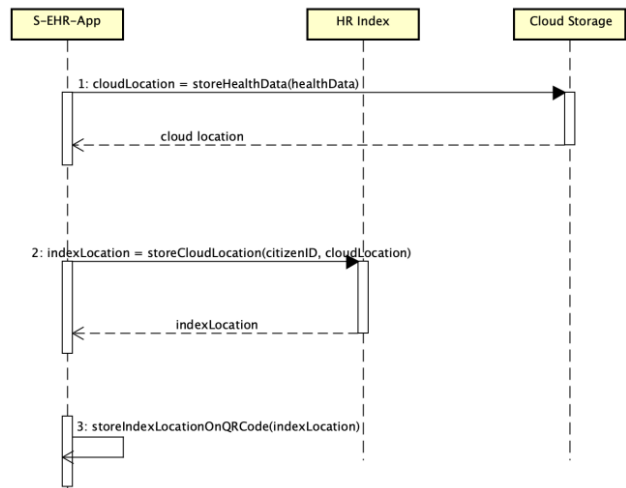


Figure 1. Uploading data to the cloud through the HR index.

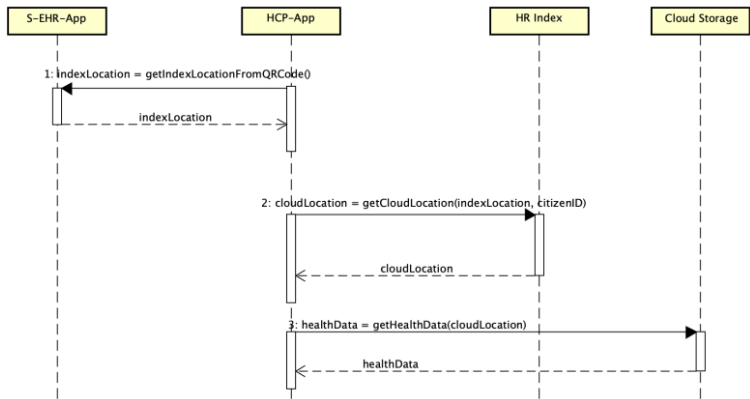


Figure 2. Downloading data from the cloud through the HR index.

Prior to explaining the flow of the proposed Health Record index (HR index), a list of specific preconditions is specified: (a) the citizen has a unique identifier (ID) (created from the S-EHR app), (b) the citizen agrees to store her healthcare data on the cloud, (c) when the storage of the healthcare data to the cloud happens, the cloud sends to the HR index the unique ID of the citizen and the address of the cloud where the data is stored (e.g. IP address of the cloud), (d) the HR index is a database consisting of a table called USERS where it stores the unique ID of each citizen [*column: ID*], and (e) when a new citizen ID is sent from the cloud to the HR index, a unique table called ID_CLOUD_LOCATION is created in the HR index, having two columns [*column: ID*, *column: location*]. In the location column, it is stored the address of the cloud where the specific citizen has stored her data. If the citizen already exists, then the ID_CLOUD_LOCATION table is just updated with the new address of the cloud.

The overall flow of the HR index is provided below (Fig.1, Fig. 2): (1) The citizen has a QR code including her personal ID and the address of the HR index (printed in the

form of a paper, in the form of a static QR code), (2) The HCP scans through her HCP-app the QR code, (3) This redirects the HCP-app to the HR index (based on the HR index address), locating the citizen from the USERS table that locates all the cloud addresses that are stored in the ID_CLOUD_LOCATION table, (3) The HR index returns to the HCP-app the different cloud addresses, (4) For each different cloud address, the HCP-app connects to the cloud of the user, retrieves the healthcare data of the citizen over HTTP and returns it back, and (5) The HCP-app visualizes the downloaded data.

4. Evaluation, Conclusions & Discussion of Results

In order to evaluate the proposed indexing methodology, two applications were created in Java for Android, using Android Studio, for uploading and downloading healthcare data based on the described HR index flow. The cloud storage that was used was Dropbox cloud-based storage system, while the dataset that was stored on the cloud repository and used for the evaluation purposes, included the demographic details of a random citizen (i.e. name, address, contacts, and ID), based on the HL7 FHIR format [7]. The overall flow of Fig. 1 and Fig. 2 was followed, providing us with the expected results.

Nevertheless, what is missing is a total of techniques to provide the ability to the citizens to store their healthcare data on private clouds, and having the facility to provide to their healthcare practitioners a secondary mean of accessing this data, without providing them a direct access (i.e. link). To this context, we will continue working on the evaluation of the health record indexing methodology, to make it more mature for global usage. It is also within our plans to provide additional security algorithms, for wider applicability, also continuing this evaluation with datasets of different sizes and formats, respecting privacy issues, based on the mechanism developed in [8].

Acknowledgment

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Evaluating Interactivity in VR Healthcare Applications Using Analytics

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Abstract. Currently, Virtual Reality-based 3D applications are more and more in use. Education is a field that makes use of this technology providing the users with a pleasant way of learning. Thus, the human-computer/smart phone interactivity increases. To measure the human-computer interactivity in a Virtual Reality-based 3D application, certain metrics may be considered (e.g.: application usage time, speed of execution of certain tasks). In this paper we use Google Analytics to observe and measure the interactivity in a medical application created for educational purposes. The application is based on Virtual Reality, and the user may observe and handle the bones of the human skeleton. The main actions monitored via Google Analytics to observe interactivity are: skeleton parts selection, zooming in/zooming out, rotation. An 80% usage percentage (measure of interaction) was achieved for the skeleton selection (foot bones), while for the other actions and selections the achieved percentage was of 100%.

Keywords. Google Analytics, Virtual Reality, interaction, 3D applications, healthcare, education

1. Introduction

Virtual Reality-based (VR) 3D applications are more and more present in medical academic education or for healthcare staff continuous education. Such applications, either for educational or medical purposes or for serious gaming, have an advantage over the usual applications. Virtual Reality may be defined as an artificial three-dimensional environment created by man on a computer, simulating reality so well that the users experience the impression of physical presence when using it. Virtual Reality, is experienced with the aid of hardware and software that enable the 3D visualization of the objects. Amongst the most frequently used equipment is the VR headset in conjunction with an app (a smart phone application). The purchase price of the headset is very low, therefore any user can afford this piece of equipment. There are also other devices that allow exploration/visualization of the 3D virtual space such as: Oculus Rift, HTC Vive, Microsoft HoloLens. The advantage of using such equipment is that they allow a detailed visualization of the 3D virtual space, with higher clarity than the VR headset. The purchase price of such devices is much higher than the VR headset's price. In both cases, using either the VR headset or other devices, the human-computer or smart phone interactivity increases. We may define VR-based 3D application

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interactivity as the process of visualization and action/handling between humans and 3D virtual objects within a certain time duration and with the aid of peripheral devices.

To measure the interactivity in a VR-based 3D application various metrics can be created: the application usage time duration, the manner of usage or of accessing certain 3D objects of the specific application and the speed of execution of certain actions within the 3D virtual space. An alternative to measure interactivity in a 3D application is the traditional one, i.e. using a test plan. In the test plan, answers to various questions related to the way the user perceives interactivity within the application are important for evaluation of the application. In this paper we use Google Analytics (GA) to observe and measure the interactivity in a VR-based educational application [1]. This VR-based application was developed for educational purposes, for medical students or any users passionate about exploring human anatomical systems. Using GA allows the automated detection of the actions performed by the user in the 3D application. The integration of such service into our app is modular and may be used to detect the interaction in other 3D applications as well.

2. Related Work and Tools

Interaction in a 3D application is presented in a system based on extended or experimental reality (XR) [2]. The main interactions within the 3D virtual space being studied are: the selection, translation and rotation of a 3D object. The metrics proposed for measuring the interactivity in this system are: time of usage of each user option, speed and precision of execution of the actions.

Using VR to explore and analyze data allows the users to visualize them in 3D and consider another perspective on them. The data analysis is presented in a 3D application developed in Unity [3]. The data presented in the application refers to the geospatial coordinates in the Massachusetts Institute of Technology (MIT) campus, made available by Twitter. The data is presented in a VR environment. The application allows the user to apply various filters such as: time intervals, searching for certain Twitter data type. In addition, it uses Leap Motion to allow the users to use their hands to select certain Twitter data. The data analysis in the early stages of their exploration is proposed in another system [4]. It allows the users to evaluate the VR-based analytics advantages. It proposed 2 data analysis methods: star coordinates and star plots. Another technology used in data analysis is mixed reality (MR). An MR-based 3D system measures both the time-related performance of the users, the errors, and the movement patterns [5]. To measure the users' performance, they had to perform several tasks: detection of previously visualized objects (memory-based detection) and cluster recognition. The users' performances improved when using this new technology as compared to the traditional one, i.e. using 2D applications.

Certain data web analysis services may be used to analyze data sets which should reflect interactivity in an application. GA provides this service [6], allowing the users to visualize certain data: audience data, acquisition data, and behavior data. This service may be used to understand online learning and the manner of use of certain learning platforms [7]. This paper will present the integration of such service in a VR-based educational application developed in Unity. The purpose of the integration of such service is to observe and measure the interactivity in the application.

3. Methods

GA was integrated into the VR application developed in Unity. The Unity editor allows its integration with the project activating a GA option.

For our research we created 8 GA type events: 5 events for the control panel and 3 for the skeleton representation. Such events are called *analytics trackers* and are predefined C# scripts. Their role is to detect when an interaction takes place between the object they are attached to and an external object (in our case a virtual point). Thus, events may be created, activated in various cases such as: when starting the application, when stopping the application or they may be activated via external events such as pressing a button. The first 5 events will activate when the user executes a zoom in/zoom out movement, right/left rotation of the skeleton or when resetting its position and scale, respectively. The rest of GA-type events activate when the user selects skull bones, pelvic bones, respectively foot bones representations.

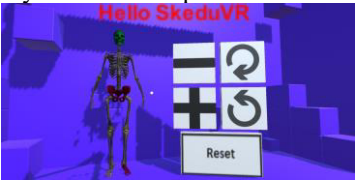


Figure 1. Main scene of the SkeduVR Application.

The control panel has five objects (Figure 1) each showing its role. By placing the pointer on one of them the user will zoom in or zoom out of the skeleton and will rotate the skeleton to the left or to the right on the y axis. The 3D skeleton will increase in size on all the 3 axes by 0.1 measurement units in the Unity virtual space, each time the user places the point on the object meant for zooming in or zooming out. The rotation to the left or to the right on the y axis is performed by 30 degrees on each selection of the object ensuring the rotation. When the user places the point on the “Reset” object the scene will reset, and the skeleton will get back to the initial position and scale. When placing the point on one of the bones, the user will receive information on it, the name and type of the selected bone (wide, short or long). The users are informed on the possibility of their activity being monitored from the start of the application. They get a message informing them that their interaction in the application is monitored. Thus, if the users agree to it, the main scene is displayed where they may visualize and handle the skeleton; then their consent is sent to GA’s API (Application Programming Interface). Their timing is also started in order to see how long they used the application. This function is also performed with the aid of GA. In this application, the administrators (the application developers) may observe the inactivity of each user in relation to the application usage time and to the actions performed in the application. The actions observed are only the functions which integrated the analytics tracker part with them (Table 1).

Table 1. Actions observed in the application through GA (usage percentage)

Action	Zoom	Zoom	Rotation_left	Rotation_right	Reset	Bone selection		
	in	out				skull	pelvic	foot
Percentage	100%	100%	100%	100%	100%	100%	100%	80%

Automatically detecting the user’s actions results in a major advantage since it eliminates the users’ subjectivity when testing 3D applications. For instance, one of the questions often raised within a test plan is: “How easy was it to access certain functions (e.g.: buttons, information texts) in the application?”. Such type of question is

eliminated when using GA. In educational applications, the information visualization and accessing in certain positions within the virtual 3D space are detected automatically via this service. Thus, in the new versions of the app the information may be concentrated under another mode/position, in order for the user to be able to read/use it.

4. Conclusions

Using GA we measured interactivity from a usage time perspective and related actions. Currently, we obtained an average of 3.5 minutes of usage per day and the zooming in/out, rotation, and respectively resetting actions were performed by all (Table 1) the users (10 active users). The activation of the GA trackers is triggered by selecting every single bone. It was noticed that some users activated most of the time only the trackers for the upper part (skull bones) and middle part of the skeleton (pelvic bones). The lower part (foot bones) was not selected by all the users, only 80% of them managed to select it (Table 1). The foot bones of the skeleton was selected only by 80% of users, because the users' gaze is not oriented at the bottom in the 3D space. To develop a successful VR-based application its interactivity must be measured. With the aid of GA in our application the interactivity may be increased by observing the most frequently and the less frequently used parts. The application deficiencies as far as the use of certain functions is concerned may be remedied by detecting of the causes thereof. One of the causes is the positioning and the color of the 3D objects that the user must observe in the 3D virtual space. GA also offers the opportunity to increase the usage time of a 3D application by keeping track of the initial time spent with the application as well as of its most frequently used areas. Therefore, the application may be personalized to focus more on each individual user's specific needs.

In the future we intend to generate more reports to reflect the application usage on a larger sample of active users. By detecting the interaction in our education application, automated tests may be generated when the user has completed more than 90% of the application, observing all the skeleton bones within a predefined time duration.

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Meta-Analysing Methodological Quality of Published Research: Importance and Effectiveness

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Abstract. The Inappropriate design of experimental studies in medicine inevitably leads to inaccurate results and biased conclusions. The aim of our study was to compare prevalence of implementing basic principles of experimental design in preclinical experimental studies published in international journals with low and high impact factor. The samples for analysis were randomly chosen among publications retrieved from PubMed and Web of Science (WoS). Implementation rate of basic experimental research principles (local control, randomization and replication) was established by careful reading of the sampled publications and their checking against predefined criteria. The difference in number of satisfied criteria among the groups was not significant, however, number of citations was significantly higher in the group of studies published in high-impact factor journals (30.5 ± 38.5 vs 2.6 ± 4.1 , $p=0.000$). The studies published in low-IF journals less frequently used pseudo replication (30% vs 56%, $p=0.000$) and more often randomized their units of observation (40% vs 5%, $p=0.000$). Prevalence of experimental preclinical studies that did not implement completely basic principles of research design was high in both low- and high-impact factor journals. Although much more cited, studies published in high-impact factor journals bore the same risk of incorrectness, bias, and consequent misleading of future researchers.

Keywords. Randomization, control experiments, replication, internal validity

Introduction

An important way of systematically reviewing studies is through meta-analysis (1). Meta-analysis is a statistical and analytical method that combines and synthesizes various mutually independent studies and integrates their results into a single, common result. If well designed and properly implemented, it can be a very powerful tool for proving hypotheses. It is based on strictly established mathematical and statistical principles for critical analysis of medical data (2).

Meta-analysis refers to the analysis of analyzes (3), with the purpose of integrating their results. The meta-analytic approach described by Glass in 1981 requires: finding the studies, evaluating studies for their importance, describing the results on a common scale and using statistical methods to summarize the importance of studies and results (3) (4). Using meta-analysis, a wide range of outcomes can be explored, as long as there is an acceptable number of research articles. The peculiarity of the meta-analysis is that

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it actually combines all the research of a topic into one major work in which many participants take part. However, there is also the danger that, when merging a large set of different studies, the structural definitions may become imprecise and it may become difficult to interpret the results meaningfully. Like any other research method, meta-analysis has its advantages and disadvantages. The advantage is its objectivity, but as with any research, its value depends on the creation of certain qualitative explanations as well as on the understanding of objective data (4). Meta-analysis became indispensable in understanding a large collection of raw data or literature that is sometimes contradictory, inconsistent, and unclear on a topic, and in understanding the true importance of statistical results when addressing a scientific topic, such as efficiency. Readers of a meta-analysis should be able to understand not only the objective of the analysis, but also methods of summarizing results and their interpretation.

An inappropriate design of experimental studies in medicine inevitably leads to inaccurate or false results, which serve as basis for erroneous and biased conclusions (5). Although numerous attempts were made in the past to prevent errors in research design, like establishing guidelines for experimental studies (6) or teaching experimental design at postgraduate studies (6), evidence shows that some of the basic principles of experimental research design are still not implemented in more than half of the studies published in medical journals (5,6). There are three basic principles of proper experimental design: having appropriate negative and positive controls for testing treatment, replicating experiments on independent experimental units a sufficient number of times and randomly assigning a treatment (or factor) that is tested and control treatment (or factor) to experimental units (5, 6). Failure to acknowledge and implement these principles when planning a study usually causes production of false positive results, which are rather a consequence of uncontrolled factors or maturation of experimental units, than of the treatment (or a factor) that is actually tested (6).

The aim of our study was to investigate the prevalence of implementing basic principles of experimental design in preclinical experimental studies, performed either on animals in vivo, or animal/human material in vitro based on meta-analysis of articles published in high- and low-impact factor journals.

1.Methods

The studies in our research were retrieved for analysis from the Web of Science and PubMed database, published in medical journals printed in B&H and worldwide. The following inclusion criteria were used: journal article, original experimental study, animal study, in vitro study and full text availability. The exclusion criteria were: review articles, clinical trials of phase I-IV, cohort studies, case control studies and cross-sectional studies. The size of the study sample preclinical studies ($n=86$) was calculated on the basis of the following assumptions: rate of inappropriate research design 0.5 (1) and width of the 95% confidence interval ± 0.15 . The formula $n = (1.96)^2 \times 4 \times p^*(1-p)/d^2$ was used for the calculation, where „n“ was the sample size, „p“ probability of inappropriate research design and „d“ width of the confidence interval (2). Since the studies retrieved by the abovementioned search strategy were numbered orderly in the PubMed database, the study sample of 86 studies was extracted by simple randomization technique, activating for 86 times random number generator in Excel, using formula `RANDBETWEEN (1; 666,342)`.

The extracted studies were analyzed for internal methodological validity, checking whether basic principles of correct experimental design (replication, control and randomization) were implemented. For the purpose of this analysis, the checklist with 8 questions was prepared, as shown in the Table 1. The results of the analysis were tabulated and described by rates and percentages when categorical, and by means, standard deviations, medians and interquartile ranges, if continuous.

Statistics: After statistical description, normality of the data distribution was checked by Kolmogorov-Smirnov test, and if not achieved, Mann Whitney U test was used for comparison of continuous variables among the groups defined by size of the journals' impact factor (IF). SPSS statistical program, version 18, was used

2. Results

Categorical variables were compared across the study groups by Chi-square test or Fisher's exact test where appropriate. Maximum acceptable probability of null hypothesis was set at 0.05. Total amount of papers which has been taken into analysis of the preclinical studies was 86. The studies from the extracted sample were divided to two groups according to the IFs of the journals where they were published: the group with IF ≥ 1.5 and the group with IF < 1.5 . Results of the survey are shown in the Table 1. Our study showed that difference in number of satisfied criteria among the groups was not significant, however, number of citations was significantly higher in the group of studies published in high-impact factor journals (30.5 ± 38.5 vs 2.6 ± 4.1 , $p=0.000$).

Table 1. Results of the survey of the preclinical studies (n = 86).

Requirement	Study groups	Satisfied n (%)	Not satisfied n (%)	Unclear n (%)	Not applicable n (%)	p
Sample size reported for the experiment?	IF < 1.5 (n=47)	33 (70%)	14 (30%)	-	-	0.396
	IF ≥ 1.5 (n=39)	24 (62%)	15 (38%)	-	-	
Number of observations reported for the experiment?	IF < 1.5 (n=47)	35 (74%)	12 (26%)	-	-	0.583
	IF ≥ 1.5 (n=39)	31 (79%)	8 (21%)	-	-	
Value of test statistics, exact p value and degrees of freedom reported?	IF < 1.5 (n=47)	7 (15%)	39 (83%)	-	1 (2%)	0.489
	IF ≥ 1.5 (n=39)	4 (10%)	35 (90%)	-	-	
Error bars correspond to the analysis?	IF < 1.5 (n=47)	19 (40%)	7 (15%)	2 (4%)	21 (41%)	0.002*
	IF ≥ 1.5 (n=39)	17 (44%)	4 (10%)	12 (31%)	6 (25%)	
Only independent observations were taken into account for statistical tests?	IF < 1.5 (n=47)	33 (70%)	8 (17%)	6 (13%)	-	0.000*
	IF ≥ 1.5 (n=39)	17 (44%)	2 (5%)	20 (51%)	-	
Is there negative control?	IF < 1.5 (n=47)	33 (70%)	4 (15%)	-	6 (15%)	0.893
	IF ≥ 1.5 (n=39)	30 (77%)	9 (23%)	-	-	
Was positive control necessary, and if so, was it used?	IF < 1.5 (n=47)	32 (68%)	9 (19%)	-	6 (13%)	0.048*
	IF ≥ 1.5 (n=39)	18 (46%)	17 (44%)	-	4 (10%)	
Were treatments randomly allocated to experimental units?	IF < 1.5 (n=47)	19 (40%)	23 (49%)	-	5 (11%)	0.000*
	IF ≥ 1.5 (n=39)	2 (5%)	26 (67%)	2 (5%)	9 (23%)	

Number of citations: mean, standard deviation, median, interquartile range	IF < 1.5 (n=47)	2.6 ± 4.1; 2.0; 3.0	0.000*
	IF ≥ 1.5 (n=39)	30.5 ± 38.5; 13.0; 33.0	
Time passed from the publication (years): mean, standard deviation, median, interquartile range	IF < 1.5 (n=47)	6.0 ± 6.6; 5.0; 5.0	0.004*
	IF ≥ 1.5 (n=39)	11.6 ± 10.2; 9.0; 12.0	
Number of satisfied criteria per study: mean, standard deviation, median, interquartile range	IF < 1.5 (n=47)	4.2 ± 1.8; 5.0; 2.0	0.146
	IF ≥ 1.5 (n=39)	3.7 ± 1.9; 4.0; 3.0	
Impact factor of the journals: mean, SD, median, interquartile range	IF < 1.5 (n=47)	1.1 ± 0.4; 1.4; 0.7	0.000*
	IF ≥ 1.5 (n=39)	4.3 ± 1.7; 3.9; 2.1	

* significant difference; SD – Standard deviation

3. Discussion and Conclusions

Our study showed that difference in number of satisfied criteria among the groups was not significant, however, number of citations was significantly higher in the group of studies published in high-impact factor journals. The studies published in low-IF journals less frequently used pseudo replication and more often randomized their units of observation than studies published in high-IF journals. The details of the analysis of preclinical studies are presented in our previous publications (4-6). The presentation of the meta-analysis approach is very valuable since in most cases it provides an explanation of statistical methods, their meaning, purpose and ultimate impact on the interpretation of meta-analysis. It is demonstrated in our study which showed similarity in methodological quality between the high and low impact factors journals cited in WoS and Pubmed. Prevalence of experimental preclinical studies that did not implement completely basic principles of research design was high in both low- and high-impact factor journals, raising suspicion to validity of their results. Although much more cited, studies published in high-impact factor journals bore the same risk of incorrectness, bias, and consequent misleading future authors to conduct fruitless research that will waste precious resources.

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Availability of Standardized Electronic Patient Data in Nursing: A Nationwide Survey of Austrian Acute Care Hospitals

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Abstract. A large amount of patient data is produced and documented in patient care. Health care professionals expect that this routinely collected patient data can also be used for secondary purposes such as measuring the quality of care or to gain new knowledge. Routine data needs to be documented in a standardized form, based on clinical terminologies, to allow this secondary use of data. In Austria, hospitals are currently moving from paper-based documentation to computer-based documentation, but parts of the documentation are still done in paper-based form or without using clinical terminologies, especially in nursing. This study aims to analyze the availability of standardized electronic patient data in nursing in Austria. We conducted an online survey of 32 senior nursing managers at 32 Austrian hospitals. The study showed that 79% of hospitals use electronic health records for nursing documentation, but only 29% of the nursing care plans are documented in a standardized way using standardized nursing classification systems such as NANDA-I.

Keywords. Electronic health records, standardized nursing terminology, secondary use of clinical routine data

1. Introduction

Documentation of patient care is fundamental to communicate the current health status and the patient's individual needs and response to care. For example, nursing documentation supports nurses in continuously reflecting their work and to develop and update the individual nursing care plan. Before the digital age, health professionals used paper-based forms [1]. Nowadays, hospitals in most European countries use electronic health records (EHRs) to collect and process clinical routine data [2]. The degree of digitalization in German and Austrian hospitals has been found to be quite low compared to other countries such as, for example, Spain or Denmark [3].

With the rising availability of electronic documentation in the form of electronic health records, there has also been an increased interest in the secondary use of clinical routine data. Secondary use of clinical data implies the vision of using the routinely collected data for secondary purposes such as research and quality improvement in health care [4], for example, validating and analyzing nursing-sensitive patient outcomes to identify new evidence for nursing practice.

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To allow individual documentation of patient care, routinely collected data is often documented in an unstructured, narrative form. For secondary use of clinical data, however, clinical documentation needs to be standardized using standardized terminologies [5]. Examples of standardized nursing terminologies are NANDA International (NANDA-I), Nursing Intervention Classification (NIC) and International Classification of Nursing Practice (ICNP) [6].

In Austria, hospitals are currently moving from paper-based documentation to computer-based documentation, although most of the clinical documentation still appears to be in paper-based form. There is no general recommendation to use standardized nursing terminologies. Hospitals can decide for themselves. Overall, it is unclear to which extent Austrian hospitals are using electronic and standardized nursing documentation as a condition for the secondary use of nursing data. The following research questions were addressed:

1. What is the current degree of use of electronic documentation in Austrian hospitals?
2. Which standardized nursing terminologies are used in Austrian hospitals?

2. Methods

We conducted a quantitative online-based survey of 39 senior nursing managers at 39 general state hospitals in January and February 2020. A cluster sampling of all general acute care hospitals ($n=90$) in Austria was used, with each cluster comprising at least 30% of all hospitals in each federal state. The survey covered sociodemographic questions as well as questions on the following three major topics: degree of electronic documentation, standardized documentation in nursing, and documentation of adverse events. In total, the questionnaire contained 19 questions and 54 sub-questions as well as an opportunity for open comments. The instrument was developed through a literature review and based on the questions from the German and Austrian IT Report survey [7].

Each nursing manager in the cluster sample was contacted personally by telephone and invited to participate. The response rate was 32 respondents from 32 hospitals (82%). Survey results were analyzed using SPSS.

3. Results

The first part of the study focused on using electronic documentation systems for different clinical enterprise functions. Participants were asked: "How do you estimate the percentage of electronic documentation for the following function?" The functions included, for example, medical documentation, nursing documentation or medication prescription, to be estimated on a scale between 0% and 100%. Table 1 shows the use of electronic documentation for the proposed enterprise functions as estimated by the study participants ($n=32$).

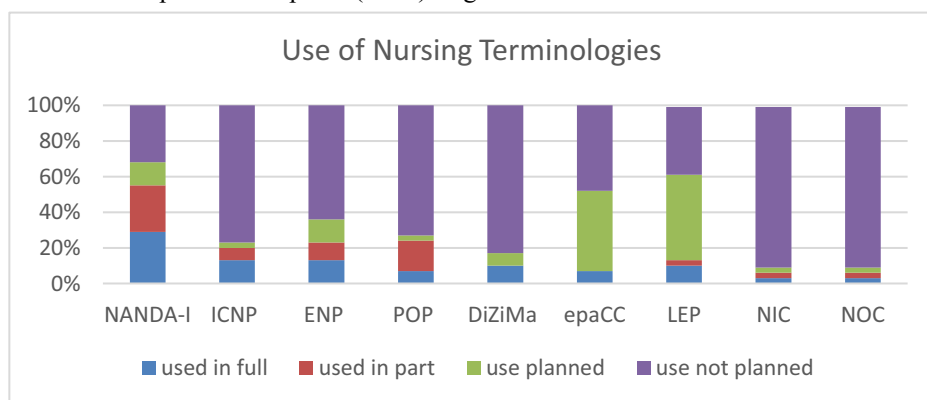
Table 1. Use of electronic documentation systems for several enterprise functions in Austrian acute hospitals (n=32).

Clinical enterprise functions	Mean	Median	Min. - Max.	SD
Order entry (radiology, laboratory, consil)	91%	100%	10% - 100%	10.8%
Patient management (admission/transfer/discharge)	91%	100%	10% - 100%	10.9%
Medical report	91%	100%	10% - 100%	18.6%
Personnel administration/ roster	91%	100%	0% - 100%	23.4%
Nurses documentation	76%	90%	0% - 100%	31.8%
Medical documentation	55%	50%	0% - 100%	31.5%
Medication prescription	31%	10%	0% - 100%	38.1%
Drug delivery	27%	0%	0% - 100%	39.2%

The second part of the survey focused on nursing documentation. We asked for which categories of the nursing care plan (nursing assessments, nursing diagnoses, nursing interventions, nursing outcomes, nursing reports) respondents (n=32) use electronic documentation systems, a combination of paper-based and electronic or a fully paper-based information system. The range for using an electronic documentation system is between 81% for nursing diagnoses and 72% for nursing assessments. The range for a combination of paper-based and electronic is between 25% (nursing assessment) and 13% (Nursing report) the rate of using fully paper-based information system for nursing care plans is between 3% (nursing assessment) to 9% (nursing report).

We also asked for which category in the nursing care plan respondents use standardized terminologies, self-developed standards, a mix of standardized terminology and self-developed standards, or narrative documentation form. Nursing diagnoses are the most standardized category with 63% of the respondent hospitals (n=32) using a standardized nursing terminology. A mix of self-developed standards and standardized terminologies is mostly used for the documentation of nursing assessments (50%), nursing interventions (47%) and nursing outcomes (50%). Nursing reports are documented to 67% in narrative form.

Another question focused on which standardized nursing terminologies, e.g. NANDA-I, ICNP or ENP, are used in the examined hospitals (n=32). We asked whether a standardized terminology is used in full or only in part or if the hospital was planning to introduce or not planning to introduce the proposed terminologies in their nursing documentation. We found that NANDA-I is fully used by 29% and ICNP and ENP by 13% of the respondent hospitals (n=32). Figure 1 shows more details.

**Figure 1.** Use of different standardized terminologies in nursing documentation (n=32).

4. Discussion and Conclusions

This study sought to gain an insight into electronic documentation and the use of standardized nursing terminologies in Austrian hospitals. On average, 76% of nursing documentation is conducted electronically in the examined hospitals (n=32). The results show large differences, however, as some hospitals still have 100% paper-based documentation while already half of the hospitals have 90% or more electronic documentation (median=90%).

The major aspect of our study was to determine the degree of standardization in the nursing care plan. As discussed in the introduction, standardized collected data is an important condition for secondary use. Standardized terminologies are mostly used for nursing diagnoses (63%), with NANDA-I being the most commonly used classification system (29%). The examined hospitals (n=32) intend to standardize more of their nursing care plans: 45% plan to start using a standardized terminology for nursing assessment while an additional 48% plan to standardize the documentation of nursing intervention.

These results, the first of their kind available nationwide, provide important basic information for our further research. A limitation of this study might be that we only included the perspective of senior nursing managers. Practicing nurses may have a different perspective.

As a next step, we are currently conducting qualitative interviews with nursing experts and will triangulate the results of the interviews with the results of the survey. The main question of this qualitative research is: What are the significances of secondary use of clinical routine data in Austrian hospitals and what are the possibilities and expectations to be used to analyze nursing-sensitive outcomes?

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Nursing Staff's Awareness of Processing Personal Data According to GDPR

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Abstract. The purpose of this study is to investigate the awareness of nursing personnel on processing patients' personal data according to the General Data Protection Regulation (GDPR) (Regulation EU 2016/679 of the European Parliament and of the Council). A cross-sectional study was conducted between May and June 2019 on a sample of 229 nurses working in the health care sector. A self-filled electronic questionnaire was constructed, evaluated for its validity and reliability, and used as a measuring tool. The participants were invited from nursing professional pages on social media. The study indicated that the nursing staff who participated were not fully informed about the GDPR and its implementation. The level of awareness of the participants was found to be related to the age, the employment in the private health sector, the education level, the position of responsibility and the years of experience.

Keywords. awareness, GDPR, personal data, nurses, health services

1. Introduction

Protecting citizens' personal information is perhaps the biggest issue in defending the fundamental freedoms and rights of people. The rapid development of information and communication technology, as well as the increased possibilities of collecting, processing and using a variety of information concerning individuals, pose risks for intrusion into the private life of the individual [1,2].

As of 25 May 2018, the General Data Protection Regulation (GDPR) (Regulation EU 2016/679 of the European Parliament and of the Council) has been applied to the Member States of the European Union (EU). It formulates a single legal framework on “the protection of natural persons with regard to the processing of personal data and on the free movement of such data” [1]. The GDPR applies to “the processing of personal data in the context of the activities of an establishment of a controller or a processor in the Union” [1]. This means that all establishments who control or process personal data should follow GDPR, including those who belong to health the sector. In the literature, there seems to be a small number of published studies that explore the knowledge or

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awareness of nursing staff, working in health services, in relation to processing and safeguarding patients' personal data according to the GDPR.

The purpose of this study is to investigate the nursing staff's awareness of processing personal data according to GDPR. In other words, to find whether nursing staff, working in the health sector, were informed about the GDPR when performing their duties in their workplace.

2. Methods

A cross-sectional study was conducted between May and June 2019. Ethical approval was obtained from the ethical committee of Faculty of Nursing of the National and Kapodistrian University of Athens. The sample consisted of 229 nurses working in the public or private healthcare sector in Athens and other Greek cities. The participants were invited from nursing professional pages on social media. An electronic self-filled questionnaire was constructed to collect the data, as there seemed to be a lack of relevant questionnaires in the literature. The team who constructed the questionnaire consisted of two nurses, two Data Protection Officers (DPO) and two lawyers, all with extensive work experience in the health services. The questionnaire consisted of 40 closed-ended questions, divided in two parts. The first part (9 items) recorded the socio-demographic and professional characteristics of the participants. The second part (31 items) recorded the data related to the awareness of the participants about GDPR, as well as its application by their organization.

The questionnaire was tested for its validity and reliability. Ten specialists in GDPR, with simultaneous working experience in the health services, rated the content validity of the questionnaire. Then, the Item-Level Content Validity Index (I-CVI) and the Scale-Level Content Validity Index (S-CVI) were calculated. S-CVI was equal to 0.97. I-CVI was equal to 1, for all questionnaire items, with the exception of items 31, 37 and 40, where the index was equal to 0.8, where the index was equal to 0.9. Therefore, the questionnaire has an appropriate sample of items. Regarding the reliability of the questionnaire, test-retest reliability was performed on a sample of 30 nurses who were asked to complete the questionnaire twice within 15 days. The withdrawal rate during the 2nd measurement was 10%. The Wilcoxon Signed Ranks test, which was used to compare the scores of the two groups in all data, indicated that there was no statistically significant difference ($p > 0.05$) between the 1st and 2nd measurement. Therefore, the questionnaire had excellent test-retest reliability.

SPSS v 24.0 was used for statistical data processing; the minimum level of statistical significance was $\alpha = 0.05$.

3. Results

The study sample consisted of 229 nurses (79.9% women) with an average age of 36.41 (± 8.04) years. The majority of the participants (56.3%) worked in a public healthcare organization (Table 1).

Even though 74.1% of the participants had been already informed about GDPR, only 54.1% of them had been officially informed in their workplace by their organization. Participants had been officially informed about the GDPR through multiple sources: booklet (54.0%), by their supervisor (40.3%), by the DPO (13.7%). The majority of

participants (83.9%) reported that the information was satisfactory, but the mean score of their satisfaction was 6.47 out of 10 (± 2.47). Moreover, 94.8% of them had not attended a GDPR training program outside their workplace.

21.8% of participants answered that there is a DPO in their organization and 55.5% of them had no idea if there was one. Only 7.5% of participants had addressed the DPO about privacy issues related to processing personal data of patients.

Regarding the comparison between demographic/occupational characteristics of previously informed participants about the GDPR in their workplace, it was found that the previously informed participants varied significantly depending on the age ($p < 0.001$), the education level ($p = 0.048$), the type of healthcare sector (public/ private) ($p < 0.001$), the position of responsibility ($p = 0.009$) and the years of work experience ($p = 0.002$) (Table 1).

Table 1. Sample characteristics and correlations between GDPR awareness in the workplace and demographic/ professional data

Variable	Value	Participants (N=229)	Have you been informed about GDPR in workplace?		p-value
			Yes	No	
Gender, N (%)	Man	46 (20,1%)	29 (63%)	17 (37%)	$p=0,176^a$
	Woman	183 (79,9%)	95 (51,9%)	88 (48,1%)	
Age (years), mean ($\pm$SD)		36,41 ($\pm 8,04$)	34,6 ($\pm 8,22$)	38,6 ($\pm 7,26$)	$p < 0,001^b$
Education level, N (%)	Two years education	33 (14,4%)	15 (45,5%)	18 (54,5%)	$p=0,048^a$
	Graduate Nurse	114 (49,8%)	71 (62,3%)	43 (37,7%)	
	MSc/ Phd	82 (35,8%)	38 (46,3%)	44 (53,7%)	
Workplace, N (%)	Hospital	210 (91,7%)	112 (53,3%)	98 (46,7%)	$p=0,410^a$
	Other health service	19 (8,3%)	12 (63,2%)	7 (36,8%)	
Type of healthcare sector, N (%)	Public	129 (56,3%)	37 (28,7%)	92 (71,3%)	$p < 0,001^a$
	Private	100 (43,7%)	87 (87%)	13 (13%)	
Health Region, N (%)	1 st Health Region	142 (62%)	59 (41,5%)	83 (58,5%)	$p=0,095^a$
	Not 1 st Health Region	87 (38%)	46 (52,9%)	41 (47,1%)	
Hospital Department (for those who worked in hospital), N (%)	Open	107 (51,7%)	64 (59,8%)	43 (40,2%)	$p=0,065^a$
	Close	100 (48,3%)	53 (53%)	47 (47%)	
Position of responsibility, N(%)	Assistant Nurse	32 (14%)	14 (43,8%)	18 (56,2%)	$p=0,009^a$
	Graduate Nurse	162 (70,7%)	83 (51,2%)	79 (48,8%)	
	Supervisor	35 (15,3%)	27 (77,1%)	8 (22,9%)	
Years of work experience, mean ($\pm$SD)		11,41 ($\pm 8,27$)	10,1 ($\pm 7,92$)	13,15 ($\pm 8,34$)	$p=0,002$

α = chi-square test, β =Mann-Whitney

4. Discussion and Conclusions

The results of our study indicate that almost one in every two nurses was not officially informed by their organization, about the GDPR and the relevant responsibilities that arise from this regulation. This lack of information could lead to significant fines against the employment healthcare agencies of the participants, due to the misprocessing of patients' sensitive personal data. Another finding is that older, more experienced participants were less informed about GDPR. A possible explanation is that older nurses, potentially due to occupational exhaustion, may not be similarly motivated for acquiring new knowledge as their younger colleagues. Moreover, the participants of the basic two-

year education (nursing assistants) were less informed about GDPR. Another finding is that the participants working in the public healthcare sector were less informed than those working in the private one. This might indicate that the private sector organizes training seminars for the nursing staff more frequently. Based on our results, no statistically significant correlation was found between the participant's awareness of GDPR and the nursing department they work or the national Health Region they belong to.

The main conclusion of our study seems to be in accordance to the conclusions of other similar studies. An online survey conducted on Norwegian citizens concerning the level of their awareness about GDPR and the impact of GDPR on individual rights, concluded that about only half of the respondents had heard of the GDPR and were aware of its content; in addition about one citizen in five had never heard of the GDPR [3]. Another earlier study, which analyzed the companies' and their employees' awareness and willingness to comply with the then-proposed GDPR in Finland, found that the overall level of awareness was low, and less than half of respondents, who were processing personal data, were aware of the impending reform of the GDPR [4].

A limitation of this study is that we followed a convenience sampling method. The participants were not randomly selected, but invited from relevant professional pages of nurses on social media. Another limitation is that the questionnaire was completed electronically. An electronic questionnaire makes it impossible to determine the characteristics of people who were invited but did not participate in the study. Moreover, those who do not use social media were automatically excluded.

The threat of patients' health and life caused by the recent pandemic of the COVID-19, as well as the subsequent emergency measures enforced by national governments, might raise questions on the implementation of GDPR or concerns on whether GDPR could be bypassed when the nurses are processing personal data. These issues could be investigated in future studies.

It is concluded that nursing staff was not fully informed about the GDPR and its implementation. Factors found to be related to the awareness of the participants of GDPR were age, type of employer (private or public), education level, position of responsibility and years of work experience. The awareness of nursing staff working in the healthcare sector regarding the processing of personal data according to GDPR needs to be raised. The regulation should be properly applied and followed by nurses and all those who process personal data in the healthcare sector. Otherwise, ignorance and improper application of the regulation carries a high risk of violating patients' sensitive personal data.

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Cross-Correlation Based Automated Segmentation of Audio Samples

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Abstract. This paper presents an audio file segmentation method in an attempt to mitigate the issue of variable durations of the same utterance by different individuals, e.g.: Speech-Language Pathologist (SLP) and dyslalic subjects. The Method section describes the manner of determination of the maximum cross-correlation value between the 2 audio files and the subsequent automated segmentation thereof in order to extract 2 valid pronunciation samples of the target consonant. The method is aimed at pre-processing audio files and supplying homogeneously-trimmed audio samples to a computerized SSD Screening system. The results obtained on a batch of 30 pronunciations are presented and briefly discussed in the third section while the last section is reserved for conclusions and perspectives.

Keywords. Phonological assimilation, audio segmentation, cross-correlation

1. Introduction

Sound production is the first link of the expressive-receptive chain of human communication. A flawed articulation (and reception) of speech sounds is a critical restriction on the ability of subjects affected by Speech Sound Disorders (SSD) to probe into the acoustic universe and resolve ideas through enunciation.

In Generative Phonology (GP) speech is described as a succession of “discrete sound segments”, where a segment is a “linear bundle of features”, i.e. speech sound attributes classified on the basis of binary opposition. To have a well-structured, rigorous speech sounds classification, such manner or place of articulation, laryngeal or tongue-related distinctive features (DFs) are assigned the + or - signs based on their presence or absence (e.g.: +/- nasal, +/-labial, +/- lateral) [1]. Context, in terms of such distinctive features, is of utmost importance because of phonological assimilation, a process whereby speech sounds change to become more similar to nearby sounds. It may be both progressive (left-to-right, sound n affecting sound $n+1$ within a certain utterance) and regressive (right-to-left, sound $n+1$ affecting sound n). Regressive assimilation seems to be working backward in time and poses a serious challenge to the attempt of devising a mathematical model for automated phoneme classification. One likely cause of regressive assimilation may be the speed (over 100 m/s) at which neural impulses travel through the motor cortical and subcortical pathways in preparation of the fine movements of the articulatory muscles [2]. More than 100 individual muscles are controlled by the phono-articulatory

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apparatus, which has the most complex behavior in the human body [3] [4]. Although proposed in other studies [5], an acoustic analysis of individually-uttered, isolated phonemes would not bring about much progress to the achievement of an effective mathematical model, since it would not reflect the genuine nature of the phonemic level of human communication. Different individuals utter the same speech segment within different durations, i.e. a more compact or a more extended audio input, which generates fewer or more corresponding features and the subsequent risk of not performing a homogeneous analysis. A Python version 3.7 script was written to mitigate the issue of variable durations by performing a cross-correlation based automated segmentation of the subjects' pronunciations. Four libraries were used to write the script: *csv*, *wave* (read/write .csv/.wav files), *array* and *numpy* (process data set). The new homogeneously-trimmed audio samples have the same length in terms of amplitude values and they will be used as input for a computerized SSD Screening algorithm [6].

2. Method

In the first step of the pre-processing algorithm, both the reference audio file (SLP's pronunciation) and the sample audio file (Subject 1 pronunciation) are read and the corresponding amplitude values are saved in two .csv (comma-separated values) files.

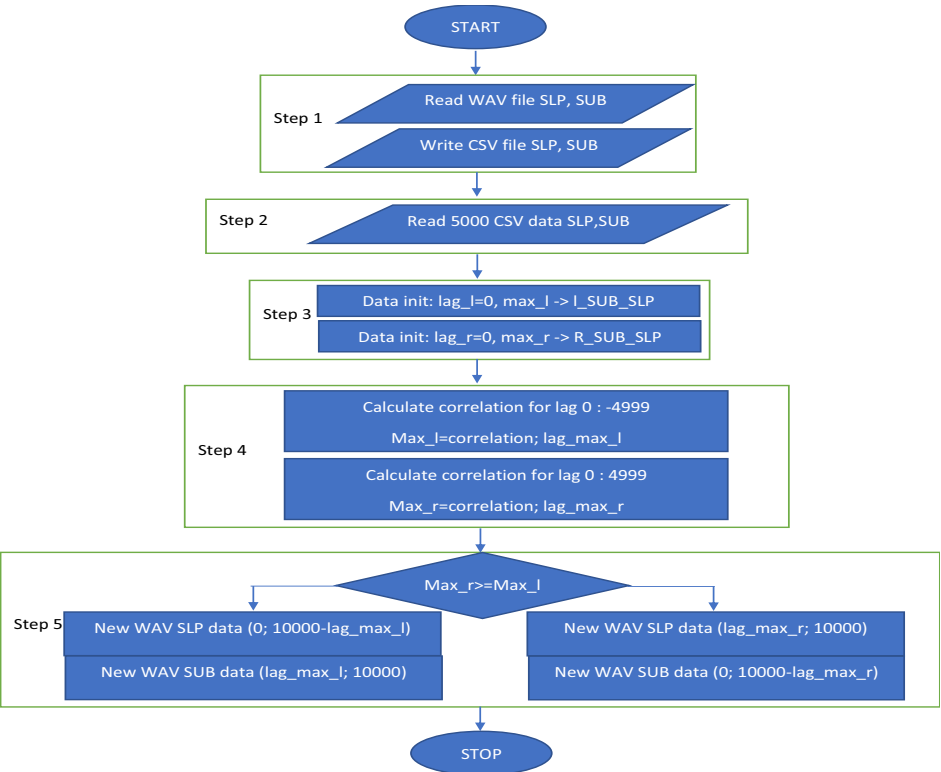


Figure 1. Pre-processing algorithm

Since the target consonant (/r/) is in the initial position of the word (/raft/, Romanian word for *shelf*) the following step consists in reading the first 5000 amplitude values of each .csv file. Such data range was considered enough to cover the target consonant. In cross-correlation, the lag is defined as the number of positions by which the sample signal (SUB) is displaced to the left or to the right of the reference signal (SLP). In the third step, the two lags corresponding to the displacement to the left and to the right of the newly-generated (5000 data) array extracted from the SUB .wav (Waveform Audio File Format) file are initialized. Two variables (max_l & max_r) were used to determine the maximum cross-correlation value between the 2 signals in both directions, left and right. In the fourth step, the algorithm calculates the correlation values between the 2 signals for each lag to the left, where lag belongs to the [0; -4999] interval. If the correlation value for the preceding lag is smaller than the correlation value for the current lag, the latter becomes the new maximum. The lag where the correlation between the 2 signals is maximum will be memorized (lag_max_l). This process is repeated for each of the 5000 displacements to the left (lags). Then the algorithm calculates the correlation values between the 2 signals for the displacement to the right, where lag assumes values from the [0; 4999] interval. The lag where the correlation between the 2 signals is maximum will be memorized (lag_max_r). The fifth and final step consists in generating the new .wav files. The two maximum correlation values are compared and, if max_r > max_l, the newly generated SLP wave file will contain the data within the [lag_max_r; 10000] interval while the newly generated SUB wave file will contain the data within the [0; 10000-lag_max_r] interval. Otherwise, if max_l > max_r, the newly generated SLP wave file will contain the data within the [0; 10000-lag_max_l] interval, while the newly generated SUB wave file will contain the data within the [lag_max_l; 10000] interval. Thus, any given pair of newly-generated reference and sample signals (SLP & SUB1, SLP & SUB2 etc.) will contain the same number of amplitude data.

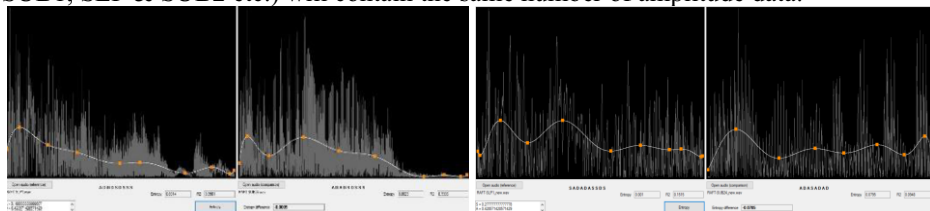


Figure 2. Initial audio segments (left) and automatically trimmed segments (right)

Figure 1 illustrates the logical data model of the pre-processing algorithm and Figure 2 shows a pair of initial audio segments (left side) and the corresponding pair of automatically trimmed audio segments (right side). The objective of the pre-processing stage was to trim off any possible silence or noise from the beginning and the end of the initial .wav files and generate consistent, homogeneously-segmented audio samples to be used as input for an automated SSD Screening System, in an attempt to further refine the discrimination rate thereof.

3. Results

In 83.3% of the cases the maximum correlation value was achieved by displacing the sample signal (SUB) to the left of the reference signal (SLP), which means that most of the subjects (primary school children) needed a longer time to achieve the full vibration of the target consonant /r/ in the initial position. The maximum lag values to the left stay

within the [-21; -3754] range, while the maximum lag values to the right (16.7% of the subjects) are included in the [25; 2246] range.

Table 1 gives a brief presentation of the maximum correlation values and the corresponding lags of the newly generated audio samples.

Table 1. Maximum correlation values and corresponding lags

Subject	max l (lag max l)	max r (lag max r)
1	0.911967 (-2155)	0.499767 (53)
2	2.009054 (-282)	1.132344 (179)
3	2.336753 (-2107)	1.332030 (25)
...		
30	1.427492 (-1032)	0.963997 (1305)

4. Conclusions

The Python script described above successfully implemented the cross-correlation-based automated segmentation of the .wav files and the generation of new valid, uniformly-trimmed, and consistent audio samples. The issue of variable durations of the same utterance was mitigated by automatically generating new audio samples which contain the same number of amplitude data.

The developed algorithm currently only deals with the target phoneme in the initial position. Future work will focus on feeding predefined audio input sequences to the pre-processing algorithm, which would bring the advantage of being able to extract and compare more targeted features. Logatomes, i.e. meaningless monosyllabic pseudowords (used in speech therapy sessions on a wide scale with primary school subjects), are the logical choice to make since they provide the opportunity to place the target consonant in the initial, medial and final position (reading .wav files and reversing the writing order when saving the .csv file in Step 1 of the algorithm) within the same vowel context and they avoid the additional load of “meaning” for subjects with a poor linguistic background.

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Google Trends and Seasonal Effects in Infodemiology: A Use Case About Obesity

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Abstract. Google Trends is a free online tool that provides information on the interest on a topic measured as Google searches in the big data era. In this work, we present methods for detection of trends and seasonal effects in online interest for health topics based on Google Trends data. We present data for the term obesity worldwide and in a convenience sample of countries (Denmark, United Kingdom, USA, Japan) over the last five years. Our analysis shows that, despite obesity being one of the global health challenges, there is a decreasing trend in online interest in the topic. We also observed seasonal effects, with less interest for the topic during December and the summer months. Identifying trends and seasonal patterns in online interest can support resource allocation and planning and allows one to evaluate the effectiveness of global and local outreach efforts on public health.

Keywords. Big data, Infodemiology, Google Trends, Data analysis

1. Introduction

Infodemiology is “the science of determinants of information in the electronic mediums, like the Internet, and in population, with the aim to inform public health and public policy”[1]. Among the relevant data sources, Google Trends is an open online tool that provides information on Internet search data for queries from 2004 onwards.

Google Trends data can serve a variety of applications in healthcare, such as tracking diseases outbreaks [2], understanding public awareness about conditions (e.g. autism, [3]), and the seasonality of muscle-skeletal injuries [4]. The analysis of temporal and seasonal trends in healthcare can be used to support decisions in the planning of staff and resource allocation. However, reporting of methods in Google Trends usage needs to be improved to allow reproducibility of the findings and thus boosting Google Trends’ potential for the healthcare sector [5]. In this paper, we present methods for the analysis of Google Trends data to reveal growing or decaying online interest for a (healthcare) topic among a population and seasonal patterns able to reveal whether such interest varies within a solar year. As a use case, we analyzed data for the term “obesity” worldwide and in a convenience sample of countries from the three continents in the Northern hemisphere (Denmark, United Kingdom, USA, Japan). Overall, this article presents the key points that need to be considered to achieve a robust methodological basis for using Google Trends data to analyze online queries, which is essential for ensuring the validity of the results.

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2. Methods

The used methodology consists of three overall phases: (1) data collection, (2) data analysis, and (3) data visualization. The first two parts are described below, while the latter is presented as part of the use case results in Section 3.

2.1. Data collection

Google Trends does not offer access to data through an official API, but it allows downloading data in csv comma separated values format. Data are available for intervals ranging from 2004 to present to the last hour, and custom intervals can be specified. Data sampling interval changes with respect to the interval length, according to Table 1. The available data is the Relative Search Volume (RSV), which is the fraction of Google queries containing the used keyword normalized concerning the peak value observed within the chosen interval. The RSV is a measure of interest for a topic. Detailed information on how to use the Trends portal and its capabilities can be found in [6].

2.2. Data analysis

STL (Seasonal Trend decomposition using LOESS) is a filtering procedure that decomposes data in a trend, a seasonal, and a residual component [7].

By using the Mann-Kendall Trend Test (M-K Test) [8] on the trend component, it is possible to reveal whether there is a significantly increasing or decreasing interest in the argument over the chosen interval. Seasonality effects can be observed by running the Kruskal-Wallis test [9] on detrended data. If a significant month effect is found, the Wilcoxon [10] test allows revealing among which months there are significant differences in interest. We implemented this process using Python 3.7 and the *statsmodel* package [11], and the software for this analysis is made publicly available.²

2.3. Use case: obesity

We downloaded Google Trends data for the term obesity worldwide and in a convenience sample of countries from the Northern hemisphere (Denmark, United Kingdom, USA, Japan) in the interval between 1-1-2015 and 31-12-2019. These data were analyzed with the statistical tools described above to investigate whether trends and seasonality effects exist in the online interest for obesity.

Table 1. Relation between interval duration and sampling time in Google Trends data

Interval duration	Sampling interval
Past hour	1 minute
Past 4 hour	1 minute
Past day	8 minutes
Past 7 day	1 hour
Past 30 day	1 day
Past 90 day	1 day
Past 12 months	1 week
Past 5 years	1 week
2004-present	1 month
Customized time range	Minimum 1 day

² Available for download at <https://cutt.ly/googletrends-sdu>

3. Results

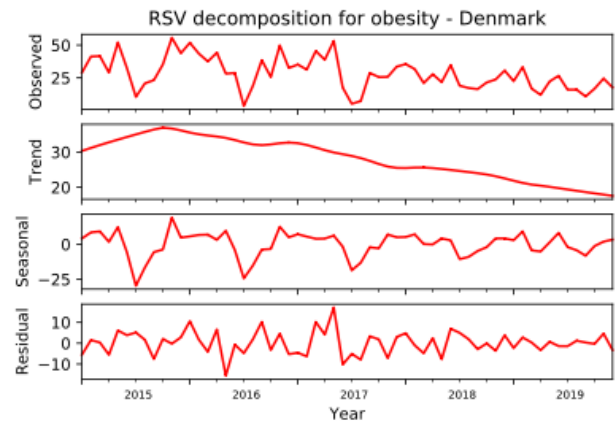


Figure 1. Seasonal trend decomposition for online relative search volume (RSV) about obesity in Denmark. The observed data are decomposed in the sum of a trend, seasonal and residual component.

Figure 1 shows the results of the seasonal-trend decomposition of online interest in obesity in Denmark. It shows that this method allows discovering behaviors (such as the decreasing trend and the periodicity, in this case) that would not be otherwise noted in the observed data. In this case, we used an additive model in which the observed data are decomposed in the sum of trend, seasonal, and residual component.

Figure 2 (left panel) displays trends worldwide and for the four selected countries. Noticeably, online interest for obesity has decreased in all countries except Japan, and changes in the slope of the trend are observed in the period 2017-2018, with a shift of several months across countries. Figure 2 (right panel) shows the seasonal component of RSV worldwide and for countries in our sample. A similar pattern is found across countries, with only Japan exhibiting a significantly different behavior during the first months of the year. Our results show that interest for obesity is increasing in the early months of the year and after the summer holidays. The significance of results for trends and season effects are shown in Table 2.

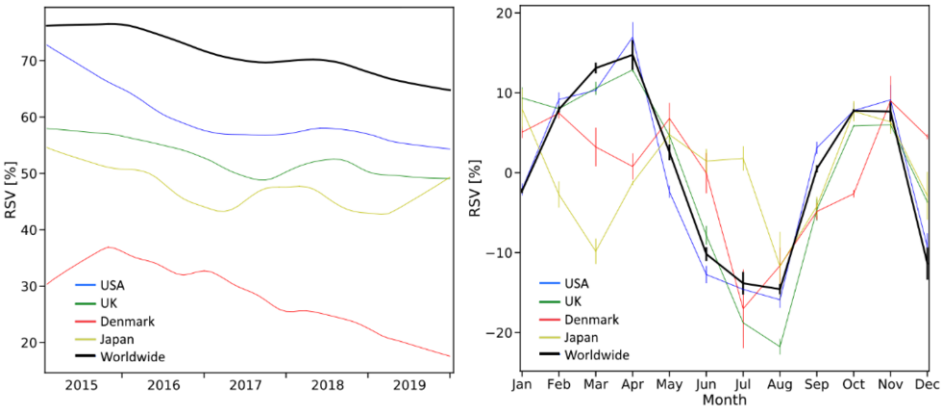


Figure 2. Trend (left) and seasonal component (right) of Relative Search Volume (RSV) about *obesity* in the last five years, worldwide and across countries in our convenience sample. We observed significantly decreasing trends and strongly significant seasonal effects – see Table 2 for a statistical analysis of these values. Errorbars in right panel show standard deviation of RSV within these months in 2015-2019.

Table 2. Significance of trends and seasonality effects in online interest for obesity

Location	Sampling Interval Trend	Seasonality
Worldwide	Decreasing (p<.001)	Yes (p<.001)
USA	Decreasing (p<.001)	Yes (p<.001)
United Kingdom	Decreasing (p<.001)	Yes (p<.001)
Denmark	Decreasing (p<.001)	Yes (p=.006)
Japan	No	Yes (p=.026)

4. Discussion and Conclusions

Despite obesity being one of the global health challenges, we observed a decrease in online interest for it in most of the countries we analyzed. This information should be used to observe whether the decreased interest corresponds to a lower burden for obesity or if, instead, newer solutions to gauge public interest need to be found. Changes in slope as those observed in 2017 show strong effectiveness of communication efforts by WHO (which issued a global warning about obesity in October 2017 [12]). The seasonality patterns of online interest can be used to allocate public initiatives about awareness on health topics during the year, such as the World Obesity Day (regularly held in October).

The main contribution of this paper is the development of a process for using seasonal-trend decomposition on Google Trends data. The process, which can be adapted to different geographical and temporal scales, is demonstrated through a use case, and the software is made publicly available for others. Understanding trends and seasonality of health related online interest can drive new research and support policymakers in a better allocation of health resources and improve the efficiency of communication efforts.

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Quantification of Lower Limb and Spine Muscle Activity in Manual Patient Handling – A Case Study

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Abstract. Manual patient handling is one of the physiological risk factors in care. The scientific focus so far, has primarily been on the analysis of lumbar compression during manual caregiving in order to improve the transfer facilitation of caregivers through technical systems. Reference is made in this context to the supportive functional role of the muscles of the lower limb. To assess biomechanical data for the quantification of lower limb and spine muscle activity in manual patient handling, an experimental study was conducted. A quantitative basis for the analysis of caregiving processes and its risk factors is established by evaluating caregivers' posture, ground reaction force components, and muscle activities during ergonomic and non-ergonomic manual patient handling in a laboratory setting.

Keywords. Health Technology, Sensors, Healthcare Workers, Patient Handling

1. Introduction

Healthcare workers experience high mechanical stress in the lower back, which results from manual patient handling and its various strenuous activities like deep bending or twisting while transferring or lifting a patient [1] [2] [3]. Most of the healthcare workers do not practice proper ergonomic techniques like bending the knees and strengthen the lower back [2] to prevent the aforementioned physiological risk factors. Maintaining non-ergonomic postures for prolonged duration day-to-day, leads to high mechanical loads among the paraspinal musculature and causes lower back muscle damage [1] [2]. Professional associations recommend squat training, as the use of the leg muscles is an essential prerequisite in order to compensate for lumbosacral loads in manual patient handling [1] [2] [4] [5]. By compression of the caregiver's sacroiliac joints (SIJs) through additional muscle forces of lower limb and back extensors, shearing of the SIJs ligaments is prevented and effective load transfer from the lumbar spine to the pelvis and finally to the legs and vice versa is achieved [6]. Already performed studies [1] [7] [8] [9] track specific caregiving scenarios based on different sensor types to identify harmful postures and movements and to estimate and analyze the physical burden of caregivers and patients. In this work, a scientific analysis based on the quantification of lower limb and spine muscle activity in manual patient handling while implicating ergonomical working

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practices is presented. The data was recorded in a laboratory setting using our Healthcare Prevention System for caregivers [10]. The case study design was approved by the *Commission for Research Impact Assessment and Ethics of Carl von Ossietzky University, Oldenburg* (6:0:0, Drs.EK/2019/078).

2. Methods

Manual patient handling is characterized by complex movements including both static and dynamic sequences, e.g. elevating a patient from a lying to a sitting position at bed's edge. In an experimental study [10], a movement pattern of the aforementioned transfer is conducted while a caregiver (60 kg, 168 cm, 24 years, f) transfers a manikin (80 kg) from a dorsal position to a lateral position in a care bed. Two different transfer modes are conducted: a conventional and an ergonomic caregiving mode (Figure 1). The entire transfer is recorded via direct measurement techniques of our existing Healthcare Prevention System [10]. Kinematic and kinetic data of the caregiving process are recorded using a 3D multi-depth image camera system [11] and a force plate (AMTI, Watertown, USA). Muscle activities of the muscles of the back extensors and lower limb of the caregiver are recorded via surface electromyography (EMG; GE Medical/Hellige Biovision Inputbox; National Instruments USB 6009 A/D conversion unit, 14 bit). EMG bipolar surface electrodes are placed with an inter-electrode distance of 1 cm on erector spinae (ES), gluteus maximus (GM), biceps femoris (BF), rectus femoris (RF) and vastus medialis (VM) in accordance to SENIAM guidelines [12]. Signals are amplified with 2500 Hz and acquired with software Dasy-Lab 4.010. Raw EMG data processing is done using MATLAB R2019a (The MathWorks, Inc., U.S.). Muscle activity of the aforementioned muscles is quantified by rectification, Root Mean Square (RMS) (reflecting the mean power of the signals and smoothing them), and mean value (for qualification of gross innervation input for each of the selected muscles) for each caregiving mode. The analysis of the acquired EMG data is based on the potential level and is related to corresponding kinematic and kinetic data of the caregiving cycle in percent (Figure 1). As an extension to [10], the quantification of the lower limb and spine muscle activity of the dynamic caregiving phases is enhanced by analyzing static postures and presenting the whole caregiving process (Figure 1). Each caregiving mode is classified into three phases according to the nature of the movement.

3. Results

Results are shown in Figure 1. In the upper part, the acquired 3D data of the multi-depth image camera system [11] is visualized according to the caregiving cycle in percent and its classification into three phases. Below, the mean muscle activity of ES, GM, BF, RF, VM and the mean ground reaction force (GRF) values for each phase of the caregiving modes are shown. When moving the manikin sideward (Figure 1, Phase 1), the highest GRF values are generated. By shifting the own body weight and therefore leaning the upper body forward and/or to the side, changes in the horizontal F_x (mediolateral) and F_y (anteroposterior) force components occur corresponding to distinct extremes in muscle activity [10]. In the first phase of the caregiving cycles, the muscle contraction of ES is concentric, which results in high muscle activity of ES with maximum support of BF. Lowering the patient to a lying position in bed again (third phase of the caregiving

cycles), results in eccentric muscle contraction for ES and therefore to high muscle activity of ES with maximum support of RF (conventional mode) and GM (ergonomic mode) respectively. While executing proper ergonomic techniques like bending the knees and straighten the back (Figure 1), the mean muscle activity of ES is reduced from 188 mV to 143 mV (24 %) in the first phase of the conducted caregiving task and from 225 mV to 130 mV (42 %) in the third phase [10]. The second phase of each caregiving mode is characterized by static postures: standing in an upright position (conventional mode) and squatting (ergonomic mode). The mean muscle activity of this phase indicates a delta between muscle activity of VM and RF. While the delta in the second phase of the conventional caregiving mode is 48 mV, the delta of this phase in the ergonomic caregiving mode is 71 mV. Accordingly, the deviation of the delta of VM and RF is 48 % in comparison of both static postures. Reaching peak knee flexion in the ergonomic caregiving mode (Figure 1, phase 2), the mean muscle activity of VM increases while RF activity is almost constant. In addition, to prevent extreme joint stress, the knee angle should not be $< 90^\circ$ in a squatting position [13]. The 3D multi-depth image camera system was used to record the scene (Figure 1) and therefore viewing the caregiving scenario from different perspectives is possible. Kinematics data indicate that the caregiver's knee angle was $> 90^\circ$ in all of the caregiving phases (Figure 1). While squatting in ergonomic manual patient handling, quadriceps muscles (VM, RF) are activated and the muscles of the thigh, hip and the back extensors are strengthened to compensate for lumbosacral loads. Comparing the conventional and ergonomic caregiving mode indicates a more consistent mean activity of the back extensors muscle due to quadriceps activation. Furthermore, horizontal force peaks are reduced with an ergonomic way of caregiving, e.g. Figure 1, phase 3. Comparing previous studies, lateral-bending and torsional moments of force at the lumbosacral disc can be prevented by reducing horizontal force peaks [1] [7].

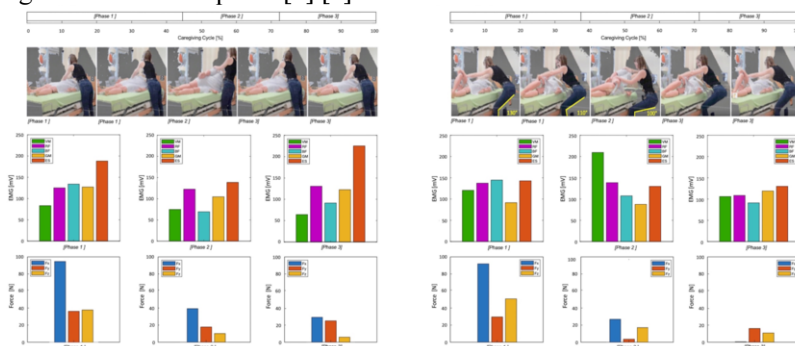


Figure 1. Manual patient handling in a conventional (left) and ergonomic (right) caregiving mode.

4. Discussion

In this experimental trial, a manikin was used for the caregiving tasks instead of a real patient. This is due to ethical and technical reasons. A manikin with 80 kg body weight was chosen to represent a realistic weight of real patients (usual range is 60 to 80 kg [1]). The case study design was designed to avoid overloading the caregiver in the respective caregiving tasks. By using a manikin instead of a real patient, cooperation and supportive behavior between patient and caregiver (intentional and unintentional or subliminal) were prevented during the measurements. The results for the GRF values are similar to

those previously reported [1] [7], and can be considered as realistic. Additionally, the activation patterns of VM, RF and BF while squatting are consistent with previous studies [13]. The conducted case study [10] was the first experimental investigation to quantify lower limb and spine muscle activity during manual patient handling and is extended by analyzing static postures and presenting the whole caregiving process.

5. Conclusions

An explorative investigation of biomechanical data for the quantification of lower limb and spine muscle activity in conventional and ergonomic manual patient handling is presented in this work. Using the lower limb as an ergonomic patient transfer technique resulted in reduced horizontal force peaks and less muscle activity in the lower back. Comparing conventional and ergonomic caregiving modes indicates a more consistent mean activity of the back extensor muscle due to quadriceps activation while squatting. Professional associations recommend squat training, as the use of the leg muscles is an essential prerequisite in manual patient handling [1] [2] [4] [5]. In the future, the herein proposed quantification technique could be used for supervised exercise and intervention programs in the education of healthcare workers. While the case study indicates the suitability of the utilized sensors, further research is needed to verify the results.

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Urgent Need for Developing a Framework for the Governance of AI in Healthcare

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Abstract. Lately, the application or integration of Artificial Intelligence in various areas of the Healthcare domain has been a prime attraction; this includes diagnostics, medicine/drugs, medical devices, interventions/procedures, imaging, therapies as well as treatment regimes, and these areas are in direct relation with the patient care, which is the core subject of the improvements envisioned through the implementation of AI. Although carrying this practice with a focused objective of improvisation in providing quality care, the overall concept of such implementations misses the governance path which can comply with any available regulatory environment, which unfortunately at this stage does not exist. As these implementations would have a direct impact on patients care, there is an urgent need to institute a robust governance and compliance framework in order to ensure the efficacy, safety, privacy, and ethical considerations. The onus of pioneering this initiative of building a governance framework for the implementation of healthcare artificial intelligence primarily rests with the Food and Drug Authority of the respective country, it is also important for this authority to further organizing the governance framework in agreement or collaboration with other international authorities.

Keywords. Healthcare AI, Data Science, Ethics, Governance

1. Introduction

As per the hype that AI has created, its implementation holds no boundaries. Applications of Artificial intelligence are limitless, starting from simple reporting to enhanced diagnosis, for report writing and decision making without human intervention, trust needs to be built up between man and machine, as a small flaw in the algorithm may lead to a fatal action or incorrect interpretation. Those implementations have a direct impact on the patient with or without the knowledge of the attending physician. In such cases, who shares the responsibility? Machines will not be responsible for their action as their behavior is just programmed. Taking into account the above argument, a proper AI governance framework needs to be designed and defined. This can be done by

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categorizing the areas of applications, the stakeholders and their responsibilities, ethical guidelines, policies and procedures for health care authorities and providers, and finally, a registry maintaining an inventory of all AI based healthcare projects and products. International arbitration and a unanimous agreement are the utmost necessity for technology transfer and AI based products to be traded across the globe.

2. Method

The paper is based on the interaction/interviews with the IT leads for various hospitals with regard to their IT infrastructure and capabilities during the implementation of CIMDR [1], and the experience gained along with the interactions with various stakeholders during the implementation of the research management system [4] and organizing research.

3. Current governance trends

Based on empirical studies, bioethics forms the core of any healthcare-related governance modality for all the advancements in medicine. As far as Big Data and AI-based biomedicine are concerned, sound and effective governance remains crucial to all endeavors that involve understanding and responding to all posed and anticipated challenges [2]. The initial effort from the FDA treating software as a medical device [SaMD] in any healthcare setting was a breakthrough [3], can be considered as a reference point in the construction of the desired framework. However, SaMD grossly deals only with third party medical device manufacturers or commercial clinical software vendors, which covers only a narrow spectrum of clinical areas, complexities, and stakeholders.

4. Considerations in building a governance framework

The most important fact to be taken into account is the mix of stakeholders involved in building or developing AI based solutions for healthcare. As a matter of fact, some of the stakeholders involved, cannot practice or follow a sound research methodology in the absence of an established IRB (Institutional review board) unlike the situation in health care institutions which abide by an established IRB. Hence a centralized IRB for AI based products, drug discovery, diagnostic methods, methods complementing clinical trials, and many other, would be ideal in this situation. Also, instituting a central product review board in order to approve and authorize the use of AI based products, methods, or services in real-time patient care is recommended.

5. Ideal elements of an AI governance framework

Stakeholders: By definition, a stakeholder corresponds to any person, department, or organization who has an interest in and is involved or affected directly or indirectly by a venture. So, when it comes to AI based healthcare solutions, the primary stakeholders

would generally include the healthcare authorities, healthcare providers/hospitals, chief information officers, or chief data officers, commercial companies providing AI based products and services, the local FDA, and also the end-user / Patient.

Centralized Review Board: This centralized authority would carry out both the pre-development and post-development review for the proposed as well as developed output. Further, the review would ideally cover both the research as well as the technical aspect of the project; hence the review board should comprise of two different teams, one dealing with the ethics, informed consents, data, documentation and research aspect ensuring good clinical practice [6] and the other covering the technical aspects dealing with the accuracy, effectiveness, and functioning of the embedded algorithms. An ethics & scientific review process for an AI application is somewhat complicated as it needs a review based on:

- Data used as a training dataset and test dataset
- The output data and output elements
- Data Processing (Clinical data, Sample, Image)
- Primary Methodology and Implementation
- The background research-based evidence
- Informed consents / waivers etc.

Secondly, the algorithm applied would also need a review; for this purpose, documenting the machine learning process, model architecture, and the methodology used for predictions and interpretation is necessary for review purposes. The post-development review would precisely cover the algorithm testing and the efficacy of the AI element within the output. In general, the technical review should include:

- Studying, analyzing and reviewing the input and output data elements
- Actual and staging data repositories(Data after the ETL process to be used)
- Data ETL (Extract load and transfer) process
- Data interpretation methodologies
- Studying the efficiency and efficacy of the algorithm
- Studying and analyzing the prediction models

Progress reports and post-implementation review reports are the essential documents to be mandatorily submitted to the authority in the defined format.

Institutional Review Boards (IRBs): Established Healthcare IRBs are the organizational representatives for all research carried out at the institution level. In the current proposed framework, these IRBs would act as an interface by the central review board, and this would speed up the review process at the authority's end. [4] The IRBs would review the proposed AI application in advance in a systematic manner in sync with the requirements of the central review board, this institutional entity would mostly deal with the ethical and research aspect of the project.

Institutional Command Center or Data Science Hub: Most of the advanced healthcare institutions have established a Command center or a Data Science hub [5] to carry out AI / Machine learning-based activities along with a well-defined testing and internal certification mechanism. Within the governance framework, these entities would interface with the centralized review board technical group.

6. Framework Implementation Methodology

Any patient care related Healthcare AI implementation should nationally be mandated to go through the regulatory guidelines, where any such development proposal needs to be submitted to the central review board authority under the FDA following the necessary documentation guidelines defined by the authority. The two-step review (Clinical and technical) would be carried out by the authority, and necessary recommendations/modifications (if necessary) would be carried out by the entity proposing the solution, followed by the approval to carry out the development. Also the mandatory progress reports should be submitted to the authority during this phase. The proposing institution/company will start then the certification process, by submitting all the necessary post-development documents to the authority, and may also need to be capable of demonstrating the output (if required). The final output would go through a scientific and technical review that estimates the accuracy and effectiveness of the AI techniques and its effects on patient care, based on which the AI product is certified to be used in practice. A periodic review report needs to be submitted to the authority for a specified time duration until the product is well established as an effective solution.

7. Conclusions

It is of utmost importance for all national healthcare authorities to build a dynamic framework to carry out the development of the regulatory guidelines for all AI implementations in the healthcare products and services, ensuring effectiveness and patient safety.

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Initiative Quality Assurance Culture for Medical Laboratory Activities in the Primary Care Units Staff: A Case Study in Roi Et, Thailand

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Abstract. The Action Research aimed to develop of Quality Assurances System for Medical Laboratory in the Primary Care Units (PCUs), Roi Et province, Thailand. Data were collected by a questionnaire, in-depth interviews within a participatory process, employing both descriptive statistics, and inferential statistics. The results revealed that the process for the system included 7 steps: 1) Situation analysis, 2) Analyze and evaluate the situations, 3) Making a plan, 4) Action within planning, 5) Observation, 6) Reflection, and 7) Evaluation and implementation. The results also concluded consisted of 4 main activities: 1) Internal Quality Control 2) Intra-facilitator and support 3) Informal Quality Assessment and 4) Participatory System Evaluation. Recommendations of the study were included the model as of the main local policies, and create and encourage quality concept as the positive attitudes for staff and generate quality of working culture among the PCUs team.

Keywords. Quality Assurances System, Medical Laboratory, Primary Care Units

1. Introduction

The importance of quality in the activity of health care laboratories is well recognized globally, particularly in developing countries.[1] Poor quality of laboratory operation can lead to inappropriate interventions, adversely affect the credibility of the laboratory, and may also lead to legal liabilities. It is, therefore, essential to improve and implement a policy on quality in health laboratories[2].

Medical laboratory analysis processes in the Primary Care Units (PCUs) consist of three processes which are 1) pre-analysis process, 2) analysis process and 3) post-analysis process. there is an error, there is a 46-68% chance of discovering it during pre-analysis, 7-13% chance of discovering it during the analysis, and 19-47% chance of discovering it during post-analysis[3].

The situation in Roi Et province, Thailand, was assessed in 2017 by the 5-Star Health Promoting Hospital Award, which is a QA standard for PCUs. The assessment

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awarded the 5-Star rating in only 26 of the 229 departments. In quality assurance, laboratory analysis passed 106 criteria,[4] representing 46%, which is well below the provincial target of 80%. Research aimed to develop Quality Assurances System for Medical Laboratory in the Primary Care Units (PCUs), Roi Et province, Thailand.

2. Material and Methods

The Institutional Review Board of Provincial Public Health Office, Roi Et, Thailand approved the research protocols (Approval No: COE 28/2018). This action research was 3 phases in this study. The first phase was preliminary. The second phase was model development and the third phase was evaluation and implementation of the project. The study period was from January 2019 to May 2019.

2.1. Population and sample

The participants included people who are related to quality assurance for medical laboratories in PCUs.

- The number of personnel under Roi Et Provincial Public Health Office and District Public Health Office 229 departments, included 1,336 people. Using simple random (multi-stage random sampling) of public health staff involved in laboratory analysis, questionnaires were sent 350 public health staff involved in the operation in PCUs. Of these, 300 were received back as a complete edition (86%).
- Additionally, there were 7 samples selected proportionally from a group of experts in public health who have experience assessing quality and standards in medical and public health laboratories in the PCUs and used purposive sampling methodology. The data were collected using in-depth interviews.

2.2. Instrument

The instrument using for investigating the quality of the system included: The Quality Assurance of System by considering four possibilities including utility, feasibility, propriety, and accuracy. It was 5 level rating scales investigating the quality of content validity item-objective congruence (IOC). The analysis congruence was analyzed by the experts in Measurement and Evaluation. The IOC of questions from the Quality Evaluation Form was between 0.884-0.977. The questionnaire for the knowledge contained 15 true-false type questions. Questionnaire for attitude and practice used 5 rating scales: strongly agree, agree, neutral, disagree, and strongly disagree. The reliability coefficient of the knowledge questionnaire was 0.703, attitude questionnaire was 0.703 and that of practice questionnaire was 0.966.

2.3. Procedure

Phase 1: Preliminary

Step 1: Situation analysis of quality assurance in PCUs. Literature review, in-depth interview with the experts related three times according to the determined conversation. The information was used to create tools for data collection.

Step 2 Analyze and evaluate the situations study the context of the situation. Analyze the current situation, problems, and needs of public health staff to plan the internal quality assurance operations.

Phase 2: Model development

Step 3 Planning. Create a manual for the "Internal Quality Assurance of Medical Laboratory in the PCUs" and meet with the quality leaders to create an action plan on training to increase knowledge, attitude, and practice.

Step 4 Action within planning. Organize knowledge development workshops by using cooperative learning techniques and manual "Internal Quality Assurance of Medical Laboratory in the PCUs"

Step 5 Observation. Follow up, provide support, give advice to the operation of quality leaders for two times, and collect data from research questionnaires and satisfaction evaluation forms.

Step 6 Reflection. Organize a learning exchange forum to reflect the development results and take off the success lessons. To lead to the planning of the next round of operations, both the weaknesses that need to be improved and the strengths that need to be continuously promoted.

Phase 3: Model evaluation and implementation

Step 7 Evaluation and implementation. Build the desired level of satisfaction with the quality assurance mechanism and criteria and standards for a medical laboratory in the PCUs.

3. Result

The questionnaire respondents can be characterized as predominantly female (72%). Aged between 25 and 50 years (79%), professional nurses or medical practitioners (47%), More than 10 years working in the department (64%).

The results revealed that the quality assurance system for the PCUs consisted of 4 main activities: 1) The Internal Quality Control 2) Intra-facilitator and group support 3) Informal Quality Assessment and 4) Participatory System Evaluation. All of 4 key mechanisms for driving quality assurance are the Quality Assurance Committee and the Quality inspection and evaluation committee of the PCUs.

The evaluation of knowledge, attitudes, and practices of 300 public health workers in PCUs showed that Public health workers had averaged a high level of knowledge after model implementation. The mean score after model implementation was higher than that before implementation. However, their knowledge did not reflect on their behavior. The data show that despite the demonstrable increase in knowledge of quality assurance processes, there was only a marginal increase in worker attitudes and practices after the implementation as shown in Table 1.

Table 1. Knowledge, Attitudes, and Practices among responded to questionnaires before and after intervention (n = 300)

Item	Before intervention		After intervention		t	P
	Mean	SD.	Mean	SD.		
Knowledge	9.27	2.45	11.0	1.62	-2.852	.008
Attitude	3.26	0.37	3.51	0.47	-3.759	.001
Practice	3.99	0.56	4.06	0.64	-1.985	.057

Note: coefficients were significant at the p< 0.05 level.

4. Discussion

This action research focused on the involvement of public health workers group in every process. Group meeting involvement was an important process to solve quality assurance problems leading to good analytical processes in a medical laboratory in PCUs. Researchers tried to take roles only as observers and providers of the necessary information.

It was found that public health staff identified screening problems in two major issues: 1) problems of specimen collection and delivery, and 2) problems with the use of fingerprints.[5] This is because public health personnel have little knowledge and expertise in laboratory examinations, but have more expertise in treatment and rehabilitation. The solution is to provide training and quality checks for sugar monitors from fingertips to health personnel. However, the educational perspective of studied the challenges and obstacles to the integration of laboratory services in Iran from laboratory experts.[6] Iran found unfair access Lack of budget Low service quality developing a national strategy for creating an integrated network of laboratories Criteria for establishing a laboratory Establishing the necessary infrastructure Strengthening the capacity of the private sector is the most important problem of the integration of laboratory services in Iran which is consistent hat has compared studies of quality improvements in England and Canada that have found successful development of an educational quality assurance system. Require human resource development because it is the heart of quality improvement operations.[7]

Recommendations of the study were included the model as of the main local policies, and create and encourage quality concept as the positive attitudes for staff and generate quality of working culture among the PCUs team.

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Illustration of Clinical Decision Support System Development Complexity

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Abstract. The dissemination of Clinical Decision Support Systems (CDSS) in the medical field is slow due to various reasons such as lacking comprehensibility, low user acceptance, specific problem settings and unique application environments. This paper presents an illustration of the complexity of the CDS development process. Guided by procedural software development models already known from the field of software engineering, we developed a CDS-specific software lifecycle and a CDS development complexity illustration. We based the results on literature research of published field reports about successfully developed CDSS. We identified important CDS peculiarities related to the development and documentation process of CDSS and later merged them with generic software engineering models. We then created a CDS complexity illustration that can be used to structure future research in the CDS field as well as any standardisation processes.

Keywords. Clinical decision support systems, software development process, software lifecycle, software engineering

1. Introduction

In spite of the presumed great potential for process optimisation and improvement of medical care through CDSS, there is a lack of evidence supporting the widespread use of such systems [1]. Recent research investigates several reasons for the slow uptake [2–4]. A lack of standardisation and best practices, thus a lack of interchangeability of CDS approaches and solutions is one aspect of this.

Computerized Physician Order Entry systems (CPOE), which aim to improve medication processes, are CDS variants that are an integral part of the digitisation of such processes [5]. The acceptance of CPOE might be related to strict legal requirements and comparatively easy to identify performance indicators, which allow comprehensive performance measurements. Transferring these basic requirements (clear standards and measurable results) to other CDS variants is a promising approach. In our research, we focused on the creation of an overview in the CDS field. The overview illustration of CDS complexity is supposed to depict the development process as well as include documentation aspects to support the standardisation of CDS development processes and to provide a basis for the comparability of CDS systems. Our research aim was to identify and illustrate the differences in development between conventional software and CDS systems.

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2. Methods

Our approach to illustrate the complexity of CDS development and interrelationships between the individual development steps had two sub-goals. Sub-goal 1 was to identify aspects of CDS development that distinguish them from conventional software development processes (CDS peculiarities). After identifying these differences to conventional software, we plan to modify a generic software development model to match the needs and requirements of CDS development. Sub-goal 2 was the identification of CDS-specific documentation aspects. For the identification of these, we used a manually created list of excerpts with statements about documentation and development. These steps led to intermediate results and findings, from which we created two figures illustrating the CDS development process and CDS complexity.

In an initial literature search, our goal was to find "field reports" of CDS developers and CDS projects using keyword searches in PubMed, Livivo and Web of Knowledge. We used the following keywords: "clinical decision support", "knowledge engineering", "software engineering", "development" and "documentation". According to the PRISMA schema, we excluded irrelevant sources due to missing documentation and development process context. In the further analysis, we used 55 of 258 sources found. We listed all development process-related statements in an excerpt list and analysed the sources qualitatively with regard to the sub-goals. These steps provided a sound overview of the CDS field and a starting point for further work.

By merging CDS peculiarities with the generic lifecycle from the software engineering field, we achieved a CDS-specific lifecycle. By further enriching this life cycle, by merging CDS-specific documentation aspects and conventional software engineering documentation aspects, we approached the illustration of the complexity of the CDS field.

3. Results

CDS software solutions often target institute or department specific problems, depending on specific requirements or are designed to work only in unique application environments. CDS researchers, whose goal is to work on the standardisation and evaluation of such systems, have the requirement to cover all variants of CDS. An important aspect of the developed illustration was therefore its applicability to a wide range of CDS variants.

The most important finding in the analysis of the field reports from the literature is the modularity of modern CDS solutions. Most systems consist of modules that can be clearly distinguished from each other [6]. The modules are either part of the category "Knowledge Engineering" or "Software Implementation". In a modular system, the importance of interfaces is therefore a crucial development aspect.

3.1. Figure 1 - CDS software lifecycle / CDS software development process

Figure 1 depicts the CDS software life cycle on the basis of a generic life cycle [7] from the software engineering field. The life cycle starts on the left side with the step "Initial Development Process", followed by "Continuous Development & System Operation" steps, and ends with the "Decommissioning" of the software.

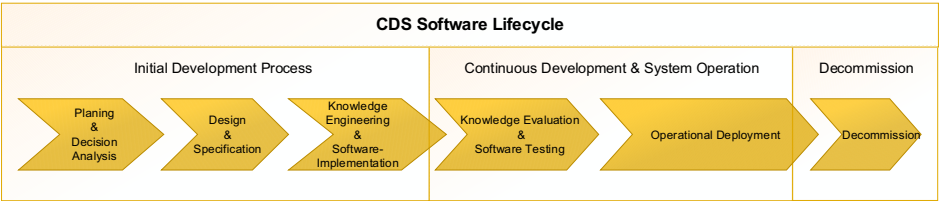


Figure 1. CDS software lifecycle.

3.2. Figure 2 - CDS-Complexity-Illustration

Figure 2 illustrates the CDS life cycle with further details. It accounts for the modular structure of CDS systems and presents documentation artefacts from different process steps, as well as their connection to the underlying concepts with regards to CDS evaluation and CDS research.

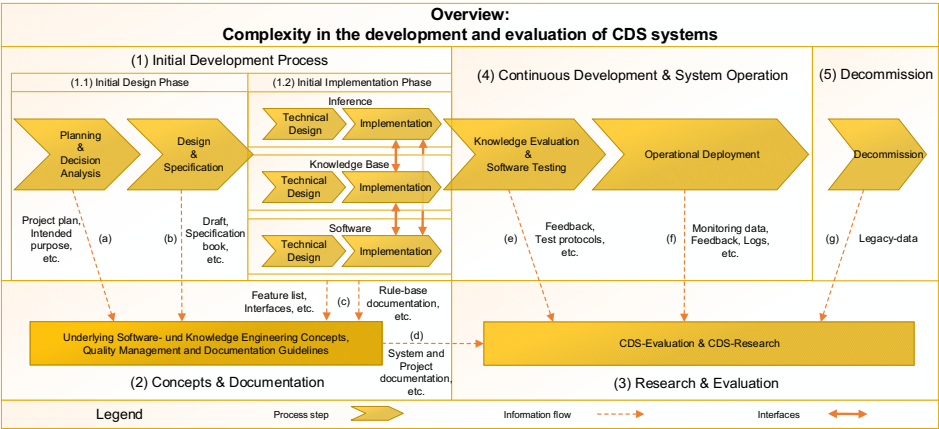


Figure 2. CDS-Complexity-Illustration with Documentation Artefacts

4. Discussion

In the results, we have included the most important findings from the analysis of the field reports about the development of CDSS. The main difference to conventional software is the necessity to include domain knowledge as well as management processes and specific knowledge-based software. A rough overview of the CDS development process is given in Figure 1, which is the basis of Figure 2. Figure 2 enables the viewer to get an idea of the basic process as well as CDS-specific features, that distinguish the development of CDS systems from the development of conventional software systems.

The CDS complexity representation contains a lot of information about the course of the development process and the associated documentation artefacts. For the future, we plan to further define the various process steps and take CDS-specific requirements into account. An example for the usage of the illustration is to address the imbedding of best practice documentation guidelines into the CDS development process. This would lead to practical fulfilment of documentation requirements of the Medical Device Regulation.

5. Conclusions

While working on the CDS field reports, we noticed that publications on CDS Systems reported far too little about the actual development process, while the topics "operation" and "evaluation" are better covered.

Most reports contained CDS evaluation results in the form of text or tables. The coverage of the CDS evaluation topic is sufficient; however, the results of these reports are not easily reproducible or usable for a CDSS evaluation from an external point of view. In the CDS field, the development processes themselves seem to be hardly standardised, apart from the available technical standards and legal requirements. This leads to a large number of different documentation artefacts and complicates the evaluation of system quality.

Our further work will aim to support standardisation efforts and the definition of appropriate objective key figures for the assessment of the quality of the CDS System. Standardised development processes should increase the comparability and verifiability of CDS Systems. We believe that better comparability of CDS Systems can and will significantly improve the dissemination and acceptance of such systems.

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Digitalizing Nursing in the Bavarian Swabia Region of Germany – Presentation of the Joint Project CARE REGIO

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Abstract. The joint research project CARE REGIO aims to modernize the care system with digital solutions. We focus on the development of a uniform electronic care record, uniform data exchange between care facilities, and technical assistive systems, which shall all be unified in a standardized care-based storage solution.

Keywords. Care 4.0, Digital Care, Transfer Management, AAL, Digitalization

1. Introduction

The necessity for digitalization in medicine and healthcare has already been investigated (1, 2). There are several digital projects to assist the nursing sector (3). For all digital projects aiming to help and develop the nursing sector, it is crucial to provide usable data about the patient and the environment. For this purpose, the data must be stored in a uniform and facility-based electronic care record (ECR). The development and definition of such an ECR are essential for all further applications. At a facility level, many hospitals have implemented electronic health record (EHR) systems, but the interoperability to the care sector lacks behind (4).

2. Methods

CARE REGIO (CR) is a research project funded by the Bavarian State Ministry of Health and Care. The interdisciplinary project team consists of Neu-Ulm, Kempten and Augsburg Universities of Applied Sciences, the University of Augsburg, and the University Hospital Augsburg. The project aims to support care delivery through

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digitalization and to develop sustainable and practical solutions. A literature analysis, expert surveys, and focus groups with various stakeholders have been carried out.

3. Results

From the literature review and expert interviews, CR has identified the following areas of digitalization as particularly suitable: 1) a uniform ECR, 2) a uniform and electronic data exchange for patient interfacility transfer, 3) technical and digital assistive systems for telemedical based diagnoses and therapies, and 4) a care-based data storage.

Using the example of patient transfer management at the University Hospital Augsburg and its partner institutions, a pilot system will be developed to make the transfer management more transparent, efficient, and easier for caregivers and patients. CR found that while existing hospital-EHRs contain a lot of patient data, specific and crucial data for care is often missing. The issue becomes particularly problematic when the ECR is used in hospitals, in inpatient and outpatient care facilities, as well as in rehabilitation facilities. Furthermore, there must be a uniform possibility to exchange the care data within the institution, but also to share the data with other institutions.

Admission and discharge from or to other facilities can be facilitated with electronic transmission of care data. This process includes static data such as name and birth date, but also dynamic data like the overall condition of a person. A uniform ECR ensures that relevant information is available in all facilities and that the time required for multiple recordings is significantly reduced. In this setting, digitalization serves as a tool to automate processes and, for example, to individualize and optimize processes with the use of technical assistive systems that rely on available patient and environment data. The necessary data will be generated by various instruments. To incorporate this, the use of technical-digital systems in the field of fall prevention is helpful. Falls are one of the most common causes of care dependency of the elderly. Technological progress opens up a wide range of possibilities to support evidence-based diagnosis and therapy.

4. Conclusions

CARE REGIO aims to support healthcare with the help of digitalization and thereby give the specialists more time for the patients. The focus is on the patient transfer management, the use of care data, assistive systems, as well as ethical, scientific, safety, and socio-economic aspects across the project.

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Online Education for Vaccination Competence Among Health Sciences Students

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Abstract. The EDUVAC project aims to develop and implement a web-based course on educating vaccination competence among health sciences students. In the current study students' feedback and evaluation is assessed which guided the partners' efforts to improve the final course content and learning material that will be available for open access. After completing the web-based course, most of the students (N=103, 75.1%) perceived their vaccination knowledge was up to date and their overall participating experience was "above average or excellent (N=119, 86.9%). While, almost all of the students (N=127, 92.7%) found that the web-based course has benefitted them and their future career. Our findings support that

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the web-based courses can provide satisfactory learning experience to University students and offer flexibility when needed especially in times that remote education is the only option.

Keywords. Vaccination, online learning, web-based course, students

1. Introduction

Immunization is without any doubt one of the most effective preventive interventions in public health of the past century [1]. By vaccination the body's immune system resists to viruses and other pathogens and can offer protection against several infectious diseases hazardous for life [2]. It is estimated that every year two to three million deaths are prevented because of certain vaccination strategies to increase immunization coverage [3].

Although vaccination is sometimes treated as no more than a simple injection, health professionals who implement vaccinations should be authorized to administer vaccines, have distinctive personal qualities, theoretical knowledge and practical skills [4]. Thus, in order to address the need of education on vaccination competence, the Erasmus+ funded project "Educating Vaccination Competence" (EDUVAC) was established. The overall aim of the project is to increase knowledge, skills and attitudes for vaccinations of future health professionals, in order to improve the vaccination coverage of different population groups [5]. More specifically, a 3 ECTS web-based course is developed (see: www.eduvac.eu), since, the benefits of the e-learning courses are well supported in literature [6] as a person-centered method of learning in aspect of higher access in education, flexibility, interaction, efficacy and knowledge. To our knowledge this is the first vaccination competence program for students that it is implemented through online learning.

The aim of the current paper is to present the students' feedback and evaluation of the developed web-based course which guided the partners' efforts to improve the final course content and learning material that will be available for open access to every stakeholder worldwide.

2. Method

Students from the five partners Higher Education Institutes (HEI): University of West Attica, Greece (coordinator); Metropolia University of Applied Sciences, Finland; Trnava University, Slovakia; University of Vic, Spain and University of Modena and Reggio Emilia, Italy, participated in the EDUVAC web-based course that was run twice (Spring 2019 and Autumn 2019) in English using the Moodle platform.

The digital content of the web-based course consisted of 6 sections: 1) vaccination basics, 2) vaccination procedure, 3) counselling the clients, 4) vaccinating refugees, migrants and asylum seekers, 5) vaccinating travelers and people on the move, 6) anti-vaccination groups and clients who hesitate to take vaccines. The content and learning material were developed in collaboration with all five project partners HEIs.

The asynchronous web-based course offered several self-study learning activities, such as PowerPoint presentations, narrated presentations (PowerPoint with audio), videos, documents in text or pdf format, quizzes, self tests, learning assignments, links and other material for further reading. Students' final evaluation was based on the submitted portfolio assignments uploaded in Moodle.

Data was collected by participant students at the end of the courses using a digital questionnaire with close-ended questions (demographic characteristics, knowledge, evaluation) and an open-ended question asking about comments, suggestions and further feedback. The questionnaire was developed for the aims of the current study based on review of relevant literature. The approval was obtained on 12.03.19 by Metropolia University of Applied Sciences which hosted the web-based courses and by other Universities when required. Statistical analysis was performed using SPSS version 21.0 and descriptive statistics is used to present the results.

3. Results

The number of participant students in the EDUVAC web-based course was 186 and 137 of them answered the digital questionnaire, which corresponds to a response rate of 73.65%. Most of them (N=125, 91.2%) were females and the majority belonged at the age of 18-25 (N=113, 82.5%), while, there was a small number (N=22, 16%) of students at the age of 26-40 years old. Additionally, some students (N=26, 19%) had a previous qualification in health care.

In regards on how they would perceive their knowledge gained from the web-based course, on a scale 0-10, most students (N=103, 75.1%) perceived their vaccination knowledge as up to date with rates between 8 and 10. In addition, considering their responses about being aware of different vaccination schedules and be able to find the different schedules targeting different populations group's, the majority of students (N=108, 78.8%) said that they have "largely or fully achieved" it and in the question if they find that "vaccinating is an important health promotion method", approximately all of them agreed (N=133, 97.1%). Moreover, most of the students (N=99, 72.3%) believe that they have "largely or fully achieved" to feel more confident in the use of the English language.

Concerning students' satisfaction of the web-based course, several aspects were evaluated by most as "above average or excellent": the organization of the course (N=109, 79.6%), the students' manuals/guides (N=91, 66.4%) and the information available in advance from teachers, such as e-mails, information and info sessions in classroom (N=94, 68.6%). They also evaluated the learning activities overall "above average or excellent" (Table 1).

Finally, most of them (N=119, 86.9%), reported that the overall experience was "above average or excellent" and almost all of them (N=127, 92.7%) think/feel the web-based course has benefitted them and their future career as well as they would encourage other students to attend this web-based course.

4. Discussion

The findings of the current study had a good impact in the students' knowledge as they perceive it and they were overall satisfied as well as with the different learning activities included in the web-based course. These results are in line with previous studies that have shown that online learning can improve knowledge, skills, attitudes and satisfaction and is more effective and beneficial for the students of health professionals comparing with traditional teaching [7,8]. Students' satisfaction is also recently supported [9] as one of the foundations for student-centered education.

Table 1. Students’ evaluation of learning activities

	Above Average or Excellent		Below Average		Poor		Don’t know	
	N	%	N	%	N	%	N	%
PowerPoint Presentations, narrated presentations (PowerPoint with audio) Videos	155	83.9	18	13.1	2	1.5	2	1.5
Quizzes, self- tests, learning assignments	101	73.7	24	17.5	10	7.3	2	1.5
Documents in text or pdf format	118	86.1	9	6.6	3	2.2	7	5.1
Links to other material	126	92	7	5.1	2	1.5	2	1.5
	129	94.2	6	4.4	1	0.7	1	0.7

Paechter et al. [10] emphasize the considerable role of the teachers and their contribution in e-learning process from the aspect of learning outcomes and satisfaction. This is reflected also in the results of the current study that the students’ manuals/guides, the information available in advance from teachers, such as e-mails, information, info sessions in classroom were all assessed by most students as “above average or excellent”.

In addition, this web-based course gave the participants the opportunity to study in English while in general they study in their mother tongue, and after the course, most of them feel more confident in the use of the English language as it is supported by researchers [11], e-learning could be helpful for students to learn English.

Finally, researchers have concluded that e-learning has a positive influence on students’ fulfillment in education [12] which is supported by the current results as almost all of the participants found that the web-based course has benefitted them and their future career and they would encourage other students to attend this web-based course.

Data was collected using a self-reported questionnaire in regards to students’ perception of gained knowledge and the overall evaluation of their online learning experience which may be valid for representing their perception but they may not reflect reality and thus, this can be a possible limitation. However, literature supports that students’ self-reported learning gain can be useful and valid indicators for their learning [13,14,15]. Finally, students’ comments and suggestions which mainly demonstrate that they liked the self-tests, the videos and the narrated presentations as a learning method, are considered for the development and improvement of the final open access online learning material.

5. Conclusions

Online education is growing and over time more students for various reasons have the opportunity not to study in a classroom. In addition, due to the recent COVID-19

pandemic, most governments closed temporality educational settings while the education and learning continued remotely. As the current study supports, online learning can give the flexibility to the academic community for effective and satisfactory learning.

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User-Centred Design of a Mobile Application for Chronic Pain Management

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Abstract. Chronic pain patients constitute a large and heterogeneous patient group and it is important to build tools and methods that can identify efficient treatment options for each individual patient. It is estimated that 20-30% of the population has suffered from chronic pain and this imposes enormous costs on society and the national welfare programs. The research project *Chronic Pain* addresses the problem of how to provide patients and physicians with relevant, valid and adapted decision alternatives in a shared decision making tool. This paper presents the results from co-creation workshops early in the user-centred design process of the chronic pain mobile application. The end-users contributed in mapping the user needs and requirements, and made paper prototyping of the user interface. The main contribution lies on how a user-centred design methodology can be applied in a clinical development context.

Keywords. User-centred design, chronic pain management, mHealth, decision support, patient-reported outcomes

1. Introduction

Pain can be described as an unpleasant sensory and emotional experience associated with actual or potential tissue damage [1]. Pain lasting shorter than 12 weeks is defined as acute pain and more than 12 weeks as chronic pain [2]. The prevalence of having experienced chronic pain in Europe is estimated to be around 20%-30% [3][4]. Despite recent advances in empirical pain research, healthcare services are still lacking methods to effectively treat many chronic pain conditions [5]. Chronic pain patients can experience reduced quality of life and higher prevalence of depression [6] and this applies enormous costs on the society related to expenditures for wage replacement and welfare programmes [7]. The sustainability of the welfare state is threatened by the lack of cost-effective treatment options combined with the high prevalence of chronic pain [8]. In this context, the research project *Chronic Pain -Decision support for personalised chronic pain care* (2019-2021) addresses the problem of how to provide patients and physicians with relevant and valid decision alternatives in a shared decision making tool,

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which also provides realistic probabilities for outcomes, side effects and adverse events. The specific sub-problem addressed in this project is the problem of getting access to patient-reported outcomes (PROMs) and experiences. The project applies a user-centred design process [9] and the outcome will be a patient data collection tool. This paper presents the results from an early project phase, where co-creation design workshops were made together with end-users. The research questions (RQs) stated were:

RQ1: *What are the user needs for a mobile decision support application for chronic pain patients and what elements are suggested for the user interface design?*

RQ2: *What are the benefits and constraints of involving end-users in the application development?*

2. Methods

The *Chronic Pain* project employs a user-centred design approach for the application development [9]. The project will be conducted in five phases: 1) design of the PROMs data collection application in close collaboration with end-user representatives 2) design of the data storage and computation environment, 3) technical development of the PROMs application, 4) building the data storage and computation environment and 5) usability testing together with end-users. The project is in an early phase, and this paper reports from the first phase, where co-creation design workshops were made together with participants from the Norwegian Fibromyalgia Association. The first contact point was an information meeting at the patient organisation, where 14 informants were recruited to contribute in the research project.

Two co-creation workshops were organised at the end of year 2019 and beginning of 2020 together with 5 informants, all female pain patients and with the average age of 52 years. In the first workshop, the informants were introduced to the project aims and the research team. They were informed about the user-centred design process and the expected commitment to the project. The informant's competence on personal devices such as smartphones and tablets were assessed by oral self-report and found to be sufficient for them to utilize the planned functionality. Additionally, a discussion was made of the practical use of activity trackers and how this kind of data could support the mobile application. The second workshop addressed the use of technology for management of chronic pain, the situation today and the performance of the mobile application in a future perspective- *what is needed to support the pain patient's situation?* For this purpose, post-it sticky notes were used, and the informants were asked to write user needs and how they expected the application to function. Afterwards, each participant presented their suggestions to the group. Paper prototypes were created for user interface design suggestions. The research team consisted of people with expertise in human factors in design, psychology, health science, statistics and medical informatics.

The data collection consisted of audio-recordings and annotations from the workshops, which had the average duration of approximately 3 hours. Qualitative methods were used to analyse and categorise the user needs and requirements for the PROMs data mobile application. The Privacy Officer at the University Hospital of North Norway approved the study with project number 02147. The participation in the study was voluntary and the informants signed a consent form.

3. Results

The results target the 1) user needs and functionality and 2) suggestions for the user interface design. The workshop participants agreed about the following functions: a virtual scale for measuring pain and stressed the importance of registering the feature of the pain: *ache, burning sensation, sharp stabbing pain or stiffness*. It was also underlined that pain is subjective regarding sensitivity and intensity. For the frequency of reporting pain, it was agreed on reporting 3 times a day: *morning, noon and evening*, each with an interval of 3 hours. An automatic notification or push notification was suggested 15 minutes before the end of the interval, possibly on a wearable and not only on the smartphone. The participants suggested a function for voice command for registering pain, like “*pain threshold 4*”, in addition to manually entering a score into the smartphone. There was a consensus about that reporting pain also on *good and painless* days was unproblematic.

It was addressed that mobile application had two different aims: individual adaption to the user’s needs and research purposes. For the individual user, the usefulness and ease of use are important factors to consider. The user must have access to own data and being able to view trends and historical data. The participants suggested registration of the following parameters: level of activeness, sleep quality, use of medication, nausea or headache and cognitive problems (*fibro-fog*). At the end of the day there should be a general registration on how the day was with symbols, energy level- what gives/takes energy (*fatigue*) and mental health regarding anxiety, mood and stress level. Regarding impacts on the pain sensation, the consumption of food and drinks and changes in the weather should be noted. A diary function was suggested with free text on actions and treatments. It was also proposed a digital reward such as badge, star or scorekeeping for consequent use of the application.

The participants made paper prototypes on large sheets, with suggestions of the user interface design and the preferred way of interacting with the application, see Figure 1. For all functions in the user interface, Norwegian language was required by the participants.

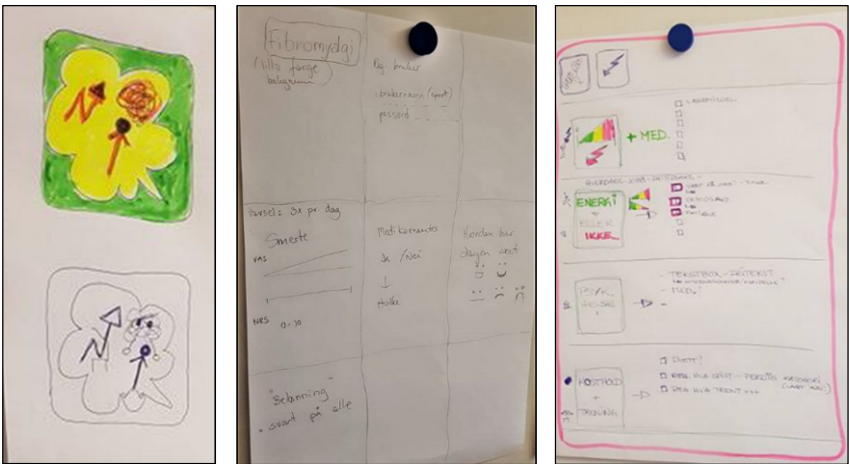


Figure 1. Suggestion for the logo of the application (left) and the functions of the application (middle and right).

4. Discussion

The main contribution of this paper lies on how a user-centred design methodology can be applied for the active contribution of the end-users in a clinical development context. The research questions (RQs) are answered based on the results. RQ1 asked about the user needs. The workshops, which were organised in an early project phase together with end-users, efficiently outlined the user needs and requirements for the application and the context of use, the method was inspired by [9]. The paper prototypes provided a good foundation for discussion, showing the functionalities and actions in a detailed way. Such visual representations are meaningful in user-centred design processes. The outcome of the workshop provided input for the following development phase, which is in progress. RQ2 asked about benefits and constraints of involving end-users. The benefit of involving real pain patients as end-users, is their first hand experiences and descriptions of the user needs. The end-users were considered as full project members, and their contribution aimed at increasing the quality of care, safety, self-management of pain and clinical outcomes for pain patients. The constraint is a time consuming procedure with multiple and long meetings, which might be physically painful for the participants, but adherence to the research project is important for the user-centred process. In addition, human factors experts need to be involved. This study has some limitations, such as a limited number of informants. However, the study participants meaningfully represented the user group of the application. Future research agenda targets continuation of the user-centred design process by conducting quarterly user workshops, and performing iterative user evaluations and deploying the application for an extensive effect study.

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Data Sharing in Pharmaceutical Supply Chains – Case European Medicines Verification System

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Abstract. We study the perceived value derived from data sharing activities by the representatives of a Nordic pharmaceutical company in the introduction of the European Medicines Verification System (EMVS). The system is an end-to-end verification protocol that would potentially enable the pharmaceutical companies to access the sales-point data from within the system, while maintaining the control of their own data. The benefits of the system are most notably in developing data sharing with the wholesalers and end-customers. Development of data sharing practices might enable more transparent logistics, and more targeted services and products.

Keywords. Data Sharing, Pharmaceutical Industry, European Medicines Verification System, Supply Chains

1. Introduction

Data sharing is a growingly important practice throughout all industries. Data can be multiplied, shared and reproduced among different actors within supply chain by using boundary resources to create new operational efficiencies, business opportunities and network effects [1–4]. However, the control of data, or “to whom it belongs to”, remains inherently important, and the question of keeping proprietary rights of data within the company is faced when creating new industrial data sharing platforms [5]. Having a clearly defined set of rules for data sharing is essential as data sharing can easily eliminate the competitive advantage that can be gained from asymmetric information [6].

One such industrial data-sharing platform that maintains the proprietary rights of the company data, European Medicines Verification System (EMVS), was introduced to pharmaceutical industry in February 2019 [7]. The platform was the first end-to-end verification system initiated by industry stakeholders to ensure the safety of the pharmaceutical products throughout the supply chain. In the platform, the proprietary data belongs only to the party that has provided it. Therefore, other parties in the system cannot see each other’s data in the system. The system does not include personal patient data. Access to data is controlled by European Medicines Verification Organization

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EMVO, which is responsible for the governance of the European hub of the system. That each actor maintains the control of their own data is the most important design principle. The European Hub provides some centralized reporting, but it is only for national medicine verification authorities.

Unlike the medicine safety systems introduced in the United States or in other countries, the EMVS was implemented in collaboration with multiple stakeholders from within the pharmaceutical industry, who also fund the system. It is therefore interesting to analyze what possibilities different actors see for this kind of system. Typically, safety-control systems are created by governmental organizations, and other external value created by this kind of more transparent system has not been seen as a priority.

We set out this interview study to examine the value of data sharing perceived by representatives of a pharmaceutical company situated in the Nordics (NPC) and by data sharing experts, prior to the deployment of the system. We investigate what the new elements for data sharing that the EMVS provides could enable in pharmaceutical industry. Data sharing between pharmaceutical company and other stakeholders in the supply chain - wholesalers, pharmacies, and end-customers - is studied.

2. Data and Methods

Our research data include 20 semi-structured in-depth interviews with 11 informants from the NPC and with 9 external industry expert informants (Table 1). Main themed questions concerned data sharing and medicine discovery, delivery, selling, and usage. The identity of informants is masked to ensure the confidentiality of informants. No ethical approval was required for the study.

Table 1. The roles of informants and the types and lengths of interviews.

№	NPC / External	Title of the informant	Type of interview	Length (min)
			Face-to-face / Remote	
1	NPC	Representative of case company at EFPIA	FTF	45
2	NPC	Serialization project portfolio manager	FTF	25
3	EXT	Researcher	FTF	50
4	NPC	Head of digitalization	Remote	48
5	EXT	Researcher	FTF	47
6	EXT	Researcher	Remote	42
7	EXT	Director of industrial policy	Remote	46
8	EXT	Researcher	FTF	40
9	NPC	Head of region partner sales	Remote	24
10	NPC	Former business intelligence manager	Remote	32
11	NPC	Business director in OCC Business	FTF	38
12	NPC	Business development director	FTF	58
13	EXT	Key account manager in healthcare unit	FTF	85
14	NPC	Senior legal counsel	Remote	43
15	EXT	Researcher	FTF	45
16	NPC	Head of business IM, R&D and end user solutions	FTF	27
17	EXT	CMO	FTF	68
18	EXT	Key account manager	FTF	48
19	NPC	Director of drug safety	Remote	44
20	NPC	Legal counsel	Remote	32

The experts were chosen based on the purposeful sampling method. The main criteria for external informants was that they were widely known as experts of data sharing either in pharmaceutical industry or other industry with already established data

sharing practices, such as the retail industry. The interviews were conducted during February – June 2018, prior the legislation concerning the EMVS came into action. Author LL conducted the interviews. Themed questions were modified.

The transcribed interviews were treated as text and coded by using Atlas.ti software. The coding was done in two rounds. Firstly, data was divided via descriptive coding to data sharing and medicine discovery, delivery, selling, and usage categories. The second round of coding used the open coding method, pertaining to the linkage of all the quotations in each category to a sub-category.

3. Findings and Discussion

Figure 1 represents the three relationships in the EMVS that pharmaceutical manufacturers, such as our case company NPC, have with other stakeholders. The interviews provided insight for all these relations.

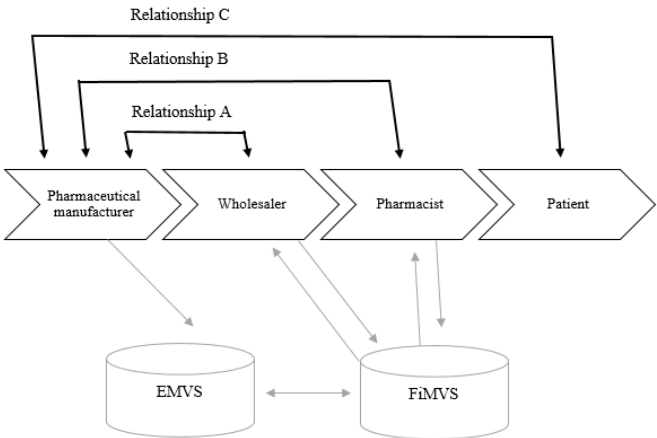


Figure 1. Data sharing between other stakeholders in the medicines verification system

In the interviews, two big drivers to motivate data sharing were recognized. Firstly, societies struggle with increasing medicine costs, creating pressure to provide evidence of cost-effectiveness. Secondly, developing a new medicine is a long process, which may normally take over ten years. However, the data collection methods and technologies have improved remarkably during the past decade, so **the process can be developed to be faster and cheaper**. For both of these issues, **collection of real-time data of the end-customers becomes essential**. Easier access to end-customer data might replace some parts in clinical studies to shorten their timespan. Rise of personalized medicine and digital treatments also increases the need for data sharing.

We discovered that the perceived potential value of the system is most notably in developing data sharing with the wholesalers and end-customers. By sharing data with the wholesalers, the logistics become more transparent, and with the end-customers, it helps pharmaceutical companies to develop more targeted services and products to the end-customers. Table 2 summarizes the key findings from the interviews.

Table 2. Perceived value of data sharing regarding the relationship types

Relationship type	Perceived value	Data sharing prospects and required actions
Wholesalers (Relationship A)	Large	The EMVS is already driving common standards for giving serial numbers for individual pharmaceutical packages. Aggregating serial numbers to distinguish between different brands of pharmaceuticals should be implemented to make the logistics more transparent and help data sharing between these stakeholders. Serial numbers could be used to improve tracking of medicine flow from wholesalers to pharmacies.
Pharmacies (Relationship B)	Minor	The medical companies will be able to achieve information on when each medicine package is sold, as the serial number of the package is then annulled from the central hub. However, companies are already performing demand projections based on the pharmacy order data.
End customers (Relationship C)	Large	All the medicine packages include the data matrix (the QR code enabling the tracking of the product), which can also be used by end users to obtain new information of the product. This data could also be linked with other personal information of the end user with their permission, to achieve greater value in interaction. Pharmaceutical companies could offer applications enabling this interaction, and use this data to enable solutions of e.g. personalized medicine.

4. Discussion and Conclusions

Pharmaceutical companies may create new value by offering digital data and information of their products to develop more targeted services and products to end-customers. However, data sharing is a tool, not a solution. New tools take a lot of iteration to get everything right – solutions take even more iteration. In pharmaceutical industry, this is doubly true due to compliance, risk mitigation and fraud issues.

To conclude, the new medicines verification system provides opportunities to increase traceability of products and develop data sharing in supply chains. The traceability systems originally stemming from industries where private actors have been interested in protecting their products from counterfeits, such as mobile phone industry, can also create new societal value in industries where the counterfeits have wider externalities, such as the effects of counterfeit drugs on public health.

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Integration of International Classification of Diseases Version 11 Application Program Interface (API) in the Rwandan Electronic Medical Records (openMRS): Findings from Two District Hospitals in Rwanda

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Abstract. World Health Organisation (WHO) has updated the International Classification of Diseases to version 11 (ICD-11) which was recently adopted for use by countries in 2019. ICD-11 can be used in Electronic Medical Records (EMR) systems with support of extended technologies like Application Program Interface (API). Integration of ICD-11 in Rwandan EMR (OpenMRS) in two health facilities was conducted in July-October 2019. Findings indicated that adapting ICD11-API in EMR is feasible. More than 50% of diagnoses were recorded using ICD-11. Healthcare providers perceived ICD-11 API as easy to learn and useful for harmonization of diagnosis, data reporting and insurance reimbursement. Integration of ICD-11 API in EMR can be scaled up to all hospitals for use in Rwanda and other countries using similar system.

Keywords. Clinical informatics, Electronic Medical Records, ICD-11 API, OpenMRS

1. Introduction

The World Health Organization (WHO) established International classification of Diseases (ICD) comprising mortality and morbidity way back in 1948 and published version six of ICD [1]. The current 11th version of International Classification of Diseases (ICD-11) is the standardized method for recording, reporting, analysis, interpretation and

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comparison of morbidity and mortality data [2]. The ICD-11 was released in 2018 and endorsed by member states in May 2019 in the 72nd general assembly [1]. ICD defines the nature of diseases, disorders, injuries and other related health problems, listed in a broad, ordered fashion granting an easy retrieval. A previous version of ICD was widely used with importance in different disciplines such as dentistry, internal medicines, psychiatry and reimbursements [3-5]. Healthcare systems have extensively used Electronic Medical Records (EMR) system to improve care, research and programmatic decision-making [6]. The use of Electronic Medical Records (EMR) system in healthcare has lacked use of standard classifications to enhance interoperability and effective use of routine data collected in EMR [7]. When data is collected using standard methods, it allows use of data for care of patients and decision-making as well as research [8]. The need for use of ICD-11 in EMR has called the WHO to develop an Application program interface that allows integration and access of ICD-11 classification in respective EMR [8]. In Rwanda, ICD-11 API was integrated in the Rwandan EMR (OpenMRS) [9] using docker technology [10]. The aim of this article is to describe the process of integration and explore how ICD-11 was used to record diagnosis in early implementation within two district hospitals.

2. Methods

We used an iterative development that applied four different methods: idea generation and prototyping, non-participatory observations, user test interviews, and descriptive analysis of codes diagnosis used in EMR. We first described the process of **idea generation**, including challenges and related approaches for integration of ICD-11 into the EMR system; The research team who authored this paper brainstormed on how ICD-11-API can be integrated in Rwandan EMR and deployed it in Masaka and Muhima district hospitals chosen conveniently. Activities of integration were done in two successive weeks and the team agreed on the approach to integrate ICD-11 API in Rwandan EMR. **Non-participatory observations**; At least two researchers observed during clinic hours how clinicians used ICD-11 API in EMR to record diagnosis after implementation. **User test interviews**; we interviewed clinicians to share their perceptions regarding usage of ICD-11 API in EMR. A semi structured interview guide was used to interview doctors and paramedical staff who used EMR at least 2 weeks after installation of ICD-11 API at two hospitals. Interviews were conducted in a private room at the clinic with one researcher interviewing and another taking notes and recording. Recorded interviews were transcribed and analyzed using informed grounded approach. **Descriptive analysis of coded diagnosis in EMR**; researchers extracted EMR databases of two district hospitals within 3 weeks post implementation of ICD-11 API and using descriptive statistics analyzed how clinicians captured diagnoses. The study sought ethical approval from University of Rwanda College of Medicine and Health Sciences Institutional Review Board (CMHS-IRB) No.378/CMHS IRB/2019.

3. Results and Discussion

The integration process of ICD-11 API into OpenMRS involved **idea generation**; researchers brainstormed on how to integrate ICD-11 API in EMR. They carefully reviewed the technical development of ICD-11 guided by WHO team who developed

ICD-11 API. Research team also reviewed EMR system used in two hospitals. Guided by national developers of OpenMRS, they reviewed how EMR could use ICD-11 API. Two scenarios were suggested; first was to copy all codes and have them as diagnosis concepts in EMR. This required minimal time, but end users could lose search functionality of ICD-11-API. Second ICD-11 API could be integrated using docker container technology, which was installed on a local server of the OpenMRS instance and was accessed through OpenMRS HTML form using embedded coding tool for web API and the updated concepts dictionary to operate with OpenMRS framework. The second approach was adopted which allowed clinicians to use search functionality. After integration on test server, the same package was replicated in two district hospitals chosen purposively after accepting to test the ICD-11 API. An IT technician at the district hospital was trained on how to guide clinicians to use new ICD-11 API features added in EMR.

Non-participatory observations; At least two researchers observed how clinicians use ICD-11 API during clinic hours. Users were familiar with search and coding patient diagnosis in EMR with minimal guidance at first time. In general, assigning a diagnosis to a patient using ICD-11 API took very few seconds from 15 to 30. Observation found that some users were struggling to get to ICD-11 searching tool due to network problems (internal network) and forgetting to locate the ICD-11 icon in EMR for them to search and save a diagnosis. Some clinicians were struggling to assign a diagnosis, which match details of the country protocols and reporting requirement from the Ministry of Health.

User test interviews; Participants interviewed in two hospitals were medical doctors (2), physiotherapists (2), ophthalmologists (1), and dental therapist (1) who used ICD-11 API as a searching functionality for coding patient diagnosis in EMR during visit. In general, all users interviewed felt it very easy to start using ICD-11 API, they could access ICD-11 search tool any time they wanted and could easily find diagnosis required for each patient received and help to record specific diagnosis. *"I can say that this search tool is really good and helped us to code diseases more accurately than before [.....] example we could record cataract in general but cataract can be caused by aging and cataract caused by trauma but ICD-API can describe it easily and is very easy to learn"* P0201. *"You see because we are using electronic system, ICD-11 API is useful because it lists all diagnosis and you have to select diagnosis for the patient that you have. It is very easy to learn and [...] no challenge faced to classify diseases"* P0102. Users reported that ICD-11 is useful in the hospital because it helps to code standard diagnosis so that everyone does it the same way. They also reported that they desired ICD-11 API in EMR because it helps standard coding of diagnosis, reporting of patient data and reimbursement from health insurances and they fully understand all ICD-11 content. *"It helps standard diagnosis and helps reporting structured data [...] I can say that it is trusted and other hospitals can use it, it is fit for clinicians, hospital reimbursement from insurances"* P0101. However, some access challenges were related to poor network for some hours in one hospital and hard to locate where to get diagnosis in EMR at first time of use. *"The challenge I faced is that during orientation I was not around, and I could not recall clicking on the correct button to get where to pick ICD-11 diagnosis but after asking I could get diagnosis needed."* P0103.

Descriptive analysis of coded diagnosis in EMR; At Masaka hospital, we found a total of 227 diagnoses were recorded in EMR within 15 days post implementation of ICD-11 API. Among 227 diagnosis recorded, 134 (59.1%) were recorded using ICD-11 API by healthcare providers. Healthcare providers who coded ICD-11 include medical doctors (74.4%), paramedical i.e. dental, ophthalmology and physiotherapists (69.8%) and medical doctor specialists (16.3%). On the other hand, at Muhima hospital, 655 diagnoses were recorded within 7 days post implementation of ICD-11 API. Of all diagnoses recorded within 7 days, 353 (53.9%) were captured using ICD-11 API. General practitioners coded 48.3% of their entries, medical doctor specialists recorded 53.3% of their entries and paramedical 91.5% of their

entries using ICD-11 API. This paper described the early integration of ICD-11 API in Rwandan Electronic Medical Records (OpenMRS). Methods of user centered design [11,12], qualitative [13] and quantitative analyses were used to explore how best ICD-11 API can be integrated and used by clinicians. These different methods helped to triangulate results for exploring barriers and facilitators to integrate and use ICD-11 API in local EMR. Working in a multidisciplinary team including ICD experts, EMR experts, and implementers' experts contributed to the effective integration of ICD-11 API that was felt useful by hospital personnel. The nature of ICD-11 API with search functionality tool helped clinicians to record diagnosis in EMR with minimal barriers at the beginning. Within three weeks of integration of ICD-11 API in EMR, over 50% of diagnosis were captured using ICD-11 API. This implies that some clinicians were still using ICD-10 in early phase of integration. By explaining the use of ICD-11 API to all clinicians and deactivating ICD-10 link in EMR may increase diagnosis capture at a rate of 100%.

4. Conclusions

In general, integration of ICD-11 API in the Rwandan Electronic Medical Records (EMR-OpenMRS) was feasible with efforts of EMR implementation researchers, IT developers, and WHO experts in ICD-11. We learnt that it is useful to standardise how diagnoses will be recorded to ensure their usability for clinical purposes, data reporting and insurance reimbursement. Integration of ICD-11 API in EMR can be scaled up to all hospitals for use in Rwanda and other countries using similar system.

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An Analysis of the Growth in Uptake of OpenWHO's Online Learning Resources for COVID-19

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Abstract. From 26 January – 21 April 2020, 9 online courses for COVID-19 were published on OpenWHO.org. The courses are available in 18 different languages, totalling 53 learning resources and more than 1.5 million course enrolments. This paper analyses key trends in the growth of enrolments in these resources. The number of enrolments increased significantly between 26 January and 21 April, with distinct spikes in growth preceded by important global milestones in the timeline of the outbreak. The surge in users demonstrates that the platform is serving as a source of digitized learning for COVID-19, helping meet the broad demand for outbreak-related information.

Keywords. OpenWHO, WHO, online learning, pandemic, COVID-19

1. Introduction

OpenWHO is the World Health Organization's (WHO) online platform for transferring life-saving knowledge to frontline responders, health care workers and the public during health emergencies. Designed in 2017 with a pandemic in mind, the platform has been put to the test by the global spread of the novel coronavirus. The objective of this research is to identify and examine patterns in the unprecedented growth in uptake of OpenWHO's learning resources for COVID-19.

The WHO's Health Emergencies Programme, which is responsible for OpenWHO, has devised an expedited course creation process for infectious disease outbreaks and acute health emergencies, turning WHO technical guidance into learning products within 72 hours and publishing the resources on OpenWHO.org, offering open, free and unlimited access to the materials in low-bandwidth friendly formats accessible via mobile or desktop devices. Initial course production is followed by multi-language translation into, in most cases, the official languages of the United Nations, Portuguese and the national and local languages most relevant to the context of the outbreak.

The learning response to COVID-19 was triggered by the WHO Emergency Committee meeting on 22-23 January. On 26 January 2020, following the 72-hour expedited course production process, an introductory COVID-19 course was launched on OpenWHO.org. First published in English, the course has since been translated into

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15 languages, including one sign language, with translation into a further 13 languages underway. The platform hosts a total of 9 distinct courses for COVID-19, each focused on a different topic relevant to preparedness and response for the outbreak, in various languages, totalling 53 resources:

1. *Emerging respiratory viruses, including COVID-19: methods for detection, prevention, response and control* was released on 26 January and is an introduction to COVID-19.
2. *Clinical Care Severe Acute Respiratory Infection (SARI)* was published 6 February and is a hands-on practical guide for health care professionals involved in clinical care management during outbreaks of respiratory diseases. It is available in 7 languages.
3. *ePROTECT Respiratory Infections* was released 14 February. The course provides a general introduction to acute respiratory infections and basic hygiene measures and is also available in 7 languages.
4. *Infection Prevention and Control (IPC) for Novel Coronavirus (COVID-19)* was launched 25 February and outlines the IPC measures needed to prevent transmission of COVID-19 in health care settings. One of the most popular COVID-19 courses on the platform, it is available in 12 languages.
5. *COVID-19: Operational Planning Guidelines and COVID-19 Partners Platform to support country preparedness and response* was launched 3 March to assist UN Country Teams (UNCT) in scaling up country preparedness and response to COVID-19. It is available in 5 languages.
6. *SARI Treatment Facility Design* was launched 24 March and provides an overview of the principles that drive the design process of COVID-19 screening areas for health care facilities. It is available in 3 languages.
7. *Introduction to Go.Data – Field data collection, chains of transmission and contact follow-up* was launched 9 April as a primer on Go.Data, a field data collection platform focusing on case and contact data. This course, as well as the two that follow, are available in English with translation into other languages underway.
8. *COVID-19: How to put on and remove personal protective equipment (PPE)* was launched 15 April as a video guide for health care workers involved in patient care activities in a health care setting.
9. *Standard precautions: Hand hygiene* was launched 21 April and outlines the WHO guidelines on hand hygiene, and associated tools and ideas for effective implementation to prevent health care-associated infections.

2. Methods

Quantitative data on platform overall use and course enrolments was extracted from the OpenWHO statistical capacity and analysed and visualised using Excel.

3. Results

As of 21 April 2020, there were 1 532 010 enrolments in OpenWHO's COVID-19 resources, reflecting an average increase of 17 814 enrolments per day since the launch of the first COVID-19 resource on the platform on 26 January 2020. This daily increase

peaked at 66 681 new enrolments on 31 March 2020 and increased from an average of 2494.33 new enrolments per day in January to 3796.97 new enrolments per day in February, 29 374.71 new enrolments per day in March and 36 784.00 new enrolments per day in April.

As illustrated by Figure 1, the increase in enrolments in OpenWHO's COVID-19 resources was significant, acting as the primary driving force behind the 1099.44% increase in total course enrolments across the entire platform between 26 January and 21 April, from 165 000 to 1 979 076. The enrolments in COVID-19 resources accounted for 84.45% of this increase.

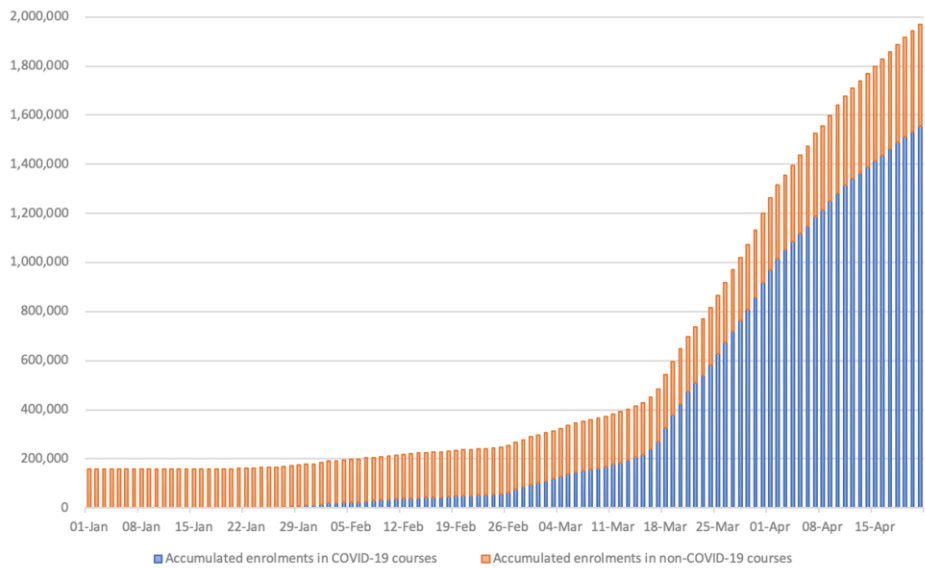


Figure 1. Accumulated course enrolments on OpenWHO from 1 January to 21 April broken down into enrolments in COVID-19 and non-COVID-19 courses.

The use of OpenWHO's COVID-19 resources, as measured by the number of enrolments in each course, followed a general upward trend following the launch of the first COVID-19 course on the platform on 26 January, as evidenced by Figure 2.

The most notable spike in enrolments followed the characterisation of the outbreak as a pandemic by WHO on 11 March. For example, the course for UNCT increased from 15 289 total enrolments on 10 March to 58 089 on 22 March and from 158 953 on 28 March to 292 375 on 3 April, reflecting an increase of 1812.32% from 10 March to 3 April or an average increase of 11 545.25 enrolments per day. This is compared to an average increase of 3057 enrolments per day during the same number of days prior to 11 March. In the same period before and after 11 March, the daily increase in total enrolments in the introductory COVID-19 course went from an average of 2276.29 new enrolments per day to an average of 8491.70 new enrolments per day and the daily increase in total enrolments in the IPC course also increased from an average of 2615.38 new enrolments per day to an average of 11 527.25 new enrolments per day.

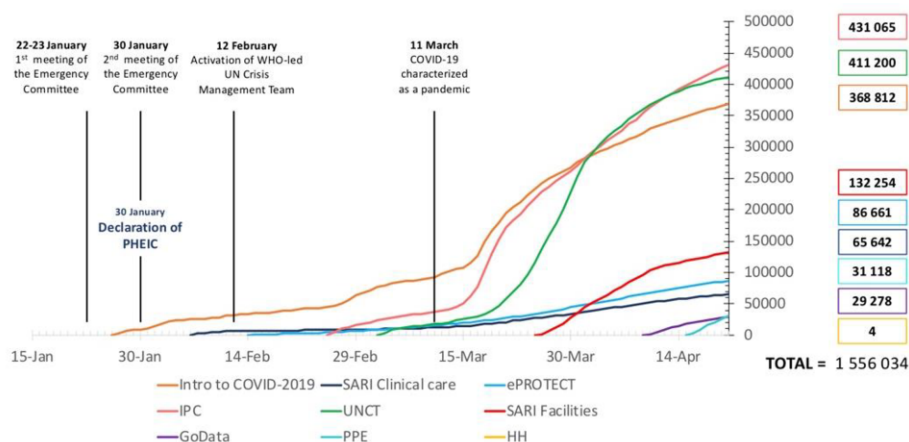


Figure 2. Accumulated course enrolments in each of OpenWHO's COVID-19 courses from 15 January to 21 April 2020, juxtaposed with critical outbreak milestones in the same period.

4. Discussion

The significant increase in enrolments in OpenWHO's online courses for COVID-19 was driven by spikes in growth which followed key events that occurred over the course of outbreak, most notably WHO's declaration of a pandemic on 11 March. These events heightened public and professional interest in the outbreak and, as a result, fuelled an increase in traffic towards OpenWHO's COVID-19 materials, particularly from users in Europe and the Americas, areas with the largest COVID-19 transmission in Feb – April.

As a result of the COVID-19 pandemic, OpenWHO's public health learning resources are in high demand not only among its traditional audiences (health care workers, students and UN staff) but also the general public. This aligns with a previous analysis of OpenWHO data which suggested that the introductory COVID-19 course attracted learners outside of traditional health professions, in line with the broad reach of the pandemic. [1] Research into user demographics is central to understanding the drivers which motivate individuals to consume learning resources for COVID-19.

5. Conclusions

That the unprecedented growth in popularity of OpenWHO's online courses coincided with milestones in the COVID-19 outbreak is a testament to the critical role that timely, free and accessible online learning platforms play during a pandemic, by facilitating the rapid, global sharing of life-saving knowledge to the audiences who need it, when they need it, in formats and languages they can understand, anywhere in the world.

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Campus Mental Well-Being: Opportunities for Digital Health

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Abstract. This paper aims to understand the student campus mental health, mental well-being and mental wellness ecosystem by systematically identifying and synthesizing research reporting initiatives using these terms. It identifies the differences and similarities in usage to identify digital health opportunities.

Keywords. Mental health, mental well-being, mental wellness, digital health

1. Introduction

The prevalence of mental disorders such as anxiety and depression are on the rise. Australian youth between the age of 18 and 24 has the highest prevalence rate of mental illness [2]. Current mental health models of care are struggling to cope with the increase in the demand for mental health services and this creates a demand that exceeds supply especially in acute care settings. This situation is driving the need for reconceptualization of the mental health service ecosystem including exploring opportunities for intervention inherent when end-user applications interact with IT infrastructure in formal environments such as schools, universities and workplaces. For example, a student on campus, connected to the campus Wi-Fi network, broadcasts a unique MAC address which is identifiable to the network and could be used to count the number and types of services connected. Similarly, browsing activities can be analyzed to deduce any characteristics of search terms that may give insight into student well-being. Understanding population level student behaviors would enable the development of systems level interventions to reduce the strain on the stressed mental health service provision and create wellness-based environments. Understanding the landscape of campus initiatives and the different terminologies such as mental health, mental wellness and mental well-being is a precursor to identifying opportunities for digital health. The success of digital health interventions in campus environment is dependent on collaboration from multidisciplinary teams who may associate their initiatives using the different terminologies, cognizant that engaged students are likely to have better academic success [8] and are likely to remain enrolled in their studies (retention) [16].

The World Health Organization (WHO), defines mental health as a state of well-being in which every individual realizes his or her own potential, can cope with the

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normal stresses of life, can work productively and faithfully and is able to make a contribution to her or his community [17]. The Oxford dictionary defines well-being as ‘the state of being comfortable, healthy or happy’ and defines wellness as ‘the state of being in good health, especially as an actively pursued goal’. These definitions show the interconnected of these terms, therefore, addressing the state of one would address the state of the others. This study investigated this interconnectedness in the campus ecosystem by systematically identifying and synthesizing research reporting initiatives in these areas to identify digital health intervention opportunities.

2. Method

In April 2020, a systematic investigation, using the Web of Science database, was undertaken using the search terms ("mental health" OR "mental wellness" OR "mental wellbeing" OR "mental well-being" AND "student" AND "campus").

2.1 Review inclusion criteria

The inclusion criteria was: (1) Population: students at university or college (2) Document type: articles or proceeding papers (3) Outcome: Initiatives to improve student mental health, student well-being or student wellness (4) Language: English (5) Timespan: five years. Studies were excluded if the student population were not in campus and if the student population were below the age of 18 years.

2.2 Article screening and data analysis

Article titles and abstracts were reviewed for potential inclusion and duplicates were removed. Studies were excluded if they did not meet the ‘Review inclusion criteria’. Semantics of the included articles were explored using NVivo's™ word frequency search with the following criteria: (1) 1000 most frequent words (2) minimum length of five letters.

3. Results

The search identified 2313 articles. Thirteen full text articles met the inclusion criteria. These were categorized into three categories: mental health [3-5; 11] mental well-being [9-16] and mental wellness [10]. Synthesized results are presented descriptively in Table 1. There were only two digital health interventions (Article 11 and Article 13).

Table 1. Campus mental health, mental wellness and mental wellbeing initiatives

Articles	Study outcome/Findings	Study design, country & sample size
Article 1 [11]	Recommendation to raise awareness, counselling, establish drop-in centers, promote recreational and recreational activities	Cross-sectional study in Northern Tanzania (n=402)
Article 2 [5]	Feasibility and acceptability of on campus mental health screening and early intervention program associated with improvements in resilience-related capacities and symptom reduction	Single arm, prospective study evaluating outcome of a 4 week intervention workshop in United States (n=63)

Article 3 [4]	Outreach initiatives capturing trends in service utilization providing insight into programming for future service and outreach initiatives	Longitudinal study survey in Canada (n=3,734)
Article 4 [3]	Campus based interventions needed to promote mental healthcare utilization	Web-based survey in South Africa (n=1402)
Article 5 [13]	Implementation of emotional intelligence programs contribute to the development and improvement in students' Emotional Intelligence	Meta-analysis of 20 eligible articles
Article 6 [7]	Involvement in school organizations was correlated to depression levels, general positive affect and life satisfaction. Social interactions were related with quality of life.	Quantitative, cross-sectional, descriptive, correlational design, survey in Philippines (n=249)
Article 7 [6]	Poor mental health in medical students and recommendation for steps to put in place to support these students	Online survey in Morocco (n=637)
Article 8 [1]	High levels of mental distress in medical student, interventions needed to improve mental health	Survey in Portugal, (n=622)
Article 9 [15]	High Factor Model (HFM) factors: erudition, peace, cheerfulness, honesty and tenacity are related to psychological variables (well-being or psychopathological symptomatology) and academic performance (adjustment and achievement)	Survey in Argentina, (n=256)
Article 10 [14]	Social media as a risk factor for mental health struggles	Survey in United States (n=546)
Article 11 [12]	Efficacy of biofeedback digital intervention in reducing self-reported anxiety and increasing perceived wellbeing	Randomized, wait-list controlled, trial in United Kingdom (n=262)
Article 12 [9]	Improving mental health through bridge network (peer support for students)	Case study, co-design process in United Kingdom (n=7)
Article 13 [10]	Online modules as a good start for coach education about mental health	Survey in US, (n=969)

Despite the different focus in each of the categories, mental health is a theme that consistently appeared in every category. The results highlight that students are hesitant to disclose mental health problems because of the negative stigma attached [16] to it.

4. Discussion

Well-being and wellness focused digital health researchers should be cognizant to include mental health focused stakeholders for a holistic contribution. Analyzing the semantics of included articles is an effective way to investigate the interconnectedness of initiatives. Digital health initiatives can converge the multidisciplinary teams driving research behind the disparate terminologies to deliver campus wide improvements to students' well-being. Innovative interventions such as anonymous virtual mental health services and providing free subscriptions to apps are examples to explore.

5. Conclusions

The approach taken at campuses are different from acute care settings where the term mental health refers to treating an illness. On campus interventions are focused on the delivery of non-pharmacological programs closely related to holistic approach of

wellness and well-being. This review shows that there is a huge contribution to be made by digital health researchers. The stigma attached to mental health presents opportunities for interventions using surrogate measures relevant to campus such as student engagement and student retention which can be anonymously analyzed when end-user applications interacts with campus IT infrastructure.

Acknowledgement

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Transition Requirements from Problem List to an Overarching Care Plan for the Support of Person-Centered Care

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Abstract. To keep healthcare effective, accessible and affordable to all we need a fundamental paradigm shift. Self-management for prevention and care with the help of healthcare professionals, having a shared view of the state of well-being, will play a significant role in this transition. The problem list is widely adopted as centerpiece of electronic health records and is although often patient oriented, but mostly limited to the institutional level. The requirements for this paradigm shift has been discussed in a series of workshops. Truly person-centered care requires to move towards a holistic problem list with an assessment and planning process resulting in an overarching care plan. The change process towards a real person-centered problem list, integrated in an overarching care plan, should be focused on the transition of health services delivery and requires a transition based on the “Quadruple Aim” principles.

Keywords. Electronic health records, problem oriented medical records, care continuity, integrated health care systems

1. Introduction

The World Health Organization’s (WHO) global strategy on people-centered and integrated health services is a call for a fundamental paradigm shift in the way health services are delivered, managed and funded [1]. This requires shifting from paying for the volume of services delivered to the value created for patients where “value” is defined as the outcomes achieved relative to the costs [2]. Continuity of care is an important aspect of quality and safety in healthcare. Concepts that are needed to achieve continuity of care are defined by the NEN-EN-ISO 13940. Linking episodes of care within the health care network will support the person-centered approach and could have substantial effects on the performance of the overall healthcare system [3]. Providers problem lists, mostly limited to their domain of expertise, must be integrated to a holistic problem list. However, this is difficult to implement from a single domain due to ambiguities in language and technology, the lack of an integrated approach and

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divergent interests. An important question here is how to accomplish a truly person-centered (holistic) problem list across the healthcare network?

2. Methods

At the MIE 2012 in Pisa a track with several workshops was organized on the Caring Village of the Future, elaborating the results of the Exploratory Workshop sponsored by the European Science Foundation (ESF) on the challenges of integrating health and social care informatics at the persons level [4,5]. During this workshop the concept of the Blue Line was introduced; this involves defining the mandatory requirements to connect all health and social care providers around the person for coordinating all services in a person-centered care plan. In the Netherlands in 2018, during 6 workshops with 21 to 23 participants each, 132 in total, consisting of specialists and general practitioners, the requirements for integrated care were discussed. In Copenhagen 2019 at the 34th PCSI (Patient Classification Systems International) conference a special track was dedicated on how to stimulate the shift towards person-centered care.

To help identify the next steps, by combining strategic directions to promote person-centered care, a workshop proposal was submitted and accepted for the MIE 2020 in Geneva, which unfortunately was canceled due to the situation related to the coronavirus pandemic. The thorough preparation and discussions for the MIE2020 workshop, incorporating the recent social and scientific findings, have led to several insights that we think are useful to share in this vision for the future article.

3. Results

The conclusion of the ESF Exploratory Workshop was that each of the care providers is in charge of just one problem and no one takes responsibility for coordinating the (in)formal services aimed at improving the patient's health and wellness. The Blue Line approach focuses at two of the strategic directions of the WHO strategy: to support people-centered and integrated health services. The first three requirements of this approach focus on interoperability at systems level; the technical interoperability required to connect the systems, the semantic interoperability required to understand the data exchanged, and social interoperability, which puts the information in the holistic context of the person rather than of the care process of the institution. With the first three requirements in place the fourth requirement, the overarching care plan, can be implemented. This links, within the privacy arrangements, the different plans of care to support the coordination of the goals and interventions by professionals and control by the patient. The fifth requirement is a social incentive framework that requires that the aforementioned elements be embraced and that funding systems gives incentives for the transition to person-centered care. The most frequently mentioned requirement, from the 2018 workshops in the Netherlands, was interoperability of systems across the domains. From the 34th PCSI, identifying governance of integrated care, an overarching care plan, and innovative funding, were recognized as the key components for the transition to person-centered care.

This emphasizes that the transformation of the problem list, from an institutional level to a holistic list at the patient level across the network, is an essential component for person-centered care. Plans should be linked to problems to achieve the goals set in

the interaction of the patient and the care provider(s). The overarching care plan gives a dynamic insight in the significant health issues and their management. It should contribute to shared decision-making, taking into account the patient's preferences, knowledge, skills and confidence to manage his own health and wellbeing.

4. Discussion

Patients First requires insight in the health issues of the patient and its management. The concept of the problem list was first introduced as the key component of the Problem Oriented Medical Record (POMR) by Weed in the late 1960s [6]. Weed also suggested to use the SOAP (Subjective/Objective/Assessment/Plan) note format. The implementation of the problem list is still a subject of discussion and ever since the introduction of the POMR there have been esoteric discussions about the term 'problem'. Its implementation into primary care was supported by the adoption of the ICPC (International Classification of Primary Care), which incorporated the episode of care concept and its documentation. It helped to improve the quality of the medical record as it required interaction with the patient about the state of his/her health issues. The **A**ssessment based on the **S**ubjective and **O**bjective data resulted in **P**lans for the patient. The associated data, the assessment and the plan are part of the episode of care record of that patient. Ideally, the problem list is intended to serve as a dynamic "table of contents" of the patient's chart [6]. It can serve as a multi-disciplinary index of the current and resolved health issues. Many problems often require coordination and continuous care over time. To interpret various problems and track progress, the concept of 'problem' has a wider scope than diagnosis within health and clinical management, can be used hierarchically, and can be used for all matters that need attention, as is the case for some medications, social status, and behavior [7]. This wider scope is also described by the HL7 International Patient Summary whereby a Health Concern is a health-related matter that is of interest, importance or concern to someone, who may be the patient, patient's family or patient's health care provider [8]. Important for the shift to person-centered care is the link between the problem and the plan via the assessment. Shared decision making can be seen as the assessment phase of the SOAP concept, resulting in the update of the plan, fitting in the overarching care plan.

More and more health care providers, each with their own isolated information systems, are involved in providing care to a growing number of citizens with multiple problems. The need to share information for coordination and collaboration across these silos is constantly increasing. Person-centered care requires coordination of the management of all their health and social issues and the longitudinal integral planning of the treatment by different providers. An overarching care plan aims to give a comprehensive overview of the different care plans, related to the problems of the patient, where each plan has a specific goal that fits the context of the patient and focuses on the desired outcome. Not only medical, but also nursing, social, educational, and patient safety issues should be aspects of the overarching care plan. In addition to the self-management potential of the patient.

The holistic problem list can be the base for the proactive advanced care planning of formal and informal care, and thus the key for person-centered care. But unfortunately the available information technology (IT) still hinders this vision [9], as the systems are not compliant to the Blue Line principles. Current IT systems are still

focused on the care process of the institution and are not primarily designed to support person-oriented care. A problem list that should serve multiple caregivers as well as the patient across multiple settings requires extensive functionality, especially in terms of management and views. The establishment of an overarching care plan requires connectivity, and semantic and social interoperability, at least at the level of the problem list and the care plans. Only then the vested interests of the current health care providers can be aligned with the objectives of person-centered care. Key elements in this transformation towards patient-centered care will include new structures for integrating and coordinating services, a strong focus on patient engagement, new payment models and an implementation based on the quadruple aim principles [10].

5. Conclusions

To implement the global WHO strategy to apply person-centered care, the overarching care plan helps to coordinate the health and social care issues of the patient and takes the patient's environment as a starting point, regardless of age. The decentralized institutional patient problem list will have to shift to a central person-oriented problem list. To integrate the POMR and SOAP concept into a proactive overarching care plan for the patient and providers in the network of care, interoperability requirements will have to be mandatory for the participants throughout the healthcare spectrum. A 'burning platform' is necessary for a paradigm shift. The recent corona crisis can be seen as such stressing the importance of coordinating the care and sharing information at the patient level across the health and social care network. So the coronavirus pandemic could boost the WHO's global strategy for integrated people-centered health services.

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Guideline-Based Decision Support System for Nursing Homes: A Case Study with the Management of Malnutrition

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Abstract. Nursing home (NH) residents are known to be at risk of preventable adverse events due to inadequate monitoring or failure to provide necessary treatments. Missed care has been partially explained by nurses' lack of knowledge. We describe a guideline-based decision support system for the management of malnutrition in NHs. Three steps are distinguished: screening, therapeutic management, and follow-up. Clinical practice guidelines have been modeled as decision trees and formalized as IF-THEN rules to be triggered by electronic health records data (e.g., weight, albuminemia). We propose a visualization of recommendations as a dashboard of gauges displaying both current and previous levels of malnutrition to inform on the effect of therapeutic management and facilitate a correct follow-up.

Keywords. Clinical decision support system, clinical practice guidelines, visualization, nursing homes, malnutrition, geriatrics

1. Introduction

As people are living longer, often with chronic conditions and loss of independence in the activities of daily living, an increasing number of older people currently live in nursing homes (NHs). Studies report that NH residents are at risk of adverse events, many of which being classified as preventable due to inadequate monitoring or failure to provide necessary treatments or care plans [1]. Evidence from hospitals has shown that when nurses work with insufficient staff and resources, they are more likely to leave necessary patient care undone [2]. Such missed care in NHs has also been explained by nurses' lack of knowledge, for instance, observed malnutrition rates range from 40 to 90%, despite the existence of clinical practice guidelines (CPGs). The deployment of electronic health records (EHRs) in health care institutions has rapidly

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increased in developed countries. Clinical decision support systems (CDSSs) connected to EHRs have already demonstrated their impact in improving care quality in both hospitals and primary care settings. If recent studies have demonstrated that CDSSs may improve the management of NH residents [3], a scoping review of the literature [4] found that very few CDSSs are currently in routine use in NHs. In order to enrich the NETSoins EHR developed by Téranga Software and widely used in French NHs, we are developing CPG-based CDS modules applied to malnutrition, pressure ulcers, osteoporotic fracture, and drug prescription². This paper focuses on the design of the CDS module that supports the management of malnutrition.

2. Methods

2.1. From textual guidelines to computer-interpretable guidelines

Several CPGs have been published for the management of malnutrition for the elderly. We chose to implement the CPGs developed by the Haute Autorité de Santé (French national agency for healthcare quality) [5]. The first step has been to formalize CPG contents as decision trees that have been translated by a gerontologist as human-readable IF-THEN decision rules validated then by dietitian and geriatrics experts.

2.2. Guideline-based malnutrition management

The management of malnutrition is organized in three steps: malnutrition screening, therapeutic management, and follow-up. If nurses are essentially the targets of malnutrition screening, physicians are also involved in the therapeutic management and follow-up, especially when the symptomatic treatment of malnutrition is not efficient to solve the problem, and when digging deeper into the clinical picture to look for underlying pathologies is necessary. Mainly five criteria are used: weight loss in the last month (WL_1m), weight loss in the last six months (WL_6m), body mass index (BMI), albuminemia (Alb), and Mini Nutritional Assessment score (MNA).

- *Malnutrition screening*: to assess the malnutrition status (MA), weight losses are first explored, then BMI, Alb, and MNA. Three MA levels are used, either no malnutrition, or moderate malnutrition, or severe malnutrition. In the presence of malnutrition (either moderate or severe), dietary intakes have to be assessed (DIA) on a three-day period. Figure 1a displays the corresponding screening decision tree.
- *Malnutrition therapeutic management*: recommendations on how to manage malnutrition are provided according to the levels of the pair (MA, DIA). Figure 1b displays the therapeutic management decision tree. Malnutrition is modeled as a function of weight loss, albuminemia, and time, MA (WL, Alb, t). In the same way, dietary intakes are varying with time, DIA(t). Both values are recorded over time to assess the longitudinal evolution of malnutrition. Once malnutrition is established (MA=moderate or MA=severe), dietary advices are provided. When MA=severe or when DIA=decreased+, oral nutritional supplements (ONS) or enteral nutrition (EN) should be added. Re-

² This research is funded by Téranga Software and the ANRT CIFRE Grant n° 2018/0307 for AA.

assessment of weight loss, Alb, and DIA have to be performed within a time period T that varies according to the severity of the clinical condition represented by (MA, DIA).

- *Malnutrition follow-up:* (MA, DIA) re-assessment is performed at t+T with $T \in \{T_{1M}, T_{15D}, T_{1W}\}$, along with DIA. At this step, the main criterion is to evaluate whether there has been an increase from DIA(t) to DIA(t+T). In each case, according to the evolution of weight and Alb, CPGs provide recommendations for the management of certain risks and the order of some lab tests, e.g., “Risk of dehydration, monitor blood tests”.

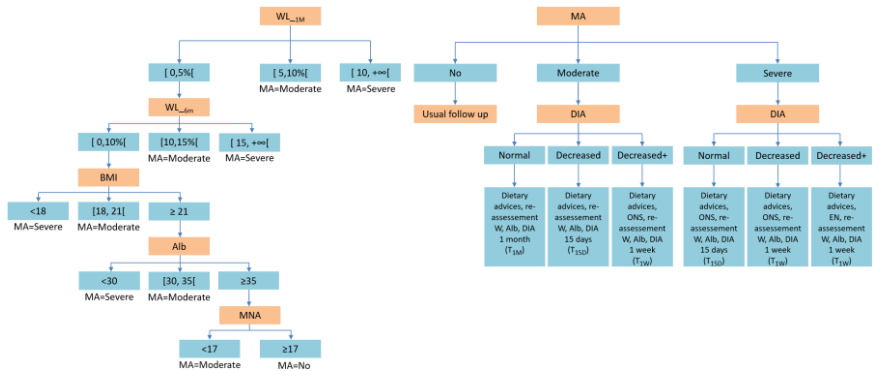


Figure 1. Decision trees for malnutrition assessment (left side, 1a) and management (right side, 1b).

2.3. Visualization of recommendations and alerts

Information visualization is defined as the use of visual representations of data, information, or knowledge to help users gain a deeper understanding of a domain’s content. The principle is that the right display would reduce the cognitive load of data interpretation. It is especially true with CDSSs to help better detection, interpretation, understanding, and evaluation of patient data for decision-making. Various visualizations of recommendations have been designed such as dashboards [6]. We proposed to implement gauges gathered in dashboards to represent the assessment of a NH resident clinical situation. In the case of malnutrition, the principle is to (i) highlight the current patient MA(t), (ii) remind the previous patient MA(t-T), and (iii) provide recommendations to support the right patient-specific management. Figure 2 illustrates the dashboard visualization included in the NETSoins EHR interface (names, patient data and picture are fake, only provided to display the CDS interface).

3. Results

We have simulated the execution of the system on the case of a 74-year-old patient, with moderate Alzheimer disease. At NH admission in September 2019, weight=72 kg, height=1.80 meter, BMI=22 kg/m2, Alb=35 g/l, and MNA=22. Weight=71 kg on March 8th, 2020, and 65 kg a month later which triggered a malnutrition alert, the display of the gauge indicating a moderate malnutrition, and the request for DIA during three days, which lead to DIA=decreased. Recommendations for dietary advices and to

re-assess the weight loss, Alb, and DIA in 15 days were displayed. On April 23rd, pre-Alb=37 g/l, patient weight=63 kg. MA is severe as displayed by the gauge (in bold in Figure 2 whereas the previous level is displayed in grey). Follow-up recommendations are displayed when sliding the cursor over the gauge.

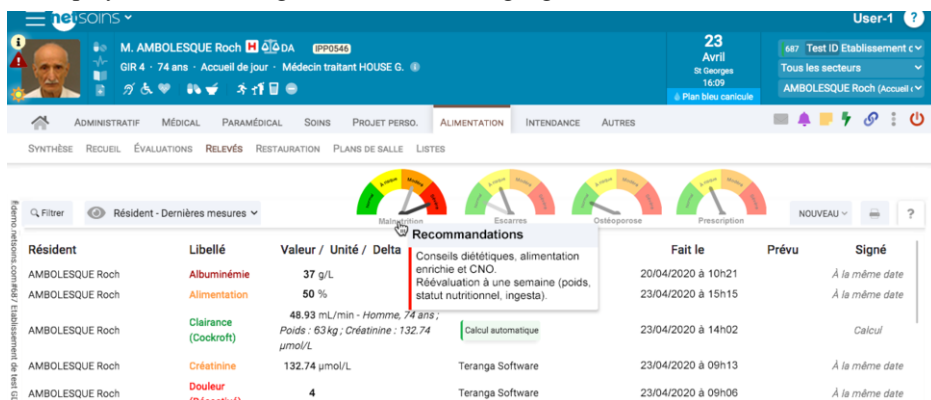


Figure 2. Dashboard visualization included in the NETSoins EHR interface.

4. Discussion and conclusions

Improving care quality in NHs would require improving the competencies of health professionals. We have developed CDSSs to enrich NETSoins, a NH-specific EHR widely used in France. The CDS modules use the same proprietary terminology as NETSoins to be interoperable with the EHR. Currently, CDS modules for the management of malnutrition and pressure ulcers are being implemented. The applications of the approach to the management of osteoporotic fracture and to support drug prescription are still to come. CDS modules usability and user acceptability have to be evaluated. Focus groups are planned with NH health professionals. The aim is also to test the idea to go for a full dashboard user interface. The clinical impact of such decision support proposal will have to be further assessed.

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Using openEHR in XDS.b Environments – Opportunities and Challenges

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Abstract. The HiGHmed research project as part of Germany's Medical Informatics Initiative aims to establish Medical Data Integration Centers (MeDIC) at each participating institution to integrate data of multiple primary information systems in a single place. The MeDICs are based on an IHE XDS.b Affinity Domain in conjunction with an openEHR clinical data repository. This paper presents two ways of storing and retrieving structured and semantically annotated data from an openEHR repository whilst keeping data integrated in an existing IHE XDS.b infrastructure. Furthermore, the paper discusses multiple benefits of the presented approach as well as challenges and corresponding solutions.

Keywords. IHE, XDS.b, openEHR, HiGHmed

1. Introduction

HiGHmed [1] is a research project that was founded within the Medical Informatics Initiative [2] of the German Federal Ministry of Education and Research. The goal of the project is to promote digitalization in the German health care sector by supporting cross institutional use-cases in the domains of patient care and medical research. Therefore, a Medical Data Integration Center (MeDIC) is currently being constructed at every university hospital involved in the project. These MeDICs aim to integrate data of primary systems in one place and to facilitate data transfer into a research context [3, 4].

In order to support the cross institutional use-cases, HiGHmed developed a concept of a digital platform consisting of an Electronic Health Record (EHR) based on an IHE XDS.b Affinity Domain combined with an openEHR clinical data repository [1]. However, this concept does not specify how these two technologies can be used in conjunction. Therefore, this paper describes the selected implementation approach at the Heidelberg University Hospital's MeDIC for integration of an openEHR repository into the existing XDS.b environment. The resulting infrastructure should support the requirements of health care professionals to retrieve relevant documents of a patient during care, but also data delivery in pseudonymized form for research projects.

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2. State of the Art

IHE XDS.b [5] is used all over the world to establish EHRs that support provisioning of relevant documents in patient care. Many of them only provide unstructured documents such as PDF files. Occasionally, EHRs are based on structured documents, examples are HL7 CDAs in Austria's ELGA [6] or HL7 FHIR resources in Finland's Kanta [7].

OpenEHR data modelling is successfully used in many projects to ensure semantic interoperable data exchange for secondary use [8 - 10]. Possibilities for combining openEHR and IHE in Slovenia's eHealth environment are presented in [11].

To the best of our knowledge, there exists no publication describing a concrete EHR infrastructure based on IHE profiles which uses openEHR Template Data Documents (TDD) as the document standard and supports patient care and medical research likewise.

3. Concept and Implementation

This paper proposes a single infrastructure to support patient care and medical research. The applied IHE profiles are XDS.b, DSUB, PIX, SeR and APPC [5]. Figure 1 provides a high-level application overview, Figure 2 shows the implemented IHE actors and transactions of each application.

To ensure that correct patient identifiers are used in all applications, the PIX actors Patient Identity Cross Reference Manager, -Consumer and -Source as well as the transactions ITI-8 and ITI-9 are used.

There are two pathways for storing data in the MeDIC. In both cases, a communication server routes the documents from primary systems to the corresponding repositories. Semi-structured data (e.g. HL7 v2 format) is sent from the communication server to an ingest consumer. This application stores data in an initial data stage, that is monitored by an ETL tool which then transforms the data into TDDs and sends them to the openEHR repository using its Document Source actor's ITI-41 transaction. Then, the openEHR repository registers the TDD in the central XDS.b registry using the ITI-42 transaction. Documents that already have a structured form (e.g. dPDFs) are stored directly in a different XDS.b repository, but are also registered in the same XDS.b registry. To convert these documents into TDDs as well, the DSUB profile is used. A subscription is created in the Document Metadata (DM) Notification Broker of the XDS registry with an ITI-52 transaction using the DM Subscriber actor of the ingest consumer. When a new document is registered in the XDS repository, the broker sends an ITI-53 notification message to the DM Notification Recipient actor of the ingest consumer, which stores the message in the initial data stage. The ETL tool can then use this message to retrieve the actual document from the XDS.b repository using its Document Consumer's ITI-43 transaction. Afterwards, the ETL tool applies the same steps as for semi-structured data.

As with data ingestion, there are also two possibilities to retrieve MeDIC data. In a patient care context, data is requested by the controlled data consumer using the ITI-18 transaction of its Document Consumer Actor. Thereby, permission to access data is decided by the XACML actors Policy Enforcement Point (PEP), Policy Decision Point (PDP) and Policy Administration Point (PAP) that are integrated into the corresponding SeR and APPC actors. Once the data has been released, it can be retrieved from the respective repositories using the ITI-43 transaction. Since both repositories represent XDS.b

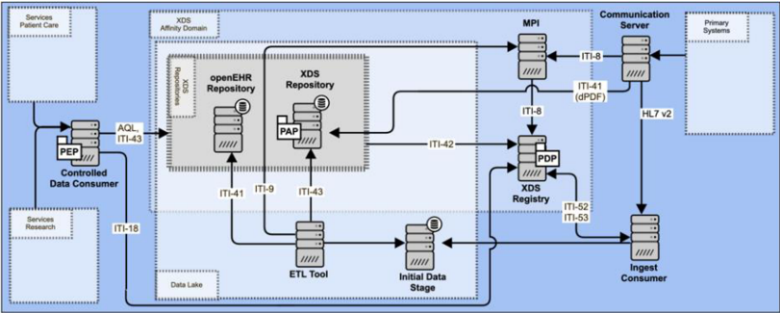


Figure 1. Application based view on the combined XDS.b openEHR infrastructure at the Heidelberg University Hospital MeDIC including XACML authorization actors PEP, PDP and PAP.

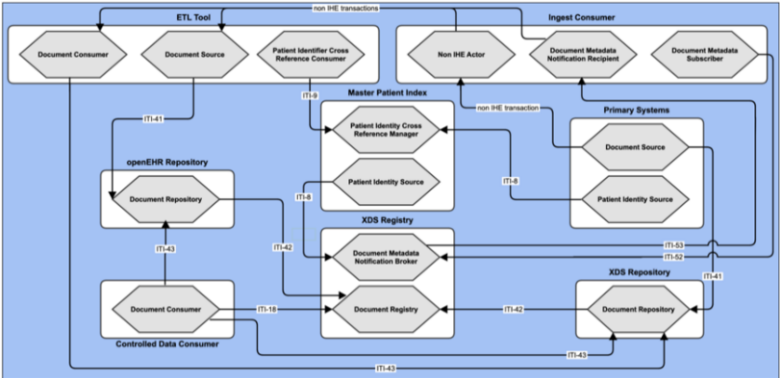


Figure 2. Detailed view on IHE actors (hexagons) and their interaction. White boxes group actors and represent applications from Figure 1.

actors, they can be queried with the same type of request, only the returned data format varies. For data queries of patient cohorts in a research context, non IHE compliant requests can be made via the controlled data consumer to the openEHR AQL interface.

4. Discussion

This paper proposes a solution for integration of standardized data management using an openEHR repository into an existing IHE XDS.b based EHR infrastructure. The implementation revealed several opportunities and challenges.

First, the selected approach enables that data used in patient care and medical research is kept in a single infrastructure and does not require any duplication. This promotes the principles of data avoidance and data economy. Furthermore, no additional data processing for transfer into a research context is necessary. For retrospective studies, data is pseudonymized on demand and only then made available. Additionally, fully structured data storage and standardized application programming interfaces facilitate integration of decision support systems into the infrastructure.

A major challenge of the presented approach is modelling of openEHR compositions from which TDDs are derived. On one hand, they have to be defined as small as possible so that they do not have to be constantly updated. On the other hand, they must not be too small so that they cause many entries in the XDS.b registry. Additionally, documents must contain references to openEHR archetypes of other documents for

accurate linking. Therefore, the presented approach is ideal for classical documents such as diagnostic reports. For documents that can change frequently such as laboratory reports, IHE On-Demand Document types should be used and registered in the XDS.b registry. In the presented approach, this document type is associated with an AQL query that is executed to construct the specific document during retrieval.

The use of TDDs limits granting of access permissions to the level of documents. Authorization for single document values is difficult, unless a TDD consists of exactly one value. However, this would create a significantly higher quantity of registry entries, which could lead to a loss of performance.

A further challenge exists when patient consent must be checked during retrieval of cohort data in a research context because non IHE compliant AQL queries are executed. Therefore, an additional ITI-18 transaction must be sent from the controlled data consumer to the XDS.b registry, containing all document identifiers retrieved in the AQL query result set. This transaction then returns all document identifiers for which a positive authorization decision exists. The ITI-18 result must then be used to filter the AQL query result set before data is transferred to a researcher.

In the future, other standardized data formats such as HL7 FHIR repositories could be integrated into existing XDS.b infrastructures using the same generic approach.

Acknowledgements

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Global Access to OpenWHO's Online Learning Resources for COVID-19

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Abstract. This poster presents the COVID-19 online learning response by the World Health Organization's (WHO) OpenWHO learning platform for health emergencies. Platform use shifted during the pandemic from being the highest in the WHO African and Eastern Mediterranean regions to the American and European regions. The largest traffic channels were search engines, social media and WHO websites.

Keywords. OpenWHO, online learning, COVID-19, pandemic

1. Introduction

OpenWHO.org [1] was designed and launched in 2017 in anticipation of a pandemic. The platform supports multi-device use and is low-bandwidth adjusted. OpenWHO transforms, translates and transfers WHO's technical guidance into learning products. Nine courses were published through an accelerated process based on WHO technical guidance 26 January – 26 April 2020 and were rapidly translated into 21 different languages with more than 2 million course enrolments from all over the world.

2. Methods

Quantitative data on top countries and use by each WHO region was extracted from the platform. Traffic channels were examined to understand the main sources of access.

3. Results

During the first 2.5 years of operations, the platform gathered a total of 100 000 course enrolments, with the majority of users in the WHO African Region (AFRO) and Eastern Mediterranean Region (EMRO). With COVID-19, enrolment numbers increased twenty-fold into 2 million by 21 April 2020. During the early phase of the pandemic, most users originated from WHO's Region of the Americas (AMRO) and European Region (EURO), whereas AFRO constituted 4% of COVID-19 platform use and EMRO 7%.

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There was no significant change perceived in the South-East Asia Region (SEARO) or Western Pacific Region (WPRO), which each comprised approximately 4% of users.

The top platform use among countries is dispersed across the globe, with at least one country from every WHO region in the top 20 (Table 1). The top 7 countries account for half of overall platform use, with India leading by far with 15% of all users, followed by Ecuador (9%) and the United States (7%).

Table 1. Platform use by top countries across the WHO regions

Rank	Country	Region	Rank	Country	Region
1	India	SEARO	11	Chile	AMRO
2	Ecuador	AMRO	12	Saudi Arabia	EMRO
3	United States	AMRO	13	Nigeria	AFRO
4	Mexico	AMRO	14	Iraq	EMRO
5	Bangladesh	SEARO	15	Egypt	EMRO
6	Colombia	AMRO	16	Nepal	SEARO
7	Pakistan	EMRO	17	Australia	WPRO
8	Argentina	AMRO	18	Canada	AMRO
9	Philippines	WPRO	19	Brazil	AMRO
10	United Kingdom	EURO	20	Peru	AMRO

An analysis of the channels directing users to OpenWHO found that the main traffic sources were search engines, social media and WHO websites. Interestingly, links in some institutional websites have brought hundreds of thousands to the platform, namely the Colombian nurses’ professional organization (OFA) and the Open University for One Health (UNASUS) by the Ministry of Health of Brazil.

4. Discussion

According to Ma and Lee, it is necessary to enhance MOOC usefulness, as perceived usefulness is ranked as the strongest predictor of MOOC adoption [2]. The AMRO and EURO regions experienced the majority of lockdowns globally and were subject to the highest COVID-19 transmission February – April 2020. OpenWHO as the content produced responded to the learning need, making learning on the coronavirus accessible. Understanding the channels that are bringing learners to OpenWHO will help identity how to disseminate platform information most effectively.

5. Conclusions

As the COVID-19 outbreak evolved, the platform was able to scale up rapidly due to planning that accounted for the worst-case scenario – a global pandemic – years before the COVID-19 pandemic emerged. Catering to global audiences with evidence-based information is of critical importance for containing and bringing an end to the pandemic.

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Accessibility and Web Quality Information for People with Disabilities in Healthcare Structures

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Abstract. People with disabilities are a major part of the society. The fact of being able to service themselves without any additional help in their everyday life is an important right, as well as the right to have equal opportunities in utilizing all health-related services in their community. Our research was carried out on a group of people with disabilities through a semi structured interview to clarify their needs regarding the accessibility of health services and the accessibility of the existing related information. In addition to the analysis of the accessible techniques of digital information, the accessibility, reliability and relevance of the information existing on health websites in Greece are evaluated. The assessment of the accessibility of information provided online is carried out based on the WCAG2.0 standard of the World Wide Web Consortium (W3C). Through these surveys and procedures, we reach conclusions on the deficiencies of accessibility and solutions for improvement are proposed. The results present the need for improvement in the information related to the healthcare sector, as we realize that a very low percentage covers the three key factors as mentioned above. With recommendations we target towards a more inclusive health care sector for all individuals.

Keywords. Healthcare, Disability, Accessibility, Information, Websites

1. Introduction

Nowadays, the World Health Organization redefines the old medical-centric concept of disability as an umbrella term, which includes harms and limitations in the activity and participation of these individuals in their daily lives. Based on this approach, disability is not just a health problem but a complex phenomenon, including the characteristics of society where a person is active and reflects their interaction with a person's body characteristics. In the Healthcare Sector people with disabilities have the same needs and rights as well as people without any disability, visible or invisible. Usually, the possibility for access to the healthcare sector is limited for these people, either because of poverty and social exclusion or due to difficulties in accessing these services [1]. In this study, we are investigating whether people with disabilities, using state healthcare structures, identify accessibility deficiencies. Our study also focuses on the existence of adequate and accessible information, in websites related to the health sector, for the better service of people with disabilities.

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2. Methods

The first part of the survey was carried out on a population of people with disabilities. The survey was conducted in 2019 in Athens. It is a qualitative survey whose purpose is to collect information regarding the access of people with disabilities to information in the health sector and the use of health-related services. The sampling method chosen for the collection of the data was the semi-structured interview. The questions conducting by the authors that composed the interview questionnaire concerned: -The use of health services by people with disabilities - The information they search, concerning the healthcare sector - The means they use to search for this information - The difficulties they experience during the search - Their point of view regarding the easiness of procedures using ICT. The selected sample were users with disabilities who acknowledge the use of information technology. People with physical disabilities and people with sensory disabilities, more specifically blindness, were selected for interviews. Forty (40) people, ages twenty (20) to fifty-five (55) years old participated in the survey; 60% of the sample were people with physical disabilities using a wheelchair while the rest were people with 85-90% blindness or total blindness. In the sample the number of men and women was equivalent. The 60% has attended or continues to attend a public higher education institution while the remaining 40% have completed their studies in secondary education.

Following the above, we proceeded with further research into the accessibility of online resources of health services especially those official/governmental used by people with disabilities[2]. The following main websites are recognized as such: 1) The website of the Ministry of Health, 2) The website of EOPYY (National Organisation for Healthcare Services). The method of assessing the accessibility was as follows: 1) Opening a web page and navigate only by using the keyboard 2) Use of a Web accessibility assessment tool. WAVE was selected. 3) Check of the code to determine if semantics is used 4) Use of a tool to contrast colours on Web pages 5) Use of the NVDA (Non-Visual Desktop Access) screen reader 6) Firefox was used as a browser, as it is one of the most accessible browser options [3].

Continuing our approach, we followed the process of searching for information in Google's search engine. This search engine was selected as it is widely used worldwide. The topics for the creation of the search commands, were selected based on the first interview to the users: 1) Accessible Health Services for People with Disabilities, 2) Doctors for People with Disabilities and General Physicians, 3) Legislation and Allowances for people with disabilities, 4) Organisations for people with disabilities. After each search, a collection of the first four (4) webpages was accomplished and the analysis of their accessibility was carried out with the use of an accessibility checker provided by the World Wide Web Consortium (W3C). The analysis was done based on the latest instructions which are also an ISO quality standard, WCAG 2.0 with the option of displaying AA accessibility that is a satisfactory level [4]. The purpose of this process was to determine whether Internet search engines display websites which are trustworthy/ reliable sources, relevant to the search that was carried out and accessible.

3. Results

1st Survey: The use of the public or private sector for health services depends on socio-economic factors, but also the benefits, accessibility and availability of each service

(public or private). The public sector is being challenged by a large percentage of users. The frequency of usage of health services is related to their pathological condition and the selection of the service depends on its accessibility. The healthcare structures are not particularly accessible to people with disabilities, (deficiencies in the accessibility of buildings and public transportation). The source for obtaining information about the health sector is the Internet. It is mentioned that this information is often missing or is in databases or applications that lack validity and are not always user friendly. The difficulties they face are linked to its individual and autonomous information. In some cases, there was a need for help from another person during the search. Concerning Medical Records, the fact that these are not kept electronically with interoperability leads to a lack of information in between various health services and the difficulty of the user in re-analyzing the events to different healthcare professionals. Regarding the accessibility of information, the users emphasized the content. In each type of disability, the information requested was specialized to the form of disability and in many cases related to the building and environmental accessibility of the service. It is observed that the sample uses information technologies frequently, especially smart applications.

2nd Survey: Results show that the two main state sources with reliable and up-to-date content, i.e. that of the Ministry of Health and that of the EOPYY, are not accessible as they have serious deficiencies in their structure and cannot be used completely or in some cases at all. Taking into account the continuity of the research with the thematics and “search commands”, it is noted that these two pages do not appear in the first suggestion in any of the searches that have taken place, resulting in the users' losing a large part of their correct and reliable information. Continuing with search commands we notice that the results are not so encouraging, as in the first suggested pages sometimes there is misleading, unreliable and insufficiently updated content. In all the searches and results we note that **only 20%** of the websites or files displayed have full accessibility, based on the Criteria of W3C for a level of **Compliance AA**. Of the total searches, the 42% were websites with relevant content and 48% was a reliable source such as organizations, universities, government body at national or international level. However, the websites that met all three criteria we set, accessibility, relevant content and reliability, made up only 13% of the total searches, which is not particularly encouraging. Websites with full and moderate accessibility but relevant content and reliable source made up 20% of the results.

4. Discussion-Conclusions

Having completed the two surveys, it is easily understood that the health sector is not particularly accessible to people with disabilities eliminating their independency when present in a health service. It is crucial to evaluate and improve the accessibility of the buildings in public healthcare services but also to share this information. The existed information, either due to technical deficiencies or not updated content, is inaccessible and invalid. In the cases where the services cannot be reached with accessible public transportation, the State should organize the transportation of people with disabilities, through frequent transportation program based on the appointments' service or upon request of the user.

For people with disabilities, especially those with blindness, it is always a challenge to be autonomous while filling in documents during their presence in healthcare structures. This could be solved by providing appropriate documents to the user, prior to

its visit in the service, in an electronic and accessible form. For the better service of people with disabilities, the government should invest in the training of its healthcare personnel towards a more “customer care” perspective. The use of assistive applications like Siri, Alexa device etc could be a solution though it is not recommended to rely on them, since we cannot predict the cost for the users and the applicability for the devices that they use [5]. The information and the health services should be equally accessible for all the users either with an existing or with a future disability.

Based on the results of the research it is our goal to eliminate the existing deficiencies in the web accessibility, especially to the governmental platforms that provide information to people with disabilities. The development of common platforms that provide interaction between users and health professionals would be very important, always with up to date and accessible content. The next step is either improvement of the already existed platform or the creation of a brand new. This project should include representatives of health services, IT specialists, people with disabilities, educators and other professionals that could collaborate and include all the needs of people with disabilities in one space fully accessible providing the ultimate user experience. Educational programmes for the new contents are essential for the users and the employees of the services seminars, informative videos or guidelines in pdf format. Regarding the existing informative websites and blogs, unfortunately, little could be done, though an approach to the authors providing information for web accessibility would be essential.

5. Limitations

Concerning the initial design of the first survey, the sampling method chosen was the questionnaire in digital form or printed. Printed questionnaire excluded the participation of people with blindness as it would be necessary to have another person as an assistant that might also influence the participant's opinion. In the case of the digital form of the questionnaire, it would not be possible to certify that blind users would have the necessary technological means for autonomous completion of the questionnaire. Besides, people with deafness and loss of speech, it was chosen not to be included in the survey, due to difficulty in communication and lack of knowledge of sign language. Additionally, there are not so many recent and reliable sources to investigate and elaborate more on the topic of disability and web accessibility.

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Fitbit Accuracy Depends on Activity Pace and Placement Location

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Abstract. This study is designed to measure the concordance of step counts recorded by Fitbit activity trackers when the devices are placed on multiple locations of the body and while subjects climb stairs at fast, slow, and medium paces. Nine participants wore 5 Fitbit trackers concurrently while performing the stair-climbing activity. The level of concordance was characterized by variability metrics derived from five step counts obtained for each study participant at each climbing pace. Results of one-way ANOVA analysis revealed statistically significant difference between mean variance, standard deviation (SD) and range of step count measurements depending on location of tracker and pace of movement. Stair climbing at a 'medium pace' produced the least variance (25.9 ± 24.5) with smallest SD (4.0 ± 2.3), whereas the 'slow pace' trial produced the greatest variance (1770.9 ± 3307.5) and SD (27.6 ± 27.1). Discordance between Fitbit step count measurements obtained at different activity levels may affect overall accuracy of step count reporting.

Keywords. Movement Measurement, Tracker Position Affects, Activity Tracking, Measurement Accuracy

1. Introduction

Wearable fitness trackers are an increasingly popular consumer item, catering to a wide variety of users on the premise that collecting data may improve fitness and subsequently health. These devices are typically outfitted with micro electro-mechanical sensors (MEMS) and optical sensors that track numerous metrics such as heart rate, blood oxygen saturation, step counts, and more. In recent years, however, there has been growing scrutiny regarding the underlying evidence - or lack thereof - that demonstrates how these sensors have been tested and validated [1]. There are now multiple discussions about the validity of the data acquired by these wearables.

Prior studies have demonstrated significant variability of step counts using pedometer functions from multiple manufacturers; measurements may be influenced by health status of the wearer, gait, speed of movement, indoor/outdoor walking, and presence of stairs, among many other conditions [2-4].

This study is designed to investigate how step count results from Fitbit fitness trackers may vary depending on their locations on the body and the speed of movement as participants climb and descend stairs.

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2. Methods

2.1. Study Design

A case series study design was employed to examine the impact of Fitbit placement on the accuracy of resulting step readings depending on climbing pace.

Nine healthy adults (7 males, 2 females, all right-handed), performed three phases of stair climbing while concurrently wearing 5 Fitbit activity trackers. Stair climbing phases were divided by pace; participants were instructed to climb up and down a stairwell at fast, slow, and medium paces, respectively. Actual speed was up to the participant to interpret, as appropriate to the pace. Between each phase, participants were given 3 minutes rest. Fitbit trackers were attached to five different positions of each participant's body, including both wrists, both ankles, and the waist, as per Figure 1.

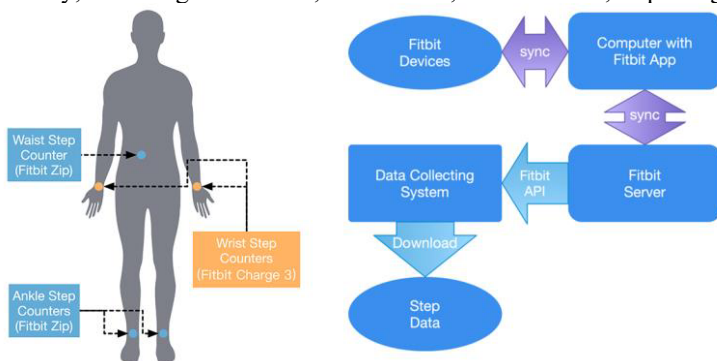


Figure 1. Activity tracker locations and data collecting system design

2.2. Data Collection

The data collection system was developed to record minute-to-minute step data from the Fitbit activity trackers. Fitbits are small wearable devices that use a three-dimensional accelerometer to measure the movement of a user. In this project, after each participant finished the experiment, data from all five trackers were uploaded to a local Fitbit server through a Fitbit application on a Windows computer. To ensure data integrity, each tracker was configured with a separate Fitbit account. The data collection system ran continuously on a local server built with Python and Go (Figure 1). Variance indicators were calculated based on step counts collected from 5 activity trackers.

3. Results

Overall, nine healthy adults (two females) were recruited with mean age 36 ± 13 , ranging from 25 to 58 years old. Average Body Mass Index (BMI) was 24 ± 2.5 , ranging between 19 and 27. Average Step counts grouped by pace are displayed in Figure 2.

Stair climbing at a 'medium pace' produced the least variance (25.9 ± 24.5) with smallest SD (4.0 ± 2.3), whereas the 'slow pace' trial produced the greatest variance (1770.9 ± 3307.5) and SD (27.6 ± 27.1). Based on the one-way ANOVA test, the mean SD in three groups was statistically significantly different ($F=5.5$; $p<0.01$).

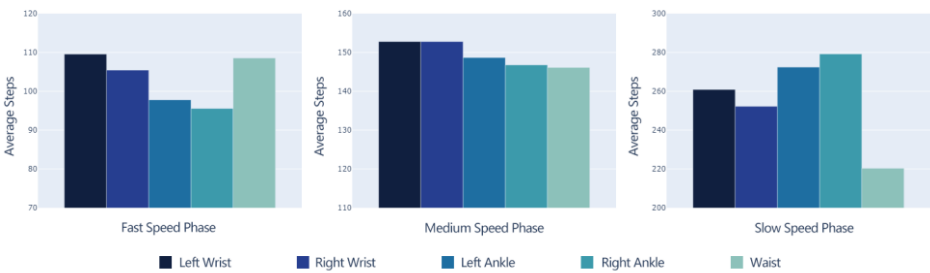


Figure 2. Average step counts by tracker location, for each pace.

Additional analysis (Table 1) revealed that the discrepancy range measured as a difference between the maximal and minimal value of step counts obtained in each experiment (MAX-MIN) was highest in the ‘Slow Pace’ group (73.0 ± 63.1), followed by the ‘Fast Pace’ group (23.3 ± 10.5), and then the ‘Medium Pace’ group (10.8 ± 5.9).

Table 1. Variability of step reporting depending on Fitbit placement and climbing pace (Mean±SD)

Pace	Variance	SD	MAX-MIN	% Mean
Slow	1770.9±3307.5	27.6±27.1	73.0±63.1	44.5±61.0
Medium	25.9±24.5	4.0±2.3	10.8±5.9	8.6±6.3
Fast	113.1±106.7	8.7±4.0	23.3±10.5	26.2±15.8

The average “MAX-MIN” expressed as percentage of mean count value in each experiment (% Mean) varied from $8.6 \pm 6.3\%$ at medium pace to $44.5 \pm 8.6\%$ at slow pace.

4. Discussion

Our results demonstrate a large variance depending on movement pace, with statistically significant standard deviations between groups. Interestingly, the ‘slow pace’ measurements corresponded with the greatest variance and standard deviation. This pace may best represent patients with limited mobility, advanced age, or even novices just beginning an exercise regimen. Thus, the results suggest that these devices may be poorly suited to track step counts for such a population.

The ‘fast pace’ trial demonstrated the second-highest variance and standard deviation, whereas ‘medium pace’ produced the smallest. On these particular activity trackers, step count results for anyone moving at a pace other than ‘medium pace’ may be sub-optimal.

The implications of such extreme variance are amplified further when combining step counts across multiple paces; results from a single session with multiple speeds (e.g. interval training) and/or analyzing results longitudinally across multiple sessions (e.g. tracking progress) should be taken in context.

Previous studies indicated the necessity for clear delineation of potential limitations of wearable devices [5-6]. Our results also highlight the need for transparency and review of the validation studies of wearables’ sensors before their use is considered in a professional context. Sensors must be subjected to the same level of scientific rigor and validation as have been applied to other patient monitoring devices. This includes establishing test accuracy and precision as compared to gold standard, and establishing a

reportable range / linearity under various testing conditions and in different subject subgroups.

Studies of patients with chronic health conditions such as obstructive pulmonary disease, diabetes and multiple sclerosis suggest that these patients in particular may benefit from decisions informed by wearables' data [7-9]. However, there must be a thorough understanding of data quality before appropriate data-driven decisions can be made.

Future studies to explore the relationship between tracker position, handedness, and variance are clearly warranted. Larger sample sizes that include an even distribution of self-reported sex and/or gender identity would address some of the drawbacks of this relatively small pilot study. Additionally, controlled speed measurements such as on a treadmill would offer more granular information about how speed affects these devices.

5. Conclusions

Step count results from Fitbit wearables may vary significantly depending on the pace at which the user moves, and by the location of the device on the body. Fitbit step count results demonstrate the least variance when used to record measurements on stairs at a 'medium pace'.

Acknowledgments

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Factors Affecting Medical Tourism Destination Selection in Greece

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Abstract. One of the main reasons for the ever-improving quality of health services in countries that are popular destinations for medical tourism and compete with the quality of services in developed countries is due to the increasing use of modern medical technology. The purpose of this study was to investigate the factors affecting medical tourism destination selection in Greece. A cross-sectional study with retrospective data collection was carried out. The study sample consisted of 446 adult patients with good knowledge/use of the English language, recently discharged from dialysis and IVF units in Greece who filled in a self-administered questionnaire. Statistical analysis was carried out with the SPSS 21.0 statistical package. Overall, 84.9% of the participants reported that the clinic's state of the art medical equipment appeared to be very important for their final decision. Moreover, 90.8% stated that the comfort of the medical equipment was another significant factor. The use of modern medical technology can improve medical tourism experience and grow the contribution to its market growth.

Keywords. Medical tourism, factors, medical technology, Greece

1. Introduction

Medical tourism refers to the phenomenon of people travelling from their usual country of residence to another country with the expressed purpose of accessing medical treatment [1, 2]. It more commonly refers to patients who are mobile through their own volition. Such medical tourists do not make use of EU rights (where the phenomenon is ordinarily known as “cross-border care”) but choose to pay out of pocket, and therefore are better cast as consumers rather than as individuals exercising their European citizenship rights [3]. Interventional treatments, such as blood dialysis and IVF, include high-tech procedures performed by specialists, thus often involving the use of modern medical technology [4]. One of the main reasons for the ever-improving quality of health services in countries that are popular destinations for medical tourism and compete with the quality of services in developed countries is due to the increasing use

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of modern medical technology [5, 6]. The purpose of this study was to investigate the factors affecting medical tourism destination selection in Greece.

2. Methods

A cross-sectional study with retrospective data collection was conducted in the second semester of 2019. The study sample consisted of 446 adult patients with adequate knowledge/use of the English language, recently discharged from dialysis (n=230) and IVF units (n=216) in Greece. Inclusion criteria were at least a session in a dialysis unit or IVF unit. The response rate was 67%. The questionnaire used was self-administered and was delivered by the principal investigator in hard copy form, after obtaining their verbal informed consent. In our research a quantitative questionnaire was developed from scratch. For its development, we carried out an extensive literature review and a qualitative study was conducted, which include 6 individuals who visited Greece for dialysis and IVF services. Interviews took place via physical presence or Skype from June 2018 to October 2018. Data was analyzed through NVivo7 and content analysis identified three important areas that affected participants' decision to visit Greece for medical tourism: clinics' characteristics, personal attributes and destination's features. These findings resulted in the formulation of specific questions in regards to the reasons/factors affecting medical tourism destination selection. The above results of the qualitative study were included in the quantitative questionnaire and before its administration, another pilot study was conducted so as to ensure face validity (4 experts) and item understandability by native speakers (n=3). The final version of the questionnaire included 30 items in regards to the factors affecting medical tourism destination selection. A reliability test was carried out using the test-retest reliability test (Spearman's correlation coefficient >0.7). The internal consistency of the questionnaire was estimated by measuring Cronbach's alpha coefficient (acceptable values >0.6). The initiation of the survey was carried out after all necessary permissions were obtained from the Ethics and Ethical Committee of the Department of Nursing, National and Kapodistrian University of Athens. Data analysis was performed using IBM SPSS 21.0 and a two-sided significance level was set at 0.05.

3. Results

3.1 Qualitative data results

According to the interviewees, the comfort of the health center was one of the main characteristics that influenced participant's decision to visit Greece for their treatment. The physical facilities of the clinic such as clean environment, modern equipment and pleasant staff increased patient satisfaction and had a positive effect on their decision. The image of health services including the latest technology medical equipment and a 24-hour customer helpdesk service was deemed as an important benefit for patients. The location of the clinic was also reported as another significant factor that influenced their decision along with its comfort. Another reason worth mentioning was the communication between the health center and the patient. Respondents highlighted that a health center that focuses on patients may help towards solving daily issues and offers a holistic approach of the medical tourism experience. Although the quality of medical

services in a particular clinic at a specific destination played an important role in medical travel decision, one of the main motivators was the financial factor. In some countries, the high cost of local healthcare is a major factor in motivating patients to seek medical treatment elsewhere. Almost all participants acknowledged that the existence of reduced prices in Greek clinics in comparison to the foreign ones was a major concern for their decision. Also safety was of paramount importance where medical services are provided and is a major concern for those travelling abroad to obtain such treatment. Hence, respondents suggested that the provision of state of the art medical equipment was an important factor for selecting a health center abroad along with the expertise of the healthcare personnel involved.

3.2 Participant’s characteristics

Most patients were female (62.8%), of a medium socioeconomic status and their mean age was 46.7 years (SD= 11.9). 52.9% of the sample were college graduates, 66.4% were married and (51.8%) had social insurance. All participants were European citizens and were able to understand the English language.

3.3 Factors affecting medical tourism destination selection

The majority of the participants (77.4%) stated that the cost of the facility was low. In particular, 87.7% of the participants answered that the total cost was affordable including the cost of the facility, transportation and accommodation. Also, 90.9% of the patients agreed about the high quality of the medical care provided. Moreover, 84.9% of the participants agreed that an important factor for their final destination decision was the state of the art medical equipment. 90.8% of the patients agreed that the comfort of the medical equipment was a significant factor which improved their experience and 88.2% stated that the new, modern and attractive facilities was a very important reason for their final decision (Table 1).

Table 1. Factors affecting medical tourism destination selection

Items	Answers				I totally agree (5)	Mean score	SD
	I totally disagree (1)	2	3	4			
The low cost of the facility	31 (7.0)	34 (7.6)	36 (8.1)	140 (31.4)	205 (46.0)	4.0	1.2
The total cost was affordable	16 (3.6)	10 (2.2)	29 (6.5)	235 (52.7)	156 (35.0)	4.1	0.9
The high quality of the medical care provided	0 (0.0)	4 (0.9)	37 (8.3)	217 (48.7)	188 (42.2)	4.3	0.7
The state of the art medical equipment	0 (0.0)	10 (2.2)	57 (12.8)	196 (43.9)	183 (41.0)	4.2	0.8
Medical equipment comfort (e.g. dialysis chair or bed, etc)	0 (0.0)	10 (2.2)	31 (7.0)	229 (51.3)	176 (39.5)	4.3	0.7
The new, modern and attractive facilities of the medical center	0 (0.0)	10 (2.2)	43 (9.6)	254 (57.0)	139 (31.2)	4.2	0.7

Values are presented as n (%) unless stated otherwise.

4. Discussion

Based on the results of the survey, participants expressed positive experiences. The contribution of new and innovative medical technology is significant and upgrades the level of provided quality. Also the ability to combine a therapy and living a new and different experience in modern and technologically advanced facilities of a medical tourism center is important. The high quality of the medical care provided by accredited professionals and combined by modern medical technology and luxurious accommodation are findings which are being widely confirmed in the relevant literature [7, 8, 9, 10]. The role of the principal investigator might have been a limitation in the expression of the participants' experiences. [11]. Moreover, since the questionnaire was designed in the English language, non native speakers might have encountered difficulties due to transcultural/linguistic differences.

5. Conclusions

The contribution of the state of the art technology and the comfort of the medical equipment are significant and reveal its contribution to the growth of the medical tourism industry. The use of modern medical technology can improve medical tourism experience and grow the contribution to its market growth. Recognizing and understanding the above characteristics is an important step towards the support and comprehension of medical tourism.

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A Protocol Entry Catalog for Intraoperative Neuromonitoring – Steps Towards an Ontology

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Abstract. In neurosurgery, intraoperative neurophysiological monitoring (IOM) with continuous measurements of neural electrical activity may reduce the risk of postoperative deficits. During an IOM, surgical information as well as neurophysiological, surgical and anesthesia events have to be recorded. So far, there is no common standard for this task available. In this paper, such a standardization with the aim of facilitating the data input and making the protocols data available for different sorts of analyses is described. We developed a protocol entry catalog with 200 standard expressions, which were divided into four categories: IOM, surgical procedure, anesthesia and others. An empirical assessment of the catalog by the IOM team showed the need for subcategories. In the final version of the catalog, the standard terms were grouped into 25 subcategories. The catalog is a first step to support systematic research into the occurrence of clinical events during the IOM and their association with postoperative neurological deficits that could enable improved surgical procedures in the future.

Keywords. Intraoperative Neuromonitoring, Intraoperative Neurophysiology, Protocol Entries, Standardized Data, Ontology

1. Introduction

In neurosurgery it is crucial to distinguish healthy brain tissue from pathological tissue. For the eyes of a neurosurgeon functional areas and tracts are not visible. Injuries in such areas lead to the occurrence of postoperative neurological deficits, e.g. motor paralysis. With intraoperative neurophysiological monitoring (IOM) continuous measurements of neural electrical activity during surgery are possible, allowing to reduce the risk of postoperative deficits [1-3].

The IOM team documents patient and surgical information, as well as neurophysiological, surgical and anesthesia events, each event with a time stamp. Further, neurophysiological baseline measurements of different evoked potentials and, later on, amplitude and latency change in the signal measurement values are added. Today, no common standard for the content of IOM protocols exists. This paper describes first steps for such a standardization, relying on the analyses of several IOM protocols, leading to a protocol

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entry catalog. The catalog was developed as part of a web-based information system called “IOM-Manager”, which has been implemented at the Inselspital department of neurosurgery. The IOM-Manager was implemented with the MEVN (MongoDB, Express.js, Vue.js and Node.js) technology stack [4].

Our protocol entry catalog has two goals: to facilitate data input during surgery and to increase the usefulness of the protocol data for later analyses. It can help to answer research questions such as “how are clinical events during IOM associated?” and to implement prediction models using the standardized event data.

2. Methods

The documentation process was analyzed by observing neurosurgical and neurophysiological IOM procedures as well as by examining handwritten protocols at the Inselspital. Based on these protocols, different data input options for digital IOM documentation such as barcode scans, voice input [5] and manual documentation were discussed and the most suitable identified together with the IOM team at the Inselspital. It was decided to use a web form with dropdown menus for selecting event descriptions from a restricted number of possibilities. This required a suitable event catalog.

The event catalog was developed in an iterative fashion. First, the latest 100 paper protocols were reviewed manually, classified based on the main diagnosis of the patients and searched for recurring entries. Then, standard texts and clusters were defined for the recurring entries. In the last step, handling of the catalog was assessed together with the IOM team in order to refine the catalog and provide a final clustering.

3. Results

The IOM unit has collected more than 4000 handwritten protocols so far. Based on the various operations, they use eleven different protocol templates, which however differ only slightly. The protocols contain patient and surgical information. The measured values of the baselines of different evoked potentials are noted in a table at the beginning and towards the end of the surgery.

During the surgery, changes in the amplitude and latency of the measured signal values are continuously monitored and recorded using inomed ISIS IOM System. In addition to that, events related to anesthesia, surgery and further clinical incidents such as signal loss or tumor extirpation are manually recorded together with a time stamp. An entity relationship model (ERM) for this IOM setting is shown in Figure 1.

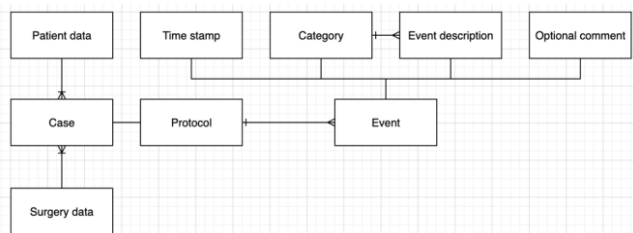


Figure 1. ERM of the catalog and its relationships to the case information. A patient can have one or more IOM cases. Through a protocol, a case will be associated with one or several events. An event consists of a time stamp, a category, an event description and optionally a comment.

The case statistics are kept in a surgical track record (book) and an additional spreadsheet. Signal curves from the medical device, which contain the measured evoked potentials during the surgery, are printed out and added to the paper protocol.

Examining the latest 100 paper protocols for recurring event descriptions led to 200 standard expressions, which we clustered into four categories: IOM, Surgical Procedure, Anesthesia and Others. Under the category IOM, all signal changes in evoked potentials and mapping settings are subsumed. An assessment of the implementation of this first catalog by the IOM team resulted in the requirement for subcategories. The main reason was the realization, that more dropdown menus with less entries in each facilitate documentation. In the final version of the catalog, the standard expressions were clustered into 25 subcategories. Many of the subcategories are taking the modalities, e.g. evoked potentials, into account (see Table 1). In the category surgical procedures, the subcategories were defined on the basis of the diagnoses such as tumor surgery.

Table 1. Part of the final catalog version with the 3 categories IOM SEP (somatosensory evoked potentials), IOM EEG (electroencephalography) and Tumor surgery.

Category	Event description	Category	Event description
IOM SEP	SEP artifact overlaid	IOM EEG	EEG burst suppression
	SEP constant		EEG changes
	SEP drop		EEG of higher frequencies
	SEP flatter	Tumor surgery	Tumor extirpation
	SEP fluctuates		Tumor preparation
	SEP new baselines		Tumor resection under dynamic Mapping
	SEP no signal		Tumor outside
	SEP reproducible		Tumor visible
	SEP slightly delayed		
	SEP stable		

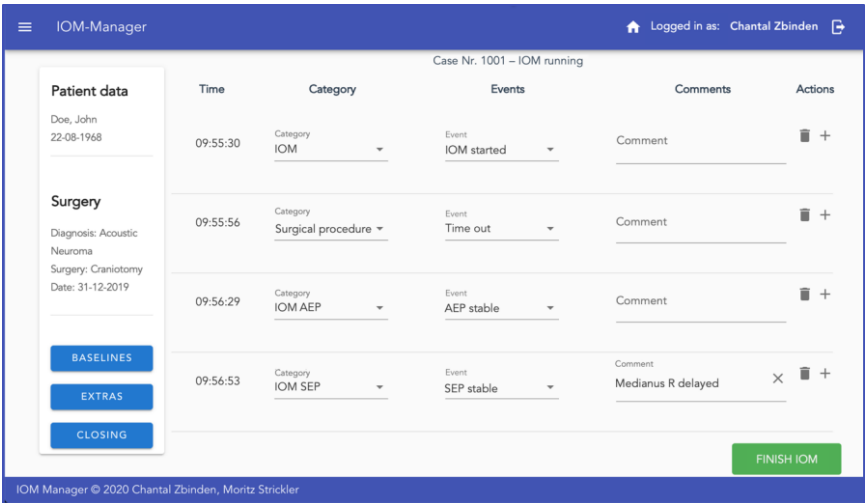


Figure 2. The picture shows how the protocol documentation in our application looks like. On the left is information about the patient and the surgery. Each entry in the protocol contains a time stamp, a category and an event description. Furthermore, a free text comment can optionally be added to each entry.

Figure 2 shows the use of the IOM catalog within the IOM-Manager. A new event can be recorded using the plus button on the right. Selecting the main category allows to select the respective subcategories, permitting rapid selection of the appropriate event

description. For each event, optional free text comments can be added. The baseline and closing signal measurement values (such as amplitudes, latencies and stimulation paradigms) can be entered using the BASELINES and CLOSING buttons on the left.

4. Discussion

During the development of the catalog, the need for subcategories was detected after an empirical assessment by the IOM team. There are pros and cons of such an empirical approach. On the one hand, a rapid result can be achieved together with good acceptance by the users. On the other hand, the resulting categories and subcategories may not be well designed, there could be overlaps, and there could be a need for more relationships that an is_a between subcategories and main categories. In addition to that, there is a risk that the protocol entry catalog is not suitable for some desired analysis tasks.

In order to overcome such shortcomings and risks, we will develop an ontology based on the catalog described here. Several authors have devised methods for good ontology development. For example, Gruber [6] describes the development of portable ontologies, whereas Noy and McGuinness provide guidelines for taxonomic work to create an ontology [7].

5. Conclusions

In summary:

- Systematic documentation of IOM events is essential for efficient analyses of events-outcome relations.
- A protocol entry catalog represents a good starting point for the standardization, but a future ontology will increase interoperability among different sites.
- The ontology allows automated reasoning, e.g., for finding new research questions just based on the concept relationships among the present instances.
- Further research should also be directed towards a standard terminology for the events and its impact on the related outcome research.

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Generation of Realistic Synthetic Validation Healthcare Datasets Using Generative Adversarial Networks

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Abstract. *Background:* Assurance of digital health interventions involves, amongst others, clinical validation, which requires large datasets to test the application in realistic clinical scenarios. Development of such datasets is time consuming and challenging in terms of maintaining patient anonymity and consent. *Objective:* The development of synthetic datasets that maintain the statistical properties of the real datasets. *Method:* An artificial neural network based, generative adversarial network was implemented and trained, using numerical and categorical variables, including ICD-9 codes from the MIMIC III dataset, to produce a synthetic dataset. *Results:* The synthetic dataset, exhibits a correlation matrix highly similar to the real dataset, good Jaccard similarity and passing the KS test. *Conclusions:* The proof of concept was successful with the approach being promising for further work.

Keywords. Machine learning, realistic synthetic dataset, privacy, generative adversarial networks

1. Introduction

In recent years, there have been significant advances in digital health that have resulted in applications such as diagnostic, self-monitoring, telehealth and clinical decision support. In addition to their potential benefits, they may also introduce risk to patients, due to technical failures, and unfit clinical validation. Validating them will ultimately need testing the application against datasets, representing the targeted population. However, this a challenging task, as datasets cannot be shared with developers, due to privacy concerns [1]. Even when sharing is possible, their generation and sharing may take several months. The problem is exacerbated by: a) the fact that datasets need to be produced specifically for each application depending on its scope, and b) by the increasing volume of digital health innovations requiring validation. Even if a developer has access to their own datasets, it is difficult for the application to be validated by a third party (e.g. a regulator) without a common dataset. Ultimately, patients may be deprived of potentially beneficial tools. Development of Realistic Synthetic Datasets (RSDs) has been identified as a potential solution to this issue [2, 3], which overcomes privacy concerns, as well as limited utility, of alternatives such as anonymization [1]. These are datasets with completely software generated entries, which exhibit the same statistical

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properties as (the equivalent) real dataset. Compared with anonymized and de-identified datasets, synthetic datasets have three advantages: a) they overcome the lengthy preparation and approval processes that are still required with anonymized data; b) they offer access to variables that may be considered sensitive and are not included in anonymized and de-identified datasets; and c) they are immune to cross-referencing of information with other datasets (although there are still some concerns to be addressed). Machine Learning (ML) has been a prominent approach to producing large RSDs. ML algorithms are trained based on the real datasets, and then produce a synthetic dataset with similar statistical qualities [4, 5, 6].

The paper presents the results of a Realistic Synthetic Dataset Generation Method (RSDGM) using Generative Adversarial Networks (GANs). GANs use two neural networks; a generator neural network that produces data, and a second, the discriminator, which trains on the real data, classifies the data generated by the former as being true or synthetic, and feeds back its success metric to the generator. The generator network will adapt the data it produces, until the discriminator cannot tell if the generated data are true or false, meaning that the synthetic and the real data are indistinguishable. Figure 1 illustrates how the GAN will begin from random (Gaussian) data (orange points), and end to data similar to the real dataset (blue points).

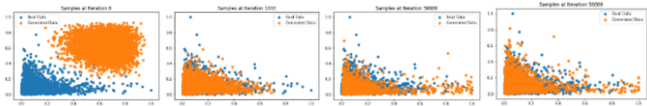


Figure 1. Output during training of the GAN (blue: real data, orange: synthetic data; 50,000 epochs)

The RSDGM was developed as part of a proof of concept project, exploring the feasibility of various methods to generate synthetic datasets, for validation of digital health applications.

2. Method

The RSDGM used the MIMIC III dataset [7] as the real dataset to train on. Figure 2 summarizes the hyper-parameters and data sample used for the experiment.

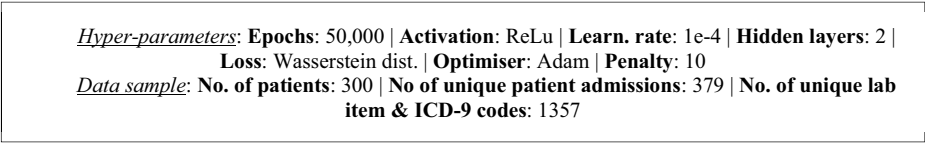


Figure 2. Hyper-parameters and data sample

The method covered both numerical and categorical fields from MIMIC III [7], including the ICD-9 diagnosis field, as well as the codes of the lab tests performed during each admission, but was short of producing lab test measurements. A preprocessing stage standardized the values of all variables between 0 and 1. Categorical variables were represented as 0 and 1, using one-hot encoding. A Wasserstein GAN [8] was implemented using two identical neural networks as generator and discriminator using the hyper-parameters shown in figure 2. A series of (informed using the theory) trial and error experiments allowed the selection of the hyper-parameters. Validation of the

synthetic dataset was performed by: a) comparison of correlation matrices of the two datasets, b) Jaccard similarity, and c) the Kolmogorov-Smirnov test. The experiments ran in Anaconda, using Tensor flow, on a GPU enabled machine.

3. Results

The method successfully produced a synthetic dataset based on the selected MIMIC III sample. Figure 3 shows the distribution of a selection of numerical variables of the two datasets, illustrating their similarity. Figure 4 shows an extract (for the same variables) of the correlation matrices of the two datasets.

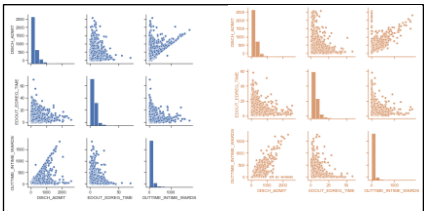


Figure 3. Distribution of a selection of numerical values in the two datasets (blue: real, orange: synthetic)

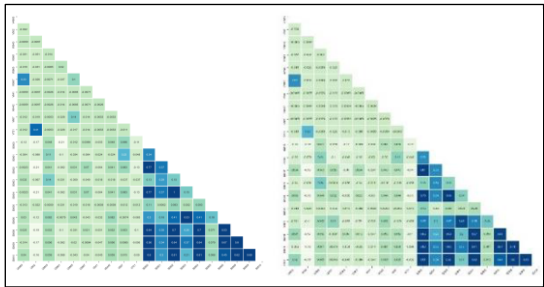


Figure 4. Extract of the two datasets Spearman correlation matrices (left: real, right: synthetic)

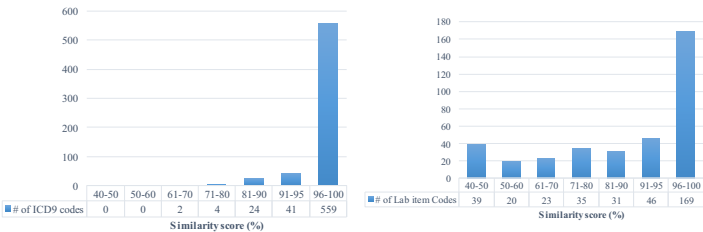


Figure 5. Distribution of Jaccard similarity of ICD-9 and lab test codes

The correlation matrix includes Spearman correlation of all variables including lab tests and ICD-9 codes. Due to the large size of the complete matrix, an extract is presented here. The correlation matrix is a good indication of equivalence of the two datasets, as it can be seen that the association between variables is very similar. Furthermore, not having identical correlations also offers some degree of confidence that the RSDGM has not replicated the datasets, potentially affecting privacy. Figure 5 illustrates the distribution of the Jaccard similarity of the ICD-9 and lab item codes, which tests the distribution similarity of these two types of variables in the two datasets.

Most of the variables (i.e. codes) had very high Jaccard similarity, with some lab codes having low similarity, which is attributed to very low frequency in the training dataset. Finally, a K-S test was performed with $p = 0.05$ to test whether real and synthetic data samples were a subset of the same population, failing to reject the null hypothesis.

4. Conclusions

The developed method was successful in generating a synthetic dataset, using a GAN implementation. Statistical validation of the resultant dataset showed that the two datasets demonstrate very similar statistical qualities. Some observed differences are attributed to low frequency of values and will be explored in the future using bigger samples. Tolerance of the difference between the datasets will need to be justified and accepted, in the context of the validated application. Future work will focus on bigger sample, optimizing the GAN, and justification of statistical tolerance between the datasets. Overall, the GAN based RSDGM showed significant promise.

Acknowledgments

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Decision Support System for Selection of e-Health Interventions

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Abstract. The main goal of this work was to design a decision support system for effective personalized cardiovascular risk prevention: *i)* to identify behavioral groups associated with clinical risk factors, *ii)* to provide recommendations associated with the objective to be achieved and *iii)* to determine the decision-making rules assigning each group to the type of mobile health intervention conveying the most appropriate prevention messages, to help patients to achieve attainable goals. The system is based on an existing data prediction model taking into account specific risky behaviors, clinical risk factors and social status, and it is embedded in a new e-health application. The system is operational. The next step will be the design of a large study to assess improvements in patient adherence to prevention messages through e-health interventions selected by the application.

Keywords. Non-drug intervention (NDI), e-health intervention, prevention, cardiovascular risk factor.

1. Introduction

The current shift of the health system towards the prevention of the risks of cardiovascular events due to chronic conditions the use of connected health interventions is becoming increasingly common. This healthcare practice provides levers to improve chronic disease management actions reducing aggravating risk factors for conditions such as cardiovascular diseases [1]. Recently developed connected health services, classified as non-drug interventions (NDIs), have inspired new techniques for motivating users to change their behavior in the context of chronic disease prevention. These studies suggest that connected health devices are NDI systems with a considerable potential for changing behaviors by favoring the adoption of health-promoting behaviors [2]. These systems usually deliver general recommendations for improving the health status of the population as a whole. For

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instance, in France, recommendations about nutrition are provided by the National Nutrition and Health Program (PNNS). However, little attention is paid to user's preferences, and patient characteristics, resulting in failure and a lack of compliance with patient-oriented recommendations. Adherence is one of the main challenges. The purpose of this paper is to design a decision support system taking current behaviors, specific clinical risk factors and social status into account, resulting in the choice of an effective NDI. Indeed, we believe that a strategy for behavioral change through commitment can be supported by levers adapted to specific goals in different clinical risk factor and social status contexts.

2. Methods

2.1. Collecting data through questionnaires

A recent study proposed a model for cardiovascular diseases that was designed to identify different types of risk-factor variables (non-modifiable variables, behavioral variables, clinical risk factors, status factors) and interactions between them [3]. We adapted "the questionnaire used in the French GAZEL cohort"². The number of questions were reduced and organized into four groups of questions:

Group A: The questions in this group relate to the identity of the user (age, sex), his or her family and cardiovascular history. The latter is used to filter data. Indeed, if the person already has a cardiovascular disease (myocardial infarction, angina, stroke, with or without paralysis), only a physician can provide adequate information on prevention. Individuals responding in the affirmative to this question are not considered by the system.

Group B: This group contains 14 questions relating to the behavior of the user. The data collected through these questions are coded by the scoring method described in [4]. This scoring process provides a quadruplet (four-valued variable) of 0/1 values [excessive alcohol consumption; smoking; unbalanced diet; sedentary lifestyle]. For example, the quadruplet [0-1-0-1] would describe someone who does not abuse alcohol, smokes, eats healthily but does not practice regular physical activity. Using this coding system, we were able to identify 16 different behavioral profiles.

Group C: Seven questions relating to the clinical status of the user, coded as binary variables (absent/present): (hypertension, dyslipidemia, diabetes, obesity, sleep disorders, stress, and depression). As this work was performed in the context of preventive strategies in individuals at risk, we assumed that at least one of these variables should be set to 1.

Group D: Two questions relating to the social status of the individual. These questions concern the professional situation (in active employment or not) and the level of study (university, secondary or primary).

2.2. Personalizing the choice of health devices

The proposed decision support system consists of a workflow into which the following milestones are embedded:

² http://www.gazel.inserm.fr/sites/default/files/2018-10/Questionnaire_2009.pdf

Step 1: Associating the behavior of the user with a list of general recommendations. In this step, appropriate recommendations from the exhaustive list of general recommendations extracted from official sources are assigned to the user, according to the quadruplet score obtained. For example, to someone with a quadruplet score of [0-1-0-1], the following recommendations extracted from “Haut Conseil de la Santé Publique (HCSP)- PNNS4”³ would be issued: a) consult a specialist to help you stop smoking because it is difficult to quit alone and b) do the equivalent of 20 minutes of physical activity every day”.

Step 2: Refining the set of recommendations according to clinical risk factors. Although this is not always the case, clinical risk factors may be linked to behaviors. Then, it is generally accepted that positive changes in behavior can decrease the risk, thereby preventing cardiovascular events. For instance, a balanced diet should influence obesity and diabetes, and decreasing alcohol dependence may reduce sleep disorders. The purpose of step 2 is to activate decision rules to select an appropriate list of actions corresponding to the recommendations, taking the individual’s clinical situation into account, to target the behaviors to be changed. Considering our example [0-1-0-1] with diabetes, the resulting output list of actions would be: “tabac info-service - Bouger plus”⁴.

Step 3: Selecting a list of appropriate connected health devices. We considered a list of published e-health levers and performed a systematic review to identify the types of behavior or risk factor they address. Examples of e-health levers are connected devices and services, such as short message services (SMS) and applications. An e-health lever is assigned by the system to a user if, and only if, it addresses a risk factor reported by the user to be present. These levers are thus, theoretically, adapted to the user, as they meet the specific needs of the user. All levers not matching the criteria for the user concerned are excluded. As an example, for our user [0-1-0-1] with diabetes, the first result via filtering presents a list of current and emerging e-health lever services types (to read, to connect) and the connected devices matched, such as “a connected glucometer”.

Step 4: Selecting a list of appropriate connected health devices for the selected actions. The custom levers are identified on the basis of their being the most effective for individuals of the same sex, social criteria or age as the subject. For example, for a man, aged 50 and belonging to a favorable social category, the list of connected health services would include SMS, social network applications and a connected glucometer.

For the modelisation of such a decision support system, preparation, modeling and verification steps are first performed in Unified Modeling Language (UML). The system was then implemented with MySQL database and JavaFX Script.

3. Results

An example of the layout of the system is shown in Figure 1: access to the questionnaires (A), a summary of behavior (B) and proposed e-health levers (C). The system is operational for evaluation ergonomic usability tests with end users.

³ <https://www.hcsp.fr>

⁴ <https://www.tabac-info-service.fr/> - <https://www.mangerbouger.fr/Bouger-Plus>

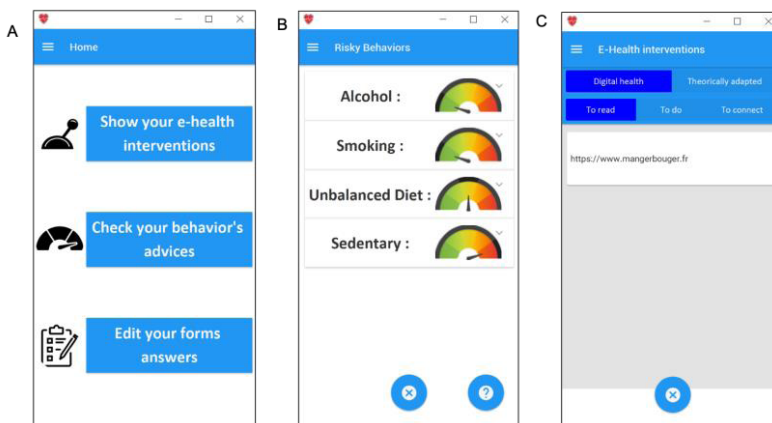


Figure 1. Screenshot of decision support system for selection e-health interventions

4. Discussion and Conclusions

This work resulted in an application with a recommendation selection process associated with a list of specific e-health interventions provided by well-defined e-health sources. However, our model does not define or provide a list of specific recommendations concerning system and technologies, as these elements are continually developing and changing. With the current implementation, it is possible to propose new questionnaires or new levers and to refine the set of variables. For instance, the group of social variables should be enriched in the future, based on feedback obtained from users. Moreover, the system can be used to challenge the proposed NDIs in terms of adherence, compliance, and complementarity for achieving the user's goals. The main perspective would be the development of a hierarchy of NDIs based on the preferences of the end user.

The next step will be the incorporation of end-user collaboration in real-life situations. A large study focusing on the users of the system will be required, considering, in particular, the user's experience and ergonomics, adapted to individuals with chronic disease, who are more likely to be subject to cardiovascular risks. Once targeted at individuals, our application should improve the users' knowledge and the following of recommendations.

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Multidisciplinary Approach for Education in Healthcare Management: Case Study from Montenegro

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Abstract. Modern education of healthcare managers is one of key preconditions in making reforms towards increasing quality of care and making the provision of health services more cost-effective and efficient. This paper presents unique multidisciplinary approach for education of healthcare managers developed and accredited in Montenegro with elaboration results of the first year of its implementation. The results confirm the interest of experts of different profiles in multidisciplinary studies, as well as the optimality in using resources at national level in Montenegro.

Keywords. Education, health care management, multi-disciplinary approach

1. Introduction

Recent decades in healthcare can be characterized as a period of transformations of proactive to reactive care, with focus put on patients as persons - patients became partners in healthcare treatment process, together with their family members and relatives. Available studies clearly show the benefits of patient engagement in increased quality of care with simultaneous reduction of costs and more effective healthcare management [1].

In order to lead and implement changes in healthcare organisations and systems, as well as to monitor and evaluate health innovations and modern practices, there is a permanent need for modern education of healthcare managers. The managers need to be capable to respond to all challenges at institutional, national and global levels, including limited financial resources, sustainability of health systems, global competitiveness etc. By respecting the diversity of national and European population health challenges and threats, as well as heterogeneity in structures and organisation of healthcare systems and institutions, multi-disciplinary perspectives for creating sustainable and flexible health system and providing good quality health are required.

This paper is aimed on presenting the concept and implementation of a master program (MSc) in Health Information Management in Montenegro. Montenegro (ME) is a small country in EU accession negotiation process, which created and implemented this multidisciplinary study program for healthcare managers adapted to the needs and capacities at national level. As a background for implementation of the program, in recent

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four years the following activities were implemented by support of EU funds (within Erasmus+ program): (i) unique educational national star model is created [2], (ii) capacity building activities of university staff members are implemented [3]; and (iii) cooperation links are established with leading EU universities in the fields.

2. Methods

The “national star model for public health education” in ME [2] defines the structure for optimal exploitation of resources (human, operational, etc.) available at three ME universities (which all together have more than 95% of total student population), all adapted to their professional and academic profiles in the field. The model defines the need for establishment of one study program for education of healthcare managers in ME, exploiting the benefits of having integral health information systems at national level, as well as having started initiatives toward implementation of innovations and technology enhanced medical practices.

In order to meet defined requirements, the following methods were applied to implement the new study program: (i) analysis of education approaches in healthcare management and cross-matching with the ME needs; (ii) creation of multi-disciplinary MSc program for health information managers and (iii) first year implementation with careful evaluation of enrolled students from the perspectives of their existing professional background, their expectation and potential impacts for their future professional contributions to enhancements of national/institutional healthcare systems.

3. Results

The degrees offered over the world generally fall into two categories: professional or academic. The two major postgraduate degrees are the Master of Public Health (M.P.H.) or the Master of Science in Public Health (MSPH). Most analysed curricula cover health prevention, health promotion, infectious and non-infectious diseases, chronic diseases, epidemiology, biostatistics, and healthcare management. In recent years, curricula have been modified to also include health economics, technology assessment, and e-health or health informatics. Consequently, it was decided to develop a Public Health programme (M.Sc.) in ME that covers these topics.

The new MSc program was accredited in 2018. It has a duration of 2 years (4 semesters), with 30 ECTS per semester (in total: 120 ECTS). Learning goals and objectives are presented in Table 1, while the multi-disciplinarily of the whole program is summarised in Table 2. The program started with a first group of 15 students in autumn 2019.

Table 1. Goals and Learning objectives of MSc program ‘Health Information Management’

Learning goals	Learning objectives
1. <i>To acquire understanding of healthcare business management and administration</i>	Demonstrate knowledge and understanding of concepts, theories, laws, tools, and practices in: (1.1) Budgeting, financial reporting and control; (1.2) Information systems; (1.3) Strategy and change; (1.4) Management and organization
2. <i>To understand healthcare delivery systems</i>	Demonstrate knowledge of the European healthcare industry and its delivery systems, including innovations in how healthcare is delivered.

3. To acquire and practice leadership and managerial skills that will positively affect performance as a healthcare manager	(3.1) <i>Conflict Management</i> - Ability to recognize conflict, to adopt appropriate conflict management behaviours; (3.2) <i>Information Competence</i> - Ability to interpret health data, financial statements, as well as typical healthcare industry data; (3.3) <i>Presentation Skills</i> - Preparation and delivering a well-organized, formal business presentation; (3.4) <i>Quantitative Skills</i> - Ability to perform statistical analysis using industry-standard software aimed on making decisions for business problems; (3.5) <i>Emotional Intelligence</i> - Understanding emotions, using emotions to facilitate decision-making and business negotiation; (3.6) <i>Teamwork</i> - Completing a complex team tasks within specified time; (3.7) <i>Written Communication</i> - Preparation of clear, short business report.
4. To integrate healthcare ethics with business and industry knowledge	(4.1) <i>Ethics</i> - Demonstrate knowledge about professional ethics in healthcare organizations and application of ethical and legal considerations in assignments, cases, and projects; (4.2) <i>Corporate Compliance</i> - Demonstrate understanding of managerial responsibility in creating and maintaining a culture of regulatory compliance.

Table 2. Multi-disciplinary structure of MSc program ‘Health Information Management’: Number of courses within specific disciplines

Learning goals	Discipline				
	Public Health	Health Informatics	Health Management	Health Economy	Health Law
To acquire understanding of the functions of healthcare business management and administration	1	1	1	0.5	
To understand healthcare delivery systems	1.5	1	1	0.5	0.5
To acquire and practice leadership and managerial skills that will positively affect performance as a healthcare manager	0.5	1	1	0.5	
To integrate healthcare ethics with business and industry knowledge	1	1	1	0.5	0.5
Total number of courses	4	4	4	2	1

A comprehensive evaluation process was developed for the new MSc program, consisting of the following steps [4]: (i) *pre-enrolment evaluation*- aimed on analysing existing education and interests for entering the program as well as their professional experience in the field; (ii) *course evaluation*- aimed on evaluation of teaching process, teaching methods and materials; and (iii) *program Evaluation after Graduation and Alumni* - aimed on making assessment of achieved impacts on professional engagement (of alumni) as well as analysing if the program met expectations of graduated students.

Table 3. Demographic structure of enrolled students: age, working experience and educational background

Age	No. of students (%)	Years of professional experience	No. of students (%)	Previous education	No. of students (%)
20-30 years	7 (46.7%)	< 5 years	5 (33.3%)	ICT	7 (46.7%)
30-40 years	3 (20.0%)	5-10 years	3 (20.0%)	Economy/Management	4 (26.7%)
> 40 years	5 (33.3%)	10-15 years	3 (20.0%)	Medicine/Pharmacy	3 (20.0%)
		> 15 years	4 (26.7%)	Law	1 (6.7%)

Table 4. Professional orientation of enrolled students: sector and expected impacts after graduation

Sector/institution of employment	No. of students (%)	Main reasons for enrolling the program	No. of students (%)	Main reasons for enrolling the program	No. of students (%)
Ministry of health	4 (26.7%)	To try for a different career	1 (6.7%)	It was a requirement of my job	1 (6.7%)
Public institutions in healthcare sector	3 (20.0%)	To start my own business	5 (33.3%)	I wanted extra skills for my job	7 (46.7%)
ICT company	5 (33.3%)	For personal interest or self-development	3 (20.0%)	To get a better job or promotion	5 (33.3%)
Other	3 (20.0%)				

In order to evaluate the multi-disciplinary concept of the whole program from the perspective of enrolled students, their professional orientation and expected impacts after

graduation, Table 3 and 4 present result of pre-enrolment evaluation. These results make a basis for further analysis of observed impacts on professional career developments of program graduates.

4. Discussion

Implementation of presented multi-disciplinary program requires highly qualified staff members, which ME universities implemented in cooperation with experienced EU partner universities: University of Heidelberg (Germany), National and Kapodistrian University of Athens (Greece), University of Health Sciences, Medical Informatics and Technology (Austria) and University of Debrecen (Hungary). The effectiveness in cooperation was achieved by organisation of thematic workshops led by EU staff members. Having in mind that majority of students are employed at national and other public institutions in healthcare sector, the needs for offering single courses within running master programs in other domains (in addition to a full new master program in public health) is well recognised. Finally, practical work in the fields is implemented by involvement of students in research projects (especially those that are nationally funded) as well as mobility programs with EU universities.

5. Conclusions

This paper presented experience in development of integrated and multidisciplinary MSc program for health managers in Montenegro. Development and first year of implementation of this program can be characterized with the following: (i) *strategical documents at national level clearly identified the needs for its establishment* (e.g. “Master Plan for the Development of Health System in ME 2015-2020”, “Strategy for the Development of the Integrated Health Information System and eHealth 2018-2023”), (ii) the program implements “*national star topology of educational programs*” which on the most efficient way uses limited resources of ME educational and health institutions, (iii) implementation of the program relies on full involvement of existing resources at the *most important healthcare institutions*: Clinical Centre, Institute for Public Health and Ministry of Health, and their close cooperation with three ME universities.

Finally, heterogeneity of the first-generation of students confirms the justification and interest of experts of different profiles in these multidisciplinary studies. The conducted research shows a high degree of organizational satisfaction, the level of acquired knowledge and confirms student expectations.

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Towards Intelligent Integration and Sharing of Stem Cell Research Data

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Abstract. Advancements in regenerative medicine have brought to the fore the need for increased standardization and sharing of stem cell product characterization to help drive these innovative interventions toward public availability. Although numerous attempts have been made to store this data, there is still a lack of a platform that incorporates heterogeneous stem cell information into a harmonized project-based framework. The aim of this project was to introduce and pilot-test an intelligent informatics solution which integrates diverse stem cell product characteristics with study subject and omics information. In the resulting platform, heterogeneous data is validated using predefined ontologies and stored in a NoSQL repository. Pilot-testing was performed on nine sponsored stem cell projects conducting preclinical and intervention evaluations. The pilot-testing demonstrated the robustness of the proposed platform, by seamlessly harmonizing diverse common data elements, and the potential of this platform for driving knowledge generation from the aggregation of this shared data.

Keywords. Data aggregation, regenerative medicine, stem cells, common data elements

1. Introduction

Regenerative medicine is a highly innovative field that holds great promise for treating and even curing a variety of injuries and diseases by repairing, replacing, or regenerating damaged cells, tissues and organs [1]. To accelerate this field by supporting clinical research on adult stem cells while promoting the highest standards of scientific research and patient safety protection, the National Institutes of Health (NIH) has established, with the coordination of the Food and Drug Administration (FDA), the Regenerative Medicine Innovation Catalyst (RMIC). The main aim of this regenerative medicine research is to identify and promote stem cell therapies that lead to introduction of new treatments of previously incurable health conditions. To facilitate that goal, we aimed at developing a platform to store and disseminate diverse stem cell product information, clinical and pre-clinical trial outcomes, and study subject information in a harmonized and interchangeable way, with the aim of promoting novel knowledge generation through data sharing. The resulting platform should increase scientific rigor, accelerate progress, and stimulate innovation and partnership by creating an ecosystem that will promote collaboration and further

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improve the standards for characterizing stem cell products. The agile and flexible nature of such a platform, based on intelligent integrative informatics approaches, allows to seamlessly integrate diverse data, while maintaining stringent quality control measures. Use of data harmonization and common data elements (CDE) mapped to cross-linked biomedical ontologies allow the search and visualization of the heterogeneous data across multiple studies and to be quickly queried and yield results that can aid directly in improving the state of regenerative medicine. The novel contributions of this paper to the regenerative medicine and stem cell community are a scalable NoSQL Data Repository for storing all data generated as part of stem cell projects, programmatic interfaces (APIs) allowing for granular and secure access and depositing of all relevant information in the platform, and an intuitive user interface and search functions allowing for fine-tuned querying of all information in the platform. The aim of this article is (1) to describe the building blocks of our innovative data management platform, (2) to review result of the platform pilot-testing, and (3) to summarize and present an outlook for further work.

2. Methods

2.1. Platform Architecture

Our platform, called **Regenerative Medicine Data Repository** (ReMeDy) is an implementation of the Signature Commons, a BD2K-LINCS [2] DCIC platform implemented through Docker and designed to store and search diverse metadata in an agile and flexible manner [3]. A Signature Commons instance was installed on a Linux server using the default installation instructions. The upload interface was built using ReactJS and Spring Boot.

2.2. Data Collection

Data for ReMeDy pilot-testing, in the format of the previously described multi-modular Common Data Elements (CDE) framework [4-5], was obtained from eight projects recently funded by the National Institutes of Health, plus a previously completed clinical trial, "Intramyocardial Injection of Mesenchymal Precursor Cells and Successful Temporary Weaning From Left Ventricular Assist Device Support in Patients With Advanced Heart Failure: A Randomized Clinical Trial", that was part of the Network for Cardiothoracic Surgical Investigations in Cardiovascular Medicine grant (Project Number: 7U01HL088942-03). The multimodular CDE template for stem cell research data sharing was populated using information available through NIH RePORTER and relevant papers published by the awarded project investigators. A representative set of 30 patients from trial 7U01HL088942-03 were included to populate the study subjects' section of ReMeDy. This included baseline, outcome, adverse events and readmission information previously submitted to BioLINCC.

3. Results

All data stored within a Signature Commons instance is designed to be organized hierarchically into three layers: resources, libraries, and signatures. For the ReMeDy implementation, resources represent the individual RMIC funded projects. Each project has one library, which contains the static CDEs, i.e., those that are not expected to change across the time course of the project, such as project information, cell product manufacturing and production information, and in-depth product characterization. Further information on the structure and organization of the CDEs contained in the libraries is provided below in the Modular CDE Framework section. Signatures represent individual study subject records and contain demographic, baseline, outcome and adverse event CDEs. As the study subject information will be updated on a periodic basis, partitioning it apart from the static CDEs will allow for easier and more reliable maintenance and retrieval of CDEs through the search functions.

3.1. Data Upload Interface

To improve the usability of ReMeDy, we implemented an interface to allow quick and efficient data upload by researchers that builds upon the core Signature Commons API. This interface allows data upload using a user friendly CVS file format, while incorporating required data features such as generating universally unique identifier (UUID) links. The upload interface allows for creation of all three data types (pre-clinical and clinical study outcomes as well as assay results for stem cell characterization), and employs metadata validators to define which key value pair elements the metadata must contain, the format of the values (including validation against ontologies), and identify required elements for ingestion. This quality control step allow for final verification of CDE formatting prior to ingestion into the database.

3.2. Multimodular CDE Framework

In order to facilitate data collection and organization within the database, we developed a multimodular CDE framework, which aims to capture all facets of information related to regenerative medicine trials. Previous attempts to create standardized frameworks for characterization of stem cells have resulted in the creation of the Minimum Information About a Cellular Assay for Regenerative Medicine (MIACARM) [4], a format in the process of being adopted by major stem cell banks including hPSCreg. However, it does not provide any CDEs to cover the other areas of clinical or pre-clinical projects needed to gain a full perspective of the work being done. Our multimodular CDE framework aims to address these deficiencies by using a scoping review approach for defining relevant CDEs [5]. The framework consists of 5 modules, which are Project (containing pertinent project status and PI CDEs), Manufacturing/Production (containing donor, Critical Quality Attributes and Critical Process Parameters CDEs), In-depth Product Characterization, Research System (containing study subject and animal model CDEs) and Outcomes. The flexible nature of our modular organization further dovetails with the ReMeDy architecture as not all sections of the framework are required to be shared across all funded projects, allowing for a more flexible and comprehensive organization of all regenerative medicine trials, regardless of their clinical or pre-clinical status, while remaining a comprehensive CDE collection.

3.3. Data Visualization and Sharing

To facilitate future research, collaboration and knowledge generation, ReMeDy utilizes a fully customizable UI and an API for data download. The highly adaptable search function allows to search using both keys and values, as well as incorporating Boolean operators to further refine your query. Further, the use of visualization schemas allows us to tailor visualization of libraries and signatures to highlight the most relevant CDEs to enhance the user experience. The API allows for downloads to be restricted by data type and retrieval of individual data records using the UUID, allowing for flexible, on-demand data retrieval.

4. Discussion

Regenerative medicine is a burgeoning medical field that has only recently been given due attention with the likes of the Regenerative Medicine Innovation Catalyst. Efforts to handle the diverse data generated by regenerative medicine trials, from stem cell characteristics, to clinical and pre-clinical outcomes, to next-generation sequencing big data, are only beginning to get under way. Considering the importance of data management and integration within the regenerative medicine community, here we present the first attempt at integrating stem cell product characterization with patient medical information and clinical outcomes, in order to promote collaboration, foster better standard practices, promote discovery and help drive stem cell product therapies toward FDA approval. The advantage of our architecture is the utilization of a NoSQL approach to import and store data, which allows us to incorporate large data sets in a schema-less nature while simultaneously employing validators to ensure stringent quality control measures and convenient tools for data import and export to improve the long-term usability and viability of our platform.

The next step in evaluating the platform will be further population of the database in coordination with researchers leading the RMIC funded projects. As study subjects are beginning to be enrolled, we plan to continue updating our database on a quarterly basis by assisting researchers in utilizing our upload interface, while simultaneously further improving our access and usability features. Data management and integration, being an important area for healthcare more broadly and regenerative medicine specifically, will only become more critical as this field progresses, a situation which ReMeDy aims to address.

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Model Driven Approach for Development of Person-Centred Care in Stroke Rehabilitation

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Abstract. Person-centred care is known as a novel approach which contributes to wellbeing, prevention, care and support of patients. There is little evidence about practising PCC in stroke rehabilitation. In this paper, we develop a novel framework for creation of person-centred services for stroke rehabilitation which supports service configuration adapted to the requirements of each patient. The framework is elaborated over evidence from neurology department of Clinical Centre in Montenegro.

Keywords. Person-centred care, model-driven, neurology, stroke rehabilitation

1. Introduction

Person-centred care (PCC) is increasingly advocated as a new approach for delivery of care which advances partnership between a provider and a patient on the way to produce a mutually agreed treatment plan. This approach improves health outcomes and increase patient satisfaction [1]. Implementation of PCC is highly linked with the existing healthcare system (the structure, organisation, cooperation models with patients, health care delivery processes, etc.) as well as with concrete domain of care (due to specific knowledge and individualised treatment plans). The stroke rehabilitation is mostly designed based on scientific evidence gathered in the form of clinical practice guidelines (CPGs) which proves to improve patient outcomes [2]. Since stroke is a chronic condition, the recommendations have to embrace the whole cycle of recovery, from the early treatment in the acute care hospital through reintegration into the community till the long term maintenance and prevention including social reintegration, health-related quality of life, maintenance of activity, and self-efficacy (e.g. [3]). Optimally, rehabilitation should be delivered by a multidisciplinary team of healthcare professionals trained in neurology, rehabilitation, occupational speech and language therapy, psychology, psychiatry and social work [3]. In this paper, we present an innovative framework for creation and planning of PCC services for stroke rehabilitation built upon

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the well-known principle in the software engineering field, known as the model-driven approach, which allows specification of processes with included commonality and variability of the constitutive element. The framework is elaborated over evidence from neurology department of Clinical Centre in Montenegro.

2. Methods

Model-driven engineering is well exploited in the literature for creation of intensive software systems by combining processes and analysis with architecture. In this paper we use an approach which integrates the following models [5]: (i) *Feature model*- is widely used for the presentation of variability among different increments in functionality (usually presented as a *feature*) as well as their interdependencies (e.g. relations *mandatory*, *optional*, *alternative*, etc.) (see Fig.1.a); (ii) *Business process model*- gives a comprehensive view on processes in the domain, with included variations which are presented with injective mapping with corresponding feature model (see Fig.1.b). Created model is elaborated by using the database for experimental research which consists of registered stroke cases of patients (944 records of different patient, age from 13 to 96 years). The experimental research included statistical analyses and classification algorithms in order to define key factors of individualised care of stroke patients for monitoring the efficiency of rehabilitation processes, often affected by conditions of other diseases (multimorbidity), smoking habit, or necessity of assistance.

3. Results

Many studies suggest that well organized, interdisciplinary rehabilitation reduces the likelihood of long-term disability by enhancing recovery outcomes (e.g. [5]). Depending on the deprivation, rehabilitation could be delivered in inpatients or outpatients rehabilitation facilities and later in a community setting. Patients should continue in inpatient rehabilitation if they are in necessity of skilled services, for example [3]: (i) bowel and bladder impairment; (ii) impaired bed mobility; (iii) dependence for activities of daily living (ADLs); (iv) inability to manage medications; (v) high risk for nutritional deficits; (vi) pain management issues; (vii) moderate to severe motor/sensory deficits, and/or; (viii) cognitive deficits, and/or, (ix) communication deficits. There is growing evidence that other physical activities, such as aerobic exercise, treadmill, body weight-supported treadmill, is effective in improving medical outcomes [3]. Physical activity should be an important aspect of home-based rehabilitation programs, especially that both patients and family members or caregivers prefer home-based rehabilitation programs over institutionally located rehabilitation. Community-based rehabilitation reduces depression and increases participation and health-related quality of life. Some studies report problems related to patient safety, fidelity of the treatment, lack of equipment and capacity to provide home-based rehabilitation [5]. The process of stroke rehabilitation is presented on Fig.1. with integrated different treatment elements. The concrete treatment plan shall be delivered based on characteristics of each specific patient, with PCC implementation approach which relies on continual communication with patients, their family members and other relatives. Having in mind that modern ICT solutions provide support to the implementation of PCC services in the form of mobile-based solutions which continually monitor patient's behavior, biochemical parameters,

as well as other healthcare indicators, selection and configuration of such services shall include: (i) the situational analysis about disease, (ii) available resources and potentials for integration with existing health information systems, and (iii) requirements and preferences of each specific patient.

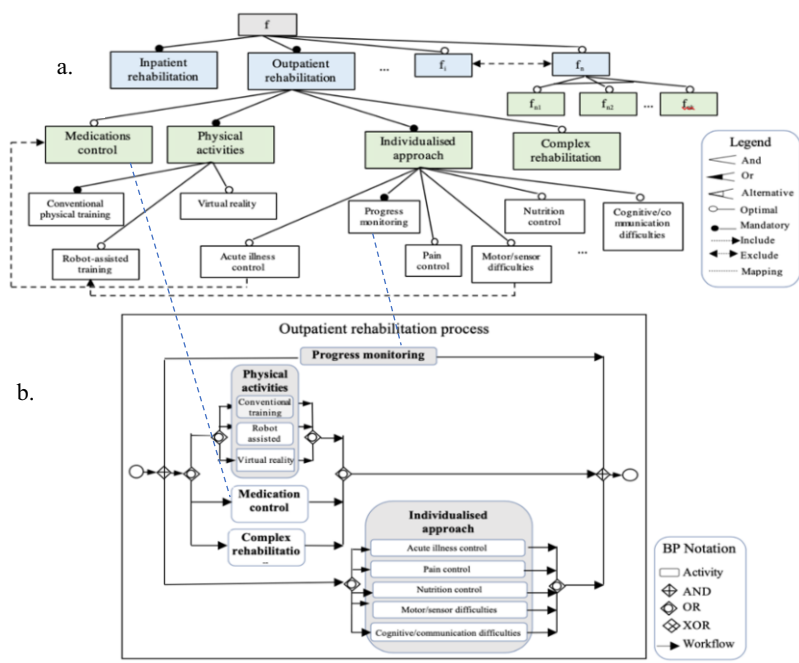


Figure 1. PCC services for stroke patients: a. feature model, b. corresponding outpatient rehabilitation business process model

The database applied for the experimental research consists of the registered stroke cases of the neurology department of Clinical Centre in Montenegro (structured records of 944 different patients, 58 variables, where 50 of them coded as scale values of [1,2,3] denoting “Yes, No, Unspecified” conditions, and 8 variables consisting of the demographic data, dates of admission and discharge from hospital). The experimental analysis aims to explore and provide insights for designing individualised PCC-approach based outpatient rehabilitation processes of the proposed model (Fig.1). The researched conditions, as prioritized by the experts of the medical centre, include outpatient rehabilitation monitoring, medication consumption control, and effect of smoking on health status of the stroke patients. The Spearman rank order correlation value of 0.39 suggests that significant number of patients are unable to perform prescribed physical therapy due to neurological effects of stroke. Therefore, the rehabilitation process planning has to be redesigned by inclusion assistance of medical workers, family or community members. The analysis for potential of IT-based control of regular medication consumption highlighted the age-related trend, e.g. 64,64% of patients using anticoagulant medication belong to highest age group (>70 years). The high risk of low acceptance of technologies in this segment reveals urgency of IT-based personalized monitoring process redesign. Due to the observed differences in recovering patterns of stroke patients, the neural network (NN) analysis is applied for the classification of the smoking and non-smoking segment (48.13% of cases) in relation to 13 variables of the

patient record, commonly applied for health monitoring. In Fig.2 the best NN models are reached classification precision of 70% in testing performance.

Select Models		Options		
Index	Profile	Train Perf.	Select Perf.	Test Perf.
1	MLP 15:36-14-3:1	0,845666	0,697872	0,634043
2	RBF 14:35-68-3:1	0,742072	0,719149	0,689362
3	Linear 15:36-3:1	0,706131	0,744681	0,697872
4	MLP 15:36-14-3:1	0,866808	0,693617	0,617021
5	PNN 16:37-473-3:1	0,894292	0,651064	0,642553
6	RBF 13:34-45-3:1	0,767442	0,710638	0,702128

Figure 2. Neural network performance for classification of “smoke” and “not smoke” segments

The sensitivity analysis ranked the variables by their influence to classification: 1)Past stroke 2)Stroke type SAH, 3)Age group, 4)Stroke type HEM, 5)multimorbidity condition high cholesterol, 6)neurological condition of speech disorder, 7)Stroke type ISHEM 8) Stroke type UNSP, 9)Days at hospital, 10) Paresis, 11) Atrial fibrillation, 12) Hypertension, 13) Deep vein thrombosis. The relatively low influence of the variables (max ratio value 1.08) revealed necessity of detecting more powerful indicators, able to detect risk effects of smoking and to be consistently captured with the help of IT .

4. Discussions

The presented research provides basis for personalised health monitoring of stroke patients in Montenegro, which enables prioritization and redesign of the suggested PCC services (Fig.1). The advantages if the suggested model-driven approach include: (i) re-use of the model for PCC service design in different institutions, (ii) measure changes over time due to the factors, having impact to the delivery of care (iii) measure impacts to quality of care and delivery of services to stroke patients, (iv) respecting patient’s and family’s opinion about his/her health and suggested health services.

5. Conclusions

In this paper, we have explored the impact of the model-driven approach for applying concept of PCC for ensuring quality of care in stroke rehabilitation. The experimental research provided insights for process redesign based on individualised health monitoring. However, the future work for the implementation of the suggested concept in real settings is planned for comprehensive evaluation and refining the model.

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Supporting Active Pharmacovigilance via IT Tools in the Clinical Setting and Beyond: Regulatory and Management Aspects

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Abstract. *Information Technology (IT) could have a prominent role towards the “Active Pharmacovigilance” (AP) paradigm by facilitating the analysis of potential Adverse Drug Reactions (ADRs). PVclinical project aims to build an IT platform enabling the investigation of potential ADRs in the clinical environment and beyond. In this paper, we outline the respective EU regulatory framework and the related Business Processes (BPs), elaborated based on input from clinicians and PV experts as part of the project’s “user requirements analysis” phase, highlighting their potential pivotal role in the design of IT tools aiming to support AP.*

Keywords. Active Pharmacovigilance, Drug Safety, Business Processes

1. Introduction

Adverse Drug Reactions (ADRs) are detrimental regarding public health and cost [1] and therefore, preventing them is critical both during drug development, as well as during clinical practice [2]. To this end, Pharmacovigilance (PV) is defined as the science and activities related with all aspects of the detection and management of ADRs [3].

The investigation of potential new or partially documented ADRs (a.k.a. “signals”) is based on the collection of Individual Case Safety Reports (ICSRs) via Spontaneous Reporting Systems (SRSSs), based on “Disproportionality Analysis” (DA) approaches [4].

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Recent breakthroughs in Information Technologies (IT) enable the use of new, emerging data sources expanding the real-world evidence space used to explore potential PV signals. The “Active Pharmacovigilance” (AP) paradigm refers to the “hot pursuit” of all possible data sources, instead of “passively” waiting for ICSRs to be submitted [5].

PVclinical project², develops a Web-based platform exploiting Knowledge Engineering (KE) technologies to facilitate the investigation of potential ADRs, by clinicians, as well as PV experts and researchers. A preliminary design of the platform, i.e. a first set of “User Goals”/design objectives and its main information workflow was presented in [6]. This paper focuses on the PV regulatory and procedural context and also discusses its key impacts on the design of novel IT tools aiming to support AP.

2. Methods

The employed “user requirements analysis” process is based on the approach described in [7] (Figure 1) aiming to consolidate various information, including end-user input, to identify “*User Goals*” (UGs). UGs are “abstract user requirements, not directly referring to specific technical approaches” [7], directly attributed to user “roles” or “actors”. UGs’ definition aims to highlight “gaps” in the currently applied Business Processes (BPs) and the resolution of potential conflicts between actors and BPs, to provide input in the overall system design. In this paper, we emphasize on the results of two parts of the overall process: (a) a “Regulatory framework overview” which was based on a thorough review of European legislation that pertains to PV and input from partners (including Pharmassist which is a Contract Research Organization conducting PV activities on behalf of pharma companies and therefore legally bound by this regulatory context), and (b) “BP identification and elaboration”. To this end, we discuss some key conclusions and their impact on the design of IT systems supporting AP paradigm. Noting a potential limitation of the applied approach, we conducted an exploratory review which was empirically validated, rather than a systematic review of literature/legislation.

3. Results

3.1 Regulatory framework

Drug Safety Monitoring Organizations (DSMOs) play a crucial role in both the pre- and post-market stages of a drug life cycle, i.e. from clinical trials and marketing authorization to post-marketing surveillance, and typically, they also maintain SRS. For example, the U.S. Food & Drug Administration maintains (FDA) maintains the FDA Adverse Event Report System and European Medicines Association (EMA) maintains EudraVigilance. Notably, the Uppsala Monitoring Centre (WHO-UMC) is the WHO PV reference centre and maintains the largest database of ICSRs in a global scale, VigiBase. Emphasizing on the EU context, the directive 2010/84 (applied on July 2012 via regulation No 520/2012 and Good Pharmacovigilance Practices – GVP - Modules I to XVI), marked a major policy update regarding the safety requirements for the human drugs. Regarding post-market surveillance, it instructed the deployment of national SRSs also enabling citizen reports. Furthermore, pharma companies were obliged to maintain

² <https://pvclinical-project.eu>

and regularly update Risk Management Plans (RMPs) and provide Periodic Safety Update Reports (PSURs). All the stakeholders were instructed to actively exchange data and finally, all the collected information are evaluated by the EMA Pharmacovigilance Risk Assessment Committee (PRAC), responsible to assess drug risks in EU [8].

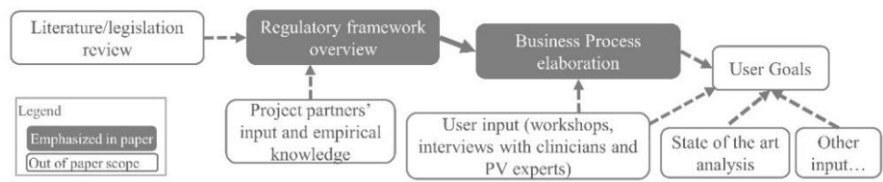


Figure 1. Overall methodology rationale.

3.2 Business Processes

Tables 1 and 2 depict the relevant BPs as they resulted after workshops and interviews with clinicians and PV experts. For each of these BPs, the potential benefits of using IT tools to support AP were elaborated to identify and prioritize the relevant User Goals.

Table 1. BPs related with PV in the clinical environment

Name	Description	Actors	Data
BP1: Visit to outpatient clinics	BP1 could include the registration of the patient and its medical history in the hospital EHR, clinical examination, ePrescription, etc.	• Doctor • Nurse	Demographics, Medical history, Lab result, diagnosis, ePrescription
BP2: Hospitalization	BP2 includes BP1 steps and also clinical procedures (e.g. an operation), computerized physician order entries (CPOE), clinical notes maintenance and patient discharge.	• Doctor • Pharmacologist • Nurse	BP1 data and also clinical notes, CPOE data, discharge notes
BP3: Service evaluation	BP3 does not refer to clinical practice but is regularly applied in hospitals to evaluate clinically relevant metrics (ADRs, in-hospital infections, errors etc.).	• Doctor • Pharmacologist • Nurse • IT scientist • Manager	EHR statistics, prioritized lists of adverse events of interest, comparison with other data sources

Table 2. BPs related with PV out of the clinical environment

Name	Description	Actors	Data
BP4: Clinical trials	BP4 includes the design of a study/intervention, the definition of patient cohorts, data collection and curation, comparison with other clinical trials and also results reporting	• Doctor • PV Expert	Demographics, medical history, genetic profiling, lab results, clinical notes, safety and efficacy reports
BP5: Update of Periodic Safety Reports	BP5 includes the review and the statistical analysis of ICSRs, literature review, clinical trial data processing and reporting to regulatory authorities	• Doctor • PV Expert	Drug safety data, statistics, documentation /reports, prioritized lists of adverse events of interest
BP6: Weekly literature review	BP6 refers to literature reviews including the shaping of queries based on keywords and synonyms against various literature sources	• Doctor • PV Expert	Documentation/reports
BP7: Risk management	BP7 includes literature review, relevant clinical trial data review, and also the calculation of risk factors	• PV Expert	Drug safety data, statistics, documentation/reports

4. Discussion

In this paper, we provide an overview of the PV regulatory context, and the identified BPs, resulted as part of the PVclinical “user requirements analysis” phase. In this section, we discuss their impact on the design of IT tools aiming to support AP. PV regulatory context, highlights the need for IT tools which could support the robust analysis of heterogeneous data sources. To this end, KE technologies can accelerate and qualitatively improve tasks regularly conducted by PV experts, pharma industry and DSMOs (e.g. compilation of RMPs, PSURs etc.). The need to integrate various data sources is also supported by the analysis of the relevant BPs, identifying a gap regarding the use of automatic reasoning capabilities, and therefore further supporting the potential of KE. It is obvious that IT tools should have the capacity to retrieve, analyse and depict succinctly metrics of DA emphasizing prowess on advanced analytics features. Furthermore, it should be considered that in the clinical setting BPs might overlap and potentially conflict. For example, while potential ADR prevention is important, more urgent duties exist and they should not be interrupted or obstructed. Notably, the engagement of various actors with different educational and operational contexts, i.e. pharmacists and nurses apart from PV experts and medical doctors, also depicts the overall complexity of the clinical setting. For instance, while complex DA analytics are useful for a PV expert focusing on risk management, they might be irrelevant or even obscuring for a clinician. Thus, the need to focus on usability is highlighted for IT tools supporting AP, both in the clinical context and beyond.

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Association Between System Usage Pattern and Impact of Web-Based Telerehabilitation in Patients with Multiple Sclerosis

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Abstract. Patients with multiple sclerosis (PwMS) increasingly use online services for managing their healthcare. The objective of this study was to investigate web log data (weblogs) generated by PwMS in the process of web-based telerehabilitation and correlate them with rehabilitation progress. The weblogs from 17 patients (female: 15, male 2; mean age: 60.1±11.4 years) were tracked for an average period of 153.6±38.3 days with the total number of log events and page visit records of 1,457 and 37,030, respectively. The time and frequency of patients' web visits were investigated as well as their adherence to prescribed exercise regimen. Rehabilitation progress was gauged by changes in quality of life, mobility, and sleep ascertained by measuring MSQOL, 2MWT and PSQI respectively. The changes in these metrics were correlated with system usage patterns. On average, PwMS visited 30 pages a day for 26.5 minutes, with a single login amounting for 27 pages in duration of 22.0 minutes. The average exercise program comprised 6.9 sets and 29.1 repetitions with average set and repetition completion rates of 46.5% and 72.6% respectively. A statistically significant association has been found between time spent in the online exercise mode and clinical improvements. The results of the study demonstrate that the patients had more pronounced outcome improvements when they increased the time of using the telerehabilitation system for home-based exercise. The results of this study could contribute to the development of more efficient home-based telerehabilitation systems.

Keywords. Telerehabilitation, weblogs, multiple sclerosis

1. Introduction

Demand for online disease management by patients with multiple sclerosis (PwMS) using web services at home has been increasing [1, 2]. The need for disease management in an open space outside the hospital [3] creates a variety of functions of the system and subsequent complex operational requirements. Using a system that combines the functions of patient education, exercise management and performing interactions requires understanding of the factors in the patient's system operation to lead to the best clinical outcomes, and it is essential that optimal operational patterns are identified. However, association between system usage pattern and impact of web-

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based telerehabilitation in PwMS has not been systematically studied. The goal of this study was to analyze web usage logs generated by PwMS during home-based telerehabilitation.

2. Methods

We conducted a retrospective analysis of web logs generated by PwMS in the course of using the MS HAT system [4] for online home-based telerehabilitation. In the analysis, the patient identifier has been de-identified. The data was stored in a relational database called “va_ms-test.” It was a Microsoft SQL Server database located on a AWS EC2 instance.

The typical patterns for patient use of the system is defined as in Table 1. During the total period of use between time at beginning (BL) and end (FU) of the study, and when logging in once, we wanted to investigate information about how patients used the system. We also wanted to see how the conditions of exercise prescribed by the healthcare provider affect the patient. Next, we wanted to evaluate how well a patient performed the prescribed exercise, and finally we investigated information about how much the patient wanted to communication with the healthcare provider. In order to find above-mentioned concerns, we took log-in time, exercise access time, exercise set completed, and log-out time from the server log of MS HAT web page. The exercise repetition number was saved by the patient in the web page, so it was taken from MS HAT database.

Sociodemographic information was measured at BL. The Pittsburgh Sleep Quality Index (PSQI) [5], the Multiple Sclerosis Quality of Life (MSQOL) [6], and the Two Minutes Walk Test (2MWT) [7] were measured at BL and FU. Comparisons were made with these outcomes and the items mentioned in 'Parameter Definition' section. All statistical analyses were performed with bivariate Pearson Correlation analysis method using IBM SPSS Statistics 26 for Windows. The results provided the correlation coefficient and the 2-tailed statistical significance.

Table 1. Definition of system usage pattern

Parameter Name	Definition
Total system usage time	cumulative system usage time from BL to FU
Total page number	cumulative number of visited pages from BL to FU
Day usage time	average system usage time for at least 1 log-in day
Day page number	average number of visited pages for at least 1 log-in day
Day number	average number of days that the patient log-in at least 1 time
Visit usage time	average system usage time on a single log-in
Visit page number	average number of visited pages on a single log-in
Visit number	average number of log-ins
Exercise set number	cumulative number of exercise sets
Exercise repetition number	cumulative number of exercise repetitions
Average set completed	average number of exercise sets completed when at least 1 set was finished
Average percent set completed	average percent of exercise sets completed when at least 1 set was finished
Total exercise time	cumulative exercise page stay time from BL to FU
Message	cumulative number of messages from BL to FU

BL: at beginning of the study, FU: at end of the study

3. Results

Seventeen PwMS aged between 39 and 76 years old used a telerehabilitation system for 153.6±38.3 days. The range of time how long the patient has MS was between 2.5 and 50.8 years and the average of education was 15.5 ± 2.7 years. The white was 70.6% and the Hispanic was 11.8%. The answers of 11.2% of severe MS severity and 29.4% of progressing disease were investigated. The average of day difference between BL and FU was 153.6±38.3 days. The total time patients spent using with MS HAT system were ranged between 6 and 68 hours with 30.7 ± 19.8 hours (mean ± SD). The average of total log-in was 86, patients visited 30 pages a day on average for 26.5 minutes, and once visited 27 pages for 22.0 minutes. The average 6.9 sets and 29.1 repetitions of exercise provided to the patient had average completion set and repetition rates of 46.5% and 72.6% respectively, and the average total time stayed in the exercise page was 13.5 hours. The patients also sent an average of 8.5 messages. The p-values of <0.01 were found the relationships between ‘Total system usage time’ and ‘PSQI sleep efficiency (FU-BL),’ ‘Visit page number’ and ‘Exercise repetition number,’ ‘Visit page number’ and ‘Day page number,’ ‘Average percent set completed’ and ‘2MWT (30sec),’ ‘Total exercise time’ and ‘Total system usage time,’ ‘Total exercise time’ and ‘Visit number,’ ‘Total exercise time’ and ‘Day number,’ and ‘Total exercise time’ and ‘PSQI sleep efficiency (FU-BL).’ Additional significant association was found between system usage pattern and impact of telerehabilitation on mobility, sleep and quality of life (Table 2).

Table 2. Parameters that were shown significant correlations.

Parameters	Correlation	p-value	n
Total system usage time			
PSQI sleep efficiency (FU-BL)	0.757	0.000	17
PSQI total (FU-BL)	-0.507	0.038	17
Total page number			
Exercise repetition number	0.507	0.038	17
Visit page number			
Exercise set number	0.895	0.000	17
Day page number (for only log-in days)	0.931	0.000	17
Exercise repetition number			
PSQI sleep efficiency (FU-BL)	0.532	0.028	17
PSQI total (FU-BL)	-0.536	0.027	17
Average set completed			
MSQOL physical health (FU-BL)	0.503	0.047	16
Average percent set completed			
2MWT (30 sec)	-0.835	0.005	9
2MWT (120 sec)	-0.729	0.026	9
Total exercise time			
Total system usage time	0.886	0.000	17
Visit number	0.702	0.002	17
Day number	0.614	0.009	17
Exercise repetition number	0.494	0.044	17
PSQI sleep efficiency (FU-BL)	0.814	0.000	17
PSQI total (FU-BL)	-0.702	0.002	17
Messages			
MSQOL cognitive function (FU-BL)	0.486	0.048	17
2MWT (30 sec)	0.721	0.028	9

BL: at beginning of the study, FU: at end of the study, FU-BL: difference data between FU and BL

4. Discussion

The study of the enhancement of clinical outcomes related to a healthcare provider's response for patients is constantly being carried out [8-10]. However, studies involving patient behavior patterns, particularly those used in the home disease management system, are limited. This study used MS HAT system weblogs to perform validation for typical usage pattern analysis that improves the clinical outcomes of PwMS. In our results, we could confirm that an increase in the patient's system usage time affected the improvement of sleep quality of patients represented by an increase in PSQI sleep efficiency and a decrease in PSQI total. It was also found that the self-paced walking ability and functional capacity of the patient were improved with the increased distance of 2MWT.

Extensions to the use of each page will help to find more detailed patterns of patient's system usage. In addition, the aggregation of information about the interaction of healthcare provider will enable pattern analysis that will lead to improve clinical outcomes. More detailed and accurate optimal system operating patterns will be found when dynamic analyses, such as sequences of system operations, are induced over static analyses. More detailed analyses for further analysis of system weblogs and patient outcomes in a larger study sample is warranted.

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Rules Based Data Quality Assessment on Claims Database

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Abstract. Data quality problems in coded clinical and administrative data have persisted ever since diagnoses and procedures were first coded and used for healthcare billing. These data are used in clinical decision-making introducing a route for iatrogenesis. As we share data on regional Health Information Exchanges (HIEs) and include them in electronic health records the potential for harm may be increased. To study this problem we applied rules-based data quality checks that have been previously tested on Electronic Health Records (EHR) data on a limited set of aggregated claims data. Medicaid claims data was used exclusively. CMS has clear guidelines for claims submitted for Medicaid patients and penalties are incurred for erroneous claims, which should ensure a high quality data source, however reports of low and varying sensitivity, specificity, positive and negative predictive value of coded diagnoses are common. To identify data quality defects in claims data in a state All Payer Claims Dataset (APCD) we applied and evaluated a recently developed rules-based data quality assessment and monitoring system for Electronic Health Record (EHR) data to test effectiveness in claims data. These rules, that are feasible for "All Payer Claims data" and Medicaid data are identified, applied and the Data Quality issue results are produced.

Keywords. Healthcare Rules, Data quality

1. Introduction

APCD data are large State databases that include medical claims, pharmacy claims, dental claims, and eligibility and provider files collected from private and public payers. Claims data provide information on how and where health care dollars are spent; it provides price transparency; health care quality; and payment reform evaluation.[1,2] This information is used to determine the rate of health care inflation, an important outcome of health care reform efforts. [2] Rules-based data quality assessment, though common in clinical research, is not often applied in healthcare facilities.[4] A large system leveraging a knowledge base of over 63,000 rules was developed and tested in healthcare data. In this work, a rules-based approach to data error identification was explored through compilation of over 6,000 data quality rules. The rules were categorized based on topic and logic yielding twenty-two rule templates and associated knowledge tables (hereafter referred to as the Rules) used by the rule templates.[4] Given common use of such rules by payers in the claims process, we posited that claims data would contain few, if any of these discrepancies. However,

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the limitations and inaccuracy in claims data has been consistently reported in the literature since the initial assessments of claims data. [5] Nine out of twenty-two rules developed and implemented by Wang et. al. (2019) [4] are relevant to data elements in APCD data.

2. Methods

Because of voluminous APCD data, only records from 2017 were subjected to the nine rules. Most of the other rules are related to Clinical data and thus not feasible to apply on APCD. The rules are to find data quality problems, for example, incompatibility, incompleteness, and data value out of range. Integrity rules are defined by database constraints and column data types. The two rules for age parameter: (1) Age and Diagnosis (incompatibility) 2. Age and Procedure (incompatibility).

Only APCD Medicaid records are taken. The total number of patients in APCD data is calculated based on the number of encounters, i.e. service start date to service end dates.

Rule 1, 2 are based on Age and diagnosis/procedure. For Rule_Age_Dx which is Age with Diagnosis incompatibility rule, three categories are defined for this rule. They are (1) Only applicable to maternity patients aged 12 - 55 years inclusive (2) Only applicable to newborns of age 0 years (3) Only applicable to pediatric patients aged 0 - 17 years inclusive. ICD codes for these categories are mapped with APCD Medicaid records and the number of invalid patient counts for APCD Medicaid are given as result set. For **Rule 2**, i.e. Age with procedure Rule_Age_Px, different categories of valid begin and end age are given along with their Current Procedural Terminology (CPT) codes. APCD data is validated based on the valid begin and end age mapping with the date of birth of the patients and the overall invalid patient counts are given in result set. **Rule 3, 4** are based on Gender and diagnosis/procedure. For Rule_Gender_Dx Gender with diagnosis incompatibility rule, gender is verified by mapping ICD codes of the Rule with APCD Medicaid codes The number of Invalid gender counts are collected, the same steps are followed for gender with procedure rule Rule_Gender_Px and the number of patients with invalid counts for APCD is collected **Rule 5** refers to gender and clinical specialty (incompatibility). The clinical specialties are narrowed to Maternal-Fetal Medicine and Obstetrics & Gynecology. The invalid gender for these records is male. The number of patients with invalid gender and clinical specialty is collected for this Rule. In **Rule 6** InPatient Only (IPO) Procedure *Admission date, hour, type* and the *discharge date* fields are taken into consideration to find invalid patient counts. The ICD codes that are required for inpatients are mapped with APCD records and the number of patients with invalid *Inpatient only feature* are taken. The last three rules (**Rule 7** Demographics data elements, **Rule 8** Time Sequence, **Rule 9** Date In Future) are focused primarily on clinical data and few of the categories can be customized for APCD data. Based on this, the validation of records was done by taking *Date of birth* and *Death* dates fields. For sequence of events, *Date of birth*, *Admit date*, *Date of encounter*, *Claim processed dates*, *Diagnosis* and *procedure dates*, *Discharge dates* fields were considered.

3. Results

Table 1. Results of Rules applied on APCD Medicaid data

Rules with (Medicaid)	AR	Rules on Medicaid data and Claims data for Number of patients	Encounters	APCD	Adverse Events
Rule 1		Age and Diagnosis (incompatibility) - total patients	175	88	0
		Number of patients with Invalid Age and with Diagnosis	5	4	0
Rule 2		Age and Procedure (incompatibility) - total patients	0	0	0
		Number of patients with Invalid Age and with Procedure	0	0	0
Rule 3		Gender and Diagnosis (incompatibility) - total patients	8549	3622	0
		Total number of male and female invalid patients	459	296	0
Rule 4		Gender and Procedure (incompatibility)- Overall patients	0	0	0
Rule 5		Gender and clinical specialty (incompatibility) - Total patients	6	3	3
		Number of invalid records for Gender and clinical specialty	0	0	0
Rule 6		In Patient Only(IPO) Procedure (incompatibility) - Total patients	0	0	0
Rule 7		Demographics data elements (value out of range) - total patients	0	0	0
Rule 8		Time Sequence	0	0	0
Rule 9		Date in the future	0	0	0

Total number of patients in APCD data is 52,185. For **Rule1:** Age_Dx - There are 88 patients that have ICD codes matching with ICD codes of Rule1 and these 88 patients have 175 encounters or visits to the medical center, the last column HAC (Adverse Events) of Table 1 reflects the number of patients with Adverse Events-Human Acquired Conditions (HAC) ICD codes, that are similar to ICD codes for Rule1.

4. Conclusions

This work demonstrates the value of using data quality rules developed for EHR data on claims data for error identification. Both claims and EHR data are collected for administrative purposes but they differ in their focus and use. While EHR data mirrors

the decisions and practice of clinicians, claims data exists to support health plan coverage decisions. This results in two perspectives on the same information. Because the APCD is mainly claims data, nine rules were identified and applied from a set of 22 possible. The remaining rules test clinical values that are not present in claims data. The resulting set of patients with the encounters, instead of an overall count of encounters, is an important data preparation step for data quality evaluation. We have demonstrated that rule based data quality assessment identifies real problems and using these rules to test the merit of claims data appears to be feasible. While there is significant additional work to be done in this area, the exploration of the rule template and associated knowledge base tables for EHR data on claims data shows the approach to be successful, the number of rules likely tractable, and their management scalable.

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Challenges of the Slovenian Healthcare System Exposed in Hospitals' Recovery Plans

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Abstract. In recent years, Slovenian public health has been a very prominent topic, both politically and professionally. In 2017, a one-off cash transfer to hospitals from the state budget in the total amount of EUR 136.24 million cash has been ensured to pay debts to suppliers of medical materials and medicines. At the same time, emergency legislation enacted the recovery plans to ensure operational and payment stability. The in-depth analysis of the recovery plans for 15 hospitals revealed that management boards highlight the infrastructure and financial challenges as the greatest, whereas the challenges concerning the services/products and patients/users are perceived to be less important.

Keywords. Recovery plan, measures, financial stability, Slovenia

1. Introduction

In recent years, Slovenian public health has been a very prominent topic, both politically and professionally. The ageing population, the increase in the number of chronic non-communicable diseases and cross-border epidemics along with the simultaneous progress of medicine, increases health care expenditure, which, according to recent figures, reach 8.6% of GDP relative to the OECD average (9.0% of GDP) [1]. The problems are particularly evident in the efficiency of public financing since the data show a low efficiency of the system in some areas in comparison to other countries [2]. The consequences are illustrated by the fact that as of 31/12/2016, 15 public hospitals showed EUR 170.34 million of the accumulated surplus of expenses over revenues, while the remaining 11 hospitals had a surplus of revenue over expenses totaling EUR 16.40 million. In 2017, the Slovenian Government proposed the Act Determining Intervention Measures to Ensure the Financial Stability of Public Healthcare Institutions Established by the Republic of Slovenia (ZIUFSZZ) [3]. It had two key objectives: a) for hospitals to take one-off measures for financial reorganization, and (b) to perform the recovery of hospitals. Its goal is to ensure business and payment stability of public hospitals and to optimize operating processes and improve efficiency.

In the past decades, health policies of some countries (e.g. Finland) went towards decentralization of systems [4], others (e.g., Croatia) towards privatization [5] or in the reorganization with the use of subcontracting services, such as Poland [6]. Constant

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searching for solutions to provide a more efficient and effective provision of health services to the population was present in all systems, while the trend towards re-centralization of at least some functions has spread enormously [7]. This trend is commonly interpreted as mere cost reduction. Health systems are reaching for the financial reorganization of existing hospitals, their pooling and closing of smaller hospitals [8]. Efforts for the recovery of hospitals have included different measures; from intervening in operational efficiencies, to measures in the field of health services content, all the way to their quality. In the reorganization of Italian hospitals, which started in February 2016, it is planned to reduce the total loss of hospitals amounting to EUR 1.4 trillion over a three-year period, which will be achieved through several measures. The closure of hospitals with fewer than 15 beds and the rationalization of hospital staff recruitment and medical technology are expected to have the most significant impact [7].

The primary objective of this paper is the review, systematization and summary of the measures for the achievement of financial stability outlined in the recovery plans of 15 Slovenian hospitals for the period 2018-2021.

2. Methods

The analysis methodology is based on an in-depth review of all measures from 15 recovery plans of the insolvent Slovenian hospitals. The recovery plans have been obtained from the hospitals and from the Ministry of Health in some cases. After the analysis of the content, structure and declared objectives, the measures have been classified into four main groups of measures considering infrastructure aspect, the aspect of healthcare services and products, the aspect of patients and users, and the financial aspect. These groups were constructed considering the main characteristics, focus, and substance of listed measures.

The analysis of the 15 recovery plans (each of them containing few hundred pages) has been very complex and effortful work. On the other side, the consistent and distinctive classification in the determined aspects and groups has been a great challenge, considering the fact that there has not been any methodology for the preparation and definition of measures. Moreover, the measures' titles have often been contradictory to the material and procedural objectives of the measures themselves.

3. Results

The recovery plans have been submitted in early 2018 and supplemented in 2019. The ZIUFSZZ represents a unique feature of the Slovenian legal order since it has imposed on the management of public institutions to independently determine the measures that will achieve a balanced business operation. According to the ZIUFSZZ and the instructions of the Ministry of Health [9], the measures should be long-term planned and supported by the measurement indicators, expected savings or earnings, the person in charge of measure execution and the deadline. Additionally, all measures should provide the independent business operation without government or any other funds and what is most important; measures should not adversely affect the quality and safety of healthcare services.

The analysis of the measures exposed the four aspects that have been most frequently emphasized and according to which measures have been counted and

analyzed. The measures classified into the infrastructure aspect contain the proposals for the new or renovated activities, resources and stakeholders in hospitals context, while measures stressing the financial aspect are those that directly address the change in revenues or expenditures. The measures classified into the aspect of healthcare services and products include the improvement, enlargement or additional operations as far as services and products are concerned. Finally, there are some measures focusing on the relations with patients and users, their segmentation, and benefits.

The in-depth analysis of the hospitals’ measures revealed that their content predominantly focuses on the infrastructure and financial aspects, while the aspect of the healthcare services and products and the aspect of the patients and users are represented less often. The correlation among hospitals’ plans has been established by four predominant aspects, whereby the infrastructure aspect is mainly focused on activities. The great number of those activities include management, administration or accounting issues, but also the redesigning the business processes and clinical paths. The number of measures according to aspect and group of measures within the aspect is presented in Table 1.

Focusing on the more detailed and specific factors’ analysis, the additional assessment of the prevailing measures in all 15 hospitals’ recovery plans has been performed; exposing 5 measures. The cost cutting (of all kind) is definitely the most frequently addressed measure, followed by the correct and timely calculation of services to be reimbursed by the healthcare fund. Nevertheless, the most numerous group of measures is infrastructure, measures within are very diversified; however, most of them are concerning organizational-administrative, business processes and reorganization fields.

Table 1. The overview of measures in recovery plans for the period 2018-2021

Recovery aspect	Groups of measures	Number of measures
Infrastructure aspect	Activities	171
	Stakeholders	11
	Resources	34
Aspect of the healthcare services and products	Services	45
	Products	4
Aspect of patients and users	Patients	9
	Users	18
	Revenues	53
Financial aspect	Expenditures	107

4. Discussion

The alarming situation in the Slovenian hospitals has not been reflected solely as negative financial results but also in the day-to-day business operations, like non-delivery of materials and medicines, late payments of salaries, long waiting times, etc. ZIUFSZZ facilitated a one-off cash transfer to hospitals from the state budget in the total amount of EUR 136.24 million cash to pay debts to suppliers of medical materials and medicines (Article 2 of the ZIUFSZZ). Besides this cash-transfer, Ministry of Health has written – off unpaid obligations for the depreciation of the asset used (Article 6 of the ZIUFSZZ) and the payment deadlines of 60 days or more were extended in cases the payment deadline is agreed in writing, and such a period does not constitute an unjust agreement (Article 9 of the ZIUFSZZ).

The in-depth content analysis of the suggested measures reveals that there are several challenges in hospitals; from infrastructural and financial to challenges in health care services/products improvement and patient/users satisfaction. It seems that there are several possibilities to optimize business and make it more efficient and effective since greatest number of measures refers to managerial, administrative and accounting issues and business processes. Additionally, the analysis revealed that the management boards emphasized the importance of financial aspect, not just on the expenditure side but also on the revenue side of the financing model. The suggested measures mainly focus on processes to achieve the number of contracted services with the financier, prioritizing the services with better profit margins. However, the measures for improving the coordination among providers of health care services; in vertical and horizontal direction have also turned out to be of great importance.

This analysis is the pioneering attempt to find the corresponding and significant factors, which restrain Slovenian healthcare system from obtaining positive financial results. It seems that the project of hospitals' recovery has tried to assess the internal reserves as far as organizational and financial optimization of the hospitals is concerned.

5. Conclusions

The problems of the Slovenian healthcare system have been accumulating for years. ZIUFSZZ offered some short-term liquidity solutions and obligated the hospitals' management board to suggest the long-term measures/solutions. The analysis of the recovery plans reveals that there are some significant challenges from the infrastructural, financial, service/products and patient/users perspective. At this (initial) stage of the recovery procedures, our findings are the result of the complex analysis, which might be upgraded at the later stages of the recovery procedure.

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Disparities in Racial and Ethnic Representation in Stem Cell Clinical Trials

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Abstract. ClinicalTrials.gov (CTG) provides integrated access to structured records of thousands of randomized clinical trials (RCT). CTG functionality allows download of the entire dataset in XML format for further knowledge discovery and analytics. This study represents an instructive use case of utilizing this functionality for identifying patient representation disparities in stem cell RCTs. The goal of this study was to determine the racial and ethnic composition of stem cell clinical trials and to identify potential disparities in minority representation. The clinical trial registration portal ClinicalTrials.gov was queried to identify stem cell trials and to compare their racial and ethnic composition to the US population data. Based on our analysis of 248 available trials, we have concluded that not all races and ethnicities are adequately represented in US stem cell trials; thus, concerted efforts are warranted for more inclusive representation of minorities in future stem cell trials.

Keywords. Stem cell therapy, Race, Ethnicity, Discrepancy

1. Introduction

In 1960, stem cells were first described as self-renewing cell colonies in bone marrow in mice.¹ Now, we know that these cell colonies were hematopoietic stem cells and that bone marrow is not the only stem cell niche in the human body.² Today, these cells are classified as adult stem cells (ASCs). In addition, stem cell classification includes embryonic and induced pluripotent stem cells (ESCs and iPSCs).³⁻⁴ Stem cells from a single donor can benefit multiple patients, in contrast to an organ transplant, where receiving a new organ involves long waiting periods and the organ is used in a single patient.⁵ However, similarly to organ transplants, there is a need of compatibility between donor and recipient in stem cell clinical trials. Previous studies have shown that due to allelic polymorphism among races, responsiveness to stem cell trials may differ.⁶ Therefore, racial and ethnical diversity could affect outcomes of the stem cell trials and broad representation of population subgroups is necessary to minimize bias.⁷ The aim of this study was to examine the racial and ethnic representation in the stem cell clinical trials and to compare it to the current racial and ethnic structure of US population.

2. Methods

For this study, we used ClinicalTrials.gov website, where we entered “stem cell” in the “Other terms” field and selected “United States” from the drop-down “Country” menu.

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We further refined the search by selecting “Completed” and “With Results,” producing 555 studies. Out of this sample, we focused on the clinical trials, where Race and Ethnicity information was documented. As a result, we identified 248 completed stem cell studies which contained data on race and ethnicity.

3. Results

Out of the 555 completed studies, only 248 studies contained information about patients race and ethnicity. 28,478 total patients were enrolled in the 248 studies. 27,155 out of the 28,478 patients were analyzed. The study results did not specify which particular subjects are identified “analyzed” during the trials (Table 1). However, it is essential to point out the 55% of the studies listed in Table 1 do not include racial and ethnic background of the donors. For that reason, for our study we were not able to analyze all data available.

Table 1. Total number of studies and patients (enrolled and analyzed)

Studies Characteristics	Completed	Completed w/Race and Ethnicity Included
Studies (N)	555	248
Studies (%)	100%	45%
Enrolled patients (N)	49,966	28,478
Enrolled patients (%)	100%	57%
Analyzed patients (N)	47,870	27,155
Analyzed patients (%)	100%	57%

According to our findings, racial composition of participants in the 248 completed clinical trials, which are 45% of all completed clinical trials in our sample analysis, where race and ethnicity is documented, is as follows: 0.35% (91 participants) are Native American or Alaskans, 6.17% (1,610 participants) are Asians, 0.18% (46 participants) are Native Hawaiian or other Pacific Islanders, 8.82% (2,301 participants) are Black or African Americans, 78.8% (20,539 participants) are Caucasians, 0.35% (91 participants) are of more than one reported race, and 5.32% (1,388 participants) are of unknown or not reported race. In addition, 10.25% (1,962) of the participants are of Hispanic ethnicity, 83.9% (16,379) are Non-Hispanics, and 4.2% (820) are Unknown or Not reported (Table 2).

Table 2. Racial and ethnic breakdown of participants in stem cell clinical trials

Race	Number Analyzed	US Population
Native Americans or Alaskans	0.35%	1.30%
Asians	6.17%	5.90%
Native Hawaiian or Other Pacific Islander	0.18%	0.20%
Black or African American	8.82%	13.40%
White	78.80%	76.50%
More than one race	0.35%	2.70%
Unknown or Not Reported	5.32%	N/A
TOTAL	99.99%	100%

Ethnicity	Number Analyzed	US Population
Hispanic	10.25%	18.30%
Non-Hispanic	85.47%	83.90%
Unknown or Not Reported	4.40%	N/A
TOTAL	100.02%	102.20%

When comparing the percentages of race and ethnicity of the participants in completed clinical studies to the percentages of race and ethnicity of the US population information from July 2019 Census, we noticed a few discrepancies. For instance, while 0.35% of participants in trials are Native Americans or Alaskans, the number of Native Americans or Alaskans in the USA is much higher – 1.30%. Black or African-American participants comprise 8.82% of all patients in stem cell trials, while Black or African-Americans are 13.4% of the US population. In addition, trial participants from more than one race are 0.35% of the analyzed patients in stem cell clinical trials, while total number of more than one race individuals is 2.7% of the US population. 10.25% of the analyzed participants are Hispanics, while the percentage of Hispanics in the US population is 18.3%. Based on the analysis, our overall observation is that American Indians or Alaska Natives, Black or African Americans, more than one race patients, and Hispanic patients are under-represented in stem cell clinical trials in the US (Figure 1).

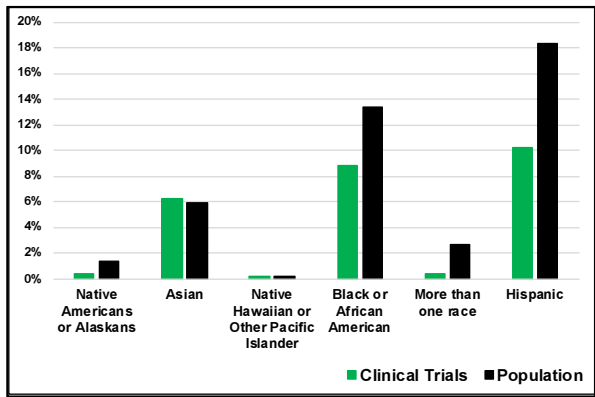


Figure 1. Racial and ethnic % of participants clinical studies on ClinicalTrials.gov vs. structure of US population in 2019.

4. Discussion

In this study we were able to utilize vast data repository of structured records of clinical trials to identify patient representation disparities. This study represents an instructive use case of potential approaches for mining these records using informatics approaches. Thousands of international and US-based stem cell clinical trials are featured on ClinicalTrials.gov – a publicly available clinical trials registry. These studies incorporate projects funded by NIH, other federal agencies, industry, and other sources. These studies are interventional, observational, patient registries, individual patients, and treatment protocol clinical trials, which include female and male participants. Over 90 distinct types of trials seek medical solutions for respiratory, cardiac, and other syndromes, as well as for many cancers. While numerous challenges complicate the recruitment process for many of these clinical trials, significant efforts must be made not to just recruit, but to track race and ethnicity.⁸ Our current analysis concludes that American Indians or Alaska Natives, Black or African Americans, more than one race patients, and Hispanic participants are under-represented in stem cell clinical trials. Previously, genetic profiles of patients from different races and ethnicities have shown to contain allelic polymorphisms. These polymorphisms have a critical impact on clinical

treatment of the patients in terms of drug metabolism/sensitivity, medical treatments, and donor/recipient compatibility of organ and other transplants. To offer the best genetic matches in the stem cell products during regenerative medicine trials, there is a need to ensure best outcomes of racial and ethnic diversity of clinical trials' participants.⁹

5. Conclusions

In previous studies, it has been shown that patients' genetic profiles influence their drug metabolism and capacity to receive optimal drug treatment, for instance, where variations of alleles vary amongst races and ethnicities. Having an adequate representation of races and ethnicities would allow patients to receive the best possible treatments in medical trials, which includes stem cell clinical trials.

Acknowledgements

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A 3D Surface Fitting Layout for Complex Networks Visualization

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Abstract. Large datasets visualization, prevalent in Bioinformatics, is a challenging task. Simple 2D layouts sometimes offer too many details to be instantly helpful, while filtering might remove critical information. Extension to 3D seems like the logical answer, however, in order to capture the complex relationships between data, the third dimension should reflect inherent properties. This paper proposes a novel method to generate 3D parameterized layouts, by using a function to correlate the *Oz* axis and biospecific features.

Keywords. Complex networks, visualization tools, 3D surface fitting

1. Introduction

Beyond a certain order of magnitude, human brain cannot fully extract useful information out of studied data [1] and data visualization techniques are used to circumvent that. Representation layouts arrange the data according to different criteria [2] in a relevant manner for large data sets. Combined with complex networks usage as a common means of arranging data [3] this approach seems to bring the Bioinformatics data together while emphasizing connections between nodes (e.g.: genes, proteins, compounds), and cluster formation [4] [5] (e.g: related genes, chemical compounds, drug families, etc).

Many network visualization tools have been developed lately: Gephi, Python's NetworkX, R's iGraph, D3.js's D3-3D plugin. Most offer different approaches to representing data from basic metrics (node degree, betweenness/closeness centrality, etc.) to force directed visualization algorithms such as Force Atlas 2 (FA2) [6], Fruchterman-Reingold [7], OpenOrd, etc.

Visualizing 2D genetic / biologic data as networks presents no obvious vertical hierarchy between vertices (genes / compounds) other than their visual size, proportional to a certain graph-specific metric. 3D networks can take advantage of spatially scattering graph elements, highlighting the distance and correlation between them [8]. However, specifically in large biological networks, there are no spatial landmarks to help the researcher interpret the 3D position of a certain node [9].

The aim of this paper is to offer more meaning to 3D network layouts in a biomedical context, i.e. to generate with the help of Octave a new type of layout which uses the *Oz* axis as a true 3rd dimension, giving the viewer a depth perception into data and revealing meaningful or even missing correlations, among genes and proteins.

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2. Methods

We have defined a 3D parabolic surface and dispersed graph nodes over it, maintaining predefined links between them, and fitting the surface equation. A characteristic emphasized is the nodes hierarchy, by positioning them into concentric circles around the centre vertical axis of the parabola. Once we associate one network metric (degree, centrality, etc.) to the Oz axis, then the importance of vertices is directly proportional to their z value. In addition, each concentric circle composing the parabola corresponds to a hierarchical level and all vertices considered equals in terms of the chosen metric lie on the same z -level and circle.

The data set used throughout this experiment consists of a medium-sized set of DNA genes and proteins with role in transcription regulation for E.coli [10]. Some basic network characteristics are: nodes (N): 424, edges (K): 519.

The selected tool for network layout rendering is GNU Octave [11]. Data characteristics of the network can be chosen as dominant (degree) to establish the value of each vertex on the Oz axis. As such, we have defined the equation of the 3D space (a parabola) which will then be used to calculate the position of each vertex in the graph:

$$z = a - x^2 - y^2 \quad (1)$$

Assuming the z values correspond to the *degree* metric, *Fig. 1. a* shows the distribution of nodes alongside the 3D surface in comparison with a Gephi OpenOrd layout (*Fig. 1. b*). Substituting z with degree values, we can calculate the x and y values such that they satisfy a circle equation $x^2 + y^2 = a - z$ of radius $r^2 = a - z$ and $O(0,0)$ is the centre.

3. Results

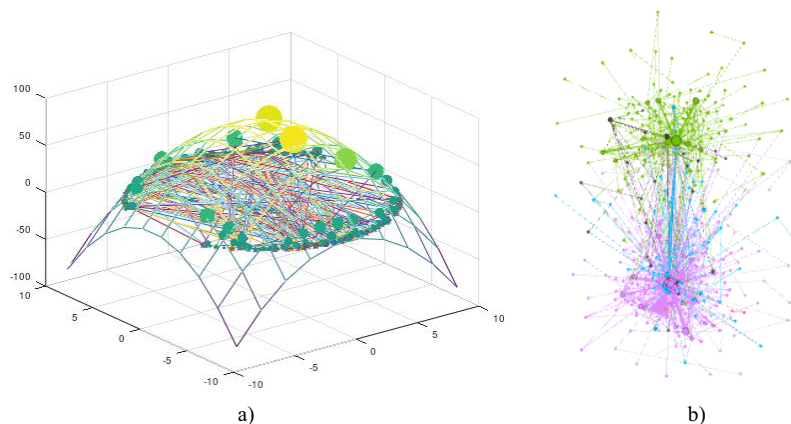


Figure 1. Graph layout rendered in a) Octave with 3D surface fitting b) Gephi

Although the Gephi (semi) 3D layout *Fig. 1. b* looks more structured and clustered, the user does not have a spatial differentiation between nodes and cannot for example quantify their importance (in the process of transcription regulation) in comparison with each other aside from node size and colour. On the other hand, in *Fig. 1. a* there is a true 3D distribution of nodes.

Considering Fig. 2 it is clear that this method also needs improvement in terms of node clustering. However, there is an important visual indicator showing the rank of each node which is equivalent to the importance of each gene with regards to the whole genetic mechanism. The larger the bubble and the closer it is to the centre, the more the user gets the idea of how essential that vertex is according to the chosen discriminating metric.

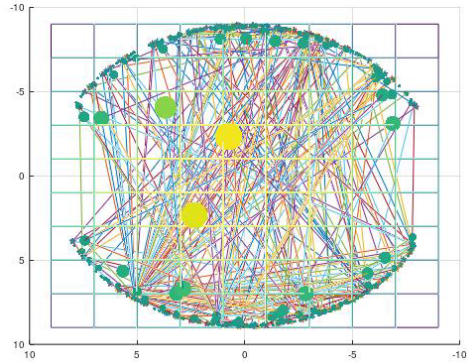


Figure 2. Graph layout rendered in Octave with 3D surface fitting – 2D view from above

4. Discussion

In order to determine how this new approach to data visualization differentiates from other existing ones, we have graded it according to certain subjective criteria. For this purpose we have chosen a basic comparison with Gephi (OpenOrd algorithm) considered to be the current standard in complex networks visualization. [9].

Table 1. Evaluation table

Criteria	Data set 3D implementation	
	Gephi	Octave
Speed	3	2
Visual appeal	4.5	3.5
Relevance/Utility	3.5	4
User friendliness	5	3.5
Customizability	3	4.5
ML capability	0	1
No programming skills required	1	0
Interactivity 0 (No)/ 1(Yes)	1	1*
Totals	21	19.5

All criteria have been evaluated according to empirical tests. In terms of speed, medium sized networks behave similarly. With Gephi (FA2, OpenOrd algorithms), average processing time for such a bio network ($N < 1000$) ranges between $t \in [5,10]$ seconds. With the new Octave 3D implementation however, since for this study we have not used optimized networks frameworks, rendering times are admittedly slower, $t \in [7,11]$ seconds. Visual appeal is subjective, yet based on the direct feedback of a small group of subjects (10 data specialists). Simplistic graphics in Octave do not outrank Gephi’s UI and this is directly proportional to user friendliness. Relevance/Utility is the category where the proposed algorithm aims to bring improvements and although not surpassing its competitor by much, it seems that the 3D innovation factor gives it an edge.

Customizability and ML capability are two strong points in Octave's arsenal which is specifically designed for mathematical and programmatic purposes, with the cost of requiring programming skills. Both tools are interactive, yet Gephi excels in this area.

5. Conclusion

In this paper we presented a new approach to 3D biological graphs visualization in a parameterized manner. This comes as an alternative to regular 3D visualization tools which fail to spatially structure the elements of such networks. 3D surface fitting graphs maintain classical attributes such as: node size and color, spatial distance between nodes, grouping nodes according to genetic similarity coefficients, biological role, etc. On larger networks, if the resulting figure risks becoming too crowded, node distribution can be adjusted by defining a composed metric so as to include more genetic specificities (upward/downward regulation role of a gene/protein, activation time, the probability of a gene playing a part in multiple metabolic processes, etc).

The most important advantage of the method proposed here is that it offers a parameterized view into 3D network visualization which helps give more insight into node position and hierarchy according to chosen criteria. Currently, the proposed technique is still under development and can be further improved to better accommodate the representation and customization of more diverse topologies.

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Using Big Data to Predict Outcomes of Opioid Treatment Programs

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Abstract. Potential of big data analytics in analyzing outcomes of opioid treatment programs (OTP) has not been fully explored. The goal of this study was to assess potential of big data in predicting OTP outcomes based on the initial intake forms which includes demographics, social and health history. The analytical sample comprised over 30,000 people admitted in OTP. Around 66% of patients reported improvements after completing OTP. We compared the results of Logistics Regression, Random Forest, and XGBoost for predictive modeling. XGBoost with sampling and threshold tuning performed the best (44% F1 score) with over 60% accuracy. Further big data exploration of OTP is warranted.

Keywords. Opioid Treatment Program, Big Data Analytics, Machine Learning

1. Introduction

Due to the persistent use of heroin and over-prescription of opioid drugs, opioid addiction has become a serious and pressing issue in recent years. According to CDC, both prescription opioid and heroin overdose deaths are on the rise since 1999 [1]. In 2017, there were over 17,000 overdose deaths of prescription opioids, and over 15,000 overdose deaths of heroin [1]. Not only are most opioid abusers exposed to high risk of contracting infectious diseases, but also they are at risk of developing other mental illness [2-3]. Apart from health concerns, the opioid crisis also exacerbates financial hardship for users. According to the book ‘Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment’, heroin users spend over \$5 billion dollars on drug-related legal fees [4].

While the extent and prevalence of opioid addiction are widely studied by the medical world, research on the effectiveness of opioid treatment programs (OTPs) are sparse. There are a fair amount of studies on various drugs used to treat opioid addictions. As early as 1965, methadone was one of the first drugs and the most frequently used medication by far for opioid addiction treatment programs [4]. In 2002, the FDA approved buprenorphine for use in medical maintenance treatment and medically supervised withdrawal [4]. It can be used in OTPs and prescribed by qualified physicians.

AIMS is a unique database that contains patients’ admission, transfer, update and discharge records from the Mount Sinai Health System (MSHS) opioid treatment programs of the New York State area since the 1960s. The database also contains patients’

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medications, daily intake logs and drug screen information. By studying the AIMS database, we hope to provide descriptive statistics of patients who enrolled in the program, construct predictive models to identify frequent offenders and to evaluate the effectiveness of the program for different types of patients.

2. Method

2.1. Dataset

Data was collected from the New York State Office of Addiction Service and Supports' (OASAS), Opioid Treatment Program. Only patients' information who received treatments at MSHS was collected. We accessed the data in 2019, so it included admission records from May 25th, 1965 to Oct 31st, 2018. There were 5 major updates of the admission form since 2000. Thus, for predictive modeling, we only included admission records after Oct 1st, 2014. Some patients were readmitted to the program multiple times. Since their conditions are different at each admission, we assume independence and treat each admission individually.

2.2. Variables

In predictive modeling, we used the difference of primary substance frequency between admission and discharge to determine patients' treatment effectiveness. We divided the difference of primary substance frequency into two levels: patients with 0 or negative difference of primary frequency were considered treatment ineffective (Label = 1); patients with positive difference of primary frequency were labeled as 0.

We only kept records where the primary abuse substance is opioid related drugs. Furthermore, records with missing values of primary frequency at admission or discharge were discarded.

Most information obtained through the admission form was used as predictors. We excluded identifiers, variables that were added in 2017 and variables with 50% or more missing values. We used patients' socio-economic status, living situations, education levels and health conditions. We defined age at admission (AGE) using admission date and date of birth. Speech, hearing, sight and mobility impairments were combined into one variable impairment (IMPAIRMENT). Impairment was a Boolean value. It was true if a patient has one or more types of impairment and it was false if a patient has no impairment. Status of Hepatitis B and status of Hepatitis C were combined into infectious disease (INFECTIOUS) by similar rules.

The project has been approved by institutional ethics board. In exploratory data analysis, we calculated summary statistics. In prediction, we randomly split the data into train (75%) and test (25%) datasets and used 5 fold validation to tune parameters. We adopted logistic regression, random forest and XGBoost, and compared the results of these models. All analyses were performed in Anaconda Jupyter Notebook, using Python 3.7.3.

3. Result

Over 30,000 patients and 46,000 admission records were included in the sample. Around 11,000 patients were admitted to the program more than once. The earliest record was from 1965 and the latest record was from 2018. According to Figure 1, while the number of clinics remained constant since 1970, the number of admissions increased drastically since 2001 and became stable after 2008.

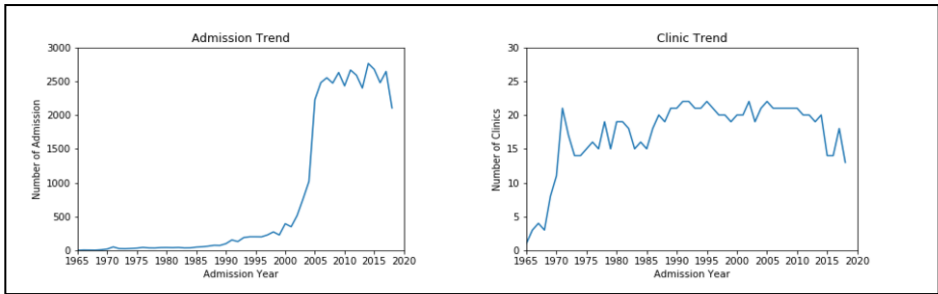


Figure 1. Number of admission records and number of clinics by year from 1965 to 2018.

The average age of patients at admission was 42 years old. Around 22,000 patients enrolled in the program were male, while only 7,700 of them were female. Around 75% of patients listed heroin as their primary abuse substance. And over 80% of these patients would consume heroin on a daily basis. The two most frequent routes of intake were through inhalation and injection. Furthermore, over 60% patients were addicted to more than one substance.

In toxicology, around 44% of drug tests detected illegal substances in patients’ systems which required further actions. Opiates, benzodiazepines and cocaine were the top 3 most frequently detected drugs. Some patients used several drugs concurrently. Combinations of these drugs were also commonly detected among patients. When constructing machine learning models, we used the difference of primary substance frequency between admission and discharge. During admission, over 80% patients reported using opioid drugs daily. This number decreased to 24% at discharge. 66% of patients showed improvement after treatment, while 30% of patients had no change and 3% of patients used more frequently after treatment.

We compared the results of logistics regression, random forest, and XGBoost. We adjusted the decision threshold, assigned class weight to minority class and employed sampling techniques to overcome the unbalanced dataset issue.

Table 1. Predictive models results.

	Baseline		Up Sampling		Threshold	
	F1 Score	Accuracy	F1 Score	Accuracy	F1 Score	Accuracy
Logistic	0.08	0.64	0.44	0.54	0.36	0.61
R.F.	0.21	0.62	0.24	0.6	0.43	0.52
XGBoost	0.07	0.65	0.45	0.57	0.22	0.63
Final Model	XGBoost + Up Sampling + Threshold			F1 Score: 0.44 Accuracy: 0.6		

Both logistic regression and XGBoost performed well (Table 1). While using sampling methods generally yielded a high F1 score, the accuracy of these algorithms were relatively low. Meanwhile, the threshold method was good at retaining accuracy, while also improving F1 score. Thus, we combined these two methods together. Our final model used XGBoost with both up sampling and threshold tuning. The model F1 score was 44%, with a 60% of accuracy.

4. Discussion

Based on logistic regression and XGBoost, both models indicated that standard opioid treatment programs are less effective on patients with brain injury or other health conditions. Since patients are required to go to the clinic 6 days a week to obtain treatment, patients with health conditions might find it hard to adhere to such a vigorous schedule. These patients would also require special medical attention throughout the treatments. In addition, patients who used cocaine concurrently with opioids showed less improvement than those that had not used cocaine. In contrast, patients who were referred by the chemical dependence treatment showed better results. These patients may have received previous treatments in other programs or are more prepared for the outpatient chemical dependence treatment format.

5. Conclusion

We analyzed the trends of admission to the OTPs for the past 50 years. There was in a significant increase in admission in the early 2000s and the number of admissions has been constant for the past 10 years. Around 66% of patients reported improvement after treatment. In predictive modeling, we constructed a machine learning model to identify patients who might not be treated effectively by the OTPs, so that additional care could be provided. XGBoost with both up sampling and threshold tuning is our best model with 44% of F1 score. Through this model, we identified that patients with brain injury or other health conditions and patients who use cocaine concurrently required additional help for continuous treatment.

AIMS is an important and complex database. In future studies, we plan to incorporate patient's medical histories into analysis and evaluate the effectiveness of the treatment program through multiple aspects.

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Classification of Intracranial Hemorrhage Subtypes Using Deep Learning on CT Scans

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Abstract. Intracranial hemorrhage is a pathological condition that requires fast diagnosis and decision making. Recently, a neural network model for classification of different intracranial hemorrhage types was proposed by a member of our research group Konstantin Kotik as part of the machine learning competition at Kaggle. Our current pilot study aimed to test this model on real-world CT scans from patients with intracranial hemorrhage treated at N.N. Burdenko Neurosurgery Center. The deep learning model for intracranial hemorrhage classification based on ResNeXt architecture showed an accuracy of detection greater than 0.81 for every subtype of hemorrhage without any tuning. We expect further improvement in the model performance.

Keywords. Intracranial hemorrhage, deep learning, neurosurgery, computed tomography

1. Introduction

Intracranial hemorrhage is a pathological condition that requires fast diagnosis and decision making [1]. The common subtypes of intracranial hemorrhage are subarachnoid hemorrhage (SAH), intraparenchymal hemorrhage (IPH), subdural hemorrhage (SDH), epidural hemorrhage (EDH) and intraventricular hemorrhage (IVH). Traumatic brain injury, cerebrovascular pathology, arterial hypertension, and even surgical intervention may be complicated by any type of bleeding or their combination. Computed tomography (CT) is a fast and reliable diagnostic tool for acute hemorrhage detection. The automation of hemorrhage detection in CT scans with computer-assisted technologies might be helpful in objectifying findings and speeding up the decision on treatment. However, the amount of neuroimaging data available for the development of these solutions is commonly limited [1].

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Recently, a neural network model for classification of different intracranial hemorrhage types was proposed by a member of our research group Konstantin Kotik as part of the machine learning competition at Kaggle (31st place out of 1345 possible, <https://www.kaggle.com/c/rsna-intracranial-hemorrhage-detection/overview>). The aim of our pilot study was to test this model on real-world consecutive CT scans from patients with intracranial hemorrhage treated at N.N. Burdenko Neurosurgery Center.

2. Methods

2.1. Model description

The solution introduced for the Kaggle competition was based on ResNext model - a simple, highly modularized network architecture for image classification [2]. A special instance of ResNext (se_resnext50_32x4d) was used with Adam optimizer and multi-label logarithmic loss function (negative log-likelihood function for several classes). “SE” in the model name stands for the “Squeeze-and-Excitation” block, which adaptively recalibrates channel-wise feature responses by explicitly modeling interdependencies between channels. Stacking these blocks together enables the construction of architectures that have only a few hyper-parameters to set and generalize well across challenging datasets. This strategy exposed a new dimension called “cardinality” (the size of the set of transformations), as an essential factor in addition to the dimensions of level and width. The final model was designed as the average of two models stacked and fitted during 3 epochs.

In the Kaggle competition, this solution was developed on a training dataset of 674.258 labeled DICOM images (CT scans). The data were preprocessed (corrupted Rescale Intercept Attribute of DICOM file set to -1000, images of 512x512 size rescaled), and appropriate window level (40 for brain, 80 for blood, 40 for soft tissues) and window width (80 for brain, 200 for blood and 380 for soft tissues) were applied. The image augmentations (horizontal flip, random crop, brightness, contrast, random rotate within 30 degrees) and test-time augmentation were used. The model was tested in a private dataset of 752.807 DICOM files resulted in a weighted multi-label logarithmic loss equal to 0.05098.

2.2. Real-world clinical dataset

A dataset of 300 CT series (32-64 images in each) from patients with hemorrhage and 101 CT series with patients with no intracranial bleeding and minor intracranial pathology were consecutively selected from the PASC archive of N.N. Burdenko Neurosurgery Center. The initial consecutive selection of data for screening was performed by a data engineer using context search (with keywords related to hemorrhage defined by a radiologist) to exclude any selection bias related to the pathology preferences coming from doctors. One junior radiologist did the screening of CT scans under the supervision of a senior doctor. The output of expert screening was the classification of 401 CT series by five subtypes of intracranial hemorrhage: epidural, subdural, subarachnoid, intraparenchymal, intraventricular. The data scientists were blinded to the complete diagnosis, full image annotations, and other medical data until the end of the test. The numbers of positive (POS, series with hemorrhage) and negative (NEG, series with no hemorrhage) classes, accuracy (ACC), precision (PREC, also

referred to as positive predictive value), recall (REC, also referred to as sensitivity), area under ROC-curve (AUC) and logarithmic loss (LOG_LOSS) were computed to evaluate model performance.

3. Results

The statistics on five hemorrhage subtypes classes in our dataset and quality metrics of model predictions are shown in Table 1.

Table 1. The quality metrics of classification for different types of intracranial hemorrhage.

Hemorrhage subtype	POS	NEG	ACC	PREC	REC	AUC	LOG_LOSS
Epidural	99 (25%)	302 (75%)	0.828	0.660	0.626	0.762	0.849
Subdural	83 (21%)	318 (79%)	0.818	0.566	0.518	0.711	0.896
Subarachnoid	118 (29%)	283 (71%)	0.820	0.829	0.492	0.748	0.881
Intraventricular	137 (34%)	264 (66%)	0.893	0.952	0.723	0.804	0.890
Intraparenchymal	188 (47%)	213 (53%)	0.835	0.868	0.766	0.803	0.941

The overall quality of classification of each hemorrhage subtype is shown in Figure 1.

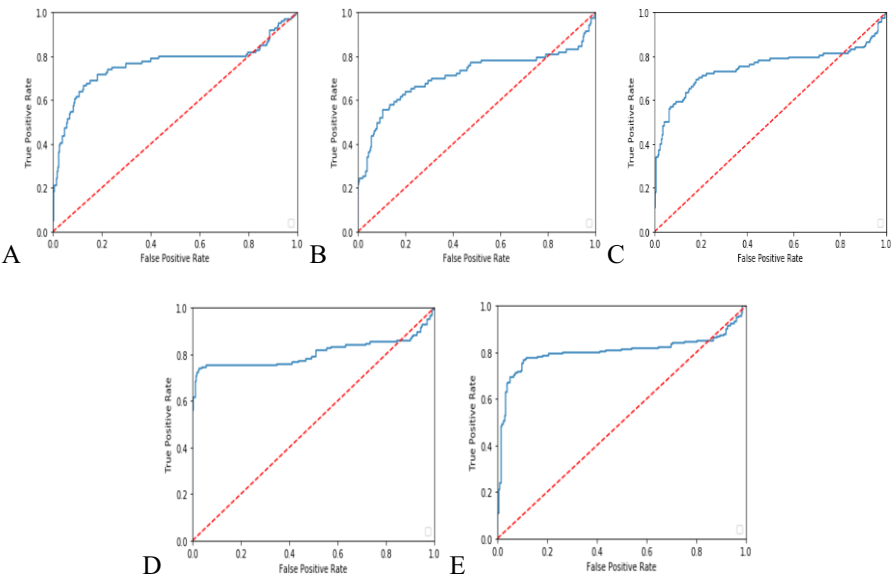


Figure 1. The relationship between true positive and false positive rate for different types of intracerebral hemorrhage: A – Epidural, B – Subdural, C – Subarachnoid, D – Intraventricular, E – Intraparenchymal

Hemorrhage was verified in 300 studies performed once or repeatedly in 260 patients (avg. age 41.8 ± 18.8 years, 148 (56.9%) men, 243 (81.0%) operated during the hospital stay). Seventeen studies were done in non-operated patients, 24 - before the day of the first surgery, 63 - on the surgery day and 195 - in the postoperative period. The primary diagnosis in most of the cases was related to brain tumors ($n = 96$), cerebrovascular

pathology (aneurysms, arteriovenous malformations, hypertensive stroke, $n=78$), and traumatic brain injury ($n = 69$). Since the selection of images was made with broad inclusion criteria, the other lesions and artifacts were found on 141 (35.2%) CT scans in addition to hemorrhagic signals including ventricular shunts and drainages – in 60 (15.0%) cases, intracranial pressure sensors - in 15 (3.7%), artifacts from other metal devices – in 47 (11.7%), other artifacts – in 6 (1.25%), poor series quality – in 6 (1.5%) cases.

4. Discussion

We presented the direct pilot implementation of the ResNexT-based model for intracranial hemorrhage classification. We designed our experiment on the real-world dataset without special optimization to understand whether the model derived from Kaggle competition could be generalizable and demonstrate the efficiency in clinical routine, as well as explore the straightaway quality of such an “out-of-box” solution. In contrast to Kaggle data, our raw CT scans contained specific signals the model had probably never seen before. However, our first results are consistent with those from other similar studies (using Convolutional Neural Networks, Long-Short Term Memory Networks) in terms of precision (more than 0.66) and recall (more than 0.75) [1], [3]–[6]. There is still room for tuning the solution (windowing, test-time augmentation, dataset exploration), so an increase in its performance is expected.

5. Conclusions

The model for intracranial hemorrhage classification tested on real-world CT scans without any tuning showed an accuracy of detection greater than 0.81 for every subtype of hemorrhage. The further improvement of the model is expected.

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Public Private Partnerships Delivering Smart Health to Combat the Tsunami of Noncommunicable Diseases

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Abstract. Key noncommunicable diseases (NCD) such as cardiovascular disease, diabetes, cancer and chronic respiratory disease are responsible for 71% of all deaths worldwide. Many of these deaths are premature and impact low- and middle-income countries (LMIC) the most. The economic realities in LMICs and their greater reliance on development assistance hinder investments in public health to adequately prevent risk factors for NCDs or manage established disease. Public private partnerships (PPP) can deliver smart health solutions to improve the health outcomes of those at risk of NCDs and those who have an illness. These solutions can range from simple digital concepts to complex technology constructs that can utilize artificial intelligence to intervene at many touch points along the patient journey. We present three case studies of smart health deployed through PPP to try improving outcomes.

Keywords. Smart Health, Digital Care, Public Private Partnership, Noncommunicable Diseases

1. Introduction

Around the world, someone dies prematurely every two seconds as a result of cardiovascular disease, diabetes, cancer and chronic respiratory disease. These four groups of illnesses, characterized by their long duration and generally slow progression, represent the key noncommunicable diseases (NCD). They are responsible for more than two-thirds (41 million) of all deaths every year worldwide. 15 million of NCD-related deaths are premature, occurring between the ages of 30 and 69. Over 85% of premature deaths are in low- and middle-income countries (LMIC) [1]. NCDs are a health crisis and appropriate action needs to be taken. The United Nations' Sustainable Development Goals (SDG), adopted in 2015 by all 195 member states, include the target of reducing premature NCD mortality by a third by 2030 [2]. However, the WHO reports that many countries are falling behind and may not be able meet this and other SDG targets [3]. Governments need to allocate a percentage of gross domestic product to address NCDs. However, many LMIC-governments are not able to meet this financing need and rely on development assistance for health (DAH). Unfortunately, not enough of DAH is allocated to NCDs. In 2018 this was less than 1% of the \$38.9

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billion provided [4]. This is one of several factors that contribute to SDG targets not being met.

2. Methods

The private sector and its for-profit businesses, as health stakeholders, have an interest in reducing the burden of illness. Pharmaceutical companies can work with health providers, both public and private, to prevent and manage disease. Embracing the role of the private sector, Pfizer launched Upjohn as a division dedicated to the fight against NCDs through a focused, strategic, and collaborative approach across the healthcare value chain [5].

Public private partnerships (PPP) have successfully demonstrated the catalysis of prevention, access and delivery of care for communicable diseases by providing complementary strengths [6]. Drivers for PPPs include overcoming constraints on government budgets and obtaining innovation through the private sector's enhanced capability [7].

Information and communication technologies (ICT) provide significant utility for the health sector. ICTs can foster patient-centered healthcare, improve the quality of care that provided, and educate health care practitioners and their patients [8].

Upjohn used both these concepts, PPPs and ICT, to address the burden of NCDs. It has partnered with health care providers to leverage ICT, from simple technology constructs such as augmented reality through to more advanced technologies like artificial intelligence, to address challenges and improve outcomes in NCDs. The approach to PPP was simple. Upjohn, as the private sector partner, was responsible for project design, financing and delivery while the public sector participant owned and operated the initiative.

2.1. Case Study - Augmented reality to overcome clinical inertia in hypertension management

Clinical inertia is implicated in poor modification of risk factors for cardiovascular disease, with almost half those with hypertension observed to have inadequate blood pressure control. A recent review showed that strategies such as physician reminders and educational interventions are effective in reducing clinical inertia and improving hypertension management [9].

Upjohn created materials embedded with augmented reality (AR) to better engage and inform healthcare providers and, help overcome clinical inertia. Figure 1 demonstrates how a brief animated video on blood pressure variability (BPV) is triggered by using a smart phone with an AR app. This material was used when detailing to physicians in their offices and at scientific meetings. The novelty of AR is an engaging aspect of a two-dimensional infographic that aims to remind physicians of the cardiovascular risk of hypertension, highlighting the importance of BPV.



Figure 1. Augmented Reality Material.

2.2. Case study - Leveraging multiple technologies to create a disease management program that improves diabetes outcomes

Joint Asia Diabetes Evaluation (JADE) combines several technologies to create a disease management program, that has been shown to improve clinical parameters in the management of diabetes [10]. JADE employs a web-enabled patient registry to capture structured clinical information; a risk engine to offer prioritised, evidence-based decision support protocols to clinicians; and data-mining to create graphical reports for patients and clinicians, which promote shared decision-making and foster therapeutic alliances.

The JADE model has improved clinical outcomes in 12 countries and regions across Asia – China, Hong Kong, Taiwan, Singapore, Malaysia, Thailand, Philippines, Korea, Macau, Indonesia and Brunei. Interventions have shown better clinical outcomes for diabetes than traditional care, as well as improved control of cardio-metabolic risk factors [11].

Upjohn partnered with the creators of JADE to make it smartphone-enabled for easier access to reports; for data inputs; and to further enhance shared management.

2.3. Case study - Artificial intelligence (AI) empowering patients with diabetic peripheral neuropathy to seek clinical intervention

The clinical impact of diabetic peripheral neuropathy (DPN) is profound. A significantly diminished quality of life results from painful neuropathic symptoms and neuropathic deficits (which include ataxia and weakness leading to falls, fractures and lacerations). Mortality is increased through foot ulcers and infections [12][13]. Diabetic neuropathy is commonly underdiagnosed. For every missed diagnosis due to gaps in knowledge, ten others are missed for lack of examination [14].

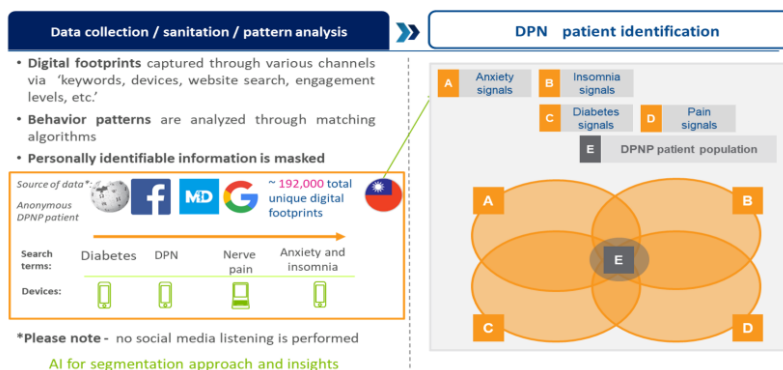


Figure 2. Using AI to improve awareness and management of DPN

In partnership with stakeholders in diabetes care (endocrinology/diabetes medical society and specialist clinicians), Upjohn used AI to identify, inform and engage patients to manage diabetes complications. Online behaviours were analysed with pattern recognition technology to identify and segment those with specific complications of diabetes.

Patient archetypes were then micro-targeted with tailored messaging via relevant media to foster engagement with clinicians (Figure 2). Linking sufferers with specialised clinicians affords early optimised management of diabetes complications that, if left unchecked, can result in significant disability.

3. Results

The objective of overcoming barriers to try reducing the burden of NCDs, such as public sector budget constraints and capacity for innovation were achieved in each of the case studies.

The effectiveness of the specific educational intervention using AR in changing physician behaviour is yet undetermined, but Dirksen and colleagues have asserted that providing direct, immediate guidance at the point of need is unquestionably a well-proven strategy for behavior change [15].

With JADE, putting technology directly in the hands of the patients, encouraging greater patient buy-in while also serving as a tool for those in the medical field helps innovate diabetes care. It also provides patients with access to their data to boost ownership of their own health and encourage dialogue between the patient and their doctor.

The partnership to help diagnose and manage DPN worked well. However, no conclusion can yet be made about the impact health outcomes as enough time has not passed.

4. Discussion

There is a need to effectively catalyze action around a health crisis that is as complex and wide sweeping as that due to NCDs. No single sector can do it alone, especially in LMICs. It is time for multilateral organizations, academia, governments, civil society

organizations, healthcare providers, and the private sector to step up in unison with a new level of urgency and impatience to curtail this soaring public health epidemic.

Embracing the role of the private sector, Pfizer launched Upjohn as a division dedicated to the fight against NCDs through a focused, strategic, and collaborative approach across the healthcare value chain. In this paper, three initiatives are described where PPPs can leverage available technology to improve health outcomes along various touch points of the patient journey, from health literacy and awareness to diagnosis and treatment. We encourage similar partnerships to enable patients to live longer, healthier lives.

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Introducing an Ontology-Driven Pipeline for the Identification of Common Data Elements

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Abstract. Common Data Elements (CDEs) are necessary for ensuring data sharing across studies, providing comparability, and enabling aggregation and meta-analyses. The process of developing a set of CDEs for a given clinical research area has typically been arduous and time-consuming. In this work we introduce an automated pipeline that can greatly aid the process by identifying, aggregating, and ranking relevant CDEs from the outcomes of studies registered on clinicaltrials.gov (CTG). The pipeline uses the Medical Subject Headings (MeSH) ontology to group and rank candidate CDEs by specific diseases. The initial CDE pipeline has been tested using an emerging research domain. The resulting CDEs output was aligned with the current recommendations in the corresponding subject area. Further development of automated means for CDE generation based on structured information from CTG and MeSH is warranted.

Keywords. Common Data Elements, MeSH tree, clinical trials, outcomes, automated data extraction, xml, clinicaltrials.gov.

1. Introduction

A major ongoing challenge in the design of clinical trials has been the lack of consensus on which common outcomes the trials should measure. The importance of developing common data elements (CDEs) has been strongly emphasized in the literature [1]. CDEs can help researchers conduct cross-study aggregations and comparisons, facilitate meta-analyses, and increase reproducibility and efficiency. An important objective for research informatics is to develop automated and semi-automated approaches that can identify relevant candidate CDEs, aggregate, rank, and visualize them so that subject-matter experts can make maximally-informed decisions when planning clinical trials and proposing CDEs across several projects.

The aims of this project is:

- 1 - Introduce an automated pipeline that collects data from ClinicalTrials.gov and parses and ranks trial outcomes to identify potential CDEs, and presents those CDEs by disease groups.

- 2 – Present results from our evaluation of the resulting CDE pipeline on an illustrative use case in an emerging research subject area.

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2. Methods

The main data source we use is ClinicalTrials.gov (CTG), a database of clinical studies maintained by the U.S. National Library of Medicine [2]. In addition to the user-interface, CTG provides a RESTful Application Programming Interface (API) that facilitates the automation of query submission, and returns the records in XML. This allows for easier automated parsing of study attributes. The specialized ontology *Medical Subject Headings* (MeSH) [3] maintained by U.S. National Library of Medicine (NLM) was used to categorize ClinicalTrials.gov records. An overview of the pipeline can be seen in figure 1. The input to this pipeline is a subject area or a broad term that the system submits to CTG as a search query, each search result is automatically downloaded and parsed for MeSH terms and outcomes. The system cross checks the MeSH terms obtained against the MeSH ontology to identify disease terms and aggregate across related diseases. Data views showing mappings between diseases and outcomes are generated at different levels of granularity (sample output in tables 1, 2, and 3). We evaluated the cross-trial pipeline by collecting CDEs related to all **stem cell** clinical trials. We chose stem cells as an evaluation area due to it being a recent field with a need for CDEs. It is also a field where trials span many different diseases and disease groups allowing us to evaluate the MeSH ontology-based aggregation and filtering.

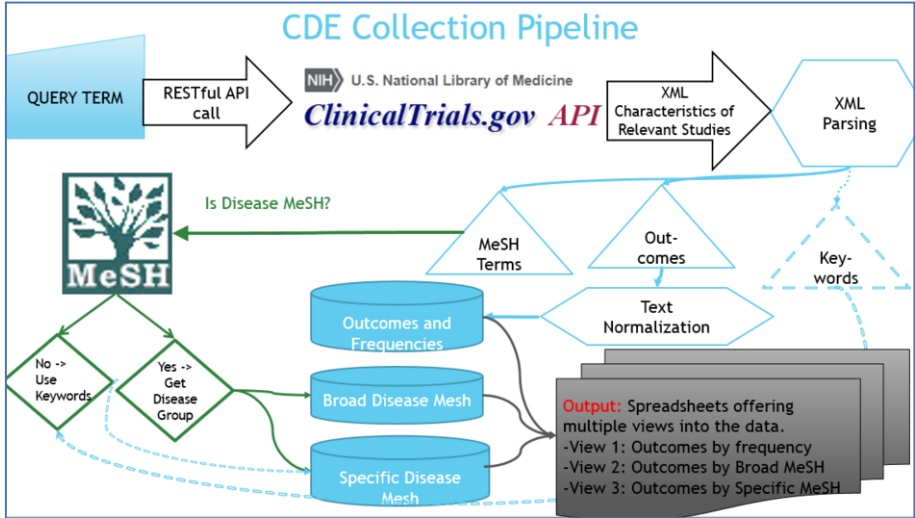


Figure 1. Steps involved in the CDEs Collection Pipeline

3. Results

3.1 Implementation of the Pipeline

We implemented the pipeline in Python 3.7. We used *urllib* library to submit the API requests, and the built-in *xml* library to parse the output from ClinicalTrials.gov. For the MeSH controlled vocabulary, the system processed the Excel file containing the data into dual mappings of node terms to numbers. The node numbers allow our system to (a) Identify which terms are disease-related (those with node numbers beginning

with ‘C’ or ‘F03’), (b) traverse the tree upward to group related MeSH terms together and aggregate outcomes across them.

We also implemented a text normalization module to handle slight variations in the way outcome names are recorded (e.g. “Event-free Survival” vs “event free survival (EFS)”, etc.). The module accounts for variations in capitalization, punctuation, and the inclusion of abbreviations.

3.2 Output of the Pipeline

With input query “stem cells” the pipeline downloaded data from 7,562 clinical trials. In total, 27,982 outcomes were identified, of which 8,934 occurred as primary outcomes, 19,781 occurred as secondary outcomes (and 733 occurred as primary outcomes in some trials and secondary in others).

Table 1. Most frequent outcomes of stem cells clinical trials. Sample view, truncated due to length limits.

Outcome	Number of Trials	Disease MeSH Terms Coinciding with Outcome, Frequency	CTG Registry Numbers of Trials With This Outcome
Overall Survival	1115	('leukemia', 373), ('lymphoma', 281), ('leukemia, myeloid', 210), ('multiple myeloma', 194) [...]	NCT03080922, NCT00597714, NCT01941394, NCT01404741, [...]
Progression-free Survival	499	('lymphoma',171), ('multiple myeloma', 136), ('neoplasms, plasma cell', 125) ,('leukemia', 103) [...]	NCT00597714, NCT02039778, NCT03283111, NCT03655145, [...]

Table 2. Sample from outcomes of stem cell clinical trials grouped by disease category (based on MeSH hierarchy), ranked by frequency. Sample view, truncated due to length limits

Broad Disease Group (with MeSH tree node)	Outcome	Number of stem cell trials With disease group and outcome
Neoplasms (C04)	Overall Survival (OS)	803
	Progression free survival	415
	Event-Free Survival (EFS)	207
	Disease-free survival	151
	Duration of response (DOR) [...]	107
Respiratory Tract Diseases (C08)	Overall Survival (OS)	6
	number of adverse events	5
	Changes of blood pressure in participants	3
	Growth measured by Z-score	3
	death from any cause [...]	3

Table 3. Outcomes of stem cell clinical trials by specific disease, ranked by frequency. Sample view, truncated due to length limits.

Specific Disease MeSH	Outcome	Number of Trials
Leukemia (C04.557.337)	Overall Survival (OS)	373
	Disease-free survival	117
	Progression free survival	103
	Non-relapse mortality (NRM)	62
Sclerosis (C23.550.823)	Safety	6
	Overall Survival (OS)	5
	Forced Vital Capacity (FVC)	4
	Expanded disability status scale 4	

4. Discussion

We can see from the results generated by the Cross-Trial Pipeline the wide variety of outcomes that have been used in stem cell clinical trials. For the 7,562 trials in CTG’s database, our pipeline was successful in collecting all the primary and secondary outcomes, grouping them by diseases and ranking them.

We can see that the top outcomes occurred hundreds of times across different studies. However, there were thousands of outcomes that occurred only once. Upon manual inspection of some of these, we found that some of them are semantically identical to more common elements but they appear unique because they are written in a specific way. For example, one of the unique outcomes is “Quality of life (QoL) assessment using the SF-36 questionnaire”. However, “Quality of Life” appears in 112 trials and “SF-36” appears in 7 trials. This means that seemingly unique items may not be unique and a more advanced NLP module might enable grouping such outcomes together. A rule-based approach employed in this project may limit current performance. The next steps will involve exploring approaches to enhance our CDE pipeline by introduction of machine learning techniques.

5. Conclusions

An automated system can greatly facilitate the process of identifying Common Data Elements by aggregating the primary and secondary outcomes of thousands of trials, grouping them by disease, and ranking them by frequency or other criteria, thus aiding the design of future clinical trials.

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Evaluating the Use of a PRO Questionnaire in Clinical Practice

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Abstract. Aalborg University Hospital in Farso uses data from a patient-reported outcome (PRO) questionnaire in order to predict if patients diagnosed with osteoarthritis will benefit from surgery. The purpose of including PRO in the decision-making is to ensure quality and transparency, to include patients in their own treatment, and to make the patients central to both the decision-making and the dialogue. Our evaluation of the use of the PRO questionnaire is based on the observation of patients filling out the questionnaire and interviews with 7 patients and a doctor. We found that there were several usability issues especially for the patients, such as navigation problems and a lack of consistency in the layout of the measurement scales. Furthermore, some questions were difficult for the patients to interpret. The interviewed patients did not report any value from answering the questionnaire. We argue that it may take more than filling out a questionnaire for the patient to feel involved in their own treatment.

Keywords. Patient-reported outcome; osteoarthritis; patient empowerment; PRO

1. Introduction

Patient-reported outcome (PRO) data contain the patient's systematic responses to questions about their health status and quality of life. The Danish definition of PRO is "patient-reported data relating to the patient's state of health including physical and mental health, symptoms, health-related quality of life and functional level" [1,2]. This definition resembles the one from the American Food and Drug Administration (FDA): "a PRO is any report of the status of a patient's health condition that comes directly from the patient without interpretation of the patient's responses by a clinician or anyone else" [3, p.2]. PRO data has been used for more than 20 years in Denmark as well as internationally, which means that hospitals, municipalities, and general practices are already working with PRO data. Danish PRO data is supposed to be collected electronically and can be used as a screening tool and/or a dialogue support tool to help the patient prepare for an appointment and to focus on the needs of the specific patient. PRO is also used with the aim of involving the patient in decisions regarding treatment. Furthermore, aggregated PRO data can be used for quality assessment and research as well as benchmarking and management.

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This paper is based on a student project and is carried out in collaboration with Aalborg University Hospital in Farsø [4]. Osteoarthritis is a degenerative joint disease and the most common chronic condition regarding the joints. Osteoarthritis occurs in people of all ages, but is most common in patients older than 65. It is stated that one in two adults will develop symptoms of knee osteoarthritis during their lives and one in four adults will develop symptoms of hip osteoarthritis by age 85 [5]. The use of PRO data can hopefully address the problem that 10-15% of all patients with knee osteoarthritis and 5-10% of all patients with hip osteoarthritis do not achieve the desired result after surgery [6]. Therefore, Aalborg University Hospital in Farsø uses information from PROs in order to predict if the patient will benefit from surgery [6]. The questionnaire is divided into two parts. One part focuses on the knees and the other part on the hips. Each questionnaire uses a combination of the Oxford Hip Score or the Oxford Knee Score and an EQ-5D Index questionnaire. The Oxford Hip and Knee Scores are a validated method and are devised as a joint-specific PRO [7]. The questionnaire consists of 12 questions regarding specific pain, joint problems, and activity limitations. In addition, the EQ-5D is an instrument from the 80's that has been used to describe, value and rate the health of patients. The doctor uses the data when a decision has to be made regarding the patient's future treatment. PRO looks at the patient's medical history and measures risk factors in order to create a data-driven value for the patient [6]. In this paper we examine how the users interact with the system and how they experience the use and usefulness of the system. We observe and interview 7 patients with osteoarthritis and one doctor.

2. Methods

We conducted field observations and interviews inspired by Contextual Inquiry [8]. The data collection consists of observing the patients answering the questionnaire and their communication with the attending nurse. Handwritten fieldnotes of the observed issues and frustrations were made during the observations. After the patients answered the questionnaire, they had their consultation with the doctor. We then conducted semi-structured interviews regarding their experience with the PRO and their dialogue/consultation with the doctor. The data from the interviews with the patient and the doctor were transcribed in order to code the data. Fieldnotes from the observations were included in the coding process. The coding is a mixture of concept-driven coding and data-driven coding [9]. The results of the data-analysis were contained within the following categories: usability, user experience, and value for the patient.

3. Findings

As a result of the usability study, we identified problems and issues regarding the measurement scales and navigation when the patients interact with the system.

There are three measurements scales: the first is for pain during an activity, the second is for pain during rest, and the third is regarding the patient's general health. The measurement scales are difficult to use for the patients, as there is a lack of visual consistency between the different measurements' scales. One is vertical, while the others are horizontal. We suggest that all measurement scales are organized horizontally and

furthermore that the scales would benefit from adding numbers or arrows for better navigation and usability.

Moreover, the general health question seems to be the hardest one to answer for the patient because “general health” is difficult to define, e.g., whether it is concerning this week, this month, or something else. Should the patient include if they suffer from back-pain, etc.? Recommendation for the general health scale is that it could indicate the criteria for each parameter in order to increase the patient’s understanding and usage.

The patient also had difficulties with the navigation in the questionnaire. We suggest a visual scroll-down indicator and a clearer progress bar. The patients are then aware of how far along they are in the process of filling out the questionnaire.

4. Discussion

The findings from the data analysis and evaluation do not only concern the usability, of the system. They also relate to the value PRO provides to the patients and the doctor.

During the interview the patients are asked about their experience in completing the questionnaire, e.g., “Do the questions in the questionnaire make sense to you?”; “Do you feel empowered/involved in your own treatment or do you feel any kind of value when answering PRO?”; and “Do you think that the use of the PRO gives you more co-determination in your own treatment?” While the patient generally expressed satisfaction with the visit at the hospital, the questionnaire, and the dialog with the doctor, the answers to the questions were not very specific. Thus, the patients provided us with answers such as “I think so”, “I am not sure”, “I do not know”, and “I guess so”.

One of the main purposes of the PRO, according to the Danish PRO secretariat, is to involve the patients in their care and to allow them to be active and autonomous participants in the decision-making process. The implicit assumption seems to be that filling out the questionnaire will stimulate reflection on their health, which again will lead to a better understanding of their own condition and increase patient empowerment. Based on this small study, it seems that the PRO does not fulfill this purpose; the patients state that it does not in any specific way create any value or make them feel more involved in their own treatment.

The data from the PRO questionnaire is used to calculate the Oxford Hip Score and is available on the doctor’s screen during consultation. Furthermore, data from other patients, with the same age, gender, and approximately the same Hip Score one year after surgery is presented. Whether the doctor will suggest having surgery depends not only on the HIP Score and statistics, but also on the patients use of painkillers, among other things. The patient must try painkillers before the doctor suggests surgery because the use of painkillers might allow surgery to be avoided.

Data is presented as graphs on the doctor’s screen, which are more easily communicated to the patients. However, the doctor does not always choose to show the data to the patients: “If I think that this patient will not understand what it is about, then I keep it out. If it is a patient who I think can understand, I use it as a basis for discussion.” For example, a case in which the doctor used the data as a basis for discussion was one in which surgery was recommended, but the patient had doubts. Patients might be so worried that the doctor might decide not to show them the data. When interviewing the doctor, we asked him if the PRO makes it easier for him to decide what treatment the patients would benefit from. He answered, “Not easier, just faster.” We also asked the doctor if his patients had experienced a greater satisfaction or increase in quality of life

if they have had surgery and the decision was based on PRO data. The answer was: “I do not know that, because we do not record whether the decision was taken for this or that reason. But perhaps we should do that in the future”.

5. Conclusions

We have examined the usability and usefulness of the PRO questionnaire and found several usability issues concerning the use of measurement scales and navigation. We offered suggestions for improving the consistency and navigation within the user interface. We also found that patients had difficulty interpreting the question on general health. Based on the interviews, we discussed the possible value of using the system from the perspective of both the patient and the doctor. Seen from the viewpoint of the doctor, the data and statistics generated from the questionnaires have a clear value in supporting the doctor's decision of whether to suggest having surgery and, in some cases, in communicating with the patient. Seen from the perspective of the patients, the value of the PRO data is less clear. Based on our small study it seems that answering the questionnaire does not add value to the patient's experience of their health situation. We suggest that there is a need for better information about the role of the questionnaire data in the treatment process. More in-depth studies are needed to understand how patients might be influenced by answering the questionnaires and the role of PRO data in the consultation process.

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Obstructive Sleep Apnea: A Prediction Model Using Supervised Machine Learning Method

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Abstract. Obstructive Sleep Apnea (OSA) is the most common breathing-related sleep disorder, leading to increased risk of health problems. In this study, we investigated and evaluated the supervised machine learning methods to predict OSA. We used popular machine learning algorithms to develop the prediction models, using a dataset with non-invasive features containing 231 records. Based on the methodology, the CRISP-DM, the dataset was checked and the blanked data were replaced with average/most frequented items. Then, the popular machine learning algorithms were applied for modeling and the 10-fold cross-validation method was used for performance comparison purposes. The dataset has 231 records, of which 152 (65.8%) were diagnosed with OSA. The majority was male (143, 61.9%). The results showed that the best prediction model with an overall AUC reached the Naïve Bayes and Logistic Regression classifier with 0.768 and 0.761, respectively. The SVM with 93.42% sensitivity and the Naïve Bayes of 59.49% specificity can be suitable for screening high-risk people with OSA. The machine learning methods with easily available features had adequate power of discrimination, and physicians can screen high-risk OSA as a supplementary tool.

Keywords. Obstructive Sleep Apnea, Prediction, Data Mining, Supervised Machine Learning Methods

1. Introduction

Obstructive sleep apnea (OSA) is the most common breathing-related sleep disorder, affecting 9-38% of the world population [1]. The OSA has serious and unpleasant consequences. If this disorder is not diagnosed or treated, there will be serious health problems and significant economic burden for both the individual and the healthcare system. The gold standard to diagnose and determine OSA severity is polysomnography (PSG). The PSG is a medical procedure performed in a specialized sleep laboratory by monitoring various aspects of the body activity during sleep. Indeed,

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these can be time consuming and costly [2]. Portable sleep monitoring devices are common replacement for PSG test. Although there is less work required in the lab, the patient should have some certain conditions [3]. Many studies used ECG, EEG, SpO₂ or the combination of two or more signals to diagnose OSA. Although these methods have shown high accuracy and good ability to predict OSA, they merely focus on procedures that require a specialist and equipment for recording and analyzing OSA [4]. Recently, many studies applied machine learning methods in medical fields including sleep medicine to classify people into healthy or ill. In a systematic review by Pombo et al., it was found that amongst the classification methods used for predicting OSA, the machine learning (ML) at 85.25% was the most used method and most popular algorithm which has good performance and reliability [5]. Due to the need for an efficient method that is simple, needs less effort and has good sensitivity for diagnosing and screening of high-risk people, in the present study we used a dataset containing self-reported variables which can be obtained effortlessly by utilizing the CRISP-DM (Cross-industry standard process for data mining) instruction, a methodology for the data mining project, in order to present a model for OSA diagnosis.

2. Methods

This study was approved by the local Ethics Committee of Shiraz University of Medical Sciences with the ethics code of IR.SUMS.REC.1396.3885. Written informed consents were obtained before performing the PSG test. To commence this study, we used CRISP-DM methodology which is a standard approach for planning a data mining project in the medical field. The steps are described as below. In the first phase, business understanding, the objective was to develop a model for predicting OSA in order to select the best model for assisting physicians and medical staff to determine and screen high-risk OSA patients. In the next phase, data understanding and preparation, the focus was on data. The data were collected retrospectively from medical records of people that had performed PSG test at Nemazi Hospital affiliated with Shiraz University of Medical Sciences from February 2013 to December 2017. The used dataset has 250 records and 49 features. The AHI was divided into two classes (OSA and healthy) with the threshold of 15[6]. At first, we eliminated 19 samples who were under 18 years of age, diagnosed with insomnia or most of the features were not reported. Records containing missing values were replaced with average/most frequented items. We used rank widget with information gain method as feature selection techniques through Orange (v.2), a machine learning free toolkit. The rank widget considers class-labeled data sets and scores the features according to their correlation with each class. In the phase of modeling to predict the accurate OSA diagnosis, the best-ranked features with information gain method were entered as inputs for the Neural Networks, Naïve Bayes, Logistic Regression, k-nearest neighbor (KNN), support vector machine (SVM) and Random Forest algorithms for training. The training of all algorithms was conducted using the same features. In the phase of evaluation and development, in order to evaluate the models, 10-fold cross-validation method was used. To compare the performance between prediction models accuracy, the area under the ROC curve (AUC), sensitivity and specificity of the models were evaluated.

3. Results

The final dataset had 231 records, of which 152 (65.8%) were diagnosed as OSA based on the threshold 15 of AHI. The majority of people were male (143, 61.9%). The variables including severe snore, nocturia, awakening due to the sound of snoring, witnessed snore, witnessed apnea, back pain, restless sleep, and BMI that have important roles in prediction of OSA based on the rank score were fed as the input of the models. In addition, the models were evaluated with other selected important features; therefore, they had no significance. In the assessed models, the parameters of accuracy, AUC, sensitivity and specificity of each machine learning algorithms are shown in Table 1, to compare the performance of prediction models. The SVM with 93.42% sensitivity had predicted the majority of OSA patients better, and the Naïve Bayes with 59.49% specificity had predicted the healthy people better than the other models. The Naïve Bayes and Logistic Regression classifier had the highest AUC with 0.768 and 0.761, respectively (Table 1). According to the results, the neural network had a better performance in the assessed models.

Table 1. The results of 10-fold cross validation of the mode

Method	CA	Sens	Spec	AUC
Naive Bayes	72.30	78.95	59.49	0.7681
Logistic regression	73.61	86.18	49.37	0.7614
Neural Network	74.91	86.18	53.16	0.7528
KNN	67.54	78.95	45.57	0.6557
SVM	72.77	94.42	32.91	0.7225
Random Forest	74.74	87.50	40.51	0.7586

Note: CA: Classification Accuracy, Sens: sensitivity, Spec: specificity, AUC: area under the ROC curve

4. Discussion

In the present study, to present a simple prediction model, the supervised machine learning methods with a standard methodology was used to predict OSA. In this study by selecting the appropriate method of feature selection, less important features were removed and models had a high accuracy, which were in accordance to the studies of Aronson et al. [7]. The goal was to ensure that high-risk OSA people will not be left without a PSG test; therefore, in order to reach a high sensitive model to avoid false negatives high sensitivity was important. Amongst the trained models, the SVM sensitivity reached a good result in determining high-risk OSA patients. This result was higher than the studies of Wu et al., and Liu et al. [6,8]. Specificity represents the probability of a negative result in people without the disease. According to the results, the Naïve Bayes with the 59.49% specificity had the highest ability to identify people with low risk of OSA, which was in line with the studies of Leite et al. and Aaronsan et al., but it was higher than the study by Wu et al [6, 7, 9]. To the best of our knowledge, there is no other study with developed models, using self-reported symptoms and easily available features with machine learning methods for predicting the presence of OSA in people. Researchers successfully applied machine learning to predict OSA patients, but the majority of these prediction models need additional equipment, sleep lab environment, and educated staff to reach features of prediction. The study of Aaronson et al. used self-reported symptoms, and socio-demographic and clinical features to build a prediction model of OSA using backward multivariable logistic regression [7].

This study population consisted of only patients with stroke and those with other comorbidities were not included. Also, the overall result of the present study was in the same line with that of the above mentioned study. Results show that the AUC of the Neural Networks, Naïve Bayes, Logistic Regression, SVM and Random Forest models were above 0.70, which was good enough to discriminate the power of the models [10, 11]. The retrospective nature of data gathering was a limitation of this study. Thus, a further prospective study is needed to confirm the clinical use of the proposed prognosticators. In addition, only people who performed PSG in Nemazi hospital sleep lab were included. With respect to this issue, a national or cohort study should be planned.

5. Conclusions

According to the results, the use of machine learning method with self-reported symptoms and easily available features for modeling has a good efficiency to predict OSA. To screen high-risk OSA patients, physicians or medical staff might use it as a fast and cost-effective auxiliary tool.

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Transfer Physical Therapists Knowledge: A Pre-Test to Minimize the Complexity of Physical Therapists' Quality Assessment of Shoulder Exercise Performance

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Abstract. Exercise therapy aims to restore normal musculoskeletal function or to reduce pain in patients with musculoskeletal shoulder disorders. Especially during long-term treatments, patients perform unsupervised exercises at home. Harmful movement deviations should be identified and avoided. Assistive technologies based on physical therapists' knowledge can support patients. In this paper, we present our approach to minimize the complexity of a physical therapists' quality assessment of a shoulder exercise performance. Four experienced physical therapists assessed the quality of 13 exercise performances shown as video recordings with a visual analogue scale and explained their ratings as free text. In some cases, the resulting assessments differed widely depending on the respective therapeutic goals. The therapists had difficulties to reduce the performances quality to a single value. Despite the existing consensus on exercises' descriptions, a more than one-dimensional scale is needed to evaluate exercises. Therefore, rating categories have to be identified for more detailed assessments.

Keywords. Exercise, Visual Analogue Scale, Shoulder, Physical Therapist

1. Introduction

Exercise therapy aims to restore normal musculoskeletal function or to reduce pain. Potentially harmful movement deviations should be avoided. Especially, when patients practice at home there is a risk of evasive movements or faults due to missing correction of physical therapists. Explicit knowledge about exercise quality is necessary to implement assistive technologies. Such assistance systems [1], [2] can support patients exercising at home by giving rudimentary feedback on the quality of exercise performance when no physical therapist can be present to identify harmful movements. The presented pre-test focuses on patients with musculoskeletal shoulder

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disorders (MSD). Based on an existing exercise catalogue, the aim is to figure out to what extent a physical therapists' exercise evaluation can be reduced to a single value in order to operate with a simplified and transparent rating for improved communication and implementation of assistance systems.

2. Methods

2.1. Participants

Four physical therapists (3 female, 1 male), working in a rehabilitation center², voluntarily agreed to participate in the pre-test. All physical therapists are experienced in treating patients with MSD and worked for at least one year in the same facility. On a weekly base, they lead therapy group sessions with predefined shoulder exercises. Therefore, a highly consistent consensus on the instructions and the quality assessments of exercises can be assumed which is important, as shown in [3].

2.2. Design

In preparation of the pre-test a researcher (BSa) learned the different exercises as well as typical faults and evasive movements from one of the participating physical therapists. Then she videotaped self-exercise performances for repeatability. The videos were replayed as often as required to the physical therapists. The physical therapists had to rate each performances' quality as they would do for patients in their weekly group sessions. For this pre-test they concretized their rating with the visual analogue scale (VAS)[4] and justified their rating with a free text explanation in a prepared questionnaire. The data acquisition ended with a group discussion. The interrater reliability is calculated with a two-way model, four raters and absolute agreement by package *irr* (version 0.84.1) in *R* (version 3.6.3).

2.3. Data acquisition

The VAS consists of a 100 mm horizontal line with the assessment's quality extremes *excellent* at one end of the line and *harmful* at the other. The physical therapists know the concept of the VAS. In the preliminary meeting, arranged to learn the exercises, the physical therapists pointed out that an unsupervised home-based exercise performance does not have to be perfect to be satisfying for the therapists' quality rating. Especially avoiding evasive movements is important. Therefore, we have extended the VAS by introducing a third orientation position *ok* in the scale, which stands for a satisfying performance quality in uncorrected home execution.

2.4. Exercises and performances

The exercises originate from the exercise catalogue the physical therapists use in their weekly group session with patients with MSD of the shoulder. The goals of the exercises are increasing mobility and **strengthening**. This exercise catalogue is also

² Reha-Zentrum Bad Pyrmont: Therapiezentrum Brunswick operated by Deutsche Rentenversicherung Braunschweig-Hannover, Germany (German Insurance Pension)

used in the study *Evaluation of the effectiveness and costs of home tele-rehabilitation with AGT-Reha in comparison to medical exercise therapy* registered in the German Clinical Trail register (DRKS00011596) [5]. Seven exercises in a standing upright position were selected to reduce diversity. Exercise *Flieger* for example is the sideways elevation of both arms and the shoulder to 90°. 13 recorded performances (named *A-M*, see Figure 1) are used for the pre-test. The first author recorded herself performing the seven different exercises in two versions: First, with the best possible performance (recording *A-G*) and second with typical faults or evasive movements (recordings *H-M*). One of the 14 recordings could not be used due to technical problems, so 13 recordings remained for usage. Every performance was recorded from a frontal perspective and additionally with a 45° side shift. The different perspectives were presented consecutive as one. Recordings enabled multiple views and were preferred to on-site execution for reproducibility.

3. Results

In total, 13 recordings were presented to and assessed by the physical therapists. It was perceived as extremely difficult to reduce the performances quality to a single value. The therapists would have preferred a concrete user scenario and a more detailed therapy goal. In general, the assessments of the rather good movements (*A-G*), were rated more positively than the ones with evasive movements and faults (*H-M*), see Figure 1. For various reasons, such as poor posture control, even the intended good performances were sometimes given a rather poor rating. Particularly interesting are the performances of exercises, where the results vary greatly between physical therapists. Performance *A* was criticized for its high execution speed and the raised shoulder girdle with arms turned inwards by two physical therapists. The different weighting of the hand position (kinking of wrists) ensures the ratings spread in performances *E* and *K*.

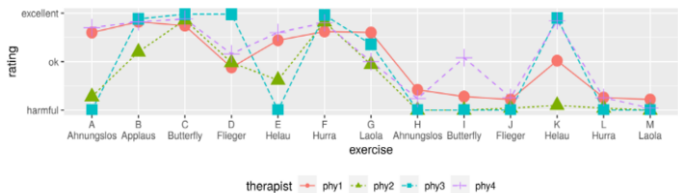


Figure 1. Assessments of the exercise performances (*A-M*) rated by four physical therapists

Table 1 shows the interrater reliability for the performances. The confidence interval for performances *A-G* shows a poor level of reliability due to the huge interval. Whereas the confidence interval for performances *H-M* indicates a poor to excellent reliability with an interval that still is huge, but less wide. It emerged from the group meeting that exercise descriptions outline the exercise but not the assessment criteria. As a reason for their quite varying assessment results, the physical therapists stated that they visited different educational institutions and advanced training, which focus on different aspects. Depending on the goal of a therapy, the importance of hand posture can differ extremely, like the assessments of performance *A* for example show.

Table 1. Interrater reliability (model: two-way mixed effects, type: mean of raters, definition: agreement)

Performances	ICC	95%-Confidence Interval	F-Test, H0: r0=0; H1: r0>0
A-G	ICC(A,4) = 0.616	-0.416 < ICC < 0.925	F(6,21) = 2.68, p = 0.0433
H-M	ICC(A,4) = 0.779	0.297 < ICC < 0.964	F(5,15.4) = 5.42, p = 0.00452

4. Discussion

The results of quality assessment vary greatly, even in a group of physical therapists of the same facility. Nevertheless, there are assessment parameters applied by all physical therapists to all patients, such as proper posture control. It is the task of physical therapists to know the criteria, analyze a patient's functional problem in the context of a movement analysis and to apply them subsequently. But a lot of the knowledge about assessing the performances' quality is implicit and cannot be easily expressed by the physical therapists. This implicit knowledge became partially obvious in the discussion of free text entries. Therefore, survey methods such as "thinking aloud" are planned for future research. The varying results lead to the question of how accurate the exercise performance has to be and whether a concrete case study and therapeutic goals would have resulted in a more consistent assessment.

5. Conclusions

Our pre-test indicates that physical therapists' knowledge about assessing the quality of an exercise performance may strongly depend on the individual patient, therapeutic goals and especially in this sample on the therapeutic concept the physical therapists works with. Moreover, the results show that a more than one-dimensional scale has to be elaborated to express the quality of an exercise-performance in alignment with an assessment by physical therapists. To build up a technical assistance system capable of supporting people in their self-exercises at home, more knowledge about effective and non-harming movements must be gathered and made explicit.

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A Digital Clinical Guideline Based on HL7 Arden Syntax for the Treatment of Children with Traumatic Brain Injury

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Abstract. Background: Intracranial hypertension is a serious complication accompanying the intensive care of children with traumatic brain injury. Intensive care of these patients is based on internationally accepted guidelines and their local editions. Objective: The goal was to develop a software system for digital implementation of the clinical protocol for the treatment of intracranial hypertension in children, based on HL7 Arden Syntax clinical decision support. Methods: Arden Syntax, an HL7 medical knowledge representation and processing standard, was used to develop a digital version of the local guideline. Results: Comparison of 37 patients given conventional treatment with a second group of 84 patients treated with the digital clinical guideline yielded statistically significant differences. Conclusion: The digital clinical guideline system undoubtedly improves the doctor's awareness of the patient's existing condition and potential complications of intracranial hypertension.

Keywords. clinical guideline, intracranial pressure (ICP), clinical decision support (CDS), Arden Syntax.

1. Introduction

Traumatic brain injury (TBI) remains one of the main causes of death and persistent disability among children involved in accidents [1]. These patients usually need intensive therapy and multimodal monitoring in intensive care units (ICUs). A typical complication is elevated intracranial pressure (ICP) and the development of intracranial hypertension (ICH), which frequently leads to cerebral ischemia and brain edema.

The treatment of ICH is based on internationally accepted guidelines [2] and their local adaptations. A local Russian guideline for the treatment of ICH in children was developed in 2015 at the Clinical Research Institute for Emergency Pediatric Surgery and Trauma (CRIEPST), Moscow, and is known as “Step therapy for treatment of intracranial hypertension in children” (step protocol) [3]. This clinical protocol is an

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algorithmic sequence of steps aimed at normalizing ICP and maintaining safe levels of cerebral perfusion pressure (CPP). It has been specially adapted for the intensive care of children with TBI.

The general trend in the digitalization of healthcare and particularly intensive care is based on the increasing use of clinical decision support (CDS) systems. One of the modern instruments for building CDS is Arden Syntax, which is a medical knowledge representation and processing standard for CDS systems, defined and supported by Health Level Seven International [4]. It defines the way clinical and scientific knowledge can be represented, computerized, and processed. Arden Syntax was first approved as a standard by the American Society for Testing and Materials in 1992 [5]. Several extensions followed. The current version (v2.10) was released in November 2014 [6].

The goal of this work was to develop a computer system based on Arden Syntax for digital implementation of the step protocol for the treatment of ICH in children with TBI.

2. Material and Methods

The digital clinical guideline (DCG) system was developed with the aid of ArdenSuite software, a commercial CDS authoring and processing platform based on Arden Syntax, created by Medexter Healthcare, Vienna, Austria [7]. The DCG system is an add-on module integrated into a hospital information landscape which includes, among other components, an ICU monitoring system (Philips IntelliVue [8]), a hospital information system (MediaLog [9]), and a monitoring database (MDB). All components are synchronized via HL7 standard protocol.

The clinical guideline (step protocol) for the treatment of ICH in children with TBI consists of seven clinical actions (steps) aimed at reducing ICP and maintaining a safe level of CPP. These clinical steps are: body position control, sedation, drainage of cerebral fluids, introduction of osmotic diuretics, controlled hyperventilation, barbiturate coma, and decompressive craniotomy. The steps are performed sequentially. However, the user has the option of repeating or deleting steps.

This clinical guideline is a “knowledge source” for programming so-called medical logic modules (MLMs), which are the basic elements of Arden Syntax. Each MLM contains enough clinical knowledge for at least one medical computation or decision.

The general architecture of the DCG system is presented in Figure 1. It includes three main blocks. The middle part known as “development and processing” is the ArdenSuite software which consists of two main modules: an IDE (integrated development environment) for writing, compiling, and testing MLMs, and the ArdenSuite server for executing the compiled MLMs. The “integration and sources” include patients’ medical documents, real-time monitoring data, and clinical knowledge guidelines. The web interface provides a device-independent graphical user interface and a message service for office and mobile applications.

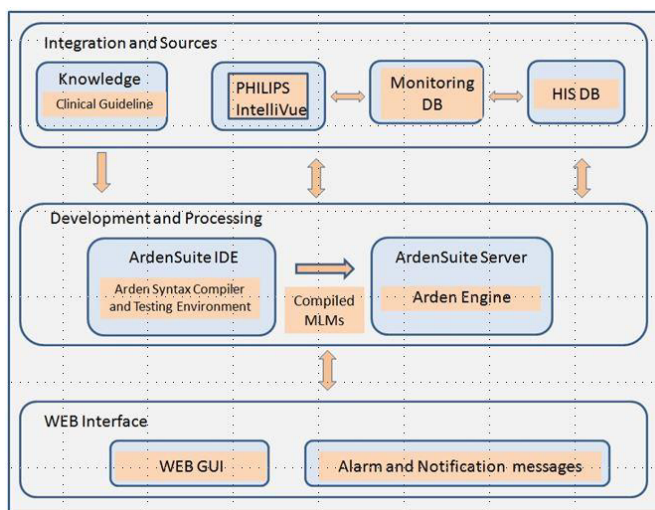


Figure 1. Architecture of the digital clinical guideline system.

The “step protocol” was introduced in the clinical setting in 2015. Since this time, all children with TBI have been treated according to this protocol. The DCG system was created in early 2017 and is being routinely used since. Between 2015 and 2019, 84 children with TBI underwent intensive care according to the protocol. The digital version of the protocol is being used since 2017. The reference group of 37 patients was created from historical data concerning conventional ICH therapy. The groups did not differ statistically in terms of the severity of trauma, clinical stage, age, gender, or the period of stay at the ICU. Each patient was rated on the Glasgow Outcome Scale (GOS) after six months [10,11]. According to the GOS, the outcomes were divided into three groups: moderate disability or good recovery, severe disability or vegetative state, and fatal outcome or death (Table 1). The STATISTICA 8 package was used for statistical analysis [12].

Table 1. Glasgow Outcome Scale in the protocol and the reference group.

GOS	Protocol group	Reference group
Moderate disability or good recovery	63 (75.00%)	18 (48.65%)
Severe disability or vegetative state	14 (16.67%)	7 (18.92%)
Death	7 (8.33%)	12 (32.43%)

3. Results

Statistical analysis of the combined frequencies revealed significant differences between groups in respect of the GOS. A significant fall of 24.1% in the number of deaths, and a rise of 26.35% in the number of favorable outcomes were noted in the protocol group compared to the reference group; Pearson’s Chi-square was 12.24 with $df=2$, $p=0.0022$, thus $p<0.05$.

4. Discussion

Obviously, the software solution developed for the digital clinical protocol is not aimed to, and cannot replace, the clinical physician. It is not possible to single out the separate effect of the digital version of the clinical protocol on the outcome of treatment. Moreover, the digital protocol inherits all limitations of the step-by-step treatment strategy for ICH. The decision to perform surgery is made jointly by several doctors and is based on comprehensive clinical data. However, the DCG system undoubtedly improves the doctor's awareness of the patient's current condition and potential complications of intracranial hypertension. It is also a useful tool for logging clinical actions of medical personnel in regard of scientific, legal, and other aspects of intensive care. The use of Arden Syntax creates a unified platform for building compatible systems to support clinical decisions, and is expected to accelerate the process of their certification.

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Statistical Analysis of Air Pollutants Concentration and Health Information Related to Respiratory Disease Patients in Bangkok, Thailand

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Abstract. Air pollution can lead to exposure to foreign particles, air that can be inhaled deep into the lungs and cardiovascular system, causing diseases such as stroke, heart disease, lung cancer, chronic obstructive pulmonary diseases, and respiratory infections. The Pearson's product moment correlation coefficient (r) was used to determine the strength of association between a pair of variables, to test the relationship between these variables and to test whether the association is greater than could be expected by chance. The linear regression between respiratory disease patients, PM₁₀, and other air pollutants were used in this study. Among PM₁₀ together with CO, O₃, and NO_x was statistically significant with P-value of <0.01 ($r = .031, .307, .561$; 95% CI = $-.570-1.437, .275-.445$, and $.223-.289$ respectively).

Keywords. Data analysis, Air pollutants, PM₁₀, Respiratory disease

1. Introduction

Air pollution is a major cause of death and disease in the world. The combined effects of outdoor and indoor air pollution cause about 7 million premature deaths every year, largely as a result of increased mortality from stroke, heart disease, chronic obstructive pulmonary disease, lung cancer, and acute respiratory infections [1]. Particulate matter (PM) can be inhaled and cause serious health problems. Some particles less than 10 micrometers in diameter (PM₁₀) can be inhaled deep into lungs and some may even get into bloodstream. People that are most likely to be affected by particle pollution exposure are elderly people and children with lung or heart diseases [2].

Traffic-related air pollution (TRAP) is a major problem in many cities in Asia, including Bangkok. Long-term exposure to the TRAP may lead to metabolism maladaptation and possible development of cardiovascular disease and diabetes mellitus [3]. An objective of this study is to analyze concentrations of conventional air pollutants and PM₁₀ obtained from the Air Monitoring Stations in Bangkok metropolitan area.

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2. Methods

This present research is a longitudinal study of concentrations of conventional air pollutants and PM₁₀ collected from January 2013 to December 2018. The air monitoring data used in this study were from January 2013 to December 2018. Conventional air pollutants and PM₁₀ were collected at 3 air monitoring stations in Bangkok metropolitan area – Nonsiwitthaya School, Huai Khwang, and Thonburi Metropolitan Electricity Authority (MEA) by the Pollution Control Department (PCD). Health information on respiratory diseases (bronchitis, emphysema, chronic obstructive pulmonary disease, and asthma) as diagnosed by physicians based on the International Classification of Diseases (ICD-10) were collected from 3 hospitals in regions of the air monitoring stations (Klang, Rajavithi, and Taksin Hospitals). The monitored air pollutants were carbon monoxide (CO), nitric oxide (NO), nitrogen dioxide (NO₂), nitrogen oxides (NO_x), and ozone (O₃). The sum of NO and NO₂ was used to describe NO_x. The treatment of data was carried out by the interpolation technique. The correlation coefficient and linear regression analysis were used to determine a potential correlation between number of respiratory disease patients, PM₁₀, and other criteria pollutants and creating an equation to predict PM₁₀ concentration in Bangkok by the Statistical Package for Social Science (SPSS).

3. Results

The variation of PM₁₀ concentration and respiratory disease patients was observed in Figures 1, 2, and 3. In Figure 1, the concentration of PM₁₀ showed a decrease from May to September an increase from October to April of next year. The number of respiratory disease patient’s tendencies decrease from January 2013 to April 2017 after that increase to December 2018.

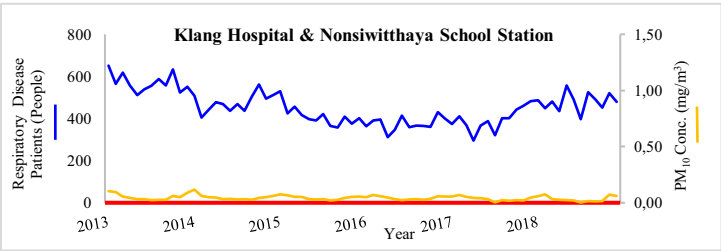


Figure 1. The data of PM₁₀ concentration and number of respiratory disease patients at station 1.

In Figure 2, the concentration of PM₁₀ showed a similar type of variation as a decrease from May to September an increase from October to April of next year. The number of respiratory disease patient’s tendencies increased from January 2013 to December 2018. In Figure 3, the concentration of PM₁₀ showed a similar type of variation as a decrease from May to September an increased from October to April of next year. The number of respiratory disease patients slightly varied from January 2013 to December 2018.

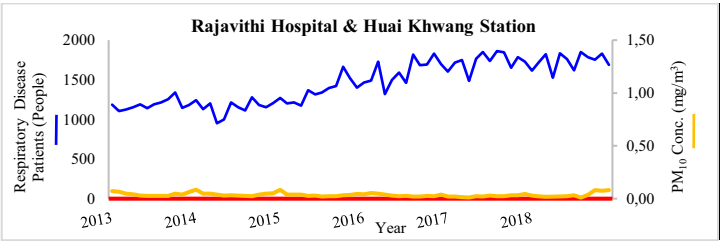


Figure 2. The data of PM₁₀ concentration and number of respiratory disease patients at station 2.

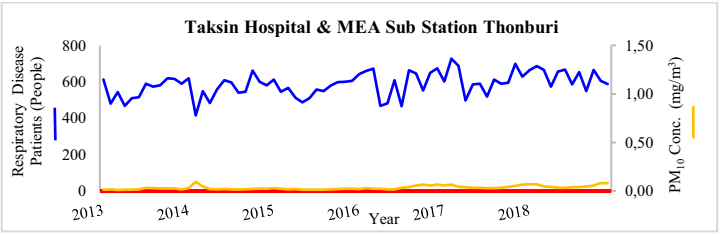


Figure 3. The data of PM₁₀ concentration and number of respiratory disease patients at station 3.

The linear regression between PM₁₀ and other criteria pollutants presented in Table 1. From this table, an equation for predicting PM₁₀ concentration can be written as;

$$PM_{10} = 11.857 + 0.433CO + 0.36O_3 + 0.256NO_x$$

Among PM₁₀ together with CO, O₃, and NO_x was statistically significant with P-value of <0.01 ($r = .031, .307, .561$; 95% CI = $-.570-1.437, .275-.445$, and $.223-.289$ respectively).

Table 1. Linear regression analysis of respiratory disease patients, PM₁₀ and other criteria pollutants

Model	Unstandardized Coefficients		Standardized Coefficients		t	Sig.	95.0% Confidence Interval for B	
	B	Std. Error	Beta				Lower Bound	Upper Bound
1 (Constant)	11.857	1.941			6.108	.000	8.042	15.671
CO	.433	.511	.031		.849	.396	-.507	1.437
O ₃	.360	.043	.307		8.358	.000	.275	.445
NO _x	.256	.017	.561		15.143	.000	.223	.289

a. Dependent variable: PM₁₀

Adjusted R Square = 0.348, Durbin-Watson = 1.984, F = 90.594, and P-value = 0.000)

4. Discussions

The concentration of PM₁₀ decreased during rainy season and increased during cold season. The effect of PM₁₀ can have many variations from season to season. PM₁₀ can be introduced from diverse sources. The mixing height becomes lower in cold season and higher in hot season and PM₁₀ gets trapped adjacent to the ground level appearing in

inversion conditions, which could lead to atmospheric stable or non-dispersion of the air pollutants [4], [5]. After the government of Thailand has taken various roles to mobilize their resources for haze management in the second stage from 2011 to 2019. The highest PM₁₀ value which adverse health effects for sensitive groups was found in February and had been decreasing in March [6]. The Pearson's product moment correlation coefficient (r) and linear regression between respiratory disease patients, PM₁₀, and other air pollutants were used to define the strength of association between a pair of variables, to test the relationship between these variables and to test whether the association is greater than could be anticipated by chance [7].

5. Conclusions

Results from this study provides a body of evidence that respiratory diseases are consequences of air pollution produced in Bangkok metropolitan areas. In addition, an equation for predicting PM₁₀ concentration might be useful for further public health interventions.

Acknowledgements

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Google Maps: Prevalence and Distribution of Uncontrolled Type 2 Diabetes Mellitus in Kalasin Province, Thailand

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Abstract. Diabetes Mellitus (DM) is a major public health problem worldwide. Most of the problems are caused by uncontrolled blood sugar level, resulting in complications and possible death. This study aimed to investigate the prevalence and distribution of uncontrolled type 2 diabetes mellitus (T2DM). A cross-sectional of 385 patients between September 2019 and December 2019, using the google maps, a questionnaire and laboratory examination. The results revealed that the prevalence of uncontrolled T2DM was 79.74% and densely distributed in the municipality. This data indicates that the prevalence and distribution of uncontrolled T2DM need to be concern and solve problems to decrease complications and death rates from diabetes.

Keywords. Google maps, Prevalence, Distribution, Uncontrolled type 2 diabetes mellitus, Glycemic control

1. Introduction

Diabetes Mellitus (DM) is a large public health problem. Worldwide about 422 million are living with DM, especially in low and middle income countries [1]. DM was the 7th cause of death and the number of deaths globally increased from less than 1 million in 2000 to 1.6 million in 2016 [2]. Majority had poor glycemic control. Uncontrolled type 2 diabetes mellitus (T2DM) can lead to serious complications. Prevalence of uncontrolled T2DM is increased in many countries, Ghana, Nigeria, Bangladesh, Sudan, and Zambia were 86.4%, 83.3%, 82.0%, 80.0% and 61.3%, respectively. [3-7].

Thailand has tended towards an increase in the morbidity rate and mortality rate per hundred thousand with diabetes every year and DM was the 6th ranking cause of death in 2018 [8]. In addition, the percentage of T2DM that could be controlled lower than the indicators of the Ministry of Public Health of Thailand. Patients with uncontrolled or poorly controlled T2DM will develop acute and chronic complications. Technologies in mobile, computer, e-mail, and internet approaches have shown evidence in enhancing chronic disease management, suggesting great potential for diabetes management technologies [9]. Google maps is a part of Google website used to search for places, get driving directions, and view maps that people around the world are extensively used by

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reason of easily accessible, convenient and easy to use. Therefore, Google maps is an option that can be used for public health to monitoring and surveillance the health risk of patients. This study aimed to determine the prevalence and distribution of uncontrolled T2DM in Kalasin Province, Thailand.

2. Methods

2.1. Study design and Sampling

This study was a cross-sectional study among T2DM patients in Kalasin Province, covering a period of 4 months from September 2019 to December 2019. There were 385 patients from 18 hospitals. They were selected by systematic random sampling.

2.2. Inclusion Criteria

- T2DM patients, both males and females without age restriction.
- Patients were registered and treated in the hospitals in Kalasin Province.
- Patients had laboratory examination results from their last 3 times of Fasting Plasma Glucose (FPG) tests or results of glycosylated haemoglobin (HbA1C) tests.
- Patients participated voluntarily.
- Patients could communicate by speaking.

2.3. Exclusion Criteria

- Patients had severe complications of the disease and were unable to provide information.

2.4. Research Instrument

This study used the standards for diagnosis of uncontrolled T2DM according to the Ministry of Public Health of Thailand's criteria for classification, HbA1C with a ≥ 7 , or FPG ≥ 130 mg./dl. The questionnaire was divided into three parts, which were

- Demographic characteristics
- Health data
- Geographic coordinates

2.5. Data collection

Data were collected using a questionnaire and laboratory examinations.

2.6. Statistical analysis

Descriptive statistics were used to describe the characteristics of the prevalence of uncontrolled T2DM in patients.

2.7. Ethic Declarations

This protocol was approved by the Mahasarakham University ethical committees number 059/2019 and passed through from Kalasin provincial public health official. Written informed consent was obtained from all participants.

3. Results

The prevalence of uncontrolled T2DM in patients was 307 out of 385 patients, accounting for 79.74% (95%CI = 75.71 to 83.77) (Table 1) and spot map of uncontrolled T2DM cases were distributed throughout the province and clustered somewhat more densely in the center of municipal area shown in the figure 1.

Table 1. Assessment of controlled type 2 diabetes mellitus classified by diagnosis

Diagnosis	Number	Percentage (%)	95%CI
Controlled type 2 diabetes mellitus	78	20.26	75.71 to 83.77
Uncontrolled type 2 diabetes mellitus	307	79.74	
Total	385	100.00	



Figure 1. Distribution of uncontrolled type 2 diabetes mellitus in Kalasin Province

4. Discussion

The results showed that 79.74% of uncontrolled T2DM was similar to the report of Ministry of Public Health of Thailand which 71.68% of uncontrolled T2DM [10]. However, limited information about the prevalence of uncontrolled T2DM in Thailand. In addition, using the google maps to create a spot map helps to identify the distributed of uncontrolled T2DM cases that distributed more densely in the center of municipal area, as patients in the municipality have a sedentary lifestyles and unhealthy diets, which was consistent with a previous study that the prevalence of DM in urban higher than rural areas [11-14]. Due to lifestyles and dietary habits that are different in each area causing patients in the municipality able to control the glycemic control differently from outside the municipality.

5. Conclusions

The prevalence of uncontrolled T2DM is very high and densely distributed in the municipality. The spot map on the google maps will be a warning sign of health risk

among DM patients in the area. Evidence based on electronic health data will support health care system.

Acknowledgments

We would like to thank all the patients who cooperated and participated in this research, the officers in the non-communicable disease clinics, research assistants, the provincial chief medical officers, and the hospital directors in Kalasin Province.

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From Many to One: Designing a Unified Flowsheet in the EMR to Replace Multiple Disparate Devices

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Abstract. This study represents a post-implementation qualitative inquiry for a maturing flowsheet design that aims to replace multiple disparate devices used for data entry. The flowsheet has already experienced multiple iterative development cycles based on formal feedback from formative and summative usability studies. This next phase focused on a semi-structured qualitative interview to provide new feedback that will be used to further refine the product. Results of the 9-item interview were both actionable and provocative, revealing multiple avenues of improvement and a new usability map that can inform future studies and design plans.

Keywords. usability, clinical informatics

1. Introduction

Patient care workflows have become increasingly fragmented as more devices are introduced into healthcare. Providers, in particular, suffer through severely disrupted patient encounters as they must switch between multiple disparate systems for both data entry and retrieval. This disjointed process contributes to significant documentation-related stress, adding to frustration, decreasing job satisfaction, and ultimately leading to burnout. This presents an increased risk for errors in patient care, while also creating obstacles to any underlying research.

This project represents an ongoing effort to integrate all components of the Deep Brain Stimulator (DBS) workflow into a unified flowsheet in Epic 2019. The current build of the flowsheet (Figure 1) is the result of multiple iterative development cycles, based on formal feedback from formative and summative usability studies. These earlier studies were designed to elicit both quantitative and qualitative feedback, and to produce a functional product. There were no pre-existing tools in the EMR that fit the needs of this specialty service at the time of implementation.

Clinical staff have now had time to explore the latest functional version of the flowsheet. So, to inform the next phase of development, this study used a semi-structured qualitative interview to capture actionable information from these experienced users.

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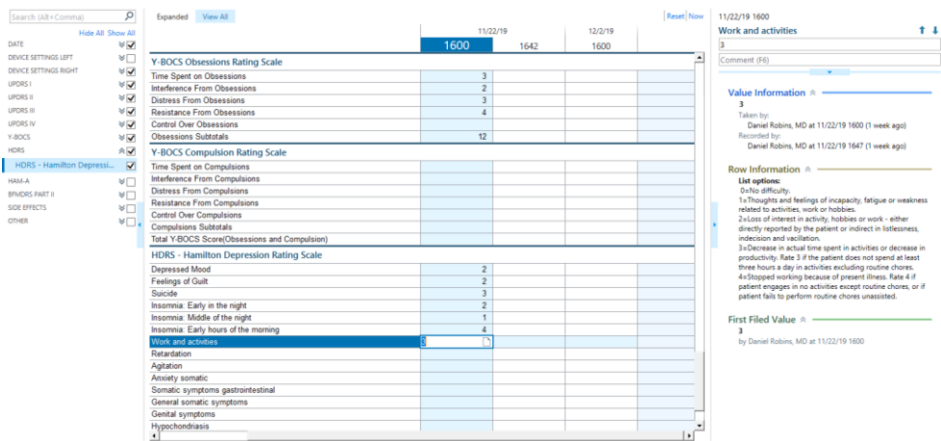


Figure 1. Flowsheet design

2. Methods

For this phase of the study a semi-structured qualitative interview was used to collect feedback about the maturing product, following a successful method that we have previously described¹. Study participants were chosen from the group of clinical and support staff who used the most recent build of the flowsheet in the second half of 2019 to access, record, and retrieve information in patients' health records. Now that these clinicians had sufficient time to explore and experiment with the most recent iteration, they were approached to provide long-form feedback about their experiences. There were nine interview questions in total, organized into three categories: content, interface, and process. Each individual question was open-ended and calibrated, designed to elicit long-form responses that describe benefits, problems, and suggestions relevant to each category (Table 1).

Table 1. Semi-Structured Qualitative Interview Questions

Content
What are the benefits of using this flowsheet to capture the responses of your surveys / rating scales?
Describe any problems with the content provided by this flowsheet.
How can we improve the content provided by the flowsheet?
Interface
What are the benefits of using this flowsheet interface compared to the previous system(s)?
Please describe any problems you had accessing or navigating the flowsheet.
What kind of functionality would make the flowsheet easier to use?
Process
Does this flowsheet improve your workflow, and if so, how?
What are your main concerns or problems with integrating this flowsheet into your workflow?
How can this flowsheet be modified to improve your workflow?

3. Results

7 clinicians provided feedback for the semi-structured qualitative interview. Results are summarized in Table 2.

Table 2. Semi-Structured Qualitative Interview Responses, Summarized

Benefits	Problems	Suggestions
Faster than paper Quick data entry Easy to review information Compare data over time Automatic totals/calculations Clean interface Row Information acts like a reminder One place for all information Standardized documentation Easy to use No paper, better for environment	Clinical workflow sometimes varies Difficult to find and open flowsheet Needs to be clickable with mouse Does not capture hand-written notation Need more space for comments Some content already out of date Few missing items Need more information near timestamp	Open flowsheet automatically Automatically fill some fields Collapse groups by default Rearrange groups More verbose row descriptions Row information displayed first More row restrictions Additional content Make some content mandatory

4. Discussion

The initial build of the flowsheet was guided by meetings with stakeholders and one-on-one sit downs with experts; these formative activities defined users, user needs, and basic workflows². The flowsheet has now experienced multiple iterative development cycles and is becoming a more refined product.

A semi-structured qualitative interview was chosen as the method to elicit feedback for this phase as it is well-suited for one-on-one discussions, easy to accommodate, and offers the opportunity to uncover additional information beyond just the starting question. Conversations are *initiated* by the pre-determined open-ended questions, but additional questions and responses are allowed to emerge as the dialogue between interviewer and interviewee develops³. In this way, copious feedback was obtained through the interviews.

Participants were quick to identify issues that would slow down the patient encounter or lead to more data entry; speed and efficiency were a key focus of the feedback, consistent with other qualitative studies of the EMR as a whole⁴. This included comments about how easily and rapidly the flowsheet could be accessed and made ready for use. Timeliness was a common theme, particularly when talking about interface design and recording patient data. A few edge cases were also discussed, such as when a more verbose comment would need to be entered by the clinician, or when hand-written notation could not be adequately reproduced in the system.

Suggestions to speed up the workflow included automatic opening of the flowsheet upon starting the patient encounter, switching to a mouse-driven interface, and beginning with a collapsed view of the groups to minimize scrolling.

Overall, this round of qualitative interviews captured multiple new points of actionable feedback that emphasize the time-sensitive nature of our clinicians. This feedback has led to the creation of a new usability map, which will influence future development cycles (Figure 2).

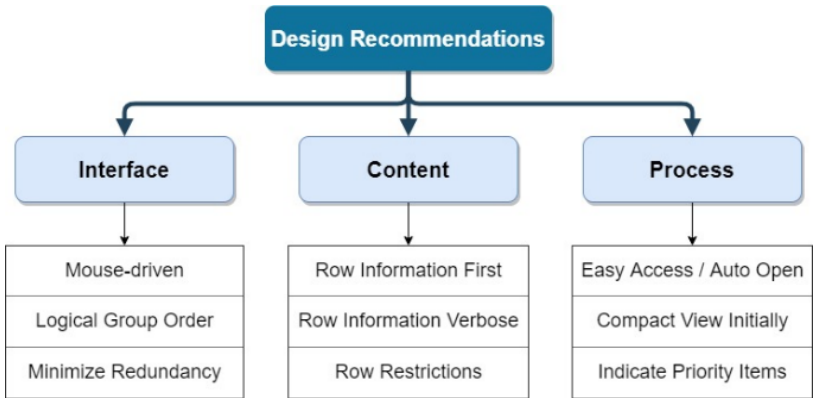


Figure 2. Usability map - design recommendations

5. Conclusions

Qualitative usability techniques can produce structured, actionable feedback for iterative development processes, which contribute to a mature digital workflow that reduces data entry burden for clinical teams.

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Sun4Patients Web Platform: Facilitating Long-Term Monitoring of Stroke Patients

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Abstract. SUN4Patients is an observational study for the monitoring of patients with first ever acute stroke. For the support of this study, an online platform has been developed which facilitates the collection of various information related to hospital discharge, health services utilization and loss of productivity of the patients. This paper presents the main characteristics of the platform and the methodology followed for its design and implementation.

Keywords. Web Platform, Stroke Patients Monitoring

1. Introduction

SUN4Patients is an observational study of patients with first ever acute stroke, hemorrhagic or ischemic. All patients, admitted in seven Public Hospitals in Greece, are monitored and followed-up for three months and one third of enrolled patients will be followed up for one year. Online tools are used broadly to support the follow-up process on clinical studies [1,2]. An on-line platform was implemented, to support the SUN4Patients project, which facilitates the collection of data from the patients.

2. Methods

The requirements' analysis phase required interdisciplinary effort to gather issues related to the researchers' methods and difficulty to collect data (e.g., patients are not giving consent, manual data entry, follow up not answering calls, and less patients reach hospitals due to COVID-19) as well as to study, analyse and translate

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questionnaires that will become part of the platform. The platform enables users to fill in questionnaires, store, analyse and export the data. The structure of questionnaires was collaboratively developed with end users, to reflect real needs. The architecture design and implementation phase followed, after which pilot testing was performed with a small number of patients by researchers. The platform's backend has been implemented in ASP.NET, frontend in HTML5, and charts in HighchartsJS library. The solution has been deployed in MS Cloud VM to ensure high availability.

3. Results and Discussion

SUN4Patients platform incorporates the whole business logic and validation controls of eCRFs, supporting innovative and multichannel data collection methods, providing statistical analysis and visual exploration of the major quality indicators and supporting effective scheduling and management of the follow-up monitoring of patients. The platform currently supports the completion of 553 CRF variables in phases (366 variables are collected on admission and during hospitalization, 39 variables on discharge, 7 variables on the 1st month, 103 variables on the 3rd month and 36 variables on 1st year) as well as the Stroke Patients Experience (41 variables) and the “1-year socio-economic consequences” (108 variables) questionnaires. End users are researchers, hospital head offices and central office administrators. Researchers perform data entry, head offices validate the entries whereas central office administrators supervise the process, analyse data and produce reports. The platform is available in <http://www.sun4patients.gr>. As of April 2020, CRFs from 300 patients have been recorded in the platform. Preliminary evaluation of the key features of the platform (ex. fill-in suggestions to researchers, scheduling, dynamic reporting and notifications) has improved the data entry time and the platform performance.

4. Conclusions

The SUN4Patients platform was developed to facilitate long-term monitoring of patients with acute stroke. The platform's key features, i.e., easy to schedule follow-up appointments, conduct electronic surveys, collect and analyse data, and produce reports on indicators about the quality of life during rehabilitation, can be extended/adjusted with other types of questionnaires and support the monitoring of other types of patients [1,2].

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System of Criteria for Treatment Evaluation of Acromegaly in Bulgaria

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Abstract. Acromegaly is a rare endocrine disorder caused by excessive and longstanding secretion of growth hormone (GH) by the pituitary somatotroph and resulting from this overproduction of insulin-like growth factor-1 hormone (IGF-1) by the liver. There are few registers and rather limited clinical data about acromegaly treatment. The analysis of acromegaly data is rarely subject to a system of criteria for evaluating acromegaly treatment. The novelty of this paper is that it presents a real-life practice case study about the implementation results of such a system in Bulgaria. The case study analysis illustrates a clinical information approach to manage thousands of records in the Bulgarian Acromegaly Database. The here reported results provide evidence about the difficulties in maintaining both GH and IGF-1 levels inside their reference values in acromegaly treatment. Ongoing research extends the evaluation results by enabling semantic interoperability between acromegaly databases based on openEHR specification.

Keywords. endocrine disease, Acromegaly, case study, treatment, Growth Hormone, Insulin-like Growth Factor-1, evaluation, clinical informatics

1. Introduction

Acromegaly is a rare disease that is difficult to discover early enough allowing to prescribe timely and adequate medical treatment to the patient. This endocrine disorder leads to deteriorated quality of life and development of severe complications like cardiovascular disease and diabetes mellitus [1]. Recent statistic data indicates increased morbidity with about 117 new acromegaly cases per million every year worldwide [2], where for example, 3 to 4 new cases per million annually are recorded in the *Bulgarian Acromegaly Database* [3] [4].

A description for the first medical treatment of this disease is recorded in 1893 [5]. Subsequent studies clarify the genesis and the main causes for the symptoms observed in acromegaly patients. Nowadays it is well known that acromegaly is caused by the pituitary somatotroph secretion of excessive quantities of Growth Hormone (GH) that in some cases are 25 times above normal. Once the GH gets into the blood circulation it triggers the liver to produce high levels of Insulin-like Growth Factor-1 (IGF-1) hormone which stimulates abnormal growth of the bones and the development of typical for

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acromegaly signs and symptoms such as enlargement of hands and feet, skull changes, increased sweating, arthropathy, visceromegaly, acromegalic cardiomyopathy, etc. [2].

In about 95% of the cases the GH hypersecretion is caused by a pituitary adenoma, whereby the GH secretion is proportional to the tumor size [6]. Therefore, the main goals in acromegaly treatment are to reduce the tumor volume and to normalize both the GH and IGF-1 levels by means of a combination of transsphenoidal surgery, radiotherapy, and medical therapy. In general, the implementation of these goals is difficult in practice. First, there is a limited number of publications with real-life clinical practice data about acromegaly treatment. Second, existing publications use heterogeneous information models to present trial data. For example, most case studies miss the semantic context in which GH and IGF-1 values are obtained [7].

The *European Reference Networks for Rare and Low Prevalence Complex Diseases* (Endo-ERN) attempts to resolve these problems by including databases like the *Liège Acromegaly Survey (LAS) Database* [4] and the *Bulgarian Acromegaly Database* [3] in a collaborative platform. In a related research paper [8] we have introduced a web application [9] for exchanging clinical documents between such databases by preserving the semantic context in clinical concepts including measurement units, reference baseline values, symptom description. The objective of this paper is to extend our previous research work by building a system of criteria, where the evaluation of therapy effectiveness will generate data for the web application. Methods and results from computer experiments using the *Bulgarian Acromegaly Database* are given in Section 2, the discussion and conclusions are given correspondingly in Section 3 and Section 4.

2. Methods and computer experiments

The *Bulgarian Acromegaly Database* contains records for 858 patients (37% male). It is one of the largest databases with acromegaly clinical data in Europe and contains data about patients undergoing treatment in the University Hospital of Endocrinology, Medical University Sofia. Clinical practice in this hospital shows that acromegaly treatment is professionally challenging, expensive, continues for years and requires individual approach to each case. The system of criteria for evaluating the effectiveness of acromegaly therapy comprises the internationally recognized key biomarkers GH and IGF-1, where in oral glucose tolerance test (OGTT) the GH level at the 120 minute must be lower than the GH level at the 0 minute [10]. Additional criteria consider results of assessment of traditional surgery and therapy with novel medications (see Fig. 1) [11]. Here we illustrate the methodology for implementing this system of criteria with respect to a female patient diagnosed with acromegaly at the age of 51. Transsphenoidal surgery is the first-line therapy in acromegaly treatment. The key biomarkers are evaluated after the surgery and decision is made how to proceed with the next steps in the treatment—another surgery, combined medication treatment or radiotherapy. The cut-off values used in this evaluation procedure are [0.0, 10.0] mIU/L and [14.0, 40.5] nmol/L accordingly, for the GH (basal and during OGTT) and the IGF-1 levels. The patient made no improvement after two transsphenoidal surgeries (“*compression on the optic chiasm and right oculomotor nerve*”) in 2003 and 2009. Therefore, the administration of the first-line post-surgery treatment with somatostatin receptor ligands octreotide and lanreotide or dopamine agonist cabergoline was discussed, and the somatostatin analogue octreotide (Sandostatin LAR) was prescribed. In non-responders to this treatment an addition of GH-receptor antagonist or radiotherapy is recommended. The Evaluation procedure repeats

periodically, and the therapy continues until both the GH and IGF-1 levels are normalized. On each stage of the life cycle shown in Figure 1 new data records are stored in the *Bulgarian Acromegaly Database* making use of international nomenclatures like SNOMED or ATC [9].

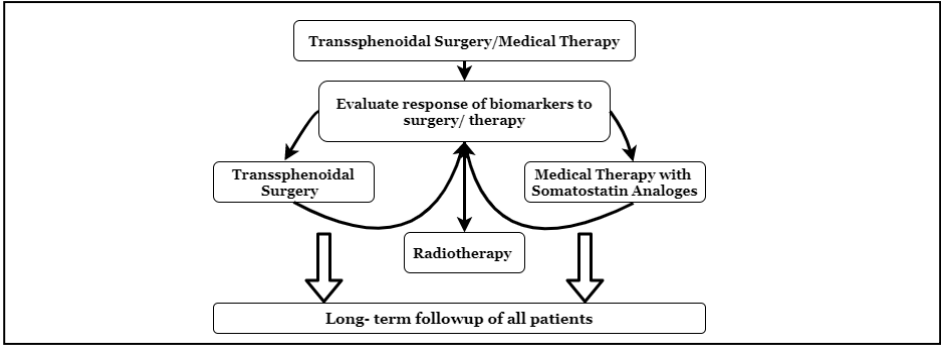


Figure 1. Life cycle of the System of criteria for evaluation of acromegaly therapy effectiveness

3. Discussion

Nowadays there is a consensus that maintaining both GH and IFG-1 levels of an acromegaly patient below the recommended cut- off values is vitally important for him. There is also consensus about the difficulties to reach such results. First, patients are diagnosed with acromegaly about their forties, while the initial subtle signs of the disease emerge 7- 10 years earlier. Next, due to insufficient clinical evidence there is no agreement over the cut-off values of the key biomarker’s levels used to set acromegaly diagnose. On the other side, there is evidence that these biomarkers have independent functions [12]. Figure 2 illustrates the difficulties in controlling simultaneously both levels of the biomarkers and evaluating the therapy effectiveness during the treatment.

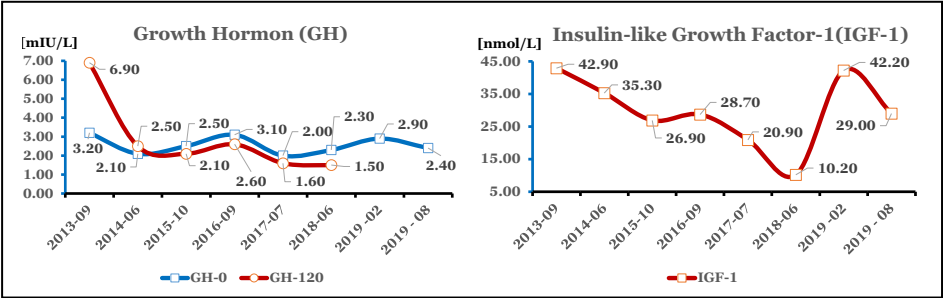


Figure 2. Evaluation of medication treatment effectiveness based on GH and IGF-1 levels

After the surgeries, our patient has GH level below the upper limit, however, in 2013 the GH at the 120 [min] has been measured much higher than its value at the 0 [min] in OGTT. The IGF-1 in 2013 has been also above its upper reference value. Because the patient did not pass the OGTT criteria she started medication therapy with Sandostatin LAR (20mg/monthly during 2013-2016, 30mg/monthly during 2017-2018 and 40mg after 2018- now). Thus, the GH, IGF-1 and OGTT criteria have been passed in 2014 and the

same treatment continued in the following years. In 2018 the patient developed diabetes type 2 and the OGTT was not conducted. Moreover, the increased IGF-1 level in 2016 and later in 2019 required an increase in the monthly dosage of Sandostatin LAR. Nowadays the patient is subject to continuous follow-up and in good health condition.

4. Conclusions

This paper analyzes a real- life clinical practice subject to a system of criteria for evaluating the process of acromegaly treatment in Bulgaria. The case study analysis illustrates a novel clinical information approach to manage thousands of records in the Bulgarian Acromegaly Database. The reported results demonstrate how difficult it is to maintain simultaneously IGF-1 and GH (basal and during OGTT) levels inside their reference values in acromegaly treatment. The case study illustrates the system of criteria by evaluating rarely reported original clinical data and may serve as a guide for successful acromegaly treatment. Ongoing research extends the evaluation results by enabling semantic interoperability between acromegaly databases based on openEHR specification.

Acknowledgement

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Discrepancy Between Personal Experience and Negative Opinion with Human Papillomavirus Vaccine in Web Forums

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Abstract. While vaccines are intended to protect people from infectious diseases, public confidence in vaccination has evolved as patients have reservation about vaccination, with a major concern about its safety. Social media may help regulatory authorities to better understand opposition to vaccination and make informed decisions for better promotion of vaccines' benefits towards the public. Our objective was to explore French web forums for potential pharmacovigilance signals associated with human papillomavirus infections (HPV) vaccines. Among 138 posts associated with a signal randomly chosen for manual review, 29% were actually adverse drug reactions to the vaccine described in clinical studies, and only 2 were personal experiences. Only 14% of the reviewed posts described positive opinion about the vaccine whereas 46% were neutral and 40% were negative. While few personal experiences of adverse reactions were actually reported by users, our case study showed a large proportion of negative opinions.

Keywords. Pharmacovigilance; Social Media; Internet; Forum; Side effects; Papillomavirus vaccines

1. Introduction

Vaccine hesitancy is a hot topic, especially in France [1] where fear of vaccination may lead to a lower protection of the population to some preventable infectious diseases. Social media are potentially interesting to investigate such hesitancy, and any information may be useful to health authorities to promote vaccine use, adherence, and confidence. Our objective was to explore French web forums to investigate signals concerning Human Papillomavirus (HPV) vaccines. These vaccines protect against a group of viruses that may cause cancer, especially in the cervix. They were first indicated for young girls. Several studies investigated HPV vaccines in social media. Suragh et al. [2] found that 49% of the 39 reported side effects associated to anxiety after vaccination on Google and Facebook were related to HPV vaccines. Between 2007 and 2015, nearly 10% of threads about HPV vaccines on Reddit concerned side effects associated with these vaccines [3]. Moreover, as the web 2.0 can affect the decision about getting vaccinated [4], investigating personal experiences and opinions

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from social media users is desirable to measure how such media may modify the perception of the population.

2. Methods

We used the open source tool Vigi4Med Scraper [5] to extract posts from web forums, and Natural Language Processing (NLP) techniques to detect mentions of drugs and adverse events from these posts [6]. Adverse events were coded using the Concept Unique Identifier (CUI) of the Unified Medical Language System (UMLS), and drugs were normalized using the Anatomical Therapeutic Chemical (ATC) classification system. First, we formatted the data in order to perform our analysis. The main steps of data-processing were:

- Standardization of dates;
- CUI UMLS Mapping to the Medical Dictionary for Regulatory Activities (MedDRA) terminology 21.1;
- Terms corresponding to the System Organ Class (SOC) “Social circumstances” and to High Level Group Terms (HLGT) containing the character string: “therapeutic procedure” were removed;
- A verbatim used by the patient and identified as a treatment but not linked to an ATC class was linked to HPV vaccines if it contained the terms “Gardasil”, “papillomavirus”, “cervarix”, “hpv”, or “vaccine” and “uterus”;
- Only drugs-adverse event couples that were coded in 5th ATC level and preferred term level were taken into account.

We then applied different decision rules for signal detection methods used in Pharmacovigilance [7-9] to generate signals:

- (1) Bayesian Confidence Propagation Neural Network (BCPNN): 95% confidence interval of the Information Component > 0 ;
- (2) Change-Point Analysis (CPA): Change with a confidence level $\geq 95\%$;
- (3) CPA combined with the Proportional Reporting Ratio (PRR) for 5 selected adverse events (“Syncope”, “Blindness”, “Anaphylactic reaction”, “Cardiac arrest”, and “Suicide”): $PRR > 1$, the couple is found in at least 5 posts, and the CPA detects at least 2 increases (confidence level $\geq 95\%$).

We randomly selected 150 posts for manual review consisting of a set of 50 posts for each decision rule. These posts were evaluated according to the following criteria: mention of the vaccine (yes/no), characterization of the opinion toward the vaccine (positive/negative/neutral), mention of an adverse event (yes/no), and relationship between the vaccine and an adverse event (yes/no). Posts considered as potential pharmacovigilance cases were reviewed by a pharmacovigilance specialist (ALL). All statistical analyses were performed with the R language and environment for statistical computing and graphics [10] using the PhVID package, and the implementation of CPA proposed by Xu et al. [8].

3. Results

We found 18,800,526 annotations (drug, adverse event, or both) in 3,482,010 posts between 06/14/1999 and 04/13/2019 (770 annotations without dates) from 21 web forums. After the data preparation steps, the database consisted of 165,663 unique {drug, adverse event} couples for a total of 2,523,564 couples concerning 1,561 drugs and 3,978 adverse events in posts between 12/1999 and 04/2019. The HPV vaccine mention was found in 5,159 couples in which 501 adverse events were detected.

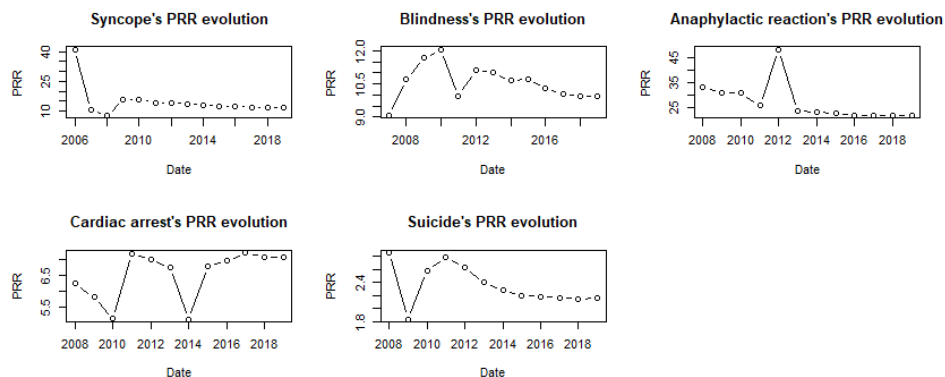


Figure 1. Evolution of the PRR for 5 adverse events.

Four changepoints were identified using the CPA method with a confidence level greater than or equal to 95%: 10/2007 (100%), 08/2009 (98%), 01/2012 (100%), and 11/2015 (99.9%). Only one (10/2007) corresponded to an increase in the average number of posts between two periods. 124 signals were generated by the application of BCPNN corresponding to 3,561 posts. No change point in the temporal evolution of the PRR was found with a confidence level greater than or equal to 95% for the 5 selected adverse events (Figure 1).

Of the set of 150 posts, 138 were manually reviewed, 11 were duplicates and one was an image (not visible). The mention of the HPV vaccine, an adverse event, and a relationship between a vaccine and an adverse event were present respectively in 126 (91.3%), 112 (81.2%), and 40 (29.0%) posts.

Among the posts in which a relationship was identified, 4 were considered as potential cases, and the others reported adverse events that were observed in studies abroad. Two posts were personal experiences of an adverse event likely to be associated with the vaccine: the first described a pulmonary embolism after vaccine with temporal causality, and the second the experience of several adverse events with no full description. Among the 138 manually reviewed posts, 63 (46%) were neutral regarding to HPV vaccines, 56 (40%) posts described a negative opinion, and only 19 (14%) corresponded to a positive opinion.

4. Discussion

In this study, 29% of the reviewed posts described a potential adverse event of HPV vaccines, and only 5% were a personal experience. Our study focused on French forums and evaluated a small number of posts. Despite these limitations, we observed

that patients often discuss what they have read or heard in other media, and not necessarily their personal experiences. Only 14% of the posts corresponded to a positive opinion towards the HPV vaccines, but this may be underestimated as the posts included in the study contained both a drug and an adverse event annotation.

There were significantly fewer personal experiences of adverse events compared to other drugs in the literature. Posts are mainly the illustration of general belief of the French population regarding HPV vaccines use, rather than a place to share personal experience about its safety. Indeed, the perception that the vaccine causes serious side effects has gained popularity among the public [11,12]. The health authorities must consider this observation for communication about vaccines, especially HPV vaccines.

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Access of Stroke Patients' to Optimal Healthcare Technology in Greece: Messages to Policy Makers

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Abstract. The aim of this study was to evaluate accessibility of stroke patients to optimal healthcare technology in Greece. Methods: The study population consisted of 313 first ever stroke patients derived from the “Stroke Units Necessity for Patients, SUN4P” registry. Descriptive statistics were used, to present patients’ characteristics and resources utilization Results: The vast majority of patients (91.7%) conducted a CT scan during the acute phase (within the first 24hours). Almost, (65%) were admitted to wards of Internal Medicine Departments, whereas only 21% of patients were admitted to a Stroke Unit. Of note, a total of 6.9% of ischemic stroke patients received intravenous thrombolytic therapy with recombinant tissue plasminogen activator (rtPA). Conclusions: Preliminary results from SUN4P underline the urgent necessity for the re-organization of acute stroke care in Greece, as rates of admissions to stroke units and rtPA treatment during the acute phase are currently below optimal.

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Keywords. Stroke, Organization of acute stroke care, Healthcare Technology

1. Introduction

Although thousands of patients suffer a stroke every year in Greece (>23,000 admissions/year) [1], the management during the acute phase is still diverse, whereas a comprehensive national strategy for stroke management over the cycle of care and mitigating the social consequences is lacking. Standard care regarding first scan during the acute phase without delay (time from symptoms onset to first scan < 4.5 hours and time of arrival in the emergency department < 20 minutes in at least 50% of patients) [2], acute stroke unit care and intravenous thrombolysis (within 4.5 hours from symptoms onset; for patients with moderately stroke severity: NIHSS between 4 and 24) is associated with a favorable outcome in patients with ischemic stroke [3]; nevertheless there is a paucity of relevant data in Greece. The aim of the present study was to evaluate accessibility of stroke patients to optimal healthcare technology in Greece.

2. Methods

The study population derived from the “Improving Stroke Care in Greece in Terms of Management, Costs and Health Outcomes- (SUN4P)” registry (ClinicalTrials.gov NCT04109612). SUN4P is an ongoing observational non-invasive prospective cohort multicenter study of patients with first-ever acute stroke, hemorrhagic and ischemic, admitted to seven public hospitals [4].

Descriptive statistics were used, to present patients' characteristics and utilization of resources. The SUN4P design was based on the European General Data Protection Regulation (GDPR) and aligned with the Declaration of Helsinki.

3. Results

The study population consisted of 313 patients admitted from July 2019 to May 2020. As shown in Table 1, the vast majority of patients conducted a Computed Tomography (CT) scan during the acute phase (with the first 24 hours of the index event). Nonetheless, a delay was evident for about half of the patients from the onset of symptoms to first CT scan (median = 4.5 hours). The majority of patients were not admitted to a specialized acute stroke unit (ASU), while almost 65% were admitted in an Internal Medicine Department. Of note, 6.9% of patients with ischemic stroke received rtPA. Delays or undefined time of symptoms onset were reported in 42% of ischemic stroke patients who didn't receive rtPA (Table 1).

4. Discussion

Preliminary results of SUN4P underline delays that could be attributed to poor recognition or neglect of stroke symptoms by patients or relatives, a wait-and-see response to stroke symptoms partly explained by 'fear of disease or hospitalization,

geographical difficulties (e.g. long distance from hospitals) transfer mode (private car vs. ambulatory), and, in some cases, limited availability of a CT scanner [5].

Hospitalization in non-specialized wards were due to the country's limited availability of ASUs (0.4/million population vs >2/million population in most European countries) [3]. Finally, low rates of rtPA administration, 6.9% vs. 18% (a target set by the European Stroke Organization [2] could be attributed to delays, patients' characteristics (e.g modestly stroke severity NIHSS<4 or severe stroke NIHSS>24 increasing the absolute risk of intracerebral hemorrhage) and in some cases hospitals' limited capacity to provide rtPA [6,7,8].

Table 1: Characteristics of patients (n=313) and resources utilization

Gender (male)	163 (52%)
Age (mean±SD)	74.6±14
Length of hospital stay, days (median, interquartile range)	6 (6)
Subtype of Stroke	
Ischemic	245 (78.30%)
Intracerebral hemorrhage	47 (15.00%)
Unclassified	21(6.70%)
Scan During Acute phase (first 24hours)	287 (91.70%)
CT in hospital of admission	251 (80.20%)
CT in another hospital or health facility	29 (9.30%)
MRI in hospital of admission	5 (1.60%)
CT Scan During Hospitalization (on top of acute phase scan / median, interquartile range)	1 (1)
Delay of patient's evaluation, (median, interquartile range)	
Time from stroke onset to first scan in hours (n=184)	4.5 (9.3)
Time from emergency room to first scan in minutes (n=271)	45 (60)
Intravenous thrombolytic therapy with recombinant tissue plasminogen activator (rtPA) to ischemic stroke patients (n=245)	17 (6.90%)
Reasons for non rtPA administration to ischemic stroke patients (n=228)*	
Delays (>4.5hours) or undefined time of symptoms onset	96 (42.00%)
Modestly stroke severity NIHSS<4	81 (35.50%)
Non hospital capacity to provide rtPA	58 (25.40%)
Risk for hemorrhage	13 (5.70%)
Severe stroke NIHSS>24	12 (5.30%)
Co-morbidities	11 (4.80%)
Hospitalization**	
Internal Medicine Department	159 (64.90%)
Neurology Department	71 (29.00%)
Acute Stroke Unit	51 (20.80%)
Less Intensive Care Unit	47 (19.20%)
Other departments and unreported departments	7 (2.90%)
Intensive Care Unit	5 (2.00%)

Notes: *Percentages do not add up to 100% as in case of some patients multiple reasons existed.

**Percentages do not add up to 100% as some patients were admitted to more than 1 department during their hospitalization.

5. Conclusions and Recommendations

Preliminary results from SUN4P underline the urgent necessity for re-organization of acute stroke care in Greece, as country rates of admissions to ASUs, rtPA treatment and time from symptom onset-to-first scan are currently below best practice. Stakeholders/policy makers, experts on the field of stroke care and Non-Governmental Organizations (donors) have to be actively engaged in order to ensure high value care by developing Stroke Units and Tele-stroke services and by improving health practitioners' co-ordination and population awareness.

Acknowledgment

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Semantic Web of Things (SWoT) for Global Infectious Disease Control and Prevention

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Abstract. This paper reports on the early-stage development of an analytics framework to support the semantic integration of dynamic surveillance data across multiple scales to inform decision making for malaria eradication. We propose using the Semantic Web of Things (SWoT), a combination of Internet of Things (IoT) and semantic web technologies, to support the evolution and integration of dynamic malaria data sources and improve interoperability between different datasets generated through relevant IoT assets (e.g. computers, sensors, persons, and other smart objects and devices).

Keywords. Internet of Things, Semantic Web, Surveillance, Global Health, Interoperability

1. Introduction

Malaria is the most prevalent mosquito-borne disease worldwide, yet it is lethal, although preventable. According to the 2019 World Malaria Report [1], there were 228 million cases of malaria worldwide in 2018 with 93% of cases and 94% of deaths occurring in Africa. Data on malaria, generated by various sources, is currently stored in different formats in various geographical locations across diverse organizations, making it challenging to access, process, and use. Advances in information and communication technologies (ICTs) such as Internet use and mobile phones, smart devices, and Big Data analytics have provided opportunities for global health to improve health data exchange, delivery of health services, and employ novel surveillance methods for disease control

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and prevention. In the recent years IoT assets have been widely adopted in health and clinical services as well as disease monitoring and surveillance [2, 3]. In addition, different types of sensors (e.g. for remote health monitoring (blood pressure and heart rate monitors and emergency notification systems) and GPS devices have been employed to generate epidemiological models of the spatial spread of infectious diseases. These provide explanatory and predictive patterns for the spread of a virus and measure the likely routes of infected persons and predict possible new outbreaks. Their use facilitates planning for preventive and therapeutic programs (e.g. vaccination). Some examples of the use of IoT to combat malaria and other infectious diseases [4] are; (i) Sensor- and SMS-enabled village water pumps (Rwanda, Kenya), (ii) GSM-connected refrigeration for vaccine delivery (Global), (iii) sensor-enabled “band aid” to monitor patients vital signs remotely (West Africa). One of the main challenges in using surveillance data is creating a mechanism by which such dynamic data, scattered in multiple heterogeneous data sources, can be consistently integrated and aggregated, shared, and analyzed to enable timely decision-making.

2. Methods and Results

The IoT assets have been utilized for malaria surveillance in various ways. Some of these include:

- Real-time satellite data collection, with focus on parameters such as temperature, pressure or other environmental indicators, remote sensing devices [5].
- Cell phone-based polarized light imaging [6].
- Tools for flight track analysis of *Anopheles gambiae* [7],
- Smart devices to capture data on travelers, data to quantify human movements, and displacement using mobile call detail records (CDRs) [4].
- Mobile phone surveillance to track and monitor malaria cases in remote villages (e.g. Botswana Mobile Device Surveillance) [8].
- Surveillance apps (e.g. Coconut Surveillance App - MEEDS, in Zanzibar for passive and active case detection) [9].

The success of IoT technologies is built mainly on their “interoperability”, which refers to “the ability of two or more systems (computers, communication devices, networks, software, and other information technology components) to interact with one another and exchange information according to a prescribed method in order to achieve predictable results” (ISO/IEC [10]). IoT by its nature is an integrated set of several devices communicating within a network and exchanging data and information with each other to achieve a common goal. Although many approaches tend to improve structural and syntactic interoperability, achieving semantic interoperability remains an ongoing challenge for IoT systems.

We are employing tools and techniques from knowledge representation and semantic web in combination with IoT to create a Semantic Web of Things (SWoT) [11] platform that uses the interoperable IoT-based surveillance data along with the domain (here malaria) knowledge for effective malaria control and prevention. We aim to provide an integrated semantic platform (Figure 1) that can be accessed by multiple users

(e.g. researchers, epidemiologists, and public health practitioners) for real-time monitoring, tracking, and analysis of datasets generated by different IoT assets operating in different platform and protocols with different levels of complexities. For maintaining the interoperability between different data sources and devices we employ the Semantics, Interoperability, and Evolution for Malaria Analytics (SIEMA) framework [12, 13], along with a graph-based formalism [14] for managing changes within dynamic distributed sources.

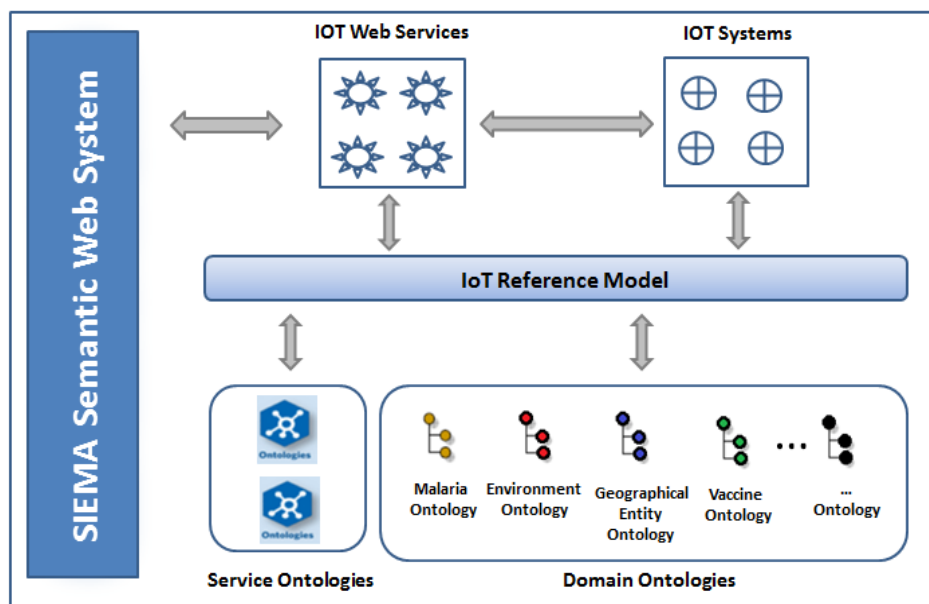


Figure 1. A schematic representation of the semantic web of things for malaria surveillance.

SIEMA deploys the IoT web services that access and manage distributed IoT devices, sensors, and systems. The semantics to define interactions and interoperability between the IoT systems and services are supported by a series of domain and service ontologies and their communication is managed through an IoT Reference Model (IoT RM) [15] that provides the concepts and definitions on which IoT architectures can be constructed. The ontologies can provide a shared common understanding of the IoT devices, their missions, resources, functionalities, and the domain they are working in. SIEMA can assist in discovering and deploying context-appropriate web services in a dynamic environment.

3. Discussion

Our proposed framework aims to improve decision making for malaria control and prevention by increasing the interoperability between malaria data sources and relevant IoT-based surveillance devices and reducing the time for data harmonization and integration. In the near-term, we will generate a registry of discoverable services using Valet SADI [16] to ensure the interoperability of IoT assets and to support dynamic data integration while considering the evolving nature of data sources coming from multiple

devices.

Acknowledgment

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Exploring Unsupervised Query Paraphrasing to Identify Relevant Search Phrases for a Literature Review

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Abstract. Literature databases have multifaceted search options, but emerging research areas do not have an established terminology and therefore it is difficult to find relevant literature when conducting a review. This study aimed to explore if an unsupervised paraphrasing approach is useful in identifying relevant search phrases for a literature review on an emerging research topic – situational leadership in critical care. Using an initial set of 12 search phrases, the system was used to propose additional phrases, which were manually classified and further used in an expanded PubMed database search. Finally, we assessed the papers found with the expanded search and compared this to the initial search results. As a result, the expanded search more than tripled the search results, from 182 to 673 papers. The expanded search also more than tripled the number of relevant papers, from 12 in the original search to 39 in the expanded search.

Keywords. Literature review, search strategy, health care leadership, unsupervised query rewriting, unsupervised paraphrasing, PubMed

1. Introduction

Literature reviews present existing knowledge on a phenomenon of interest, by critically analysing and summarising previously reported research through a rigorous and systematic approach. There are many types of literature reviews and the choice of review design is based on the purpose of the review [1]. Although reviews differ by type, the search process to find relevant literature is similar. The identification of relevant search terms, phrases, synonyms and language variations is important in an efficient search [2]. This includes identifying database specific terms and phrases, such as the controlled vocabulary of Medical Subject Headings (MeSH), which is maintained by the National Library of Medicine in the United States.

To date, literature databases have multifaceted search options developed for researchers for enabling robust search strategies [3]. The exploitation of various approaches and resources for bridging the gap between user queries and terminology used has been widely studied, such as query expansion using MeSH terms (see e.g. [4-

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8]). Previous work focusing on the use of database filters to improve precision of papers obtained have shown inconsistencies between different filters and raised the question of missing relevant literature if used as only search approach [9]. A more recent approach to advance search results includes the “Best Match” sort order for PubMed [10]. It is based on a two-stage ranking architecture where it first retrieves documents using a classic term-weighting algorithm and thereafter re-ranks the top 500 documents using an algorithm trained on past search statistics. However, the terminology in the body of evidence matures in time, and hence emerging research areas do not necessarily have an established terminology to be used. Therefore, finding appropriate search terms may still be difficult.

The aim of the present study is to explore the use of a recently proposed query rewriting and paraphrasing approach [11] – which relies primarily on distributional and sequential statistics about words – for the purpose of identifying relevant (multi-word) search phrases that can be used further when conducting a literature review on an emerging research area. In this paper, our phenomenon of interest is *situational leadership in critical care*.

2. Methods

In the first step, we identified a list of 12 initial phrases deemed to be central to the phenomenon of interest, i.e. *situational leadership in intensive care*, based on domain expertise (see Table 1 for original phrases). We searched the PubMed database (<https://pubmed.ncbi.nlm.nih.gov/>) with each of these 12 original phrases together with “intensive care” (e.g. “*situational leadership*” AND “*intensive care*”). The search was limited to full texts, papers published within 5 years and papers written in English.

As a second step, we used a recent query rewriting and paraphrasing approach (see [11]) that works in an unsupervised manner by combining 1) a semantic word n-gram (embedding) model, 2) a statistical language model and 3) a document search engine, where all these components have been indexed or trained on a PubMed abstracts data set. This system was used to extract 100 related (para-) phrase candidates for each of the 12 initial phrases. Two domain experts then classified these into four classes: 1 = synonym, 2 = relevant phrase, 3 = covers topic but is irrelevant for the search at hand, and 4 = irrelevant phrase. Consensus was sought if the domain experts disagreed.

In the third step we compared the papers obtained from searching with the initial phrases to a similar search using the automatically suggested phrases in addition to the initial phrases. All phrases that were classified as belonging to classes 1 and 2 in the second step were considered relevant and included in this expanded PubMed search on the topic. Two domain experts then manually classified the papers from these two approaches into three classes: A = relevant paper, B = on the topic but not important to the current review at hand, and C = irrelevant paper. We explored possible differences between the distribution of the classifications done to the papers found with the initial search phrases and the papers found with the expanded search with the Chi-square test.

3. Results

A total of 104 out of 1200 automatically generated phrases were classified as synonyms (n= 18) or relevant phrases (n= 86) by domain experts in the second step of the study.

In the third step, the expanded search more than tripled the results from 182 to 673 papers. The number of papers found with the initial phrases and the expanded search are presented in Table 1 together with the number of phrases added to each initial search phrase. Examples of automatically generated phrases used in the expanded search and classifications of these phrases by domain experts are found in Table 2.

Table 1. PubMed search findings with initial phrases and the expanded search

Initial search phrase	Initial search results	Number of phrases added to initial search phrase	Expanded search results
"situational leadership"	0	8	8
"situational medical leadership"	10	4	58
"medical team leadership"	68	13	168
"operational leadership"	0	4	134
"operational medical leadership"	70	15	100
"emergency leadership"	89	21	196
"medical emergency leadership"	63	13	331
"medical emergency team leadership"	19	0	19
"rapid response team leadership"	7	0	7
"resuscitation leadership"	0	25	355
"advanced cardiac life support leadership"	1	0	5
"advanced life support leadership"	7	1	7
Total	334	Total	1388
Duplicates	152	Duplicates	715
Final total	182	Final total	673

Table 2. Automatically generated new phrases for the initial phrase example "*medical team leadership*" with the classification done by the domain experts

Rewritten suggestions for the original search phrase: " <i>medical team leadership</i> "	Classification done by domain expert
Medical leadership, team	synonym
Leadership and medical teams	synonym
Physician leadership, interdisciplinary team	relevant phrase
Clinical team leadership	relevant phrase

The expanded search tripled the number of relevant papers retrieved (from 12 to 39). We found 182 papers with the initial search phrases, among these, 12 were classified as relevant, 32 were classified to be on the topic but not important to the review at hand, and 138 were classified as irrelevant. We found an additional 491 papers with the expanded search using the phrases suggested by the system that were classified relevant for the topic. Out of these 491 papers, 27 were classified as relevant papers, 89 were classified to be about the topic but not important to the review at hand and 375 were classified as irrelevant papers. The distribution of the papers that were classified to be relevant, on the topic but not important to the review at hand, and irrelevant in the search done with the initial phrases was similar to the distribution of the classifications done of the papers found with the expanded search $\chi^2(2, N=673) = 0.10, p=0.86$.

4. Discussion

The expanded search more than tripled the search results from 182 to 673 papers. Correspondingly, the expanded search also more than tripled the number of relevant papers from 12 to 39 papers. These findings indicate that the use of unsupervised query rewriting and paraphrasing approaches can be beneficial in identifying additional relevant search phrases in the context of searching for relevant literature in large databases such as PubMed. As future work we plan to explore how the approach used here may work in tandem with methods that are more directly tailored to PubMed searching, e.g. methods exploiting MeSH terms for query expansion [see e.g. 4-8]. Further, given that the present approach is trained in an unsupervised fashion, we also aim to explore how it can support search and information retrieval in text databases that lack relevant and/or tailored lexical resources, like MeSH and search history logs.

5. Conclusions

This study showed that the use of an unsupervised query paraphrasing system helped to identify additional relevant search phrases for the purpose of conducting a literature review on an emerging research area. Hence, the use of this or similar paraphrasing approaches may be used as one part of a rigorous search strategy.

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Applying Artificial Intelligence to Predict Self-Reported Poor Health Among Black and Hispanic Caregivers with Mild Cognitive Impairment

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Abstract. We applied artificial intelligence techniques to build correlate models that predict general poor health in a national sample of caregivers with mild cognitive impairment (MCI). Our application of deep learning identified age, duration of caregiving, amount of alcohol intake, weight, myocardial infarction (MI) and frequency of MCI symptoms for Blacks and Hispanics whereas frequency of MCI symptoms, income, weight, coronary heart disease (CHD), age, and use of e-cigarette for the others as the strongest correlates of poor health among 81 variables entered. The application of artificial intelligence efficiently provided intervention strategies for Black and Hispanic caregivers with MCI.

Keywords. artificial intelligence, health disparities, mild cognitive impairment

1. Introduction

Approximately one in five Americans age 65 or older have preclinical Alzheimer's disease (AD), mild cognitive impairment (MCI) [1]. The prevalence of MCI is higher in Hispanics and Blacks than non-Hispanic Whites (27.3% vs. 19.1%) [2]. Two proteins including β -amyloid (plaques) and tau (tangles) abnormally increase in number during aging and in AD; no medications are currently available for MCI [3]. Deep learning (a subset of machine learning where artificial neural networks, algorithms inspired by the

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human brain, learn from large amounts of data) has the potential to assist personalized recommendations based on their contextual and lifestyles and situational factors among caregivers of AD. Deep learning, representing the latest iteration in a progression of artificial intelligence (AI) technologies, has made advances in solving problems which have resisted the best attempts of the AI community [4]. Despite its popularity, deep learning has rarely been applied in behavioral medicine. The purpose of the study was to build deep learning algorithms to predict self-reported poor health based on aging, behavioral, and demographic factors as the groundwork for future targeted interventions for Black and Hispanic caregivers with MCI in the U.S.

2. Methods

We applied a data mining process to a publicly available national dataset, a survey of 1,373,755 Americans from the Behavioral Risk Factor Surveillance System (BRFSS) from 2016 to 2018, to build a model for predicting self-reported poor health. BRFSS is a U.S. phone based survey to collect data regarding health-related risk behaviors. We used R 3.6.1, Weka 3.8.3, and Deep Neural Network-BigML to conduct AI based analytics. We extracted 275 demographic, behavioral and physio-psycho social variables using R 3.6.1. First, 81 of total 275 variables were selected by caregiving and behavior experts as relevant to poor health based on the literature [1,3,5,6]. During feature selection, we applied deep learning in BigML, which evaluates the importance of attributes by predictive ability of each feature considering redundancy between them. The outcome variable was the dichotomized self-reported poor health [the respondents were asked to rank their general health on a five-point Likert scale (1 excellent, 2 very good, 3 good, 4 fair, 5 poor), 4 or 5 corresponded to a “Yes”]. The respondents answered “Yes” to the question [During the past 12 months, have you experienced confusion or memory loss that is happening more often or is getting worse?] were identified as caregivers with MCI. BigML with default configuration were chosen. We applied correlation, entropy, and learner based techniques to create different views of the dataset to check algorithms dependency and selected eight final variables based on the criteria of clinical meaningfulness based on an understanding of the literature on reasons for poor health among people with MCI [1,3,5,6]. Next, we organized the variables into three categories: demographic, physiological, and behavioral factors. Next, we iteratively applied C4.5 algorithms to build the prediction models for self-reported poor health among caregivers with MCI. For cross-validation (10-fold), the dataset was randomly divided into training and evaluating datasets for the model validation before applying the algorithms. We chose the final models based on the model predictive accuracy, interpretability, and clinical meaningfulness, and the area under the receiver operating characteristic curve (AUC). Lastly, neuro-science nursing and behavioral science experts interpreted the models according to clinical meaningfulness.

3. Results

Study participants (n=897, 0.07%) were identified as caregivers with MCI. Age 65 or older were 44.26% (n=397). Over half of caregivers with MCI were female (58.42%, n=523). One of ten participants (n=77, 8.58%) identified themselves as Black or Hispanic caregivers. Half of caregivers with MCI reported their health as poor (n=438,

48.83%). Descriptive statistics for the study variables are summarized in **Table 1**. While age (importance 12.02% for Blacks and Hispanics) and weight (importance 8.96% for Blacks and Hispanics, 8.55% for others) also selected by deep learning algorithms, they were excluded in the final prediction model due to their relative lack of interpretability (e.g., proxies for number of chronic illnesses) and applicability.

Table 1. Descriptive Statistics for Study Variables (n=897)

		Blacks or Hispanics n=77 (%)	Others† n=820 (%)	χ² test p-value
MCI symptoms	Always, Usually	15 (19.48)	116 (14.15)	0.06
	Sometimes	22 (28.57)	164 (20.00)	
	Rarely, Never	40 (51.95)	529 (65.51)	
Income	<25K	39 (50.65)	282 (34.39)	0.00
	≥25K	27 (35.06)	429 (52.32)	
Exercise	Yes	43 (55.84)	546 (66.59)	0.07
E-Cigarette use	Yes	1 (1.30)	43 (5.24)	0.21
Poor health	Yes	42 (54.55)	396 (48.29)	0.35

†Others: non-Hispanic whites, Asian or Pacific Islander, or Aleutian/Eskimo/American Indian

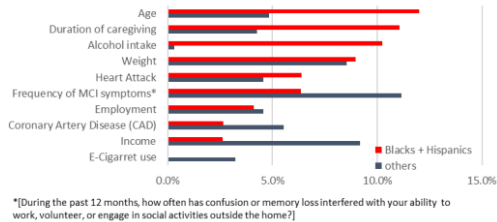


Figure 1. Ranking of Factor Importance for Poor Health Applying Deep Learning

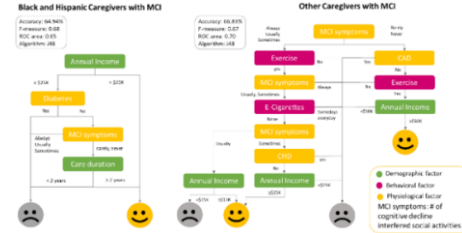


Figure 2. Prediction Models for Self-Reported Poor Health for Caregivers with MCI

4. Discussion

Among the many risk factors for self-reported poor health, deep learning found that frequency of MCI symptoms interfering with social activities was a key determinant (variable importance: 6.37% for Blacks and Hispanics, 11.17% for others, **Figure 1**) among US caregivers with MCI. Consistent with the literature, our findings indicate that frequency of MCI symptoms is a strong predictor of functional ability and the need for care in older people [5]. MCI is also associated with impaired activities of daily living, unplanned hospital admissions, and the need for long-term care [5]. Our study found that among Black and Hispanic caregivers with MCI under poverty (annual household income ≤\$25,000), whose MCI symptoms have interfered with social activities during the past 12 months, were likely to report being in poor health regardless of their caregiving duration whether inexperienced or experienced (**Figure 2**). Novel findings were observed for those who used electronic cigarettes. Among caregivers who exercised

and experienced MCI symptoms interfering with social activities, the use of e-cigarettes increased their probability of experiencing poor health (**Figure 2**). Although electronic cigarettes have not been on the market long, there is clear evidence that the aerosols of most electronic nicotine delivery systems contain toxic chemicals [7]. Considering the paths among these predictors will be an important next step. Is exercise enough to improve the general health for caregivers with MCI? If not, such a pattern would suggest behavior intervention for cessation of e-cigarette smoking as treatments when MCI symptoms occur, rather than only exercise advice. Targeting patients whose social activities are curtailed due to their MCI symptoms may be appropriate for effective interventions. Additionally, this study is the first of its kind to document the prevalence and impact of MCI among caregivers. MCI can affect a person's ability to learn new skills and complete tasks [6]. Understanding the prevalence, frequency, and impact of MCI symptoms can offer insight into the types of interventions that can support needs and explain why some caregivers are more burdened than others. We used the Deep Neural Network function of the BigML platform to automate the discovery of the parameterization for our classification task. This approach obviates a primary practical challenge to using deep learning: determining the optimal settings for the hyperparameters of the model (e.g., the appropriate number of hidden layers) [4]. The lack of transparency and interpretability of the model's predictions is a major limitation of such methods; nonetheless, the combined use of traditional machine learning algorithms such as C4.5 with the Deep Neural Network automatic optimization features of emerging platforms like BigML is suggested for similar studies.

5. Conclusion

Our deep learning algorithms revealed the strongest predictors of self-reported poor health among caregivers with MCI to be aging, frequency of MCI symptoms interference with social activities, exercise, e-cigarette use, and income. This new knowledge adds insights about behavior and supports symptom science interventions for caregivers with MCI and other aging-related future interventions.

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Effective Design of Serious Games for Children with Chronic Diseases: The Role of Parents and Caregivers

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Abstract. Research on digital games explicitly designed for medical or health-related purposes has grown rapidly over the past years. Serious games have been used to convey health-related information to children, to engage them in health decision making, to promote healthy behaviours, and to influence health outcomes. In this process, parents represent an important, yet often neglected, target audience. Studies increasingly stress the importance of engaging parents and caregivers as agents to support their children, and of involving them directly in some part of gameplay. The present work reviews the latest research on games for children with chronic diseases from the perspective of parents and caregivers, concluding that further research is needed, in order to create evidence-based games that are tailored to the specific challenges faced by both paediatric patients and their parents.

Keywords. Serious Games, Chronic diseases, Parents, Caregivers

1. Introduction

The term serious games (SGs) refers to games specifically designed for purposes other than mere entertainment. They are developed according to pedagogical principles and serve education and training purposes, supported by gaming techniques and entertainment [1]. Serious games are considered a useful tool to bring about better outcomes in healthcare. Research on digital games explicitly designed for medical or health-related purposes has grown rapidly over the past years, targeting diverse clinical areas [2]. Baranowski et al (2016) noted that SGs “offer exciting, innovative, potentially highly effective methods for increasing knowledge, delivering persuasive messages, changing behaviours, and influencing health outcomes” [3]. A substantial number of studies have thus been published on SGs addressing diverse aspects of health and care. Important application areas include health communication, health promotion and preventative care, health management and rehabilitation and behaviour modification for patients and education for medical professionals. Given the interwoven nature of child health and support environment, parents and caregivers play

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an important role in game-based interventions for children with chronic physical or psychological health problems. The present work investigates the gap in past studies related to the analysis of the role of parents and caregivers in SGs interventions reviews.

2. Methods

We conducted an exploratory review of the literature through searches in 2 scientific electronic databases (ScienceDirect, and PubMed). We used keywords in various combinations such as Serious Games and parents, caregivers. For inclusion, articles had to: (1) be relevant to the role of parents, caregivers in serious games for Children with chronic diseases (2) be published in English and in scientific peer-reviewed journals.

We identified and examined 86 articles deemed to be relevant. Of these, we excluded 56 out of 86 because they did not satisfy one or more of the requirements, particularly papers that made no concrete reference to the role of parents or caregivers in the design, implementation and/or validation of the SG intervention. Hence the high number of exclusions. Additional papers were consulted from citation snowballing and the final review comprised.

3. Results

Parents are an important target audience of games for children with chronic health conditions. However, the role of parents or caregivers in SGs-based interventions for children's health is not properly analysed. No dedicated study was found on the subject. Nonetheless, SGs studies often encourage the involvement of parents or caregivers in gameplay, given that they typically play a significant role in managing children's health, particularly in the case of young children [4]. Besides games directly targeting young people and the emergence of dedicated solutions for parental education on managing children's chronic condition [5], [6], studies increasingly stress the importance of engaging parents as agents to support their children or involving them directly in some part of gameplay [7], [8].

In the case of young asthma patients, researchers conclude that games alone are unlikely to yield a positive behaviour change and that the child's environment must also be influenced [9]. Asthma studies explicitly involved parents in some part of gameplay. With the active involvement of parents, gaming platforms can enable home-based intervention for children with autism (Autism Spectrum Disorder, ASD) [5]. Joint parent-child programs are deemed beneficial in the case of children and adolescents suffering from anxiety [10]. Similarly, games can help reduce the burden of medical procedures on patients, parents, and clinical care providers [11]. Parental involvement is expected to enhance potential benefits and increase adherence in exergaming programs that promote physical activity in children for prevention, treatment or rehabilitation [12]. Complementary activities involving parents are encouraged, as a means to enhance consolidation of taught material using the "Emotiplay" game for learning about emotions in children with autism [13]. Solutions to improve parental communication skills are expected to help parents become effective support agents for their children, and thus enhance the benefits of SGs programs [7].

SCERTS model educational approach is considered as very important, sharing the goals of learning between parents and children with chronic diseases, through collaboratively creating learning experiences [14]. The simultaneous use of two digital tablets proposed as an innovation aspect of an automated serious gaming platform GOLIAH to deliver intervention at home for Autism, since can provide interaction between children and parents. The same feature appears only in the game of ComFim [15]. Although teachers and parents are eager to use technology to support learning of children's with autism, there are just a few related applications involving parents and caregivers [16]. In the case of Junior Detective Training Program (A multi-component social skills intervention) the participation of parents is also limited to helping children in a part of the game. Furthermore, in the case of "Let's Face it" (Using computerized games) parents are restricted only to send log data since the game was designed not directly involving parents or caregivers. The role of guidance that provides feedback to the participants is the main implication of therapists during game sessions.

Only in case of GOLIAH there are games dedicated to collaborative actions between children and their parents or therapist or caregiver. Furthermore, GOLIAH according to literature seems to be the only gaming platform that involves clinicians at the hospital with parents at-home [17]. In case of children with Attention Deficit Hyperactivity Disorder (ADHD) the involvement of their parents in the joy of achievement in a serious game could have enhanced the child's appraisal of the game's positive feedback and its effect on his/her self-esteem. (Improving executive functioning in children with ADHD).

4. Discussion

This review has some limitations. First, we included only games that were described in the scientific literature. Second, conclusions were drawn on a small number of game studies, as fewer data exist for programs for children with chronic diseases. Furthermore, these studies are typically small in scope and not conclusive.

Often the issue of games for children's health is approached from a narrow perspective, resulting in its diverse facets not being properly analysed. Child patients are not the same as adult patients. Evidence shows that the child's environment must also be taken into consideration. Appropriate measures to influence the child's environment are needed, most importantly their parents. Parents need to be empowered for the continued management of their child's chronic condition.

There is limited evidence to support the effectiveness of serious games used to care for and support children with physical or mental disabilities. The effectiveness of interactive media to educate the parents of children with chronic conditions is also questioned [6]. Studies, however, reveal important trends that should be explored further. Games for health alone are unlikely to be the sole factor behind any positive behaviour change. The child's environment must also be influenced, therefore the inclusion of a parent or an adult into the serious game seems to indicate that this may be key to finding improvements. While the child may look outside to their peers for social cues, parents still have a strong influence on their child's behaviour. Additionally, the inclusion of the parent may introduce other elements into the environment once they are finished playing the game. For instance, conversations between the parent and the child could be around a situation from the game and not from "real life." This may alleviate some stress in the conversations.

5. Conclusions

Future research into this relationship will be important to understand the key mechanisms into parent involvement and develop evidence-based games tailored to the specific challenges of children and their parents. A limited understanding of proper design principles among the development and implementation side can compromise the use of a medical serious game. Our recommendation would be to include parents in the design, implementation and validation of SGs interventions for children health.

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Developing Patients' Experiences Database After Hospital Discharge: Another Step in Improving Stroke Care

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Abstract. The aim of this study was to assess stroke patients' experiences in regards to hospital stay and during discharge. A cross-sectional study with retrospective data collection was conducted including patients (n=135) with first-ever acute stroke, who were admitted in seven Public Hospitals in Greece ("Stroke Units Necessity for Patients, SUN4P" registry). The translated version of the NHS-Stroke Questionnaire in the Greek was used. 48.2% of patients rated their overall experience from the care they received as very good/excellent. 66% of patients reported that they participated in decision making about their care and 21.5% reported not having received help from the hospital's social services regarding any benefits/aids, thus lowering their overall patient experience score (p=0.017). Decision and policymakers must consider factors affecting stroke patients' experiences during their hospitalization. The development of a national stroke

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patients' experiences database can help prioritize relevant actions and draw up a commonly accepted management and services redesign framework for patients.

Keywords. Patient Experiences, Stroke Care, Disease Management

1. Introduction

Stroke is the second leading cause of death and the leading cause of disability in adults worldwide [1]. In Greece, stroke along with ischaemic heart disease, is by far the leading cause of death [2]. Stroke has devastating consequences for patients, their families, caregivers and communities in general. Existing approaches that focus on assessing patients' experiences and their perceptions of the disease and underlying treatment [3-11] are increasingly being recognized as key objectives by the research community towards the improvement of management of stroke patients and quality of care. The aim of this study was to assess stroke patients' experiences in regards to hospital stay and during discharge.

2. Methods

A cross-sectional study with prospective data collection was conducted including patients with first-ever acute stroke, hemorrhagic and ischemic, who were admitted in seven Public Hospitals in Greece (as derived from the "Stroke Units Necessity for Patients, SUN4P" registry ClinicalTrials.gov NCT04109612 – patients' experience survey duration: 2019-2021) within 48 hours following the onset of symptoms. Patients (n=135) who had been enrolled in the study and had given their informed consent received a telephone call from non-hospital staff field researchers, about a month after discharge. The questionnaire used (N = 35 questions) was developed following the translation and intercultural adaptation of the NHS-Stroke Questionnaire (Healthcare Commission 2005) in the Greek language, and its pilot study (n=50), conducted to ensure face validity. It includes questions to patients' opinion regarding stroke diagnosis, treatment and care during hospital stay and discharge. Statistical analysis was carried out using SPSS. Descriptive statistics were used to present mean (standard deviation) and median (interquartile range). Correlations were conducted using Student's t-test and Pearson's and Spearman's correlation coefficients. Multivariate linear regression was performed when more than two independent variables were statistically significant at the level of 0.2 ($p < 0.2$). The two-sided significance level was set at 0.05. Patient enrolment in the study was initiated following the research protocol approval by the Bioethics Committee of the Nursing Department and the Scientific Committees of the study centres/hospitals. Patients were briefed in detail about the purpose of the study and their right to voluntary participation. All principles of Bioethics and Ethics were respected in full accordance with the General Data Protection Regulation of E.U. 2016/679 and aligned with the Declaration of Helsinki.

3. Results

More than 1/2 of the participants were men and mean age was 72.1 years (SD=15.0). About 80% of patients suffered an ischaemic stroke and the median length of hospitalization was 7 days (IR=6.0). Eight out of ten (80.7%) patients reported that their stroke was diagnosed early and 71.9% that they were admitted to the hospital as early as possible. 90.4% and 87.4% had confidence in their doctors and nursing staff, respectively. Among those in need of speech, physiotherapy and psychological support services during their hospitalization, 60%, 74.2% and 63.8% received relevant services. 60.5% reported having participated in the formulation of decisions about their care and treatment, 37% reported that only occasionally was the nursing staff numerically adequate and 55.6% had been informed about the medications' possible side effects. 21.5% reported not having received help from the hospital's social services regarding any benefits / aids. A total of 48.2% of patients rated their overall experience from the care they received as very good/excellent. Lower level of disability and self-dependency on daily activities before admission were associated with more positive overall patient experience score ($p=0.042$ & $p=0.05$). Multivariate regression (Table 1) revealed that stroke patients who received help from the hospital's social service on seeking for available benefits (aids) rated higher their experience compared to patients who did not receive relevant assistance ($p = 0.017$).

Table 1. Bivariate and Multivariate Analyses Results

Bivariate Analyses – Characteristic	Mean Score (SD)	P value
Self-Dependent On Daily Activities Before Admission		0.05
Yes	3.3 (1.3)	
No	2.8 (1.2)	
Level Of Disability (Or Dependence On Daily Activities) According To The Modified Rankin Scale (Mrs) - Before Admission	-0.176	0.042
Help From The Hospital's Social Service On Seeking For Available Benefits (Aids)		0.042
Yes	4.1 (1.3)	
No	3.2 (1.1)	
Multivariate Regression Analysis ($R^2=0.155$)	Beta Coefficient	95% CI / P value
Help From The Hospital's Social Service On Seeking For Available Benefits (Aids)	-1.074	(-1.942 - 0.206) / 0.017

4. Discussion

These mid-study SUN4P results revealed positive doctor/nurses-patient interpersonal relationships, patient confidence in doctors and nursing staff confidence and early stroke diagnosis. However, care gaps in terms of supporting services, efficient information flows and gaps in patient empowerment, mostly concerning patient decision participation during hospital stay were also noted. These deficiencies could be attributed to the lack of centralized acute stroke care pathways [12] and limited digital functionality and workflow management systems [13,14]. Better organized stroke care is associated with more positive patient experiences [4]. Therefore, high-quality information provision can allow stroke patients to effectively manage stroke implications and actively participate in healthcare decision-making [15], thus

addressing timely and effectively these types of challenges and care gaps; challenges and gaps that jeopardize continuity of care and quality of care, in general. A phone survey entails by nature significant drawbacks in terms of decreased response rates due to the lack of face-to-face contact with the researcher, challenging communication strategies and timing constraints (time of the call and length of the actual interview).

5. Conclusions

Evaluating stroke patients' experiences using tools that correspond to the Greek context provide important information about the quality of care of stroke patients in the country. The development of a stroke patients' experiences database on a national level can help prioritize relevant actions and draw up a commonly accepted management and services redesign framework for stroke patients. Decision and policymakers must consider factors affecting stroke patients' experiences during their hospitalization and causing burden on themselves and caregivers following their discharge and during the rehabilitation phase. This type of accumulated knowledge on different aspects of stroke management constitutes an important step in shaping a more lucid framework for the management of these cases in order to redesign and improve the care provided.

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The Dissemination and Communication Plan and Activities of the CrowdHEALTH Project: “Collective Wisdom Driving Public Health Policies”

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Abstract. Determining the dissemination and communication plans and activities of research projects is an important part for transferring research outputs to the target audience. This paper presents the dissemination and communication plans and activities of the CrowdHEALTH project. Towards this end, the methodology and results are presented in this paper.

Keywords. Dissemination strategy, Communication

1. Introduction

The dissemination and communication plans and activities aiming at putting science into practice can be challenging [1]. Numerous theories and models concerning the dissemination plans and activities can be found in literature [2], [3]. The CrowdHEALTH project “Collective wisdom driving public health policies” [4] implemented a dissemination strategy [5] based on European Council guidelines, European research projects, and on peer-reviewed papers published on scientific journals [6].

2. Methods

The first step to define an appropriate dissemination strategy was the identification of the objectives, target groups, key messages, the tools, and activities. The objective of the dissemination strategy involved a broad promotion of new, progressive ideas, concepts, and solutions to target groups with the aim of adapting the new knowledge and the project’s outcomes. Key messages were communicated to the target audience in an appropriate language. Based on other public dissemination and communication deliverables the most common high impact dissemination activities and tools were the

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use of digital media (website, blog, social media), press releases, printed materials (Flyers and Brochures), publication in scientific journals, participation in conferences with oral presentations, posters and workshops, participation in booths and exhibitions and participation in initiatives with other EU projects to foster synergies. In more detail, digital visibility targets the public, policy makers and industry and was considered an efficient and reasonable way of communicating project and its results. The Blog includes abstracts of the public deliverables and tasks related to project and targets the public. Publications in scientific journals were also proposed to enhance the dissemination of the project results in academia, influence research community and get feedback from peers. Articles to newspapers and magazines can be also implemented to engage audience, consisted of policy makers, professionals, and general public. Participations in conferences with oral presentations, posters and workshops can communicate the project’s results to the scientific community and academia whilst participation in other events such as booths and exhibitions can target industry. Building momentum throughout the entire project lifecycle is considered important; for example, timings for sharing findings. For this reason, it is prudent to identify and plan critical time points, consider external influences and supporting groups (ex. EFMI working groups), and utilize existing opportunities such as upcoming conferences, other events, and exhibitions. The final phase recommends monitoring the KPIs to assess performance regarding dissemination activities and readjust the strategy if there are any failures or enhance the plan accordingly should success occurs (Figure 1).

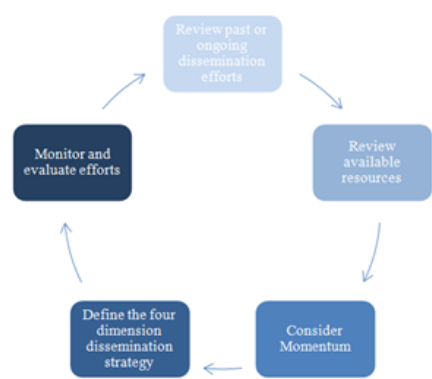


Figure 1. Steps in developing the dissemination strategy

3. Results

The type and number of the dissemination and communication plans and activities completed from M1 to M36 are presented in the following table (Table 1).

Table 1. Type of activities and KPIs

Type of dissemination and communication activities	KPIs
Website and Blog	1 Website within the 5 SERP and 26 blog entries with 1,083 views (avg).
Publication in Journals	40 publications indexed in IEEE, Scopus, Elsevier, and PubMed.
Participation in Conferences	56 participations in conferences with audience ranging from 150-60,000.
Participation in Workshops	6 participations in Workshops with demonstration to hospital, policy making institutions, and stakeholders
Participation in Exhibitions	4 participations in exhibitions
Dissemination presentations	7 dissemination presentations to policymakers, HEIs, hospital and enterprise
Articles in e-magazines and newspapers	17 articles in 4 different languages published in e-magazines and newspapers with their audience ranging from 22,000 to 795,236
Social Media	3 Social media (Twitter, Facebook, ResearchGate) with more than 100 posts and 2,142 reactions 70% of Twitter and Facebook shares exceed 500 views.
Flyers	2 Flyers created and distributed in major events
Demos and videos	7 Demos and Videos released
Activities with other EU projects	8 activities with more than 9 projects involved

4. Discussion

Up until M36, the CrowdHEALTH website was updated with information related to the latest consortium meetings, dissemination activities and blog entries. Also, the downloads section included material relevant to the project, such as videos, demos, press releases and public deliverables. Website visitors, visits and hits have been increased from 2017 to 2020 and the website appears in the top 5 list of the SERP. The Blog was created and set up in M12. Up until M36 partners are encouraged to provide relevant information to keep the blog updated with at least one blog per month. In M36 the blog has 26 blog entries. Dedicated pages in Social Media were also created on Facebook and Twitter to target public. ResearchGate account was also created to engage scientific community with the project, share results and accept feedback. More than 100 shares of posts were achieved on social media. Printed material: Two flyers were designed to promote the project to events, conferences, and exhibitions, including the CrowdHEALTH logo, a description of the CrowdHEALTH project, the consortium and connection links to website and social media. Events: A list of the most significant dates and events for the last period of the project and beyond the project life cycle were identified. The project was represented in 56 conferences with posters and oral presentations, 6 workshops, 7 other presentations such as lectures in universities and 4 exhibitions. In addition to that publications in scientific journals were increased to 40 papers the last period of the project. Finally, networking activities with other projects were completed [7]. Consortium participated in seven initiatives to foster synergies with more than nine European Horizon 2020 and Erasmus+ projects [8], [9].

5. Conclusions

CrowdHEALTH proposed and implemented a methodology for the dissemination and communication plans and activities. During project lifetime, emphasis was given to digital visibility. Digital visibility was encouraged in order to raise awareness of the general public about CrowdHEALTH project and its benefits on public health and policy making. Website, Social media, e-magazines and other interactive means of digital communication facilitated direct communication between consortium and audience whilst support a bottom –up approach of the project’s long-term implementation. Number of comments, shares, likes, as well as views were suggested as evaluating measures of activities related to digital visibility. Participation in high impact conferences and the release of scientific publications in journals were also achieved. For the evaluation of the activities related to conferences and other events the number of participants was measured, and regarding the publications the number of papers published as well as downloads and citations were also measured. All the initiatives outlined above were considered important for CrowdHEALTH to build a discrete identity, influence scientific and academic community by introducing new technologies and take the opportunity to analyse feedback from distinguished experts. Also, the Impact Creation Board consisted of experts in related fields was created to give external feedback on project’s dissemination activities. CrowdHEALTH dissemination activities continue beyond the end of the project. Conferences and other events have been identified in order to promote project further.

Acknowledgments

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Determining and Evaluating the Dissemination and Exploitation Plans and Activities for the CrowdHEALTH Project: The Role of the Impact Creation Board

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Abstract. Determining and evaluating the dissemination and exploitation plans and activities of research projects can be a challenging task. This paper presents an overview of the role of the Impact Creation Board in the identification and assessment of the dissemination and exploitation plan and activities for the CrowdHEALTH project “Collective wisdom driving public health policies”. Towards this end, a stepwise methodology was applied and the feedback from the Impact Creation Board members, and results of each step were analyzed and shared with the consortium.

Keywords. Evaluation, Dissemination strategy, Exploitation

1. Introduction

The implementation and evaluation of plans and activities aiming at putting science into practice can be a challenging task [1]. In literature, several theories and models that define dissemination plans and activities can be found [2], [3] whilst mixed methods both quantitative and qualitative are used to evaluate such efforts [4]. The CrowdHEALTH project “collective wisdom driving public health policies” [5] implemented a dissemination strategy [6] based on European Council guidelines, past and ongoing projects, and on peer-reviewed papers [7]. In addition, CrowdHEALTH established the Impact Creation Board (ICB) consisted of 12 experts on Health Informatics and academia, with solid healthcare and technical background in order to keep the outputs aligned with the IT industry demands, address patients’ and health providers’ needs, receive direct feedback regarding technical issues and dissemination plans and get feedback.

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2. Methods

The stepwise methodology (Figure 1) followed was a three-step process. The **first step** involved a virtual meeting in which technical and communication leaders and ICB members participated and the project was presented. An open questionnaire enabled ICB members to give their feedback. A content analysis was applied to extract the main key points and the results were communicated to the consortium. The **second step** involved an interaction of ICB with the consortium and a presentation of the first results of the project in ICIMTH workshop. An instrument was used that allowed ICB to give their feedback in open-ended questions in relation to the communication activities and dissemination tools of the project. A content analysis was applied to extract the main key points. The results were communicated to the consortium. The **third step** involved a report distributed to the ICB members regarding the dissemination and exploitation efforts of the project. An instrument with 10 items in Likert-scale was administered. ICB members were requested to fill-in the questionnaire to evaluate the impact of the dissemination and exploitation activities. The data was analysed and the results were extracted and visualised in a bar chart. The results were communicated with the consortium.

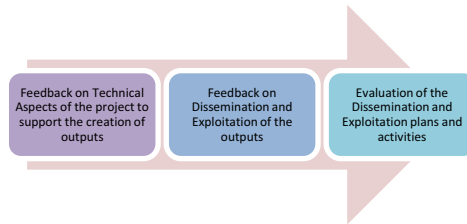


Figure 1. The step wise methodology

3. Results

3.1. Step 1

ICB gave feedback in 6 areas: the coding items, the information to be extracted by patient records, data privacy, representation of aggregated information, Policy Development Toolkit (PDT) methods, and generalization of the models.

- ICB highlighted the importance of coding, mentioning that coding items in a large field of interest (social, lifestyle and health data) need more coding systems.
- Concerning the kind of the aggregated information that need to be extracted by the individual records, ICB concluded that clinical activity, outcome measures, prevalence of infection, errors and safety threats should be considered.
- As far as health data protection aspects are concerned, the ICB members suggested that data protection aspects can be well supported by Fast Healthcare Interoperability Resources (FHIR) but General Data Protection Regulation (GDPR) should be taken into consideration.
- For the representation of the aggregated information SNOMED CT has adopted a model: concepts are organized in hierarchies formed via its relations. Additionally, based on the relevant ISO standards, intelligent interoperability solutions have been piloted in several countries and many examples can be found in literature.

- Different methods can be applied on available relevant (sub)sets of data to ensure that a PDT answers the right questions. A data dictionary should provide the names of the data items that are relevant. The questions suggest which methods to be used and which data should be included and analyzed.
- Policy models should be explored and tested for feasibility and usefulness in the project to develop a solution beyond ad hoc. For the generalization of the models to different scenarios, organizations, regions, or populations is that the data should be such that the ensuing model can in principle also be used (although with perhaps updated criteria) in other environments.

3.2. Step 2

Based on ICB feedback, the first outputs were produced and presented to the ICB with Demos. The second step of the process resulted in the dissemination and exploitation activities and tools (Demonstrations in exhibitions, Participations in conferences with posters, Oral presentations and workshops, Journal publications). Furthermore, the exploitation models of the project were further defined (Data-As-a Service, Information-As-a-service, Platform-As-a-Service).

3.3. Step 3

The last step included an evaluation of the dissemination and exploitation impact. 30% of the participants agreed and 70% of the participants strongly agreed that the applied dissemination methods achieved their aim. All participants strongly agreed that the dissemination strategy reached valuable results. 40% of the participants agreed and 60% strongly agreed that the dissemination of the project was sufficient. 40% of the participants agreed and 60% strongly agreed that the dissemination and exploitation of the project was efficient. 40% of the participants agreed and 60% strongly agreed that the dissemination activities of the project can be continued beyond the project lifecycle. 60% of the participants agreed and 40% strongly agreed that based on the dissemination activities which took place during the project lifecycle, possible investors and customers were attracted. 10% of the participants disagreed, 40% neither agreed nor disagreed and 50% agreed that the PDT presented is an effective tool for policy making. 10% of the participants neither agreed nor disagreed, 60% agreed and 30% strongly agreed that CrowdHEALTH can be exploited as Data-as-a-service model. 10% of the participants neither agreed nor disagreed and 90% strongly agreed that CrowdHEALTH can be exploited as Information-as-a-service model. All participants agreed that CrowdHEALTH can be exploited as Platform-as-a-service model.

4. Discussion

ICB feedback focused on data privacy aspects, the kind of the aggregated information to formulate health policies, the coding items and systems, the methods to guarantee the PDT answers the right questions and finally the use of conceptual model in order to generalize the model to other regions, populations or scenarios. Dissemination activities, tools and the exploitation models were further defined based on the delivered outputs. Although, it was suggested that the project's dissemination was sufficient and

efficient, there was ambiguity in the question whether PDT is an effective tool for policy making. CrowdHELATH could be exploited as Data-as-a-service model, Information-as-a-service model and Platform-as-a-service model with the last one gaining the consensus of all participants and all participants agreed that dissemination and exploitation activities attracted possible customers and inventors and that dissemination activities can be continued beyond the end of the project including education [8], [9], and empowerment of healthcare professionals [10], [11].

5. Conclusions

CrowdHEALTH proposed and implemented a step wise hybrid approach to define and evaluate dissemination and exploitation based on ICB feedback. The Impact Creation Board was a group of experts who had an active advisory role throughout the project lifecycle that helped keeping the project aligned with the current needs of the industry, healthcare providers, communities and patients as well as policy making institutions. ICB provided technical feedback and proposed relevant dissemination activities and were requested to evaluate the dissemination and exploitation activities.

Aknowledgments

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Understanding the Food Habits and Physical Activities of Diabetes Cohort in Qatar

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Abstract. In this study, we analyze the food and lifestyle-related factors for a Diabetic cohort from Qatar, where the prevalence of diabetes is among the top in the Middle East region. Statistical analysis shows that the diabetic group is consuming a lower amount of fast foods, soft drinks and meats as a meal but a higher amount of vegetables and fruits compared to the control group. Though the diabetic cohort consumes a lower number of snacks and desserts, they consume a higher amount of sugar for tea. Interestingly, we find the diabetes cohort is spending a lower amount of time in sedentary life but their involvement in different physical activities is lower than the control group. Overall, we conclude that the Qatari diabetic cohort, considered in this study, is following standard guidelines for food and drinks but they may need to improve the physical activity level following physician guidelines.

Keywords: Diabetes, Fast food, Physical activities, Qatar Biobank (QBB)

1. Introduction

Diabetes mellitus, commonly known as diabetes, can be described as a collection of metabolic conditions which may arise from the defects in insulin discharge [1] and this prolonged hyperglycemia associated with diabetes can be related to long-term impairment and failure of multiple organs. A population-based study forecasted that diabetes prevalence in Qatar would be around 24% by the year 2050 [2]. To mitigate such health-related problems, cohorts are established in different parts of the world to identify the complex interaction of food, lifestyle, environmental and genetic factors that may contribute to diseases like diabetes. The Qatar Biobank (QBB) is the largest repository from the Qatari population to conduct such studies to mitigate the health problems and we, in this study, considered a Qatari diabetes cohort based on QBB data. It has been shown that maintaining a healthy lifestyle and food habit may reduce the susceptibility to diabetes [3]. But we could not find any research work that mainly focused on the dietary habit and lifestyle-related factors of the diabetes cohort from Qatar. To fill this gap, in this study, we compared a Qatari diabetes cohort against the control

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group considering their food habits, drinking habits, and other daily life physical activities.

2. Materials and Methods

2.1 Ethical Approval

This study was conducted under the regulation of the Ministry of Public Health, Qatar. All the procedures were approved by the Institutional Review Board (IRB) of Hamad Medical Corporation, Qatar and only de-identified data were collected from QBB.

2.2 Cohort Description and Questionnaire Considered for this study

In this study, we considered a cohort consisted of 500 subjects, among which 250 were diabetic, and 250 were none-diabetic (control group). The control group was free from any type of diabetes, obesity or cardiovascular disease. Each subject, based upon their approval, when they arrive into QBB for participation, was asked multiple questions by the clinicians to collect valuable information about their background, dietary habit, and lifestyle-related factors. The details of the questionnaire can be found in [4, 5]. All the subjects from this cohort were Qatari nationals. Both diabetes and the control group contained ~50% male and ~50% female. In this study, we only considered questionnaires that are related to food habits, drink habits, and the physical activities of the participants.

2.3 Dataset pre-processing

All the responses of the participants were encoded numerically in such a way that a higher number represents the more frequent events. For example, for the question “How often did you eat fried chicken last year?” we encoded the responses as 0 (“never or rarely”), 1 (“1-3 times per month”), 2 (“1-3 times per week”), 3 (“4-6 times per week”), 4 (“once per day”), 5 (“2 or more times per day”). Any question, having more than 50% missing values was discarded and for the remaining cases, we replaced each missing value by the mean value of corresponding metrics calculated from the corresponding group.

2.4 Statistical significance of the variables

We used the Anderson-Darling test [6] to check if the variables are normally distributed. For normally distributed variables, we used the student’s t-test [7] to determine the significance level for each variable when comparing the diabetic versus the control group. For other variables, we applied a Mann-Whitney [8] test for the same purpose. We only considered the statistically significant variables ($p\text{-value} < 0.05$). For each variable, we also computed the mean value for the diabetes group and the control group.

3. Results & Discussions

We observed that the diabetes group is consuming less fast or junk foods (e.g., French fries, fried chicken, burger, hotdogs, etc.) than the control group (Table 1). This indicates

that after the onset of the disease, the Diabetes group is more cautious about consuming such kinds of food than the control group.

Table 1. Summary of fast food consumption for Diabetes versus Control group

Fast Food Items Consumption	Mean	Mean (Control)	p-value
Chicken shawarma	1.844	2.112	0.001
Middle-eastern style fast food	1.532	1.964	<0.001
French fries	2.060	2.572	<0.001
Potato chips	1.928	2.336	<0.001
Burgers, Hotdogs	1.568	2.300	<0.001
Pizza	1.824	2.272	<0.001
Fried chicken	1.612	2.032	<0.001

We also observed that the diabetes group is consuming less bottled juice, soft drinks or soda, Diet soft drinks or soda, and energy drinks than the control group (Table 2). But the Diabetes group is still consuming more sugar (compared to the control group) in the regular tea or herbal tea as part of their drink habit (Table 2). We also observe that the diabetes group is consuming less snacks or desserts (e.g., cake, doughnut, ice cream, chocolate bar) than the control group (Table 2).

Table 2. Summary of snacks, drinks, and sugar consumption for Diabetes versus Control group

Drinks and Sugar Consumption	Mean (Diabetes)	Mean (Control)	p-value
preserved fruit juice (canned/ bottled)	1.872	2.20	0.004
Soft drinks, sodas	1.780	2.476	<0.001
Diet soft drinks, sodas	1.520	1.788	0.016
Energy drinks	1.144	1.396	<0.001
Number of teaspoons of sugar with tea or herbal tea	2.204	2.532	0.002
Desserts and Snacks			
Cake, Doughnuts	2.036	2.344	0.002
Chocolate bar	2.424	2.684	0.030
Ice cream	2.172	2.480	0.002

Moreover, we observed that the diabetes group is consuming more healthy foods (e.g., raw vegetables, green leafy salad, mixed salad, fresh fruits, dates) than the control group (Table 3). Interestingly the diabetes group is more cautious in consuming canned fruits, most likely to have additional sugar, than the control group (Table 3). We observed that the diabetes group is consuming a smaller amount of meat-oriented dishes (e.g., chicken curry, kofta, meat kebab, chicken kebab, etc.) than the control group (Table 3).

Table 3. Summary of fruits, vegetables, and meat consumption for Diabetes versus Control group

Fruits and Vegetables Items	Mean (Diabetes)	Mean (Control)	p-value
Raw vegetables	3.664	3.316	0.008
Green leafy salad (e.g., lettuce)	3.908	3.500	0.001
Mixed salad (for example with tomato, onion, cucumber, other vegetables)	3.696	3.336	0.005
Fresh fruits	3.644	3.304	0.006
Dates	3.796	2.804	<0.001
Canned fruits	1.224	1.384	0.019
Meat Items as part of Main Meal			
Light meat (chicken)	3.404	3.624	0.049
Chicken curry	1.768	2.060	<0.001
Kofta	1.656	1.924	<0.001
Meat kebab	1.696	1.916	0.001
Chicken kebab	1.748	2.008	<0.001

We analyzed the amount of sedentary time that the cohort was spending in front of the electronic devices. From Table 4, we can observe that the diabetes group spent a

lesser amount of sedentary time, both on weekdays and weekends, with electronic devices like computers, TV, DVDs, and mobile phones. We also considered the amount of time spent on different types of physical activities by the diabetes and control group. Though the differences in physical activities were not statistically significant, we found that, on average, the diabetes group was spending less time than the control group on walking, a moderate level of physical activities (swimming, bicycling at a regular pace, yoga, gym, etc.), and sports (football, weight lifting, fast bicycling, running, aerobics) (Table 4).

Table 4. Time spent in different activities for Diabetes vs. Control group

Days with electronic devices (in sitting position)	Mean (Diabetes)	Mean (Control)	p-value
Weekdays using computers	0.960	1.508	<0.001
Weekends using coputers	0.676	1.176	<0.001
Weekends using TV, DVDs, mobile phone, i-pad, etc.	2.176	2.516	0.004
Physical Activities (in minutes)			
Heavy sports activities (running, fast bicycling, fast swimming, singles tennis, football, weight lifting, aerobics)	2.880	4.228	0.145
Moderate physical activities (swimming, bicycling at a regular pace, gym, double tennis, yoga)	3.600	4.788	0.233
Average walking time per day	9.996	10.636	0.645

4. Conclusions

Based on our analysis, we observed that the diabetes group in Qatar, in general, is following the standard guidelines suggested by the physicians in terms of food habits and physical activities. The participants should be more careful about the sugar intake with tea and improve the physical activity level based on physicians’ guidelines. Additionally, the control group (non-diabetic) should be cautious in their lifestyle and dietary habit; otherwise, they might be susceptible to diabetes as well.

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An Efficient Method to Predict Pneumonia from Chest X-Rays Using Deep Learning Approach

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Abstract. Pneumonia is a severe health problem causing millions of deaths every year. The aim of this study was to develop an advanced deep learning-based architecture to detect pneumonia using chest X-ray images. We utilized a convolutional neural network (CNN) based on VGG16 architecture consisting of 16 fully connected convolutional layers. A total of 5856 high-resolution frontal view chest X-ray images were used for training, validating, and testing the model. The model achieved an accuracy of 96.6%, sensitivity of 98.1%, specificity of 92.4%, precision of 97.2%, and a F1 Score of 97.6%. This indicates that the model has an excellent performance in classifying pneumonia cases and normal cases. We believe, the proposed model will reduce physician workload, expand the performance of pneumonia screening programs, and improve healthcare service.

Keywords. Deep learning, pneumonia detection, convolutional neural network

1. Introduction

Pneumonia is a severe health problem, common in individuals younger than five years and older than 65 years, causing millions of deaths every year [1]. Pneumonia diagnosis often begins with blood tests to identify infection, but precise identification is usually hard. Using chest X-rays is an alternative method for pneumonia diagnosis [2]. An early and accurate diagnosis from initial clinical inspection and interpretation of chest X-rays is always difficult, mostly due to the difficulty of detecting it and differentiating it from other possible pulmonary anomalies. Using chest radiography as part of the routine evaluation of diagnosing pneumonia patients is recommended [3]. In the interpretation of pneumonia from chest X-rays by a clinician, experience and capacity are important factors. However, subjectivity and discrepancies are often the key problems attributed to pneumonia diagnosis in reaching group consensus, making detection of pneumonia using chest X-rays a difficult task that needs skilled radiologists.

Diagnosing pulmonary diseases from chest X-rays have been investigated previously by many researchers [4-6] using the ChestX-ray14 dataset provided by the National Institute of Health with labels of pulmonary diseases. The dataset has more than 100,000 X-ray images with frontal views having annotations for 14 diseases. A dataset was extracted from the ChestX-ray14 dataset by Paul Mooney [7] which contains

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pneumonia and normal cases. In this study, we used this pneumonia chest X-ray dataset and developed a deep learning architecture for the identification of pneumonia cases. The aim of this study was to develop an advanced deep learning-based architecture to precisely identify the absence or the presence of pneumonia symptoms in chest X-ray images and provide a diagnostic tool for pneumonia classification. The model we propose in this paper is based on the CNN architecture that is combined with various preprocessing techniques and parameters for fine-tuning.

2. Methods and materials

2.1. Study Data

For this study we considered pneumonia chest X-ray images, available from Kaggle [7], provided by Paul Mooney. The dataset contained 5856 chest X-ray images (normal=1583, pneumonia=4273) with frontal view. The size of the images was 1024 x 1024 pixels. We downscaled the size of the images to 224x224 using bi-cubic interpolation for inputting the images into the model. The dataset was split into 80% training and 20% testing. The training set was further split into 80% training and 20% validation. Hence, training set has 3747 images (normal=1014, pneumonia=2733), validation set had 937 images (normal=254, pneumonia=683), and the testing set had 1172 images (normal = 317, pneumonia = 855). The training and validation set was used for model training and validation and the performance of the trained model was evaluated using the test set. One-hot-encoding was used to convert the labels to categorical labels such as positive and negative. We evaluated the performance of the model using different metrics, such as accuracy, specificity, F1-score, precision, and recall.

2.2. Model Architecture

We propose a CNN model based on VGG16 architecture [8]. The model has 16-convolutional layers forming the feature extraction base for the network with two fully connected layers and a final logistic regression layer forming a predictive base for the network. A small 3x3 receptive field was used throughout the model that convolves with the input at each pixel (with stride 1). We also added a batch normalization layer after each convolutional layer for regularization. Batch normalization stabilizes the output of the convolutional layer [9]. We split the convolutional layers into four blocks. Every block consisted of two convolutional layers with batch normalization and one max-pooling layer that reduced the dimensionality of the feature maps to keep the important features. In the first two blocks, we used strides of 2x2 for pooling layers and for the last 2 blocks, we changed the strides to 3x3 to extract more specific features to generalize the network. After that, we used the flatten layer to take feature maps and convert them to a single vector for the fully connected layer. We added two fully connected layers to create the correct label prediction base for the network. We then used the SoftMax activation function to classify the labels at the final logistic regression layer. The model was trained using the pneumonia chest X-ray dataset. The weights of the networks were randomly initialized. The entire model was trained using the Adam optimizer using parameters ($\beta_1=0.9$, $\beta_2=0.99$) and the preliminary learning rate $1e^{-4}$. The model was implemented using Python Keras library with Python TensorFlow library as a back-end and was trained on Kaggle freely available P100 GPUs.

3. Results

Table 1 shows the classification results for the test data in the form of a confusion matrix. Out of all test data (1172), the model correctly labelled 1132 images, which means that it had an excellent accuracy of 96.6% (Table 2). The model also correctly classified 839 of the 855 images belonging to pneumonia cases, meaning that it had high sensitivity/recall (98.1%). Of the 317 images belonging to normal cases, 293 images were labelled correctly by the model, indicating considerable specificity of 92.4%. Out of the 863 images classified as positive (i.e., pneumonia) by the model, the classification was correct in 839 images. This means that the model precision was high (97.2%) (Table 2). The model labelled 309 images as negative (i.e., normal), but the labelling was correct for 293 images. Thus, the negative predictive value (NPV) achieved by the model was 94.8%. Given that the model had high recall and precision, its F1 score was also high (97.6%). It is noteworthy that the accuracy of the model over validation and test sets were approximately equal (96.5% & 96.6%, respectively).

Table 1: Confusion matrix for the proposed model over the test data

		Predicted label		Total
		Pneumonia	Normal	
True label	Pneumonia	839	16	855
	Normal	24	293	317
	Total	863	309	1172

Table 2: Classification performance metrics for the proposed model over test data

Accuracy	Sensitivity (recall)	Specificity	Precision (PPV)	NPV	F1 Score
96.6%	98.1%	92.4%	97.2%	94.8%	97.6%

4. Discussion

In this study, we developed a deep learning model to discriminate between pneumonia cases and normal cases based on X-ray images. A total of 5856 high-resolution frontal view images of chest X-rays were used for the training, validating, and testing the model. The model achieved an accuracy of 96.6%, sensitivity of 98.1%, specificity of 92.4%, precision of 97.2%, NPV of 94.8%, and F1 Score of 97.6%. This indicates that the model has an excellent performance in classifying pneumonia cases and normal cases. The model proposed in this study showed superior performance in comparison to other existing models. To be more precise, Rajpurkar et al. [4] proposed a CNN-based model to identify pneumonia using chest X-rays obtained from ChestX-ray14 database. F1 Score was the only performance metric assessed in the study, and it was much lower than the F1 score results found in our model (43.5% vs. 97.6%) [4]. Another CNN-based model was used to detect pneumonia and other seven diseases based on chest X-rays obtained from the ChestX-ray8 database [5]. The model had a precision of 66%, recall of 93%, and F1 Score of 77%, indicating that it had lower performance than our model [5].

In the future, we plan to optimize our model by using more X-ray images from different sources to be universally applicable. We are also planning to extend the model to detect novel coronavirus disease (COVID-19) and other respiratory diseases. Furthermore, the performance of the model over X-rays images will be compared with

its performance over computed tomography (CT) images. By demonstrating efficacy and accuracy of the model in detecting pneumonia and other diseases, we will upload the developed model in a free cloud-based platform to provide an instant diagnostic tool worldwide, especially in remote and economically underdeveloped areas where the access to skilled radiologists is limited. We recommend biomedical researchers to exploit our data and codes that will be uploaded to a publicly available database to improve the performance of the model and help move the field forward. Researchers should also assess the clinical and cost effectiveness of using such AI tools.

5. Conclusions

In this work, a deep learning model was developed to identify pneumonia using images of chest X-rays. The model showed an excellent classification performance, which was higher than the performance of models mentioned in previous studies. We expect that the model will reduce physician workload significantly, improve the performance of screening programs, improve healthcare delivery, and enhance the development of telemedicine. Further studies should be conducted to assess the effectiveness of this model. We will optimize the model by testing it using more images and extending it to detect other diseases (e.g., COVID-19) using CT images in addition to X-ray images.

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Semantic Reconciliation of Standard and Localized Medical Terminologies for Knowledge Interoperability

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Abstract. The heterogeneous localized concepts of various hospitals reduce interoperability among localized data models of Hospital Information Systems (HIS) and the knowledge bases of clinical decision support systems (CDSS). The leading solution to overcome the interoperability barrier is the reconciliation of standard medical terminologies with localized data models. In this paper, we extend the semantic reconciliation model (SRM) to provide mappings among diverse concepts of localized domain clinical models (DCM) and concepts of standard medical terminologies such as Systematized Nomenclature of Medicine - Clinical Terms (SNOMED CT). In the extended SRM, we insert the explicit semantics only into the word vector of the localized DCM concepts instead of the implicit semantics, which enhances the system's accuracy with a lower computational cost. The extended SRM performed well on the datasets of localized DCM and SNOMED CT with a precision of 0.95, a recall of 0.92, and an F-measure of 0.93.

Keywords. Semantic reconciliation, health informatics, ontology matching, knowledge interoperability, clinical decision support system

1. Introduction

A clinical decision support system (CDSS) is used to increase the patient care quality, reduce the chance of decision-making errors, enhance the physicians' performance, and reduce medical cost [1]. CDSS adoption is facing a challenge and a barrier for knowledge base integration because of its low-level interoperability with clinical workflows in hospital management and information systems (HIS) [2]. The standard virtual Medical Record (vMR) meets the interoperability objectives, however; it needs to bind its classes and properties with the concepts of standard terminology such as SNOMED CT, to maximize system interoperability [3].

A semantically interoperable mapping model is required to map and reconcile the standard terminology concepts with localized DCM concepts. In our previous work [4], the semantic reconciliation model (SRM) accomplishes the semantic mappings between SNOMED CT concepts and DCM concepts. Our previous system embedded the explicit

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and implicit semantics into word vectors of the standard and non-standard concepts in each iteration, which increased the system’s accuracy but made it a computationally expensive method. The explicit semantic means the direct relationships with other concepts such as synonyms, hypernyms, hyponyms, and meronyms within the same or other terminology. While the implicit semantic means the collection of it’s lexical chain as the sum of indirect relationships such as relatedTerms, typeOf, and partOf. In this study, we discard the implicit semantics inset into word vectors and perform the standard mappings (i.e. string, label, child, and property matching) before the explicit semantics embedding. Once a concept is mapped using any of the aforementioned standard mapping techniques then the concepts will be considered as a mapped concept without checking their explicit semantics. For instance, a concept of DCM “Gender” is mapped with SNOMED CT concept “Gender” using standard string matching algorithm. While a DCM concept “Laryngeal” cannot match with SNOMED CT concept “Larynx” using string matching, and these concepts are mapped using child matching with same five child concepts in DCM and SNOMED CT. A DCM concept “Smoking Status” cannot map with SNOMED CT concepts “Smoking Monitoring Status” using string, label, and child matching. Therefore, we inset the explicit semantics of all words in both of concepts into their word vectors and find the similarity score, it was 0.926. The extended method maintains the system’s accuracy with a lower cost of computation.

2. Methods and Materials

The important feature of SRM is to embed the semantics into the word vectors of standard and non-standard ontology concepts. We designed and implemented an application programming interface (API) to organize two phases of matching algorithms depending on the selected algorithm execution scheme. Figure 1 depicts the architectural flow of our extended SRM for mapping localized DCM to standard terminology concepts.

The system’s component Execution Control loads and fetches concepts from each

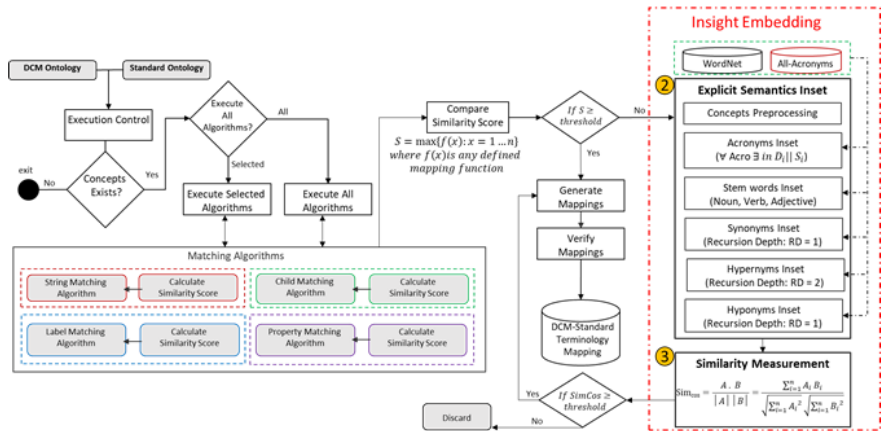


Figure 1: Architectural view of semantic reconciliation of standard and localized terminology of the standard and non-standard ontologies to execute the standard matching algorithms. According to the defined scheme of Execute Selected Algorithms or Execute All Algorithms, the system executes Matching Algorithms in phase one, the matching

algorithms include String Matching, Label Matching, Child Matching, and Property Matching Algorithms. In the String matching, we compare each word of DCM concept with each concept of SNOMED CT using 4-gram. If the concept is matched with any SNOMED concept then these are considered as mapped concepts and fetch the next concept. If the concept is not mapped using string matching then we map the child of those concepts. If childs of DCM concepts are mapped with childs of SNOMED CT concept then it considers as mapped concept. Similarly, the process will continue for property and label matching till the end of concepts. These algorithms calculate similarity score based on their algorithmic logic. If the similarity score exceeds the threshold value (0.8) then the DCM and SNOMED CT concepts are considered as mapped concepts, otherwise, we send the fetched concepts for insight embedding.

In phase two Insight Embedding, we insert the Explicit Semantics into the word vectors of the standard and non-standard concepts. The Concept Preprocessing component performs basic operations like tokenization and stopword. The component Acronym Inset transmute all the acronyms to their corresponding full form through the All-Acronyms Library. The Synonym Inset module finds the synonyms of each word from the online open-source library, such as WordNet and ConceptNet repositories, and inserts them into word vectors. The synonym recursion is limited to the depth of the second level of the hierarchy due to performance of the multi-dimensionality of the concepts.

The Hypernyms Inset is responsible to embed the hypernyms for generalization of a concept into the word vector. We extended the recursion depth for the hypernym embedding up to second level, because the two levels of hypernym cannot effect the multi-dimensionality of a concept. Therefore, the Hyponyms Inset is used to embed the concepts' hyponyms for its specialization. We selected the first level of recursion depth for it because the child concepts can highly affect the multi-dimensionality feature.

After semantic inset, we calculated the similarity score using the cosine similarity formula for word vector. When the similarity score exceeds the threshold value, which is 0.8, then those concepts are mapped, else the concepts are discarded and the next iteration of concepts will be started. The Verify Mappings module is in charge of verifying the mapped concepts. Finally, the system stores the mapped concepts into repository.

3. Results and Discussion

In this study, we used SNOMED CT which has more than 300,000 concepts, 200 properties, and a maximum depth of 9. The DCM in the current study increased from 199 (previous dataset) concepts to 214 (modified dataset) concepts and seven properties of the head and neck cancer domain. Our extended study showed a precision of 95%, a recall of 92%, and an F-measure of 93% using corresponding standard formulas. The extended study showed better results concerning computational time from 11,812 seconds to 7403 seconds, which is a significant improvement in execution time.

We also evaluated our extended system with existing systems of ontology matching AgreementMakerLight (AML) [6], GOMMA [5], and LogMap Lite [7]. We measured the precision, recall, and F-measure of all these methods using their corresponding standard formulas. It is observed that our proposed system's results are better than the existing systems and Figure 2 illustrates the evaluation results, graphically. The existing

systems have given very significant results on large biomedical standard ontologies and these systems are not evaluated on standard and non-standard terminologies.

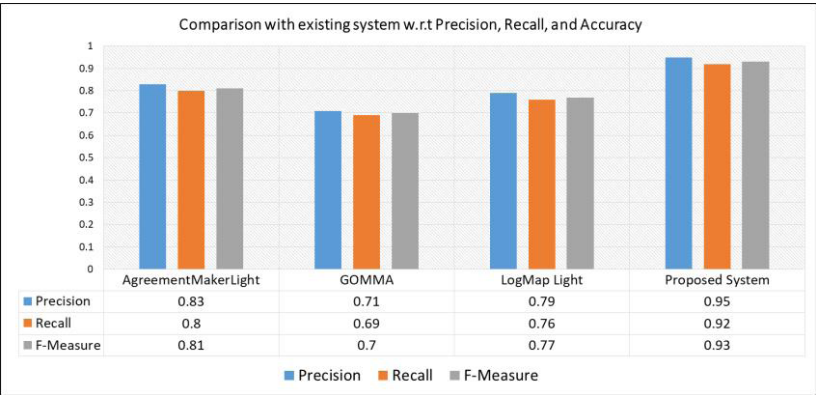


Figure 2: DCM and SNOMED CT mapping comparison with existing systems

4. Conclusion

We observed that the explicit semantics embedding into word vectors increases the matching accuracy, while the implicit semantics embedding also enhances the execution time of matching algorithms. In our extended method, we map the source and target concepts using standard matching algorithms during the first phase, if the similarity score is less than the threshold then we embed the explicit semantics into vectors. Our system mapped concepts with 95% precision, 92% recall, and 93% F-measure, and the extended methodology also reduced the execution time from 11,812 seconds to 7403 seconds for 214 concepts of the DCM.

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Cardiovascular Diseases in Qatar: Smoking, Food Habits and Physical Activities Perspectives

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Abstract. Cardiovascular diseases (CVDs) trigger a high number of deaths across the world. In this study, we investigate the food, drinking, smoking, and lifestyle-related habits for a Qatari CVD cohort to understand the implication of these factors on CVD. Statistical analysis shows that the CVD group is consuming a lower amount of fast foods, soft drinks, snacks, and meats compared to the control group. Alarming, the level of smoking is still higher in the CVD group, and the consumption level of healthy items (e.g., cereal, cornflakes) in breakfast is relatively lower compared to the control group. Interestingly, the CVD cohort is spending more time walking and avoiding heavy sports, compared to the control group, but their involvement in moderate physical activities is lower than the control group. Overall, we conclude that the Qatari CVD cohort is following most of the standard guidelines related to food items and heavy sports; however, the cohort should reduce smoking habits, and may modify the moderate level of physical activity based on physician guidelines.

Keywords: Cardiovascular diseases (CVD); Fast food; Smoking; Physical activities; Qatar Biobank (QBB)

1. Introduction

Cardiovascular diseases (CVD) are among the leading causes of mortality across the world [1] and stroke and ischemic heart disease are ranked among the top ten factors of death in the Middle East region [2]. The prolonged hyperglycemia associated with CVD can be related to the long-term impairment and failure of multiple organs. To mitigate such health-related problems, cohort based studies are established in different parts of the world to pinpoint the complex interaction of health and lifestyle-related factors that may cause diseases like CVD. The Qatar Biobank (QBB) is the largest repository for cohort based studies specific to the population of Qatar and, in this study, we considered a Qatari CVD cohort based on QBB resources. It has been shown that maintaining a healthy lifestyle and food habit may reduce the susceptibility for CVD [3]. But we could not find any research work that mainly focused on the dietary habit and lifestyle-related factors of the CVD cohort from Qatar. To fill this gap, in this study, we compared a Qatari CVD cohort against a control group considering their food and drinking habits, smoking habits, and other daily life physical activities.

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2. Materials and Methods

2.1 Cohort Description and Questionnaire Dataset preparation for this study

In this study, we considered a cohort consisting of 500 subjects from QBB, among which 250 subjects were for the CVD group and the remaining 250 subjects were forming the control (without CVD) group. All procedures were approved by the Institutional Review Board (IRB) of Hamad Medical Corporation, Qatar and only de-identified data were collected from QBB. Each subject, based upon their approval, when they arrived into QBB for participation, were asked multiple questions by the clinicians to collect valuable information about their background, dietary habit, and lifestyle-related factors. The details of the questionnaire can be found in [4, 5]. All subjects included in the study were Qatari nationals. Both the CVD and the control group contained ~50% male and ~50% female participants. All the responses from the participants were encoded numerically in such a way that a higher number represents more frequent events. For example, for the question “How often did you eat soft drinks, soda in the last year?” we encoded the responses as 0 (“never or rarely”), 1 (“1-3 times per month”), 2 (“1-3 times per week”), 3 (“4-6 times per week”), 4 (“once per day”), 5 (“2 or more times per day”). Any question, having more than 50% missing values was discarded. For the remaining cases, we replaced each missing value by the median value of corresponding metrics calculated from the respective group.

2.2 Statistical Significance of the variables

We used the Anderson-Darling test [6] to check if the variables were normally distributed. For normally distributed variables, we used the student’s t-test [7] to determine the significance level for each variable when comparing against the control group. For other variables, we applied a Mann-Whitney [8] test for the same purpose. We only considered statistically significant variables (p-value<0.05).

3. Results & Discussions

We observed that the CVD group was consuming a smaller amount of fast food (e.g., French fries, potato chips, fried chicken, burgers, hotdogs, pizzas etc.) than the control group (Table 1). This indicates that after the onset of the disease, the CVD group was more cautious about consuming such kind of food compared to the control group.

Table 1. Summary of fast food consumption for CVD versus Control group

Fast Food Items Consumption	Mean (CVD)	Mean (Control)	p-value
Chicken shawarma	1.920	2.112	0.021
Middle-eastern style fast food	1.652	1.964	<0.001
French fries	2.192	2.572	<0.001
Potato chips	2.076	2.336	0.003
Burgers, Hotdogs	1.848	2.300	<0.001
Pizza	1.916	2.272	<0.001
Fried chicken	1.720	2.032	<0.001

We also observed that the CVD group was consuming a lesser amount of soft drinks/soda, diet soft drinks/soda, and labneh than the control group (Table 2). Also, the CVD group was consuming a lower amount of caffeine (coffee, cappuccino) (Table 2). We also observed that the CVD group was consuming less snacks or desserts (e.g., cake, doughnut, ice cream) than the control group (Table 2). We also found that the CVD group was consuming a lower amount of cornflakes and cereals as part of their breakfast and consuming more dates than the control group. Moreover, we observed that the CVD group was consuming less meat-oriented dishes (e.g., chicken curry, kofta, meat kebab, chicken kebab, etc.), pasta and starters (sausage, meat, fish starters) than the control group (Table 2).

Table 2. Summary of snacks, drinks, and cereal (in breakfast) consumption for CVD versus Control group

Drinks and Sugar Consumption	Mean (CVD)	Mean (Control)	p-value
Dates	3.304	2.804	<0.001
Soft drinks, sodas	2.044	2.476	<0.001
Diet soft drinks, sodas	1.424	1.788	<0.001
Labneh	2.132	2.340	0.047
Filter coffee, cappuccino	2.724	3.012	0.039
Cold milk with cappuccino	2.368	2.596	0.021
Desserts and Snacks			
Cake, Doughnuts	2.140	2.344	0.046
Ice cream	2.308	2.480	0.05
Breakfast			
Cornflakes and cereals	1.692	1.844	0.045
Main Meal			
Light meat (chicken, duck)	3.392	3.624	0.022
Chicken curry	1.904	2.060	0.047
Kofta	1.776	1.924	0.045
Chicken, meat, or sausage starters	2.144	2.464	<0.001
Fish and seafood starters	1.968	2.112	0.05
Italian-style pasta, lasagna	2.108	2.416	<0.001

We also analyzed the amount of sedentary time, the cohort was spending in front of electronic devices. From Table 3, we can observe that the CVD group spent a lower amount of sedentary life (though the difference was not statistically significant at the level of $p\text{-value} < 0.05$), both on weekdays and weekends, with electronic devices like computers, TV, DVDs, and mobile phones. We also compared the amount of time spent on different types of sports, physical activities, and walking for the CVD and control group. Although the difference in physical activities was not statistically significant, we found that, on average, the CVD group was walking more than the control group and avoided heavy sports (weight lifting, football, running, aerobics, fast bicycling) more than the control group (Table 3). But the CVD group was spending less time on a moderate level of physical activities (bicycling at a regular pace, swimming, gym, and yoga) (Table 3).

Table 3. Time spent on different types of physical activities for CVD versus Control group

Days with electronic devices (in sitting position)	Mean (CVD)	Mean (Control)	p-value
Weekdays using computers	1.320	1.508	0.123
Weekends using computers	0.980	1.176	0.094
Weekdays using TV, DVDs, mobile phone, i-pad etc.	2.556	2.544	0.936
Weekends using TV, DVDs, mobile phone, i-pad etc.	2.528	2.516	0.939

Physical Activities (in minutes)			
Heavy sports activities (running, fast bicycling, fast swimming, singles tennis, football, weight lifting, aerobics)	3.392	4.228	0.144
Moderate physical activities (swimming, bicycling at a regular pace, double tennis, yoga, gym)	3.872	4.788	0.319
Average walking time per day	12.144	10.636	0.346

Alarminglly, we observed that patients in the CVD cohort still continued their smoking habit compared to the control group (Table 4) and found it difficult to quit after 20 years of smoking. Our work also found that for passive smoking, when the CVD patients were aware of their surrounding smoking area, they tried to avoid shisha smokers, but were exposed to passive smoking from cigarettes. More effort is required from the ministry of health and media to encourage people to stop smoking and avoid smoking areas.

Table 4. Smoking habits for CVD versus Control group

Active smoking	Mean (CVD)	Mean (Control)	p-value
Number of cigarettes/cigars/pipes per day when you were 20 years old	19.329	14.747	0.004
Number of cigarettes/cigars/pipes per day	17.367	1.176	0.094
Time (minutes) spent in water pipe (shisha)	67.769	63.333	0.328
Passive Smoking			
Time (hour) per day spent in a room while other people are smoking (cigarettes, cigars).	1.024	0.944	0.792
Time (hour) per week exposed to other people are smoking (water pipes (shisha)).	0.480	0.508	0.499

4. Conclusions

Based on our analysis, we observed that the CVD group in Qatar is generally following the standard guidelines suggested by physicians in terms of food habits, walking, and heavy sports. More effort is needed to encourage individuals to follow instructions from physicians for breakfast menus, reduce their smoking habits, and increase the moderate level of physical activity based on proper physician guidelines.

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The Impact of Clinical Decision Support Systems (CDSS) on Physicians: A Scoping Review

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Abstract. Clinical Decision Support Systems (CDSSs) are used in a clinical setting to help physicians make decisions to improve clinical performance and patient care. There are many benefits to the implementation and adoption of CDSSs, such as reducing the rate of misdiagnosis, improving efficiency and patient care, and reducing the risk of medication errors. On the other hand, CDSSs can have several disadvantages. For example, physicians can see CDSSs as a threat to their clinical autonomy. CDSSs can also be very costly to adopt, maintain, and support. These advantages and disadvantages can have both positive and negative impacts on physicians. We conducted a scoping review to explore the impact of CDSSs on physicians. We searched the following electronic databases: CINAHL, PubMed, and Google Scholar. Two reviewers independently selected the retrieved studies and extracted data from the included studies. A narrative approach was used to synthesize the extracted data. We included 14 studies of the 300 retrieved studies. We identified the following positive impacts: work efficiency, providing more personalized care, improving care and knowledge, increasing confidence in making decisions, improving prescribing behavior, and reducing the number of ordered laboratory and medical imaging tests. Several negative impacts were also reported by the studies, namely: inefficient documentation, interruption in the patient-physician communication, and an increase in unnecessary referrals.

Keywords. Clinical Decision Support System (CDSS), impact, physicians

1. Introduction

Decision Support Systems (DSS) which were first used for business management, were later modified and implemented in hospitals to become a Clinical Decision Support System (CDSS) [1]. A CDSS has many different functionalities, such as producing alerts if a dangerous interaction between two drugs exists and reminders of preventative care [1]. There are many benefits to the implementation and adoption of CDSSs, such as reducing the rate of misdiagnosis, improving efficiency and patient care, obtaining access to relevant clinical information in one place, reducing the risk of medication errors, and providing access to a trusted, reliable source that would help make better decisions [2]. On the other hand, there are disadvantages as well, where CDSSs can be

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seen by physicians as a threat to their clinical autonomy [3]. Also, it is very costly to adopt, maintain, and support [3], and it is hard to make it align with the complex workflow of a healthcare organization [1]. In addition, some CDSSs are stand-alone software systems that lack interoperability, which means they cannot be integrated with electronic health records (EHRs) [1]. These advantages and disadvantages can have both positive and negative impacts on physicians. This review aims to explore the impact of the CDSS on physicians as reported through the literature.

2. Methods

This review was conducted using the Joanna Briggs Institute (JBI) guidelines [4]. For this review, the following bibliographic databases were searched: Google Scholar, PubMed, and CINAHL. Since Google Scholar showed millions of results, and both PubMed and CINAHL showed thousands of results, only the first 100 relevant studies from each database were scanned for this review. Therefore, only 300 studies were included in the study selection process. The search terms were selected based on population, intervention, and outcome. This review focused on physicians in all different specialties, including in-training physicians such as interns, residents, and fellows, excluding medical students. There were no age, ethnicity, or gender restrictions in our search. The study selection process included reading the title and abstracts of each study and then reading the full text to identify those that meet all eligibility criteria. An excel sheet was developed to extract data from the included studies. A narrative approach was then used to synthesize the data of this review.

3. Results

Out of the 300 studies retrieved, only 14 studies were included. All studies reported that CDSS had a positive impact on physicians ($n=14$, 100%), and eight studies reported negative impacts (57%). This shows that positive impacts were more reported than negative impacts by physicians using CDSSs.

Four studies reported that the CDSS helped physicians be more efficient and finish tasks faster [5-8]. One study reported that physicians were able to give patients more personalized information and education while using the CDSS [9]. Improved knowledge for physicians and improved care for patients were reported in four studies, where it helped physicians with diagnosis, and it even helped them ask patients important questions that they forgot to ask [9-12]. Three studies reported that physicians were more confident in making decisions when using the CDSS [9,13,14]. Improved prescribing behavior was also reported, where more appropriate prescribing was mentioned in three studies [13,15,16], and reminders for physicians to prescribe medicine to their patients was reported in one study [17]. Two studies reported a decrease in the number of ordered tests and medical imaging, which led to cost-saving [5,18].

As for the negative impacts, physicians reported in seven studies that it took them a long time to document using CDSS, which was inefficient [5,6,8,9,10,13,15]. Two studies reported on how physicians lacked communication with their patients, where they looked and talked to them less [6,14] as a result of using the CDSS. One study reported that CDSS use led to an increase in unnecessary referrals [14].

4. Discussion

4.1. Principal Findings

This scoping review aimed to explore the impacts of the CDSS on physicians as reported through the literature. From the 14 studies that we included, we found seven main positive impacts and three negative impacts. The two most common positive impacts were the improvement of the physician's knowledge and care for patients and efficiency. The most common negative impact was that it took too much time for physicians, where they spent more time using the CDSS compared to when they were doing the same tasks without it, which was inefficient.

A few of the included studies reported that CDSS helps improve clinical practice overall by improving physician performance which was reported in previous work [19-23]. The practitioner performance was improved using many categories such as diagnostic systems, reminder systems, disease management systems, and prescribing systems [20]. The improved practitioner performance was linked to the automation of prompting users instead of requiring users to activate the system [20]. Also, CDSSs can specifically help improve the provider's performance with preventative care reminders and medication orders [21]. CDSSs can also help in conducting clinical studies [23].

5. Conclusion

In this study, we identified a number of positive and negative impacts of CDSS on physicians from the 14 studies reviewed. The need for ongoing adjustments to CDSSs and successful user training during the adoption of CDSSs is very important. We would advise future researchers to study other healthcare providers' interactions with CDSS.

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Health Informatics Association of Qatar (HIAQ): Building a Digital Health Ecosystem

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Abstract. Qatar's digital health initiatives are growing through the development of research capacity, innovative technologies, and academic programs to serve the national health needs of the country. The digital health community of Qatar lacks the adequate representation of a professional body to serve the needs of the community. The purpose of this paper is to develop a strategic framework for the Health Informatics Association of Qatar (HIAQ) and present the preliminary findings of this effort. We utilized a multi-stage mixed methods approach in the development of HIAQ's strategic framework. We first reviewed the relevant literature, interviewed key stakeholders within the region, validated our findings with local stakeholders, and adapted the strategic directions to conform with Qatari laws. We present the purpose, organizational structure, vision, mission, and aims of HIAQ. Future work will engage the digital health community to further refine and adapt HIAQ's strategic direction to serve the local needs of Qatar.

Keywords. Qatar, Health Informatics, Middle East, North Africa

Introduction

For the past five years, Qatar has witnessed large scale growth in its educational, research, technological and policy-related digital health initiatives to support the 2015 Qatari national eHealth vision which is "to improve the overall health in Qatar and deliver healthcare of the highest standard by providing the public, patients, and clinicians with appropriate and timely information" [1]. The national eHealth strategy plays an important role in achieving the 2022 Qatari National Health Strategy goals and objectives which promises: a holistic and modern patient-centered health care system that enhances and empowers patients through an integrated healthcare delivery system that is strongly built on a robust digital health infrastructure [2]. To support the need for expert knowledge required for these national digital health initiatives, Hamad Bin Khalifa University, College of Science and Engineering, created two postgraduate digital health programs (Master of Data Analytics in Health Management and the Master of Information Systems in Health Management) that will create a new generation of digital health experts that will help achieve the objectives of both the national health and eHealth strategies [3].

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Over the past year, different entities within the Qatari digital health community have discussed the need to unite and sustain future efforts through the creation of an umbrella organization that will support, evaluate, broaden, and increase the digital health initiatives in the country. In Qatar, such an organization does not exist. The purpose of this paper is to share our preliminary efforts in developing the Qatari digital health strategic directives that will guide the efforts of the digital health community in Qatar. We refer to this new entity as the Health Informatics Association of Qatar (HIAQ). This article only provides the groundwork for future discussion and development of the organization.

1. Methodology

From January 2020 to April 2020, a multi-stage mixed-methods approach was used to gather and evaluate multiple information sources in the development of an initial strategic framework for HIAQ. In the first phase, we collected and analyzed academic and grey literature sources related to other health informatics associations found in the region. Second, we conducted interviews with four health informatics association leaders within the Arab world to gain insights into their strategic plans and initiatives for digital health in their respective countries. Third, we developed an initial structure for HIAQ and solicited input from five local stakeholders and four regional stakeholders to validate our initial strategic HIAQ framework. In addition to this, the authors reviewed Qatari Laws for the development of Academic associations to ensure that HIAQ's strategic direction aligns with Qatari laws. Once the information gathering and validation process were complete, the authors of this work provided their input in the development of an initial strategic framework for HIAQ.

2. Results

For the retrieval of the literature sources, we conducted a simplified search on Google using the following terms: Health Informatics, MENA, Association, Arab. Entering the terms in Google, we retrieved approximately 876 results of which we found five to be relevant. The researchers of this work reviewed the relevant studies and related websites from several different health informatics associations within the region such as Kuwait, Jordan, and Saudi Arabia. We then contacted via email the representatives of twenty different health informatics associations from around the world of which four responded. To ensure that the strategic framework aligned with Qatari laws, we found one primary Qatari source from the Ministry of Administrative Development, which provided guidelines for the development of academic associations. After the development of the HIAQ strategic framework, we contacted five of Qatari digital health experts of which three responded by providing input into this initial work.

2.1. Purpose, Structure, Vision, Mission, and Aims of HIAQ.

What follows below, is a summary of the preliminary work which includes the purpose, structure, vision, mission, and aims of HIAQ.

- **Purpose:** We envision HIAQ to be a scientific association representing all digital health stakeholders within Qatar and is inclusive of researchers, healthcare professionals, policymakers, industry, and patient groups. HIAQ's primary purpose will be to nurture, guide, and develop the nascent digital health ecosystem of Qatar.
- **Structure:** HIAQ will be an umbrella scientific association that will represent all digital health stakeholders in Qatar. HIAQ's organizational and membership structure will be developed using Qatari bylaws for the creation and management of scientific associations with best-practice input from regional health informatics associations. HIAQ will also be accessible to corresponding members from other countries within the region that do not have national representation in their home countries.
- **Vision:** At this point, we strongly believe that HIAQs vision will be to bring together a community of likeminded stakeholders to develop and sustain the innovative digital health ecosystem that will serve the national health needs of Qatar.
- **Mission:** The mission of HIAQ will be to engage the public, educate digital health professionals, and act as a reference point for policymakers for the use of digital health solutions to improve the delivery of healthcare in Qatar.

2.2. Key Activities

Several key activities will be conducted and supported by HIAQ, which include:

- Host a national digital health conference every two years.
- Provide networking and professional development opportunities for HIAQ's members.
- Create a scientific journal and/or newsletter showcasing the digital health initiatives in Qatar.
- Guide the policymakers for the implementation and evaluation of the national eHealth plan.
- Promote digital health research, innovation, and technology transfer of local digital health initiatives.
- Promote professional awareness between members and maintain responsible, and ethical behavior in the management of health data.
- Seek and maintain formal channels of communication with any relevant professional or governmental organizations.
- Provide resources for educational content and workshops to support the learning needs of digital health professionals in Qatar.

3. Conclusions

Qatar has a nascent but strong digital health community that needs national representation to unite the efforts of the digital health workforce. HIAQ will play an important role in sustaining and developing the Qatari health informatics ecosystem to achieve the goals of both the national health vision and eHealth plan. The work presented in this article is preliminary, and future work will focus on obtaining more feedback from the digital health community in Qatar to build a sustainable, relevant and long-lasting association that will serve the needs of its members and the country.

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Machine Learning Models Reveal the Importance of Clinical Biomarkers for the Diagnosis of Alzheimer's Disease

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Abstract. Alzheimer's Disease (AD) is a neurodegenerative disease that causes complications with thinking capability, memory and behavior. AD is a major public health problem among the elderly in developed and developing countries. With the growth of AD around the world, there is a need to further expand our understanding of the roles different clinical measurements can have in the diagnosis of AD. In this work, we propose a machine learning-based technique to distinguish control subjects with no cognitive impairments, AD subjects, and subjects with mild cognitive impairment (MCI), often seen as precursors of AD. We utilized several machine learning (ML) techniques and found that Gradient Boosting Decision Trees achieved the highest performance above 84% classification accuracy. Also, we determined the importance of the features (clinical biomarkers) contributing to the proposed multi-class classification system. Further investigation on the biomarkers will pave the way to introduce better treatment plan for AD patients.

Keywords: Dementia; Alzheimer's Disease; Mild Cognitive Impairment; ADNI

1. Introduction

Age-related cognitive decline and impairment is a major public health problem among the elderly in developed and developing countries [1]. When age-related cognitive decline has mild effects in few activities of daily life, it is termed as mild cognitive impairment (MCI) and when this reaches a more aggressive form of impairment affecting almost all activities of life including memory, communication, planning, preparing, etc. then it may be termed as Dementia [1]. Alzheimer's disease (AD) is the most common form of Dementia, which accounts for 50% to 60% percent of all cases [1]. Usually, Dementia is preceded by MCI, and there exists a grey boundary between them which makes it difficult to identify the early onset of Dementia. Identifying novel risk factors can help determine the early onset of MCI and Dementia, especially during middle age

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(45 to 65 years) which has the potential to delay or mitigate the risk of developing one third of Dementia cases [1]. There is no single test that is prescribed to determine dementia due to AD. Physicians mostly rely on a variety of approaches and tools to make a diagnosis which includes blood tests, brain imaging in addition to memory and cognitive tests. Developing tools that can automatically differentiate the status of a person as being cognitively normal (CN), MCI or AD will help address this important problem. In this work, we propose a machine learning-based technique to distinguish control subjects with no cognitive impairments, AD subjects, and subjects with mild cognitive impairment (MCI), often seen as precursors of AD. To further validate the outcomes from our model, we investigate the relative importance of clinical biomarkers that were used in the model development based on the SHapley Additive exPlanations (SHAP) [2].

2. Materials and Methods

2.1 Dataset Description

The data used in this research was collected from The Alzheimer's Disease Neuroimaging Initiative (ADNI) [3]. The ADNI dataset includes 20 features known to be important for the diagnosis of AD. It contains 819 Control Subjects, 399 cases of Dementia, and 1050 cases of MCI. The features include demographic information such as gender, marital status, and age as well as genetic information such as APOE4, where presence or absence of this gene is the strongest risk factor for AD [4]. The clinical assessment considered for this study were the volumes of hippocampus, ventricles, brain, fusiform gyrus, entorhinal and middle temporal cortex, and average fluorodeoxyglucose (FDG)-positron emission tomography (PET) (FDG-PET) of angular, temporal, and posterior cingulate. Except for APOE4, all others are volumes of different regions of the brain that were calculated in mm³. We considered all the above mentioned measurements as a feature vector to develop the proposed classification model to distinguish AD, MCI and the CN group. Recently, Shabaz et al. [5] worked on a similar problem and the authors considered six different machine learning (ML) algorithms which reported an 88% accuracy in distinguishing AD subjects from others. However, Shabaz et al. considered the Clinical Dementia Rating Scale Sum of Boxes (CDRSB) as one of the features. CDRSB is a clinical tool used to differentiate CN vs. MCI vs. AD and it was designed to be, primarily, used by clinicians, to support in diagnosing and determining the severity level of dementia. Unfortunately, its reliability is suboptimal in very mild dementia cases [6]. Researchers developed a modified version of CDRSB (mCDR) to make it easier to use [7]. CDRSB depends on the clinicians' experiences, and its performance in early-stages of dementia has a lower reliability. As a result, we excluded CDRSB from the feature vector for our proposed model.

2.2 Machine Learning Model Development and Evaluation

Five different ML models: Gradient Boosting Decision Trees (XGBoost), Neural Network (NN), Random Forest (RF), Support Vector Machine (SVM), and Linear Discriminant Analysis (LDA) were trained and evaluated against the dataset using a nested ten-fold cross-validation for model selection and assessment.

3. Results & Discussions

Among the five different ML algorithms we explored, XGBoost showed the best results. From Table 1, we can see that the XGBoost-based model achieved the highest performance with 95.20% accuracy when we included CDRSB as a feature and 84.44% accuracy when we left CDRSB out of our feature list. We also observed high values of multiclass Matthews Correlation Coefficient (MCC), which demonstrates a high degree of confidence in our reported accuracies. Table II shows the normalized confusion matrix for the three categories for our best performer (XGBoost) algorithm.

Table 1. Summary of the performance of the models

Performance Metric	XGBoost	NN	RF	SVM	LDA
Considering CDRSB					
Accuracy (%)	95.20	92.00	94.03	88.38	83.84
MCC (%)	92.85	88.09	91.12	82.88	75.92
Without Considering CDRSB					
Accuracy (%)	84.44	78.22	81.46	76.00	74.63
MCC (%)	76.822	67.88	72.78	64.42	64.42

Table 2. Normalized confusion matrix for XGBoost; Rows (columns) denote true (predicted) labels

	Accuracy (%) Considering CDRSB			Accuracy (%) without Considering CDRSB		
	CN	AD	MCI	CN	AD	MCI
CN	96.29	0.00	3.71	84.48	0	15.52
AD	00.10	98.29	1.62	0.00	97.62	2.38
MCI	2.86	6.10	91.05	19.05	9.71	71.24

SHAP values for each feature, highlighted in the X-axis of Figure 1, represent the relative importance of corresponding features in the classification task of distinguishing AD, MCI and the CN group. From Figure 1, based on the model without considering CDRSB, it is obvious that highly contributing features in the classification task were the scores from the clinical assessment tools Mini-Mental State Examination (MMSE) [8] and Rey Auditory Verbal Learning Test (RAVLT) [9]. Values on the X-axis of Figure 1 represent the relative importance of features in this classification task. The average score of the AD group was less than the MCI and CN group’s average score (Table 3), which clearly indicates the effectiveness of these tests. Age was a contributing factor, and the average age of AD (74.87) group was higher than the MCI (72.88) and CN (72.84) group.

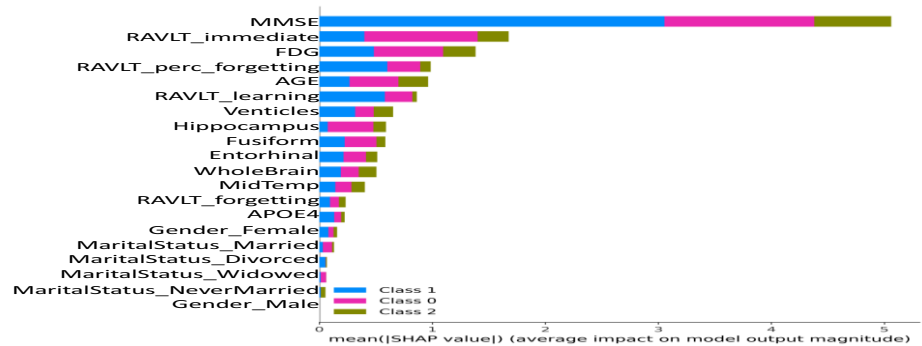


Figure 1. Summary plot showing variable importance based on SHAP values. Values on X-axis represent the relative importance of features in the classification task; Class 0: CN, Class 1:AD, Class 2: MCI

Table 3. The average value for different clinical measurements for AD, MCI and CN group

	Scores from Assessment			Region of Brain Volume (mm ³)			
	CN	MCI	AD	CN	MCI	AD	
MMSE	29.09	27.62	23.17	Wholebrain	1028182	1028720	984537
RAVLT_learning	6.02	4.12	1.92	Fusiform	17652	17468	16153
RAVLT_forgetting	3.69	4.56	4.54	Entorhinal	3687	3492	3055
RAVLT_immediate	45.49	34.58	22.99	Hippocampus	7145	6791	6079
FDG-PET	1.27	1.24	1.11	Ventricles	36347	40443	47888

The current study demonstrates that the average volume of the whole brain, and specifically Hippocampus, Fusiform, and Entorhinal areas are decreasing in contrast to ventricle size that are relatively increasing (Table 3). FDG-PET, an advanced model of imaging, contributed heavily in differentiating AD vs. MCI vs. CN. Our findings show that the classification relied upon the glucose metabolism within specific areas of the brain reflecting the function of the different regions [10]. The results demonstrate that patients with lower values for AD (1.11) compared to MCI (1.24) and CN (1.27) have a less active metabolism in the brain related area which impacts cognitive function.

4.Conclusions

Based on our analysis, we showed the effectiveness of the cognitive test for AD in the clinical setup. We also showed that combining other clinical measurements from imaging data improves the performance of the model to distinguish AD from MCI and the CN group.

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The European Educational Programs in Biomedical and Health Informatics

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Abstract. In this research, almost 2000 universities and colleges were checked in order to find related educational programs at all academic levels. More than 1000 academic leading degree programs in those domains have already been identified. The detailed records of the related educational programs will help to understand the current educational needs and priorities. Although, the growth of the related educational programs is not the same in each country. The data are available via a special website.

Keywords. Education, Biomedical and Health Informatics

1. Introduction

The established European Federation for Medical Informatics (EFMI) Accreditation and Certification Committee (AC2) launched by the EFMI Board and endorsed by the EFMI Council in 2017 has as its main task to explore ways to develop and implement the Accreditation and Certification initiative in Europe [1], [2]. The Committee in order to achieve its aim, has collected data on the educational programs in specializations in Health Informatics, Medical Informatics, Biomedical Informatics, Bioinformatics, Nursing and Dental Informatics, Health and Medical Technology, Health Engineering, Medical and Biomedical Engineering at all academic levels across Europe.

2. Methods

The research is limited only to European countries that are members of the European Federation for Medical Informatics. Specifically, this study has covered almost all 32 EFMI countries members. In more detail, at the EFMI website (www.efmi.org) the user can find a mapping informed of the data collected across the countries, which have completed this process and for the countries, which are still validating the data. Almost 2000 universities and colleges were checked in order to find related educational programs at all academic levels [3]. About 180000 courses in total were checked, from Portugal to Russia, and from Iceland to Cyprus, and Israel.

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3. Results

The information is collected for each study program: university, department/faculty, study program name, academic level (e.g. undergraduate / postgraduate / doctoral / postdoctoral studies), type of education (full time / part time), mode (on campus / e-learning) [4], [5], specializations, director of the education program, details about contact person of the program, curriculum, time table, learning outcomes, competencies and program's language (English – local – bilingual). Additionally, program's ECTS and academic staff's details are included. Currently, the collection of data focuses on only on academic degree programs. Finally, the data on this database is published in the appropriate established website (<http://www.bmhi-edu.org>). This website is continuously developed and updated, and it is already available on the network. As the verification of the included information is still in progress some information is not still available to the public. Only the registered users may have access to that content.

4. Discussion and Conclusions

In our case, the data of the research comes from European Countries and provide information about programs in Health and Medical Informatics, Biomedical Informatics, Bioinformatics, Medical and Biomedical Engineering etc. In addition, this study has included only the academic degrees of bachelor, master, or doctoral and postdoctoral level in related educational programs. While the certificates, short courses, modules, summer schools, exchanges studies, lectures and seminars were excluded. Evaluation of implementation of international recommendations [6] is possible through the accreditation process ensuring the quality of education in health informatics.

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The educational database is an EFMI task under the AC2 initiative approved in 2017.

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The Accreditation Procedure Ensures Quality of Education in Biomedical and Health Informatics

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Abstract. The Accreditation and Certification Committee (AC2) of the European Federation for Medical Informatics (EFMI) has initiated, firstly, a collection of data on the existing academic programs in Europe in Biomedical and Health Informatics in Europe, and, secondly, the implementation of the accreditation process for programs. This paper presents the background and the procedures to be applied for the implementation.

Keywords. Accreditation, Education, Biomedical and Health Informatics

1. Introduction

In Europe, the academic leading degree programs in Biomedical and Health informatics (BMHI) are usually evaluated by national accreditation committees. Not always are the members of these committees well informed about the international level of (education in) health informatics. Therefore, when a program is accredited by a national accreditation committee, this does not always mean that the program is of a European quality level in BMHI [1]. The applied guidelines in terms of BMHI educational standards are the International Medical Informatics Association (IMIA) recommendations [2], [3], [4]. Recently, EFMI has established an Accreditation and Certification Committee to implement the accreditation process in Europe. The established EFMI Accreditation and Certification Committee (AC2) tries to fill in this gap among other tasks as well [5], [6].

2. Methods

The AC2 Committee developed the standard operating procedures for implementing the Accreditation process by comparing national and international similar established procedures. The outcome of this report was presented at the EFMI Council in April 2020 and was unanimously approved by the representatives of the 32 national associations, institutional members, and working group chairs.

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3. Results

The approved standard operating procedures is the following:

Preparation: After the submission of the application for accreditation by the Institute or the Programme, where it is evident that its hierarchy has approved the application, EFMI Board approves the application for consideration, and assigns the EFMI AC2 Committee to appoint the accreditation panel, consisting of 3 members of the appropriate status selected from a pre-defined list of experienced evaluators with knowledge to perform the task of the evaluation and reporting back to the AC2 Committee.

Documentation: The educational institution prepares its application material for accreditation and completes a self-assessment report. Thereafter, the panel visits on-site the educational institution for a duration of 2-3 days, interviews director, teachers, administrators, students, alumni, and stakeholders, and prepares the panel's on-site report.

Reporting: The EFMI AC2 Committee validates the accreditation on-site panel's report. The educational institution will receive a draft of the accreditation report and can provide corrections on factual elements in the report.

Decision: The EFMI AC2 Committee decides on Accreditation based on the final accreditation report.

The Accreditation Criteria for the final decision are: Need and relevance; Knowledge; Learning Outcome Objectives; Organization and implementation; Internal quality assurance and development.

The decision is endorsed by the EFMI Board upon recommendation of the EFMI AC2 Committee.

Duration: The Accreditation issued by EFMI has a duration of 3 years. Re-accreditation will be required after the expiration of this period. 3.3. Step 3

Fees and Expenses: The institution requesting EFMI Accreditation will pay to EFMI a fixed fee. Special pricing is offered to the existing EFMI academic Institutional Members for accrediting their respective programmes. Accredited institutions wishing to become EFMI Institutional Members may receive 2 years of waiving of their membership fees. More information on the procedures are uploaded at the EFMI website (www.efmi.org) The Institution covers the travel, hotel, hosting, and all local transportation costs of the panel site-visit. members. For flights economy class is remunerated. EFMI pays per diem at EC rates to each member of the site-visit panel. No direct payment of any expenses is allowed between the Institution and the panel site visit members.

Dissemination. The EFMI AC2 Committee will use its developed database of educational programmes as it has been published at the EFMI website (www.efmi.org) to invite programme directors across Europe to consider following the accreditation by EFMI of their programmes.

4. Discussion and Conclusions

The accreditation should be seen by the colleagues in BMHI as a quality assurance process and an important requirement for improving their programmes. Information (e.g. leaflets) about the accreditation process will be made available at EFMI conferences and events. Furthermore, the EFMI website (www.efmi.org) will provide institutions' comments on the experience and the benefits of accreditation. Scientific journals

endorsed by EFMI will be encouraged to organize special issues publishing results of those educational Institutions that participated in the Accreditation process.

A viable plan should be to target to reach at least 10 programmes per year. In the first pilot stages of the implementation (1-2) years less numbers are expected.

Based on experiences from other similar activities the accreditation process requires admin/secretarial support preparing and supporting all documentation, timely decisions, and no delays for reaching final endorsement.

A prompt reaction of the EFMI administration at all stages of the decision making will improve the outcome and efficiency of the accreditation process ensuring the quality of education in Biomedical and Health Informatics in Europe [7]. Furthermore, by improving the quality of education in BMHI in Europe we increase, upgrade, and update the certified qualifications of the healthcare professionals [8], [9], and of the graduates in BMHI supporting the health care systems in Europe

Acknowledgments

The AC2 Committee has been appointed by the EFMI Council and consists of: John Mantas (Chair), Catherine Chronaki, Arie Hasman, Inge Madsen, Anne Moen, Rebecca Radell, and Lacramioara Stoicu-Tivadar.

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The Importance of Health Informatics in Public Health During the COVID-19 Pandemic

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Abstract. The COVID-19 pandemic became a challenge to all the health care systems across the world causing at places collapse of the healthcare systems and endangering the healthcare professionals and consequently the public health. One powerful tool for the healthcare systems and the policy makers is Health Informatics. This brief article presents the challenges faced by Health Informatics in supporting healthcare professionals and public health authorities in the world.

Keywords. Health Informatics, COVID-19, Pandemic, Public Health

1. Introduction

The coronavirus disease 2019 (COVID-19) is an infectious disease caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).[1] First identified in December 2019 in Wuhan, China, it resulted in an ongoing pandemic. The first case may be traced back to 17 November 2019. As of 5 June 2020, more than 6.60 million cases have been reported across 188 countries and territories, resulting in more than 390,000 deaths. More than 2.83 million people have recovered]. The virus is primarily spread between people during close contact, most often via small droplets produced by coughing, sneezing, and talking. According to the World Health Organization (WHO), there are no vaccines nor specific antiviral treatments for COVID-19. WHO declared the pandemic on March 11, 2020. [2]

2. Methods and Results

The COVID 19 pandemic is causing to the healthcare system extreme strains as the infection spreads rapidly and the cases increase exponentially when there is no social distancing measures and hygiene protection. A few of the infected cases will require intensive care treatment and the lack of it will cause death. Even with ICU treatment the lack of successful specific therapeutic scheme may be prolong the survival of the infected case, but a large percentage may suffer death in the end. Clinical treatment is greatly facilitated with Informatics [3] assistance when EHR systems [4] exist providing the full

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profile of the patient (hence, timely pinpointing comorbidities) and Decision Support Systems assist the healthcare professionals in the treatment in a very hectic and under pressure environment. Furthermore, telehealth, remote patient monitoring, patient engagement, AI-based drug discovery, precision medicine, and bioinformatics, clinical surveillance, and predictive modelling [5] are the unique Informatics supporting clinicians, biologists, epidemiologists, public health experts, and policy makers.

3. Discussion and Conclusions

It has been shown, so far, that the only effective protection from COVID-19 infection is the social distancing, personal hygiene, and societal and country lockdown. As these extreme measures cannot be applied for prolonged time, due to the social character of the human beings, and hard economic effects to the world economy, it seems that at least a second wave of the spread is unavoidable in the next months. This kind of infectious diseases either disappear by themselves or become endemic with seasonal and regional appearances for many years, or they can be sufficiently treated when drugs will be invented. The hope for a successful vaccine that will totally erase the threat may still be far away.

The Medical Informatics and Nursing Informatics community [6], [7] play an important role by supporting the clinicians in using all the appropriate tools and methods to facilitate improved diagnosis and therapy of their patients. Whereas, Health Informatics is supporting epidemiologists, biostatisticians, public health experts and policy makers in providing tools and methods in collecting massive big data, analysing them, visualizing the data and the information, comparing, planning, and designing epidemiological and policy making approaches. Those scientific and evidence-based methodologies have been highly effective in challenging the fake news stories, the misinformation, and disinformation or the spread of it through the internet and the social media, which is now called infodemic.

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Subject Index

3D applications	225	business processes	342
3D surface fitting	362	cancer treatment	123
AAL	265	cannabis	5
abduction	135	Cardiovascular diseases (CVD)	465
accessibility	306	cardiovascular risk factor	326
accreditation	484	Care 4.0	265
acromegaly	413	care continuity	292
active pharmacovigilance	342	caregivers	119, 437
activity tracking	310	case study	123, 213, 413
ADNI	478	chatbot	209
adoption	111	chest CT scan	13
Adverse Drug Reactions (ADR)	205	chronic diseases	437
adverse events	51, 55	chronic pain management	272
aging	119	classification	51
air pollutants	399	clinical	187
allelic variation	195	clinical decision support	
Alzheimer's Disease	478	(CDS)	35, 395
AMR	75	Clinical Decision Support System(s)	
annotation	55	(CDSS)	205, 261, 296, 461, 470
anonymization	43	clinical guideline	395
antibiotic resistance	75	clinical informatics	280, 407, 413
applied text analysis	17	clinical practice guidelines	115, 296
architecture	159	clinical trials	379
Arden Syntax	187, 395	clinicaltrials.gov	379
artificial intelligence	13, 51, 191, 433	common data elements	334, 379
assisted reproductive technology		communication	445
(ART)	139	comorbidities	83
assistive robots	183	completeness	167
assurance	35	complex networks	362
audio segmentation	241	computed tomography	370
automated data extraction	379	computer graphics	71
automated machine learning	13	confidence	179
AutoML Vision	13	confirmatory factors of nursing	59
awareness	237	control experiments	229
Axon evaluation	203	convolutional neural network	457
ballistocardiography	103	coping	147
barriers	87	coronavirus disease	13
Bayesian methods	83	COVID-19	9, 13, 284, 304, 487
benefits	87	critical care	175
big data	103, 245	critically ill	171
big data analytics	1, 366	cross-correlation	241
biomedical and health		data aggregation	334
informatics	482, 484	data analysis	245, 399

data collection	155	ethnicity	358
data management	47, 79, 103	european medicines verification	
data mining	387	system	276
data privacy protection	43	evaluation	413, 449
data quality	350	evaluation studies	95
data science	253	exercise	391
data sharing	276	experts reasoning	115
data-use	143	exploitation	449
decision support	272	factors	314
decision support systems	187	failure	147
deep learning	370, 457	fast food	453, 465
dementia	119, 478	financial stability	354
design characteristics	209	flexion	135
dhis2	143	florence nightingale	28
diabetes	453	forum	417
digital care	265, 374	general data protection regulation	
digital health	179, 288	(GDPR)	43, 47, 237
digitalization	265	generative adversarial networks	322
disability	306	genetic data	47
disclosure	63	genomics	139
discrepancy	358	geriatrics	296
disease management	441	GIS	131
dissemination strategy	445, 449	global health	425
distribution	403	glycemic control	403
downtime	147	Google analytics	225
DRGs	217	Google maps	403
drug abuse	5	Google trends	245
drug interactions	107	governance	253
drug safety	342	Greece	314
drug synergy	91	growth hormone	413
Drug-Condition Interactions (DCI)	205	guideline definition language	187
Drug-Drug Interactions (DDI)	205	H1N1	17
Drug-Gene Interactions (DGI)	205	hazard analysis	179
e-health	9, 119	health behaviour	131
e-health intervention	326	health care	163
e-learning	39, 87	health care leadership	429
ED overcrowding	199	health care management	330
ED wait time prediction	199	health cloud repository	221
education	163, 225, 330, 482, 484	health disparities	24, 433
elderly	131	health enabling technologies	39
electronic data capture	79	health informatics	17, 461, 474, 487
electronic health record(s)	111, 151, 195, 233, 292	health information systems	147
Electronic Medical Records		health IT	95
(EMR)	155, 205, 280	health record index	221
endocrine disease	413	health services	237
epidemic	17	health system	179
epidemiological indexes	21	health technology	249
ethics	253	healthcare	221, 225, 306
		healthcare AI	253

healthcare education	209	literacy	119
healthcare rules	350	literature review	429
healthcare technology	421	Long Short-Term Memory (LSTM)	199
healthcare workers	249	machine learning	51, 75, 151, 191, 322, 366
hiding decision tree rules	99	malnutrition	296
HiGHmed	300	markov processes	151
HIV data	167	measurement accuracy	310
HIV-indicator	143	measures	354
HL7 FHIR	155, 221	medical data privacy	99
hospital information system	159, 217	medical economics	151
hospital statistical form	28	medical education	83
hospitalization	195	medical informatics	163
human-robot-interaction	183	medical laboratory	127, 257
hypertension	91	medical robotics	123
ICD-11 API	280	medical technology	314
IHE	300	medical tourism	314
image classification	13	medication error	63
impact	470	medication review	107
impact on care	183	mental health	288
INCA	123	mental well-being	288
incident reporting	63	mental wellness	288
infection COVID-19	21	MERS	17
infection disease	21	MeSH tree	379
infectious disease	17	mHealth	272
infodemiology	245	Middle East	474
information	306	mild cognitive impairment	433, 478
information alert	67	model-driven	338
information management	63	monitoring	33, 143, 175
information surveillance	67	morphometric analysis	203
infrastructure	79	mortality	28
innovation	123	movement measurement	310
Insulin-like Growth Factor-1	413	multi-disciplinary approach	330
integrated health care systems	292	multi-diseases	205
intensive care unit	175	multiple sclerosis	346
interaction	225	national healthcare system	217
internal validity	229	natural language processing	55, 95, 191
internet	417	NCDs	131
internet of things	425	neurology	338
interoperability	159, 425	neurosurgery	55, 191, 370
intracranial hemorrhage	370	non-drug intervention (NDI)	326
intracranial pressure (ICP)	395	non-verbal communication	91
intraoperative neuromonitoring	318	noncommunicable diseases	374
intraoperative neurophysiology	318	noninvasive	171
IQCare	167	nonverbal communication	71
justification	179	North Africa	474
k-means clustering	143	Norway	9
KenyaEMR	167		
knowledge interoperability	461		
lessons learned	39		

nurses	111, 237	protocol entries	318
nursing homes	296	public health	33, 487
nursing practice	59	public private partnership	374
nursing-care	183	PubMed	429
obstructive sleep apnea	387	Qatar	474
online learning	163, 267, 284, 304	Qatar Biobank (QBB)	453, 465
ontology	159, 318	quality assurances	127
ontology matching	461	quality assurances system	257
openEHR	300	quality improvement	67
OpenMRS	280	race	358
OpenWHO	284, 304	randomization	229
opioid treatment program	366	rare diseases	213
opioids	5	readmissions	51
organization of acute stroke care	421	real-world data	151
oscillometry	171	realistic synthetic dataset	35, 322
osteoarthritis	383	recovery plan	354
outcomes	379	recurrent neural network	199
pandemic	5, 24, 284, 304, 487	regenerative medicine	334
papillomavirus vaccines	417	registry	79
parents	437	relational epidemic surveillance	17
patient empowerment	383	replication	229
patient experiences	441	reporting	167
patient handling	249	respiratory disease	399
patient safety	51, 59	safety	35, 63, 179
patient-reported outcome(s)	272, 383	SARS	17
person-centred care	338	SARS-CoV-2	33
personal data	237	search strategy	429
personalized medicine	205	secondary use of clinical routine	
pharmaceutical industry	276	data	233
pharmacogenetics	195	seismocardiography	103
pharmacovigilance	417	semantic reconciliation	461
phonological assimilation	241	semantic web	425
physical activities	453, 465	sensitive data	47
physical therapist	391	sensors	249
physicians	470	serious games	437
pilot rare disease registry	213	shoulder	391
PM ₁₀	399	shoulder-joint	135
pneumonia detection	457	sickle cell disease	71
polypharmacy therapies	205	side effects	417
population health	17	Slovenia	213, 354
prediction	387	smart health	374
preferences learning	115	smart phone	33
prevalence	403	smoking	465
prevention	326	social factors	111
primary care units	127, 257	social media	5, 24, 417
privacy	155, 322	social networks	87
privacy-preserving	99	software development process	261
PRO	383	software engineering	261
problem oriented medical records	292	software lifecycle	261

standardized data	318	unsupervised machine learning	1
standardized nursing terminology	233	unsupervised paraphrasing	429
statistical analysis	135	unsupervised query rewriting	429
stem cell therapy	358	usability	407
stem cells	334	user interface	103
stroke	421	user-centred design	272
stroke care	441	vaccination	267
stroke patients monitoring	411	VCM icons	71
stroke rehabilitation	338	virtual intervention	24
students	267	virtual reality	225
students views	87	virus	21
supervised machine learning methods	387	visual analogue scale	391
supply chains	276	visual analytic(s)	91, 107
surveillance	425	visualization	71, 91, 296
telemedicine	9	visualization tools	362
telerehabilitation	346	wearable	175
text classification	191	web platform	411
timeline	71	web tool	139
timeliness	167	web-based course	267
topic modeling	191	weblogs	346
tracker position affects	310	websites	306
transfer management	265	WHO	284
treatment	413	wireless	175
uncontrolled type 2 diabetes		wrist monitor	171
mellitus	403	XDS.b	300
uniform classification	28	xml	379

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Author Index

Abd-Alrazaq, A.A.	457, 470	Baroy, J.C.C.	267
Abdellatif, A.	296	Bartzis, G.	314
Abhichaya, A.	59, 67	Basteris, A.	245
Abizeyimana, T.	280	Batalov, A.	370
Abujazar, M.F.A.	478	Battelino, T.	213
Adlassnig, K.-P.	187, 395	Bazarbashi, M.S.	253
Agher, D.	326	Behrends, M.	163
Ahokas, A.	267	Bellika, J.G.	272
Al Manir, M.S.	425	Belmin, J.	296
Al-Absi, H.R.H.	453, 465	Benning, N.-H.	163
Alam, T.	453, 457, 461, 465, 470, 474, 478	Betts, H.J.	28
Alcantara, C.	5, 24, 433	Bilici Ozyigit, E.	322
Alexiou, K.	75	Bistaraki, A.	314
Alexopoulou, H.	421, 441	Borziak, K.	334
Ali, A.A.M.	478	Bott, O.J.	163
Ali, T.	461	Bouaud, J.	296
Almuhaizea, M.A.	253	Bousquet, C.	417
Almulla, H.	474	Brandi, M.	326
Al-Shagathrh, F.	253	Brauer, M.	123
Alshehri, J.	253	Brenas, J.H.	425
Althani, D.A.	474	Brinkmann, A.	249
Altmann, U.	79	Broadwell, P.	5, 24, 433
Amcheslavskiy, V.G.	395	Broască, L.	362
Ammenwerth, E.	95, 233, 330	Buavaroon, S.	59, 67
Ancușa, V.-M.	362	Bürkle, T.	318
Andersen, N.S.	383	Bygholm, A.	383
Antonakos, G.	33, 171, 175	Byiringiro, J.B.	280
Antoniadou, G.	135	Cabrera, M.	195
Arseniev, S.B.	395	Camara, G.	71
Aruasa, W.K.	111	Cavani, D.	267
Arvanitis, T.N.	35, 179, 322	Celik, C.	280
Attias, M.	284, 304	Chaiyakarm, T.	131
Audeh, B.	417	Chanmonthon, W.	127, 257
Aumatel, X.P.	267	Chardalias, K.	21
Babic, A.	143, 167, 183	Chatzistefani, N.	135
Bachi, K.	366	Chebon, S.K.	111
Baig, M.A.	253	Chen, R.	187
Baker, C.J.O.	425	Cheng, N.	199
Bales, M.E.	5, 24, 433	Chirchir, L.K.	111
Bamdeg, J.	147	Cho, H.	5, 24, 433
Bamidis, P.D.	209	Christopoulos, C.	75
Banaye Yazdipour, A.	87	Cillessen, F.	292
		Ciocârlie, H.	362

Clarke, D.J.B.	334	Geronikola, N.	119
Cui, W.	1, 366	Gesicho, M.B.	143, 167
Dalamaga, M.	33, 171, 175	Gkaliagkousi, E.	342
Danilov, G.	55, 191, 370	Gois, S.	123
Davis, N.	5, 24, 433	Gonçalves, A.A.	123
Davoody, N.	209	Gradellini, C.	267
de Bruin, J.S.	187	Greer, M.L.	350
de Oliveira, S.B.	123	Grendova, K.	267
Deng, N.	5	Groselj, U.	213
Deserno, T.M.	39	Halminen, O.	276
Despotou, G.	35, 179, 322	Harkener, S.	79
Despres, S.	326	Harrison, S.	35, 179
Diagne, I.	71	Hasman, A.	v
Diallo, A.H.	71	Hatzitolios, A.I.	421, 441
Diekmann, R.	249	Hein, A.	249
Dimitrellos, E.	75	Heinze, O.	300
Diomidous, M.	21, 33, 171, 175	HiGHmeducation Consortium	163
Dornauer, V.	95	Hoeffner, K.	95
Drepper, J.	79	Hofdijk, J.	292
Eamratsameekool, W.	127, 257	Hoffmann, I.	163
Efthymiou, A.	119	Holl, F.	265
Elfadl, A.H.	478	Househ, M.	v, 453, 457, 461, 465, 470, 474, 478
Elgert, L.	391	Hurd, Y.	366
Elghafari, A.	379	Ilieva, I.	119
Eraković, J.	338	Ishankulov, T.	55, 191
Estragues, P.G.	267	Islam, M.T.	478
Evangelou, C.	441	Jahn, F.	95
Evangelou, H.	421	Jähne-Raden, N.	103
Evangelista, J.E.	334	Jankovic, S.M.	229
Fagerlund, A.J.	272	Jalent, M.-C.	326, 342
Farzi, M.R.	304	Jeong, I.c.	346
Feretzakis, G.	13, 75, 99	Jovanović, T.	354
Ferri, P.	267	Kaitelidou, D.	314, 421, 441
Fifelski, C.	249	Kaldis, V.	13
Figee, M.	407	Kallergi, M.	135
Finkelstein, J.	1, 195, 310, 334, 346, 358, 366, 379, 407	Kalles, D.	13, 75, 99
Fotteler, M.	265	Kalliontzakis, I.	421, 441
Fouque, M.	326	Kancheva, I.	119
Freire De Castro Silva, S.L.	123	Karagkiozi, E.	421, 441
Friedrich, P.	265	Karagkouni, I.	411, 421, 441
Gadde, M.A.	350	Karampela, I.	33, 171, 175
Galanis, P.	411, 421, 441	Karapetiantz, P.	417
Gallos, P.	v, 411, 445, 449	Karema, N.	280
Gamhewage, G.	284, 304	Karlgren, K.	209
Garcia-Longarte, S.	139	Kawsar, F.A.	478
Garin-Muga, A.	139	Kayiganwa, M.	280
Gavrilidis, G.I.	342	Keshavarz, Z.	387
George, R.	284, 304	Khiewkhern, S.	399, 403

Kimiafar, K.	87	Lukianov, V.I.	395
Kiourtis, A.	221	Ma'ayan, A.	334
Kivekäs, E.	63	Machajova, M.	267
Klass, M.	300	Magdalinou, A.	445, 449
Kock Wiil, U.	245	Mahler, A.	265
Kolangi, G.	342	Mahmut, E.-E.	241
Kolstad, M.	183	Makashova, E.	55
Konstantakopoulou, O.	314, 411, 421, 441	Malo, S.	159
Konstantinidis, S.T.	209	Manios, E.	421
Konstantinou, E.	267	Mansourvar, M.	245
Kopka, M.	203	Mantas, J.	v, 237, 437, 445, 449, 482, 484, 487
Kopka, R.	203	Marc, D.	280
Koponen, S.	63	Markopoulou, V.	237
Korompoki, E.	411, 421, 441	Markov, E.	413
Kostanjsek, N.	280	Martsoukou, M.	75
Kosyrkova, A.	55	Mas, M.R.	267
Kotik, K.	55, 191, 370	Masic, I.	229
Koufopoulou, C.	13	Matträ, S.	131
Kouridaki, A.	421, 441	Mavraganis, G.	421, 441
Kouzi, I.	421, 441	Mavrogiorgou, A.	221
Kowalski, C.	249	Mayberg, H.	407
Kramer, F.	265	Mecugni, D.	267
Krastev, E.	413	Meier, L.	47
Krikščiūnienė, D.	338	Melchenko, S.	55
Kulau, U.	103	Meneton, P.	326
Kulenovic, A.	205	Menikou, I.	119
Kuo, A.	199	Merli, D.	265
Kurscheidt, M.	151	Merzweiler, A.	300
Kuusisto, H.	63	Mess, E.V.	265
Kyriazis, D.	221	Meyer, O.	249
Lada, M.	75	Michelidou, S.	75
Lagumdzija-Kulenovic, A.	205	Milionis, H.	421, 441
Lahti, S.	267	Mintus, B.	119
Lakraflī, C.	115	Mittelman, M.	433
Lamy, J.-B.	51, 71, 91, 107, 115	Moen, H.	429
Lau, S.	249	Montandon, L.	445, 449
Laursen, M.	383	Mouazer, A.	107
Lee, J.H.	17	Mugisha, M.	280
Lee, S.	461	Muhiyaddin, R.	470, 474
Leethongdissakul, S.	127, 257	Murko, E.	213
Levänen, L.	276	Myrou, A.	421, 441
Lewandowski, R.	338	Nantschev, R.	233
Liaskos, J.	237	Nasiri, M.	387
Lillo-Le Louët, A.	417	Nasseh, D.	43
Linardaki, Z.	342	Natsiavas, P.	342
Liu, J.	346	Nazeemudeen, A.	453, 465
Lo, M.	71	Ndiaye, N.	284, 304
Loupelis, E.	75	Ndikubwimana, B.	280

Negreeva, A.	370	Saalfeld, B.	391
Ngugi, P.N.	167	Saikali, M.	51
Nicola, S.	225, 241	Sakagianni, A.	13, 75
Nieri, A.	237	Sakellari, E.	267
Nifakos, S.	209	Sakka, P.	119
Nikolopoulos, M.	33, 171, 175	Saranto, K.	63
Nikula, A.	267	Sarbaz, M.	87
Nishihara, Y.	183	Sarivougioukas, J.	217
Ntaios, G.	411, 421, 441	Sariyar, M.	47, 318
Odlum, M.	5, 24, 433	Savopoulos, C.	421, 441
Ognjanović, I.	330, 338	Schauer, D.	5, 24
Orlov, Y.	191	Schmid, S.	265
Örtl, M.	265	Schmidt, T.	147
Panagiotopoulou, M.	306	Schramm, W.	151
Papastavrou, E.	119	Sedki, K.	107, 115, 326
Papastefanatos, G.	411, 441	Seidel, K.	318
Papastefanatos, S.	411, 421, 441	Šendelj, R.	330, 338
Pappa, D.	437	Seneca, R.	119
Parvanova, I.	358	Seppälä, T.	276
Paskal, A.M.	203	Seroussi, B.	296
Paskal, W.	203	Shaban-Nejad, A.	425
Patrao, M.	5, 24, 433	Shah, U.	457
Pattichis, C.S.	209	Shah, Z.	453, 457, 461, 465, 470, 474, 478
Pedersen, S.G.B.	383	Shifrin, M.	55, 191, 370
Peltonen, L.-M.	429	Shin, E.K.	17
Perifanou, D.	267	Sigg, S.	103
Perimal-Lewis, L.	288	Siskou, O.	411, 421, 441
Petropoulou, S.	75	Siwina, S.	127, 257
Phajan, T.	403	Skarmoutsou, N.	75
Phuwilert, P.	403	Smaradottir, B.F.	272
Pietruski, P.	203	Som-Ard, J.	131
Piroux, C.	284, 304	Songkhamchai, L.	59, 67
Pitassi, C.	123	Stanimirovic, D.	213
Pobiruchin, M.	151	Stathakarou, N.	209
Potapov, A.	55, 191, 370	Stausberg, J.	79
Pournik, O.	387	Steiner, B.	391
Prnova, J.	267	Stoicu-Tivadar, L.	225
Pronin, I.	370	Stoicu-Tivadar, V.	241
Pronkina, T.	55	Stratigou, T.	33, 171, 175
Pujol, C.R.	267	Strickler, M.	318
Qi, T.	334	Strong, O.	83
Ragina, N.	83	Strunina, Y.	55
Rappelsberger, A.	187, 395	Stylianides, A.	119
Ratanaopad Suwanlee, S.	131	Subramaniam, K.	374
Refae, M.A.	453, 465, 478	Sucre, A.	139
Rezaee, R.	387	Surasak, T.	59, 67
Richter, J.	261	Swoboda, W.	265
Robins, D.	1, 310, 407	Sy, A.	284, 304
Saab, A.	51		

Tagliani, M.	119	Wang, J.	39
Talburt, J.B.	350	Wang, Z.	350
Tanaka, K.	155	Warnecke, J.M.	39
Tapsoba, L.S.	159	Weber, P.	445, 449
Tcharaktchiev, D.	413	Wei, C.	310
Tenhunen, H.	276	Were, M.C.	143, 167
Teynor, A.	265	Wettstein, R.	300
Theocharis, T.	135	White, S.	35
Thitisutthi, S.	399	Williams, P.A.H.	288
Thomander, H.	267	Winter, A.	95
Thongkum, W.	399	Witte, M.-L.	163
Tippenhauer, K.	47	Wlodarski, P.K.	203
Tommila, M.	429	Wolf, K.-H.	391
Tountopoulou, A.	421, 441	Wolf, M.C.	103
Tran Ngoc, C.	280	Wongprachum, K.	403
Traore, Y.	159	Wright, G.	28
Tsampalas, E.	421, 441	Wynn, R.	9
Tsirintani, M.	306	Yamaguchi, N.	183
Tsopra, R.	107, 115, 326	Yamamoto, R.	155
Tsukanova, T.	55, 370	Yoon, S.	5, 24, 433
Tumusiime, D.	280	Yoosook, W.	131
Turnbull, N.	131	Yousif, F.	474
Twizere, C.	280	Yukalang, N.	131
Tzortzis, E.	33, 171, 175	Zagidullin, T.	55
Utunen, H.	284, 304	Zakharova, N.	370
Uwase, M.	280	Zamboulis, C.	342
Vagelatos, A.	217	Zbinden, C.	318
Valakis, K.	75	Zhang, F.	195
Vasilopoulou, S.	421	Zikos, D.	83
Velentza, A.	75	Zimeras, S.	21
Vemmos, K.	411, 421, 441	Zinszer, K.	425
Vemmou, A.	421, 441	Zoulis, E.	v, 237, 437
Verykios, V.S.	99	Zowalla, R.	151
Vidakis, K.	221	Zozus, M.	350
Vogel, S.	261		

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