Handbook of Research on

Essential Information Approaches to Aiding Global Health in the One Health Context

Jorge Lima Magalhães, Zulmira Hartz, George Leal Jamil, Henrique Silveira, and Liliane Carvalho Jamil

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The interdependence of humans, animals, plants, and their social and abiotic environment is highlighted by past and recent pandemics. A good example to understand and tackle threats to ecosystems is the COVID-19 pandemic. A syndemic is a complex and multilevel phenomenon of epidemics interacting synergistically at individual, societal, and environmental levels. Understanding the syndemic nature

of pandemics will facilitate the adoption of a One Health approach to improve planetary health. To address the eco-complexity underlying One Health issues, the development of intelligence management systems through a planetary perspective is of key importance. This requires the capacity to capture, process, and communicate data on human, animal, and plant health and well-being, and on their social and environmental determinants. The implementation of such systems will need political commitment at all levels of action, deployment of adequate resources and expertise, reliable and comprehensive data flowing pathways through interoperable, flexible, and secure data sharing systems.

The COVID-19 pandemic brought a challenge to the health area and generated an enormous amount of information, some accurate and some not, which made it difficult to locate reliable sources of information. Scientific knowledge has become the best way to mitigate this infodemiological process. Observatories are instruments to support decision making, seeking to integrate different sources of information and communicate the results using research methodologies such as the COVID-19 Scientific Evidence Observatory. Created by members of the research group Information in Science, Technology, and Innovation in Health, of the IBICT, it aims to meet the informational demands of the most varied audiences. Its development methodology involves a knowledge management team that uses the methodological rigor of the systematic literature review to seek, evaluate, synthesize, and enable access to reliable and qualified sources of information. It provides access to different sources of national and international information from the Kaleidoscope of Science.

In an increasingly connected world, information regarding the contagion and spread of COVID-19 has been an important weapon to enable better coping with the disease. The use of information technology can assist in the prevention, care, and monitoring of patients. In addition, remote service using applications avoids the overload of health centers and contagion. This research reports the experience of a research project initiated in Brazil at the Oswaldo Cruz Foundation, with the objective of developing an application and big data for the new coronavirus in a public health clinic using information management and One Health concepts. Initially, the application requirements were defined through interviews with users and health professionals. The partial results obtained so far demonstrate improvements in the different processes of the health center with the use of the application. The use of big data for the analysis of information makes it possible to define better health policies for the population in a more precise way

Foreword

It is widely recognized that we are living through an "Information Revolution", a time of exponentially growing amounts of data. We have so much data that we worry how not be overwhelmed, how to stay afloat, how to navigate the ever-expanding ocean.

However, as this Handbook demonstrates, achieving better human health is not just a matter of obtaining ever more data on human health. The framework of One Health – a key theme in this volume – crystallizes the notion that humans, animals, plants, and their social and abiotic environment have co-evolved together, and that their fates are interdependent. If humans overly perturb natural ecosystems or interfere in nature, we should not be surprised if, at some point, a virus finds its way from animals to humans and leads to a global pandemic. The more we take multidimensional eco-complexity seriously, the more we realize our need to break open our numerous data silos, to pull together their contents – be it on human health, on animal and plant health, on food systems and the urban landscape, on climate and air, or on social and political factors – and explore in multi-, inter- and transdisciplinary fashion their interactions, potential feedback loops, and tipping points. There is even the possibility – another theme of this book – that epidemics interact synergistically at individual, societal, and environmental levels to create a syndemic. Traditional medical knowledge, on its own, will not furnish the tools for an adequate response to global health challenges.

And yet, data and technology and the One Health paradigm, together, are still not enough. To turn data into knowledge, and then into effective policies, requires a knowledge management system – which is the focus of many of the following pages – that extracts, evaluates, and synthesizes data, that gives access to trustworthy and qualified sources, communicates the resultant insights, and turns that knowledge into good decision-making. The COVID-19 pandemic has laid bare, as never before, our data management failings. It has exposed how all too often current organizational arrangements and bureaucratic structures slow down responses and hinder the effective flow of data and therefore the innovations that this may prompt. It has highlighted the need to devise better ways to manage data in order to improve global health surveillance, to monitor and prevent health threats, to develop more quickly healthcare interventions that are cost-effective and widely accessible, to train and support health professionals, and to protect the planet.

This book could not be more timely. Stronger global pandemic intelligence will require advances in how we identify and extract reliable and comprehensive data and we enable it to flow in real time through secure global data-sharing mechanisms. But the following chapters are a corrective to anyone who thinks that this will mean ever increasing data centralisation. A number of case studies are explored that illustrate the power of local capacity-strengthening in data management, and the importance of cooperation based on mutual understanding, trust, and appropriate institutional and regulatory arrangements.

Several contributors investigate how the growth of information technologies and health research has given rise to the phenomenon of "big data", and new ways of utilising large pools of data to understand human health better, to uncover new drugs or treatments and, increasingly, to tackle global health challenges. Good data management also leads to good quality-control of such "big data" enterprise, avoiding the perils of "garbage in, garbage out". A number of chapters dig deep into a series of case studies of the application of "big data", especially in Brazil, including for public health management, for tackling dengue, zika, and chikungunya, and in the research of the Oswaldo Cruz Foundation in public health clinics.

This book explores, furthermore, the phenomenon of an infodemic, the rapid dissemination of inaccurate information by taking advantage of an increasingly networked world and therefore of the ability for misinformation to be spread rapidly across geographies like a highly transmissible data virus, indeed as fast as any real virus – if not faster. Our data management systems need to be capable of responding by spreading, at least equally quickly, reliable scientific information.

One of the fundamental questions – and the contributors to this volume do not shy away from it – is how open or closed our approach to data should be. COVID-19 vaccines, the theme of one of the chapters, were developed in record time thanks to the sharing of critical genomic data and to the smarter generation of trial data. Where cooperation among researchers during the pandemic has been high, it has resulted in an unprecedented level of scientific production. The lesson appears to be that we need innovation in management, in organisational structures, and in business models too – across all kinds of markets and economic agents – as much as in medical data itself. Many chapters of this book explore successful institutional innovations and investigate the management of information as a collaborative tool, and even as a subsidy, for global health. Brazil has been something of a pioneer in this, in the form of Product Development Partnerships such as that for the antiretroviral Atazanavir. Such an approach involves cooperation, by agreements, between public and private institutions, for the development, transfer, and absorption of technology relating to products of strategic importance, starting from Brazil's own needs and working outwards to the needs of the world. Smartly, this approach has been used to support Brazil's own industrial policy and innovation in health – including in areas previously dominated by big multinational pharmaceutical corporations. Doing so has generated useful lessons for the rest of the world, which are reported in this handbook.

COVID-19 has connected all of humanity in that rarest of phenomena: a truly globally shared experience. And, it has shaken us from our collective complacency. Had the virus been even more virulent, we would not have coped at all. Will we now globally learn and share the lessons? Will we strive to work together even more, for the good of all? The present work was written in the shadows of a global pandemic, but its contributors manage to maintain a message of hope. For sure, we are still in trouble, stumbling in our efforts to find a way out of the pandemic, and we are far from prepared for the next. Nevertheless, thanks to the availability of ever-growing amounts of all kinds of data, we have also amazing opportunities – provided that we develop good systems to manage and use the data well. We also need to reconfigure our mindset and take seriously, by deploying the One Health and planetary health approaches, the mutually entwined health of the planet and of the humans living on it. This handbook points to the necessary tools. It is up to all of us to apply its important lessons and make the most of the opportunities for the sake of current and future generations.

Andrew Farlow
Oxford Martin School, University of Oxford, UK

Preface

World is flat! The speed of informational data and the knowledge generated is unprecedented in history. Likewise, humanity's food crossing oceans and fiercely devouring the habitats in which we live, the globalized set in which we live, brings magnificent scientific and technological advances, but also enormous challenges for One Health.

It is urgent to reflect on global health in the event of endemics, pandemics and syndemics! This attitude requires a non-trivial stance in the 21st century. The avalanche of informational data in the knowledge age – known as Big Data – has brought with it new process models. This fact favored better processing of informational data, in the quickest and most reliable way of essential information for decision makers.

How do we face the challenges of humanity in the face of the information revolution of data (even inaccurate) and diseases at the same speed? How can we not leave aside man's interaction with the environment and scientific advancement, geography, and its healthy ecosystem? How do we move forward in the infodemic, connected world and live far beyond the absence of disease? How can we have better ways to manage quality in health and strengthen management systems?

Questions like these were on our minds. Considering our professional experiences and scientific and technological research throughout our careers, we see a growing gap in searching these answers. Undoubtedly humanity has advanced for the best, but it has also brought new paradigms that lack unconventional forms of research and innovation. This time, we contribute to the arduous task of having a healthy and happy life.

The foreword and introduction to this book, followed by 16 chapters, present the collaborative experiences of 53 authors from 21 institutes around the world. It is worth talking about successful networking, challenges, and opportunities. Only with the dissemination and appropriation of knowledge we will overcome the diseases that plague us, whether emerging or re-emerging.

Chapter 1: The interdependence of humans, animals, plants, and their social and abiotic environment is highlighted by past and recent pandemics. A good example to understand and tackle threats to ecosystems is the COVID-19 pandemic. A syndemic is a complex and multilevel phenomenon of epidemics interacting synergistically at individual, societal and environmental levels. Understanding the syndemic nature of pandemics will facilitate the adoption of a One Health approach to improve planetary health. To address the eco-complexity underlying One Health issues it is of key importance the development of intelligence management systems through a planetary perspective. This requires the capacity to capture,

process, and communicate data on human, animal and plant health and well-being, and on their social and environmental determinants. The implementation of such systems will need political commitment at all levels of action, deployment of adequate resources and expertise, reliable and comprehensive data flowing pathways through interoperable, flexible, and secure data sharing systems

Chapter 2: The COVID-19 pandemic brought a challenge to the health area and generated an enormous amount of information, some accurate and some not, which made it difficult to locate reliable sources of information. Scientific knowledge has become the best way to mitigate this infodemiological process. Observatories are instruments to support decision-making, seeking to integrate different sources of information and communicate the results using research methodologies such as the COVID-19 Scientific Evidence Observatory. Created by members of the research group Information in Science, Technology and Innovation in Health, of the IBICT, it aims to meet the informational demands of the most varied audiences. Its development methodology involves a knowledge management team that uses the methodological rigor of the Systematic Literature Review, to seek, evaluate, synthesize, and enable access to reliable and qualified sources of information. It provides access to different sources of national and international information from the Kaleidoscope of Science.

Chapter 3: In an increasingly connected world, information regarding the contagion and spread of COVID-19 has been an important weapon to enable better coping with the disease. The use of information technology can assist in the prevention, care and monitoring of patients. In addition, remote service using applications avoids the overload of health centers and contagion. This research reports the experience of a research project initiated in Brazil at the Oswaldo Cruz Foundation, with the objective of developing an Application and Big Data for the New Coronavirus in a public health clinic using Information Management and One health concepts. Initially, the application requirements were defined, through interviews with users and health professionals. The partial results obtained so far demonstrate improvements in the different processes of the health center with the use of the application. The use of Big Data for the analysis of information, makes it possible to define better health policies for the population in a more precise way and in a shorter time.

Chapter 4: From the One Health (OH) perspective, the achievement of better Public Health results depends on effective strategies and interventions based on integrated research in diverse sectors of activity (human health, animal health, agriculture and environment). The central topic in the United Nations 2030 Agenda aims at a world free of hunger, poverty and severe disease through the achievement of 17 Sustainable Development Goals- SDGs). The objective of the present study is to evaluate countries and applicants of technologies patented between 2015-2020. From this methodological perspective, searches have been carried out in this study on the global patent database documents available, using specific search strategies for technologies related to challenging diseases for achieving SDGs, such as neglected communicable and non-communicable diseases: diarrhea, tuberculosis, malaria, obesity, cardiovascular diseases, diabetes, lung cancer, human schistosomiasis and Zika.

Chapter 5: The objective is to describe the implementation and development of the Training Program for Health Surveillance Actions (2013-2018), which focuses on improving the performance of Health Surveillance. It is an evaluation research with a qualitative method. Key informants were interviewed, documents and literature were analyzed. The analysis enabled the construction of the Timeline, the retrieval of the chronology of the events that marked the development of the program, its implementation, and the identification of innovations and controversies. We identified 3 organizational axes: Conception/

Formulation; Implementation/Monitoring; Evaluation/communication. We found that the program went beyond the traditional approach to surveillance and met regional diversities. There were controversies about the responsibility for monitoring the Program's actions, whether they belonged to the technical areas related to the indicators or to the management of the Program at the Ministry of Health.

Chapter 6: The process of knowledge construction, widely discussed in the literature, follows a common structure that encompasses transformation of data into information and then into knowledge, which converges social, technological, organizational and strategic aspects. The advancement of information technologies and growing global research efforts in the health field has dynamically generated large datasets, thus providing potential innovative solutions to health problems, posing important challenges in selection and interpretation of useful information and possibilities.COVID-19 pandemic has intensified this data generation as results of global efforts, and cooperation has promoted a level of scientific production never experienced before concerning the overcoming of the pandemic. In this context, the search for an effective and safe vaccine that can prevent the spread of this virus has become a common goal of societies, governments, institutions, and companies. These collaborative efforts have contributed to speed up the development of these vaccines at an unprecedented pace in history.

Chapter 7: The appeal for new business models is at high level nowadays in all market sectors, involving all economic agents. Dealing with classical, non-responsive, bureaucratic structures, traditional organizational arrangements impose delays on management, ineffective control features and, more critical, limitations to innovate. In this chapter we analyze the proposition for new business models with the consideration of two huge pressuring motivations: to innovate in the Healthcare sector and adopt emerging technologies. Both dimensions, brought opportune facts for business models development and application, but, with an immense and uncontrolled dynamicity, also produced a confuse, turbulent scenario where the academic and scientific knowledge, always demanded, was not developed, and communicated efficiently. To address this imperfect scenario, we present our reflections around perspectives on building and applying business models supported by emerging technologies for the Healthcare sector, offering a background to foster these discussions in further studies and decision-making contexts.

Chapter 8: The 21st century brings an information revolution unprecedented in human history. The knowledge management of the data generated daily is a constant challenge for organizations and in all areas of science. Nevertheless, extremely relevant to the health area since it promotes the individual's well-being and health. In this sense, the quality of data, information, processes and production of products and health care for the populations of the countries, has increasingly become a global concern. Therefore, thinking about health only as a burden is a short-sighted thought. The new era of Big Data requires innovative knowledge management for Global Health, where quality is also guiding the new times. This chapter presents a reflection of the new times and management challenges for quality in Global Health and One Health.

Chapter 9: In this chapter we aim to approach new ways to understand how emerging technologies can better be applied in organizational contexts. For this purpose, collaborative methodological approaches were addressed - multi, inter and transdisciplinary paradigms - aiming to promote a better level both of comprehension and adoption of technologies, paying special attention to the Healthcare sector and to the OneHealth initiative, just defined as an interdisciplinary front. As an overall goal for the chapter, the adoption of those methodological principles is advised to the reader, enabling a better understanding of those technologies and their way to be effectively implemented.

Chapter 10: The participation of the National Health Surveillance Agency (ANVISA) in the granting of patents for pharmaceutical products and processes in Brazil took place since 2001, giving this sector of the Ministry of Health unprecedented legal competence, until then exclusive to the entity of the National Institute of Industrial Property (INPI). This chapter proposes to analyze the technical and legal aspects inherent to patenting combined with the ability to make political decisions in favor of implementing flexibilities in the patent examination of medicines that may be favorable to public health. John Kingdon's Multiple Flows Model was the methodology chosen to understand the most relevant factors that influenced the government's agenda for the creation of Anvisa's prior consent. The results allowed to outline the political window that materialized the formulation of the public policy in question, as well as to call attention to the fundamental importance for the protection of the current needs of humanity and of its future generations inserted in the concept of One Health.

Chapter 11: Informational age in the 21st century is also known with the Age of Knowledge. The great differential of organizations has been the strategic innovation through the best way to manage the existing knowledge. The management of information and knowledge generated in the health area is no different, as is the case with the pharmaceutical sector. The major challenge of public health research is to promote the use of scientific and technological knowledge produced in more effective health policy and action strategies, in order to provide effective health gains. New technologies are promising tools to support public health management. The current scenario, in which the world has been affected by the Covid-19 Pandemic, has reinforced this understanding. This chapter aims to highlight the importance of using Big Data tools to make public health policies more effective. Examples of successful cases in different areas of Brazilian public management will be presented, aiming to reinforce the relevance of these tools for Public Health Systems.

Chapter 12: In the information age is urgent to work in a collaborative network, as well as the identification of researchers in specific areas in the globalized world. In this time, half of the world's population does not have access to essential health services, and more than one billion are threatened by neglected diseases. Information management helps in the identifying, extracting, and treating Big Data in healthcare. In Brazil, the Lattes Platform is the main curriculum repository for scientists and professionals in the different areas of scientific knowledge. After processing were identified 105 specialists. Scientific articles published in Dengue, Zika virus and Chikungunya are 11.743. The computational tool ScriptLattes proved to be efficient to extract, identify and recover data from the curricula present in the Lattes database, contributing to the management of scientific knowledge in public health. Thus, Dengue, Zika and Chikungunya Infection's Data extracted from the platform generate information to assist in the knowledge management and decision makers for public health.

Chapter 13: Productive Development Partnership (PDP) established by the Ministry of Health comprehends cooperation, by agreements, between public and private institutions for development, transfer and absorption of technology regarding strategic products, in accordance with the demands of the Unified Health System. The PDP program represents one of the most important initiatives for building an industrial policy and systemic innovation in the health area, also could promote the strengthening of the national production, public-private integration, favoring the incorporation of new technologies, which were dominated only by big multinational corporations in the private pharmaceutical sector. Additionally, the establishment of a PDP with a pharmaceutical company from a South American country, which is also part of Mercosur, expands the range of interaction beyond those already existing with American,

European and Asian companies, strengthening technical development-scientific of the region that will be able to catalyze the interaction with other companies, also from the region.

Chapter 14: Brazil was one of the first countries to adopt significant health policies to better attend people with HIV. The integrated analysis of the high cost of medicines, public health and access to medicines comprises extremely complex task and Productive Development Partnerships (PDP) was the mechanism used by the Brazilian government, with a view to technological development and training of national production complex. The PDP of atazanavir was formalized in late 2011 and the agreement includes the transfer of technology, manufacturing, and distribution of the drug. The PDP emerges as a solution found by the government to minimize the Ministry of Health drug spending and encourage the local production. However, one should not ignore that there are risks associated with regulatory barriers and problems in negotiations with the holders of technology. Thus, this chapter presents a case study of the successes the management information of the productive development partnerships in Brazil as a collaborative tool for global health.

Chapter 15: Relevance is the basic value of any training project, in the cutting-cross of knowledge, attitudes and competencies to be transmitted through the pedagogical process. Trends in science and the new directions of global health research requires personnel with vision, maturity, and skills for strategic planning. We are looking a deepening gap between the professional status quo and the aspirations of society. This chapter aims to reflect on the role of the University focusing on the pillars that support it, in the context of training health professionals, and the central role of communication in the exercise of the profession and in health promotion. The approach is based on a theoretical review and the case study of Cape Verde, as a SIDS. The role played by these professionals would have a direct impact on the definition of public health policies. These would be based on knowledge, the interface of innovation in health, management, and social organization, and on dialogue to improve systems from the perspectives of One Health and Global Health.

Chapter 16: Health gained a global prominence and became a right declared by the World Health Organization, since 1948. In the 21st century, it starts to be understood as a complete well-being of the individual, far beyond the absence of disease. In this context, the right to happiness translates as an expression of the aspirations for the realization of the Right to Health. Thus, this chapter aims to understand, in the light of the Freudian perspective, the aspects of soul life that lead the individual to the exhausting task of seeking happiness and seeks to reflect the possible contributions that legal science can offer to the improvement of individual well-being as a right health in the context of global health. Freud's theories about the formation of the psychic apparatus, his conception of malaise caused by culture and legal interventions that can possibly contribute to the reduction of individual unhappiness are presented.

This handbook contributes for workers in the public health area, whether academics, managers, decision makers and even those who think they are not involved with the subject, since it is interdisciplinary and multidisciplinary, and everyone craves well-being and a healthy planet.

Covid-19 showed us one of humanity's greatest vulnerabilities: selfishness. On the other hand, it showed that collective work, sharing essential data and coordinated management for planetary health, could give hope to every participant in this ecosystem in which we live.

The reflection remains: we need to reconfigure our thinking to achieve full individual and collective happiness. This well-being goes far beyond the absence of disease, it presupposes a unique health for a planetary health.

Good reading!

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Introduction

OneHealth is an integrative approach of healthcare knowledge, potentially defining a new way to practice this essential activity Worldwide. OneHealth evolved from a promising trend to improve fundamental strategies for Healthcare, to a provider of answers for actions and planning under the new challenges imposed by Covid-19 pandemic

In this context, the handbook project evolved from an interesting and strategic discussion of a relevant network to that of OneHealth evolution under strong and unprecedented pressure, providing results, despite the unimaginable time constraints imposed on researchers and practitioners who, suddenly, had to redirect their efforts to help mankind to survive this threat.

We can imagine this project as a dramatic narrative of research methods, results, and knowledge-sharing battling an abnormal event but, at the same time still keeping the spirit of OneHealth initiative as it was thought in the initial book project, aiming at understanding information management under critical circumstances.

Presenting this book to our audience, must be considered relevant as it synthesis knowledge produced under this special context, certainly a content which will be registered in our professional and human interactions, as valuable and applicable. Possibly, this is one of the most critical texts about information management, and we are honored with the result. In this introduction, we aim to guide our readers through the chapters, their interconnections and relevance for the book project objectives and its potential to help understanding the moment when our book was generated.

In Chapter 1, authors João Paulo Magalhães, Tiago Correia, Inês Fronteira, Mohsin Sidat, Fernando Passos Cupertino de Barros, Cláudio Tadeu Daniel-Ribeiro António Pedro Delgado and Paulo Ferrinho address the syndemic as a concept to understand the synergic relationships of pandemics considering the OneHealth potential to improve the healthcare sector. Authors reflect on data and information captured from nature, involving humans and their ecosystem, aiming to build up intelligent systems to promote a better management structure able to respond to threatening events, resulting in intended actions for OneHealth initiative.

An important case study of the Covid-19 Scientific Evidence Observatory, is documented by Jorge Biolchini, Eliane Azevedo Gomes, Elaine Cristina Ferreira Dias and Tatiana Figueiredo on Chapter 2, a methodologically-supported association which promoted and continues to work with the objective to manage massively produced knowledge, regarding the Pandemic, This case study also revokes the principles of “Observatories” as data repositories to assist managers and practitioners to conduct

knowledge-production that is effectively associated with decision-making through communication instruments and processes oriented to the scientific community. A task which is critical and fundamental during the extremely demanding scenario that emerged with the Pandemic.

Emerging technologies were approached in several chapters, as the continuous flow of innovative trends met these turbulent times, resulting in potential applications to face Covid-19 Pandemic. A One-Health study approaching the information management through application of Big Data, was reported by Joaquim Teixeira Netto, Zulmira Hartz and Jorge Lima de Magalhães in Chapter 3. Along the undeniable importance of this topic, as to preserve the methods and plans to use Big Data, this study was carried on Oswaldo Cruz Foundation, a major OneHealth player in the Brazilian and global scenario, which cooperates to react to the Pandemic, producing overall guidance towards feasible and optimized policies, and contributes both to technological fields and Healthcare, delivering the OneHealth initiative objective to promote a responsive scientific network.

Adelaide Maria de Souza Antunes, Alessandra Moreira de Oliveira, Suzanne de Oliveira Rodrigues Schumacher, Mateus Pinheiro Ramos and Cristina Possas approached, in Chapter 4, the issues proposed in the United Nations 2030 Agenda. They examined patent applications done by countries from 2015 to 2020 and classified them according to the seventeen Sustainable Development Goals, SDGs. This methodological approach was applied to neglected communicable and non-communicable diseases, like diarrhea, tuberculosis, malaria, obesity, cardiovascular diseases, diabetes, lung cancer, human schistosomiasis and Zika, aiming to understand this relationship as a base for strategies and policies to be adopted in global scale.

In Chapter 5, which analyzed one surveillance qualification program - the Training Program for Health and Surveillance Actions - in the period of 2013 to 2018, authors Ana Cláudia Figueiró, Eduarda Ângela Pessoa Cesse, Gisele Cazarin, Juliana Martins Barbosa da Silva Costa and Yluska Almeida Coelho dos Reis observed the program´s evolution, using a qualitative research approach. This case study shows results, regarding aspects of innovation promotion, along with controversies, enabling a deep learning on the subject. Among these signals, as an experienced contribution to the reader, it is possible to identify the impacts of regional diversities over the traditional ways to conduct surveillance in the healthcare system and management principles regarding defining and adopting indicators to build up the intended surveillance results.

Innovations can emerge in situations where unexpected opportunities require market reactions, like it happened in the Covid-19 Pandemic. In Chapter 6, authors Hugo Garcia Tonioli Defendi, Vanessa de Arruda Jorge, Ana Paula da Silva Carvalho, Luciana da Silva Madeira and Suzana Borschiver analyzed the fundamentals of open science, discussed the massive data generation, and large datasets according to several aspects of the Pandemic, aiming to relate to studies for vaccine development. As a critical objective during this crisis, vaccine production came as a result of emerging technologies application. Data modelling offered an alternative to the traditional paths of knowledge production, resulting in a productive outcome for the future, as new methods of analysis and tools application towards immediate, precise, and demanding knowledge for decision-making.

Business models can be an innovative answer for dramatic market changes and incoming restrictions. Evaluating how this can be applied to Healthcare sector, George Leal Jamil, Arthur Henrique Oliveira Melo, Guilherme Jamil Rodrigues, Liliane Carvalho Jamil and Augusto Alves Pinho Vieira, in Chapter 7, discuss the fundamentals of business models design, towards its application in the health sector. The

study also reinforces the importance of business models as a main vector of innovation, as it happened during critical times in the business competitive scenario.

Jorge Lima de Magalhães, Luc Quoniam, Zulmira Hartz, Henrique Silveira and Priscila da Nobrega Rito, authors of the Chapter 8 focused on the promising and continuous challenge of knowledge management with support of the powerful new technology platform, the Big Data. Knowledge management, a remarkable interdisciplinary topic for many years in different contexts, gains a modern perspective when supported by a new technology infrastructure, allowing opportunities for technologies to become tools and resources for knowledge creation and overall management. This chapter reflects this bidirectional, essential relationship enlightened by quality factors in OneHealth initiative.

For Chapter 9, authors Carlos Anezio Ribeiro de Souza Junior, Elezer Lemes, Nubia Boechat and Jorge Lima Magalhães present an advanced studies of data management and scientific modelling with various success cases in the Brazilian public Health system. Examples of cases using Big Data were reported and analyzed, producing a panel of up-to-date technology applications and development for critical and demanding scenarios, target to decision-making at the level of Health policies definitions and operation. The paper shows that under management principles, these resources can provide an unprecedented level of qualified answers for decision makers.

Emerging technologies applied to Healthcare issues and environments are usually perceived as openness regarding different contributions from different scientific fields. To better understand this complex relationship in diverse levels of maturity for collaboration, George Jamil, in Chapter 10, recalls the principles of multidisciplinarity, interdisciplinarity and transdisciplinarity. With these methodological approaches, the author observed, analyzed and offers reflections on ways to develop and apply research methods and principles, aiming to scientific gain and development.

Jaqueline Mendes Soares and Marilena Cordeiro Dias Villea Correa applied John Kingdon's multiple streams model to study the role of Brazilian National Health Surveillance Agency (ANVISA). They analyzed the technical and legal aspects inherent to patenting combined with the ability to make political decisions in favor of implementing flexibility in the patent examination of medicines that may have an impact on public health. This opportune study, reported by authors in the Chapter 11, shows how the industrial property public workers have a valuable intervention on granting patents in the pharmaceutical area to protect public interests in a competitive arena.

Healthcare systems face global challenges to build and propose business models and collaborations which can enable fast and precise adjustments for efficient planning. In Chapter 12, authors Carla Silveira, Marcos Emiliano Lima Alves Hir and Henrique Koch Chaves analyzed how the network to collaborate for excellence planning can be used to address an extreme situation, regarding lack of access to essential health services and threat by neglected diseases, with the support of information management. They studied the critical actions taken to react to dengue, zika and chikungunya diseases, with help of information available in researcher´s official database Lattes, kept in the Brazilian governmental Education infrastructure.

Chapter 13 presents the Productive Development Partnership - PDP - proposal and the work developed by Michele Vieira Espindola and Jorge Carlos Santos da Costa. PDP program is one initiative which promotes national production sharing and strengthening to build an industrial policy for systemic innovation. Authors also evaluated how the PDP established with a pharmaceutical company in South America expanded the overall interaction with global companies, contributing for the regional technical

development and growth of scientific production, presenting an efficient action towards an improvement of regional and global markets.

Still observing the PDP program, authors Carla Silveira, Wanise Barroso and Marilena Correa present a case study on the antiretroviral Atazanavir in Chapter 14. This is considered by authors a success case, that was mainly based on the responsive information management incorporated in the PDP program. These results are critical to address factors such as complexity, strategic risks, costs and, finally, the access of people in need to the drug. PDP resulted in a safe business environment where national and regional producers could compete, maturing the market.

Chapter 15 brings up the importance of human resources for healthcare business models proposals and actions, focusing on training programs and processes. Authors Isabel Inês Monteiro de Pina Araújo, António Leão Correia e Silva, Antonio Pedro da Costa Delgado and Deisa Semedo highlight parameters such as training projects and mapping of knowledge, competencies and attitudes that should be transmitted to the trainees in these programs, leading to solve the gap between the professional habits and culture and what the society demands from health professionals. They address issues such as the need for a societal vision, maturity on dealing with human contexts and strategic planning.

Finally, in Chapter 16, authors Rodolfo Andrade Carvalho and Jorge Lima de Magalhães promote an interesting and opportune dialogue between Psychoanalysis and Law, regarding the Happiness concept. Happiness is worked as an expression of the aspirations of one's Right to Health as whole complete well-being individual, rather than the absence of disease. From Freudian point of view, the authors studied the potential psychic apparatus, as an implication of cultural and legal interventions, which ultimately, could result in the increase, reduction or inexistence of happiness in individual contexts, leading to different health problems.

All these contributions, produced under complex conditions, are expressed in many study cases and contextual theoretical chapters, constitute a document of the actual scenario of management and business factors - such as technology availability, business models, human resources and market demands - with undeniable social and healthcare requirements for immediate, precise and strong actions. New organizational proposals, new professional training guidelines and social and legal requirements are being produced, which will impact the social context, and the market in future years.

Our book not only documents through a scientific report of the pressured reaction but structures the thoughts which can lead to strategic planning for the sector, adopting alternatives for organizational structures, emerging technologies resources, such as Big Data, analytics and web-based systems. This contribution for future scenarios, hopefully will contribute for decision-making, from the operational to the strategic and regulatory level, providing continuous planning abilities for innovative solutions to face huge challenges, and at the same time preserve these capacities for next events and for our future.

We, editors, wish you a good reading, good health, and strong and effective planning!

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Section 1

Global Health in the One Health Context

Chapter 1
The Syndemic and One Health Nature of Pandemics:
Arguments for Renewed Attention to Intelligence Management

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ABSTRACT

The interdependence of humans, animals, plants, and their social and abiotic environment is highlighted by past and recent pandemics. A good example to understand and tackle threats to ecosystems is the COVID-19 pandemic. A syndemic is a complex and multilevel phenomenon of epidemics interacting synergistically at individual, societal, and environmental levels. Understanding the syndemic nature of pandemics will facilitate the adoption of a One Health approach to improve planetary health. To address the eco-complexity underlying One Health issues, the development of intelligence management systems through a planetary perspective is of key importance. This requires the capacity to capture, process, and communicate data on human, animal, and plant health and well-being, and on their social and environmental determinants. The implementation of such systems will need political commitment at

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all levels of action, deployment of adequate resources and expertise, reliable and comprehensive data flowing pathways through interoperable, flexible, and secure data sharing systems.

INTRODUCTION

Pandemics have been a presence in our planet from immemorial times (Acharya et al., 2021). As humans and the goods they trade have spread across the world, so have infectious agents. This was intensified by mass migrations, both intended and involuntarily, since at least the XV Century. Pandemics' apparently has been increasing in frequency– most pandemics being of zoonotic nature. Zoonosis constitute 61% of all known infectious diseases and more than 335 emerging diseases had been reported and increasing over the last decades (Jones et al., 2008) - in part attributable to social, atmospheric, geologic, hydrologic, biospheric and other Earth-system processes being altered through human actions. As a result, pressing calls to build a robust global warning and response system, that is able to capture relevant and reliable data, allowing communicability between systems and with the technological capacity and adequacy of resources to inform evidence-based decisions, have been recurrent in recent years (Asokan & Asokan, 2015; Gates, 2015). These acknowledgements demand for combined syndemic frameworks and One Health approaches and avoidance of vertical and ineffective siloed actions when considering overall planetary health and well-being outcomes (Altmann et al., 2020; Ferrinho et al., 2020; Ruckert et al., 2020; Valensisi, 2020).

BACKGROUND

The interdependence of humans, animals, plants and their social and abiotic environment is highlighted by past and recent pandemics, and it is most relevant in understanding and tackling threats to ecosystems (Acharya et al., 2021; Amuasi et al., 2020; Waugh et al., 2020).

Indeed, balanced ecosystems are important to support adequate interactions between humans and animals and protect and prevent the hazards of animal to human and human to animal transmission of diseases (Corman et al., 2019; Corvalan et al., 2005). Human action has been a major force behind the disruption of ecosystems, leading to pollution (e.g., air, light, thermal, noise, soil) through different agents (e.g. plastic, non-disposable tools, radiations). The outcomes are manifold and include loss of biodiversity, induced desertification, and deforestation, changing seasonal meteorological patterns, increase in illegal wildlife trading, changes in patterns of human and animal migration, the global increase in density and spread of entomological disease vectors, and blurred boundaries and distance between species. As a result, pandemics, climate disasters and other adverse events, from which populations may never fully recover, are likely events in the coming years (Kluge & Monti, 2021; Pérez-Escamilla et al., 2020; Singla et al., 2020). The COVID-19 pandemic is a dramatic illustration of this.

Two different yet complementary concepts allow to better grasp such human-nature interdependence: syndemic and One Health.

The term syndemic was first introduced by Singer (1996) to describe and better understand synergistic interactions between endemic and/or epidemic, communicable and/or non-communicable (NCD) and not necessarily neglected (ND) diseases, and their social and environmental determinants. Some examples of syndemic approaches include 'SAVA' (Substance Abuse, Violence, and AIDS) (Singer,

1996), 'VIDDA' (Violence, Immigration and associated isolation, Depression, type 2 Diabetes, and Abuse) (Mendenhall, 2012), or 'PHAMILIS' (Physical Health problems, Abuse, Mental Illness, Loss, Instability, and Substance use) (Marcus & Singer, 2017). Although the concept has remained relatively unchanged at the definitional level, several developments have argued for more accurate meanings of synergistic interactions, as it can encompass mutually or serially causality and synergism (see Tsai, 2018 for a synthesis).

As to One Health, its roots can be traced back to the late nineteenth century (think of initial approaches to microbiology by Louis Pasteur and Robert Koch and of the basis of modern medical education and practice by Rudolph Virchow and Sir William Osler), and its contemporary revival was boosted by several initiatives including the 'One World, One Health symposium' in 2004 held by the Wildlife Conservation Society. Through the cases of Ebola, Avian Influenza, and Chronic Wasting Disease, the symposium aimed to show the current and potential movements of diseases among human, domestic animal, and wildlife populations (Mackenzie, et al. 2013). One Health enables the development of transdisciplinary explanations of health and disease occurrence through a comprehensive study of humans, animals and plants ecosystems and theirs social and environmental contexts, and encompasses initiatives and approaches that deal with complex systems. Due to the interface of humans, animals and plants, One Health underlines the relevance of a planetary approach and involves dynamic and transdisciplinary governance and management bodies, in order to include veterinary, medical, agricultural and environmental practices (Anderson et al., 2010; Mardones et al., 2017; C Stephen & Karesh, 2014).

Syndemic and One Health are intertwined in the sense that syndemic models explain how pandemics deeply influence One Health outcomes, accentuating misinformation and disinformation[1], leading to infodemics of fake news and enhancing fear-related behaviors that contribute to social isolation, discrimination and stigmatization, violence, avoidance of health care services and increases in healthcare related avoidable morbidity and mortality, exposing the weaknesses of health care and environmental protection systems. A syndemic perspective may be a useful conceptual tool with the potential to help policymakers and One Health professionals in their endeavors to protect the ecosystems and improve and manage the health of human, animal and plant populations. It helps to explain how pandemics impact the environment and its effects on individuals, communities and countries throughout the world (Delgado et al., 2020; Ferrinho et al., 2020; Fronteira et al., 2021; González-Guarda et al., 2011; Greer et al., 2019; Heymann, 2008; Lemke et al., 2020; Marchant-Forde & Boyle, 2020; McGonagle, 2017; Robalo et al., 2020; Van Damme & Van Lerberghe, 2000; World Health Organization, 2021).

However, turning these principles into practice is still a challenge, mostly because of the need to integrate data from multiple sources. Indeed, contemporary political, cultural, legal and regulatory policies lead to non-dialoguing data sets on human and non-human disease and their social and environmental determinants, which undercut One Health surveillance and comprehensive policy development (Uchtmann et al., 2015). The challenges to the integration and implementation of the One Health concept can be summarized as follows::

- The need to recognize the importance and role of dynamic transdisciplinary collaborations (e.g. veterinarians, epidemiologists, statisticians, physicians, public health professionals, social scientists, economists, political scientists, biologists, ecologists, environmental scientists and policy makers);
- The need for new mechanisms to capture and integrate currently non-dialoguing data (e.g. omics, biological, sociological, economic, clinical, ecological) from a variety of sources and the devel-

opment of infrastructures and techniques for data sharing, integration, mining and interpretation, while respecting privacy and ownership concerns;
- The identification of One Health joint priorities and resources, operationalization and institutionalization of One Health strategic plans, and the ability to apply systems thinking to address complex and multifactorial challenges.

This essay fosters the intertwine between syndemics and One Health specifically by reflecting on the data management and on how to translate the resulting information into intelligence systems for policy development and effective actions.

MAIN ARGUMENT OF THE ESSAY

To improve the policy responses during disruptive events such as pandemics, we argue that coordinated and harmonized actions linking a vast array of fields of knowledge and their professionals (social sciences, human and veterinary health and agricultural and environmental sciences) and policymakers are needed to acknowledge their syndemic nature, leading to integration into a One Health planetary approach. These actions should promote a shift on the way organizational cultures, structures and systems will thought and encourage synergies to improve One Health surveillance and intelligence management on a local, regional and global scale, to develop and implement effective policies and action (Arnold & Wade, 2015; Duboz et al., 2018).

The eco-complexity underlying One Health data management through a planetary perspective will entail sustainable and integrated surveillance, including social, environmental and biological (human, animal and plant) variables and omics data sets (Bisdorff et al., 2017; R. Wang et al., 2011). Also, it will require infrastructures, technological capacity (including cloud platforms and interoperable, secure, flexible, and decentralized systems) and adequate human expertise and workforce with the most diverse backgrounds (scientists, practitioners, data managers, etc.), dedicated to the systematic collection of the most varied and reliable data. In order to process all data flowing to One Health intelligence systems, it will make use of existing as well as fit-for-purpose newly developed analytical tools, including artificial intelligence mechanisms, and systems thinking to address the syndemic nature of the phenomena being tackled.

Also, to reduce the expected burden of disease from current and future pandemics, gaps and overlaps need to be addressed in existing segregated structures, and consideration must be given for resources availability (e.g., workforce and funds), adequate research hypotheses and methodologies, real time risk assessment and management, including climate change events, emerging zoonotic infections and antimicrobial resistance, and credible communication processes and channels. Therefore, multidisciplinary, interdisciplinary and transdisciplinary perspectives at local, national and global levels are required. Also required will be the need to turn data management systems into intelligence management systems (IMS). Briefly, while data refers to the collection of information, based on values and experience, intelligence refers to the incorporation of the cognitive ability to decide on how to transform data into actions (Rothberg & Erickson, 2005; Y. Wang, 2015). IMS will be 'naturally' necessary as policy-makers and One Health professionals seek to better capture the interactions of human, animal, plant and social and environmental conditions that together affect planetary health.

Bellow we list some key dimensions that the debate on the development of IMS to One Health approaches of planetary challenges will need to foster.

1. Multilevel Integration of Knowledge and Actions

IMS will further underscore the need for integrated methods of practice, research and political commitment with a planetary perspective at all levels of action (Asokan & Asokan, 2015; Häsler et al., 2020). IMS will build on the recognition that, on the one hand, knowledge ownership by individuals, communities and civil society organizations at the local level are key contexts to promote sustainable change and translate knowledge into action with impact on social inequities, health and well-being. On the other hand, that success will require a link between national priorities and global health governance, through leadership and solidarity of a coalition of countries and global actors involved in research and policy development of One Health approaches - the United Nations, the World Health Organization, the World Organization for Animal Health, the Food and Agriculture Organization, the United Nations Environmental Program, the World Trade Organization and philanthropic Foundations and global funders, to name a few (Sheikh et al., 2020; World Health Organization, 2019; Xie et al., 2017). Thus, IMS calls for political independence from external economic forces and compromise to scale up investments, at all levels, by governments, public authorities, development banks and other global funding mechanisms targeted to prevent and reduce potential threats, provide early warning systems and improve preparedness and response to health emergencies (Benis et al., 2021; Greer et al., 2019; Kluge & Monti, 2021; Peprah et al., 2020; World Health Organization, 2021; Xie et al., 2017).

2. Changes in Analytical and Methodological Approaches

Current research methods, multicomponent interventions and analysis have been failing to really understand the way the syndemic and One Health dynamics contribute to diseases, risk factors and social constructs of these, and the extent to which health risks interact and disseminate in society, including its values, sociocultural beliefs, attitudes, practices, discourses and customs. Approaches will have to go beyond the individual level, mapping the temporal cascade of health determinants and using agent-based models (Emirbayer & Mische, 1998) to understand diseases and risk factors dynamics and incorporating insights from diverse fields of knowledge (e.g sociological, anthropological, psychological, political and economic). Continuous risk assessment and management through One Health IMS will encourage research driven by syndemic thinking, bioinformatics and computer sciences (including artificial intelligence methods) one the one hand, and data sciences, including the study of metadata, digital footprints and the analysis of large collections of documents, on the other. These processes will enhance early outbreak warning systems capacity, machine learning-based prognostic models, early diagnosis, isolation and treatment solutions, and One Health understanding of its determinants, disease trends, outbreaks, pathogens and other causes of health emergencies. Another methodological challenge will include the ability to build counterfactual-based approaches, using inference mechanisms to identify which risks are contributing the most for any syndemic under study (Dananjayan & Raj, 2020; Falzon et al., 2019; Pearl & Mackenzie, 2018; Shrestha et al., 2020; Tsai, 2018).

3. Communication

Communication plays a major role in IMS both as inputs as well as outputs of ecosystems. The number of features, data and information that will be available to and from One Health IMS will require approaches to reach wider group of stakeholders, capturing and feeding relevant data, information and knowledge to assist them to take the best evidence-based decisions with a One Health planetary perspective when called to do so. This means that governance mechanisms, as transparency, accountability, analytic capacity, participation and intelligence are needed more than ever to improve sharing of information and allow stakeholders to communicate more accurately and proactively. Also, siloes and sectoral actions and communication channels are, according to syndemic thinking, detrimental, resulting in duplication of efforts and the ineffective use of resources, and hamper infodemic management. Additionally, siloes and sectoral actions can lead to delays in collecting and feeding data to IMS and timely signal hazards that can evolve to health emergencies. Further, wider risk communication to communities, through new digital ways of engagement, can act as important assets for IMS by providing near real-time data and to achieve more effective and sustainable actions, avoiding misinformation and disinformation proliferation (Benis et al., 2021; Duboz et al., 2018; Greer et al., 2019; Labrique et al., 2020; Tsai, 2018; World Health Organization, 2021).

4. Academic Training

These renewed approaches should be envisaged in academic training for all scientific domains, to transform data into relevant information, information into knowledge, knowledge into effective policies and interventions, and interventions into desirable changes and effects in well-being and health (Arnold & Wade, 2015; Asokan & Asokan, 2015; Rüegg et al., 2018). Education and training institutions should apply consistent One Health core competencies in education programs, aiming to create a body of specialized professionals in One Health, focusing on a transdisciplinary approach among human, animal, plant and environmental health disciplines, in order to take advantage of the benefits of shared knowledge, shared professional experience and expertise and available resources. Depending on country-based professional cultures and education systems, the acquisition of competencies in One Health can vary between specific training programs either at the graduation or postgraduation levels. Some key areas deserving consideration in the syllabus include antimicrobial resistance, zoonoses, vector-borne diseases, food safety and security, surveillance and information systems, field epidemiology, plant biology, applied philosophy, law, economics, agriculture and livestock, wildlife, policy mechanisms, ecology and environmental health, and social and behavioral sciences. Also, cross-cutting skills should be considered, as management, communication and informatics, values and ethics, leadership, teamwork roles and responsibilities, and systems thinking. Additionally, education should consider the role of historical, cultural, political, economic and scientific aspects and contexts to apply principles of research and evaluation methods to policy and programs implementation. Considering One Health more as an approach than as a discipline, it would also be important to follow a step-by-step method to provide a framework that helps to set clear program objectives and optimizes core competencies already existing in education and training institutions (Craig Stephen & Stemshorn, 2016; University of California, Davis et al., 2018).

CONCLUSION

Contemporary societies are interconnected at a global scale, while at the same time struggle to preserve national and local economic, social, political and cultural life. These efforts are irrelevant if the most diverse ecosystems are not protected and preserved as well. The COVID-19 pandemic is as a window of opportunity to show the need to rethink scientifically and politically public health emergencies, so that the same issues and mistakes of the past can be avoided when another health threat arises (Correia, 2020). This requires a balanced understanding of the synergistic effects involved in global human, animal and ecosystems development. Syndemic theory facilitates such an understanding and has the potential to reshape the way researchers, decision-makers and communities approach One Health planetary challenges (Greer et al., 2019; Horton, 2020; Kluge & Monti, 2021; Shrestha et al., 2020; Tchounwou, 2004; United Nations, 2016; World Health Organization, 2021).

The eco-complexity underlying One Health intelligence research through a planetary perspective will require an IMS, that capture the nature and interactions of human, animal, plant and social and environmental conditions that affect planetary health. IMS implementation will, first, need political commitment at all levels of action, deploying adequate resources and expertise and acknowledging inter-sectoral coordination and solidarity. Second, it will need reliable and comprehensive data flowing through interoperable, flexible and secure information systems and analytical capacities, to produce information and knowledge for action. Lastly, these actions will lead to risk assessments, management and communication, based on scientific evidence to better inform the population and reduce misinformation and disinformation. The persistence of these issues will symbolize a moral failure to acknowledge and correct current inadequate frameworks used to mobilize and manage knowledge when responding to pandemics (Liu et al., 2020; Sheikh et al., 2020; Smith & Upshur, 2020). By shedding light on new ways of thinking will contribute to improve coordination, collaboration and solidarity, most needed to protect and ensure health and well-being for all at once. This is the current flagship for the United Nations' sustainable development agenda, although it is yet unclear whether the models of countries' development and persons' expectations lie in dialectical forces that inevitably make the world an uneven space for happiness.

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KEY TERMS AND DEFINITIONS

Abiotic Factor: Non-living chemical and physical elements of the environment that affect living organisms and the functioning of ecosystems.

Biotic Factor: Living organism that shapes its environment.

Epidemic: The occurrence in a community or region of cases of an illness, specific health-related behavior, or other health-related events clearly in excess of normal expectancy.

Information: Facts that have been arranged and/or transformed to provide the basis for interpretation and conversion into knowledge.

Policy: Guide to action to change what would otherwise occur based on resources allocation

Social Environment: The role of social structures, processes, and factors in the production of health and disease in populations.

Syndemic Theory: Two or more epidemics interacting synergistically and contributing, as a result of their interaction, to the clustering of excess burden of disease in a location or population, more than just the sum of both and simple additive associations.

ENDNOTE

[1] Misinformation refers to unintentional errors, inaccuracies, or misleading information, while disinformation is deliberately deceptive, false, or misleading (Rubin, 2019).

Chapter 2
Coping With the Infodemic With Scientific Knowledge Management:
A Case Study of COVID-19 Scientific Evidence Observatory

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ABSTRACT

The COVID-19 pandemic brought a challenge to the health area and generated an enormous amount of information, some accurate and some not, which made it difficult to locate reliable sources of information. Scientific knowledge has become the best way to mitigate this infodemiological process. Observatories are instruments to support decision making, seeking to integrate different sources of information and communicate the results using research methodologies such as the COVID-19 Scientific Evidence Observatory. Created by members of the research group Information in Science, Technology, and Innovation in Health, of the IBICT, it aims to meet the informational demands of the most varied audiences. Its development methodology involves a knowledge management team that uses the methodological rigor of the systematic literature review to seek, evaluate, synthesize, and enable access to reliable and qualified sources of information. It provides access to different sources of national and international information from the Kaleidoscope of Science.

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BACKGROUND

The world is facing a major challenge with a highly infectious virus that is globally spreading, having so far generated more than 142 million cases and 3 million deaths worldwide (World Health Organization, 2021). At the same time, a huge excess of information, some accurate and some not, makes it difficult to find suitable sources and reliable guidance when needed. This intense and growing amount of information has been spreading even more rapidly through the Internet and social media platforms, disseminating information that is either false or insufficiently validated about the disease and the pandemic phenomena.

The exponential growth of information that has been generated, developed by researchers and published in many scientific journals to meet the needs of professionals, as well as the increasing information volume addressed to lay people to clarify them and mitigate the problem of disinformation, have both contributed to a great paradox, since it ends by feeding the very infodemic about COVID-19.

Infodemic, a term that results from the conjugation of the words information-epidemic, refers to a "large and significant increase in the volume of information associated with a specific subject, which can multiply exponentially in a short time due to a specific event, such as the current pandemic" (Pan-American Health Organization [PAHO/WHO], 2020). In this situation, rumors and misinformation arise in parallel with valid information, in addition to the manipulation of information with sometimes dubious or even malicious intent, and social networks amplify this mixed nature of information.

The exponential scale of infodemic and the complexity of the necessary response to this social phenomenon give rise to a new field of research, which requires information synthesis and complex coordination of specialized knowledge from different disciplines, giving origin to this new field of knowledge called "infodemiology".

In July 2020, while recognizing the severity and importance of responding to infodemic during the COVID-19 pandemic, the World Health Organization (WHO) promoted the first scientific conference on the field of infodemiology (WHO, 2020), in which more than 100 specialists were gathered to address infodemic with evidence-based tools and interventions.

During the conference, four pillars have been defined for infodemic management: (1) information monitoring / surveillance; (2) strengthening literacy capacity in digital health and science; (3) encouraging processes to improve the quality of information, such as fact checking and peer review; and (4) accurate and timely translation of knowledge, minimizing factors that can cause distortion, such as political or business influences.

In line with infodemic management practices, our group of research has been motivated to develop information means and resources in order to help the scientific community and society in general to deal with the worldwide serious problem in public health, consequent of the Coronavirus Disease of 2019, represented by the acronym COVID-19. As soon as the pandemic virus reached the population of Brazil in March 2020, the research group conceived the COVID-19 Scientific Evidence Observatory (OECC) in this same month, in order to translate information into knowledge, with the mission of publicly spreading it to different kinds of public, both academic and professional, as well as laypeople. Designed to become a differentiated and qualified source of quality information, warranting scientificity and reliability throughout the whole process of knowledge management, the Scientific Evidence Observatory addressed to COVID-19 utilizes methods and techniques of scientific dissemination and provision of accessibility. By collecting, selecting, producing, and communicating scientific information with strict methodological criteria, the Observatory promotes the availability and circulation of knowledge throughout society.

Being the result of a project developed by a group of researchers at the Brazilian Institute of Information in Science and Technology (IBICT), the main objective of the Observatory is to assist everyone who is interested in quality information about COVID-19, so that they can orient themselves, both in the personal and in the collective spheres. Consequently, people can be assisted to be well informed and make appropriate decisions regarding different aspects of this overall collective health problem. The process of producing quality based knowledge and reliable information in the COVID-19 Scientific Evidence Observatory is based on research that is conducted with high methodological rigor, making available and communicating scientific evidence that strictly follows a set of process quality requirements. This guideline provides the condition to deliver information that is available in a clear, objective, useful, and applicable manner.

Taking into account that the present text is supposed to be consulted by multiple and diverse readers, such as academic researchers, health professionals, managers of different sectors, educators in all levels, and society in general, the following structure was composed for accomplishing this purpose: In the first section, we briefly discuss infodemic and misinformation phenomena during the COVID-19 pandemic. In the second section, knowledge and information management in this context are studied in a coupled way, in order to understand how different social groups to deal with the pandemic in an informed and integrated way can potentially use scientific knowledge management principles. In the last section, supported by previous scientific study, the motivation for developing and implementing an observatory is discussed, as well as the methodology that was used and the results developed thereby are presented. This last section is based on the analysis of the case study of the COVID-19 Scientific Evidence Observatory development process and structure.

THE INFODEMIC DURING THE COVID-19 PANDEMIC

The excess of information, which is an often conflicting phenomenon, makes it difficult to find which pieces of information are truly useful to guide, reassure, and provide confidence in people. This very phenomenon can hinder decision making by managers and health professionals, especially when there is no time available to evaluate the evidence that is at disposal.

During the COVID-19 pandemic, social media and communication technology resources played an important role in keeping us informed and updated. However, easy access to information also fueled the dissemination of the incorrect type of it (mis-information) as well as the erroneous kind of it (disinformation), distorting modalities of information, relative to the multiple and diversified aspects of the pandemic, such as, for example, the ways by which the disease is contracted, disseminated, treated, and prevented.

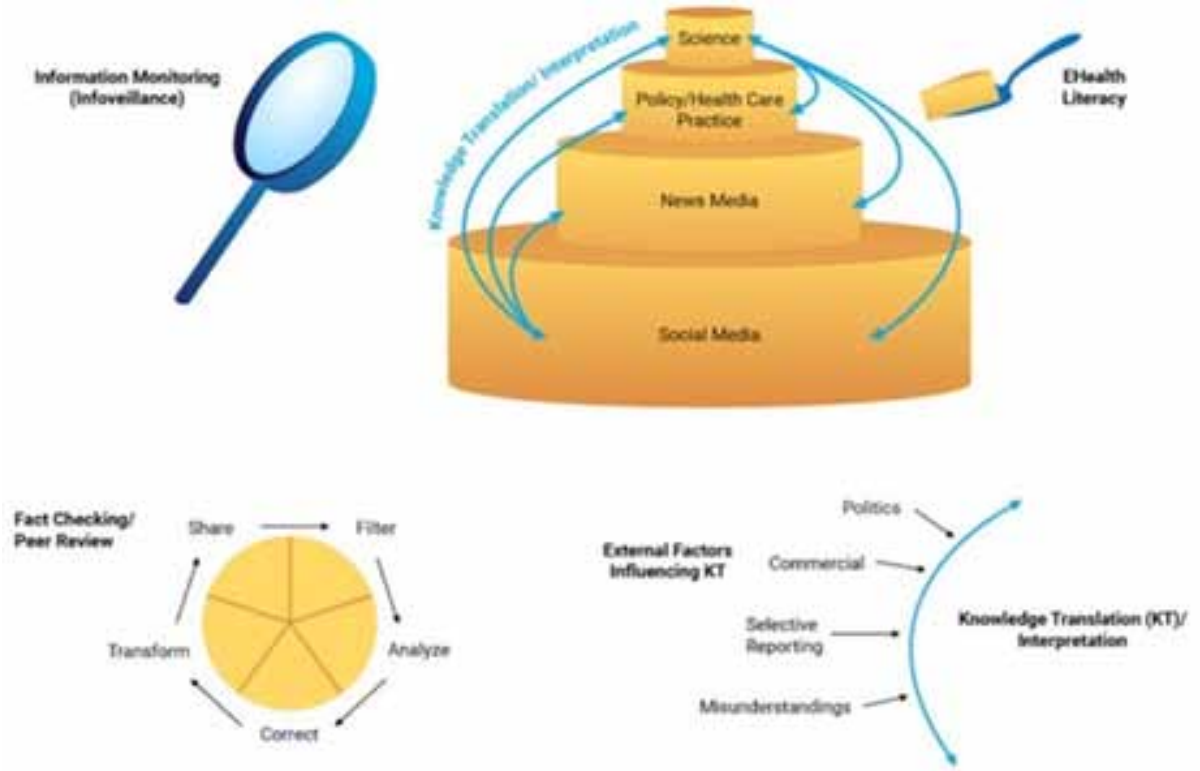
Wardle and Derakhshan (2017) present a conceptual framework for examining information disorder, identifying three different types: mis-information, disinformation, and mal-information. Using the dimensions of damage and falsehood, they describe the differences between these three kinds of information:

- Mis-information occurs when false information is shared, but with no intention of causing harm.
- Disinformation occurs when false information is deliberately shared to cause harm.
- Mal-information occurs when genuine information is shared to cause harm, often turning private information into public (Wardle & Derakhshan, 2017, p.5).

In this way, mis-information is truly false information, but the person who discloses it believes it to be true; Dis-information is also false information, with the difference that whoever discloses it knows that it is false and does it intentionally, and the third category called Mal-information is really based on reality, but it usually causes harm either to a person, a social group, an organization, or a governmental entity such as a municipality, a state or province, or a country.

In figure 1, the authors describe how the erroneous and harmful information intersect around the concepts of falsehood and damage.

Figure 1.



During the COVID-19 pandemic, the infodemic phenomenon has been prominent. The term "infodemic" refers to a "great increase in the volume of information associated with a specific subject, which can exponentially multiply in a short time due to a specific event, such as the current pandemic" (OPAS, 2020). In this situation where and when infodemic is present, rumors and misinformation both arise, in addition to the manipulation of information that is done with dubious intent, and all this is amplified by means of using social networks.

Authors like Gunther Eysenbach, who coined the term 'infodemiology' in 2002, identified opportunities during the COVID-19 pandemic to develop tools and approaches to deal with infodemics. The author developed a model that is composed of four pillars for managing infodemics, using the metaphor of a layered 'wedding cake', as can be seen in Figure 1. In the author scheme, the layers are displayed

as being proportional to the amount of information generated by these groups. The model also presents the flows of information and knowledge that occur between all these different levels (Eysenbach, 2020).

This schematic model represents science as being the smallest layer of the 'cake' in terms of the amount of information it generates, which is represented at the top of the layers for presenting rigor in its information production. Social media is described as the biggest and last segment of the symbolic cake of the model, representing the large amount of produced information, which is generated or amplified by the public in an unfiltered and amplified mode of propagation.

The first pillar of management is the translation of knowledge that is accessible to all individuals, highlighting that the knowledge translation process is subject to different kinds of extraneous influences, such as political, commercial, or other kinds, which distort the reliable scientific message.

The second pillar emphasizes that within each layer there are processes of refinement of knowledge, such as fact checking and peer review.

The third pillar corresponds to the development of 'e-Health Literacy'. In the age of the Internet, the end user can consume information at any level, at any stage of refinement, making e-Health Literacy an essential skill to be developed by every person in a digital world. Digital health literacy, a term that has been developed later on, is defined as "the ability to search, find, understand, and evaluate health information in digital sources, and to apply the acquired knowledge to approach or solve a health problem".

Finally, in the fourth pillar under the image of a magnifying glass contained in Figure 1, the author brings the monitoring of information and surveillance processes that he called 'infoveillance'. The author's idea is similar to the epidemiological surveillance that is conducted in the pandemics evolution, in order to detect outbreaks of misinformation and rumors, so that people may be able to fight them by means of facts or interventions.

In an attempt to understand the misinformation epidemic phenomenon and discuss the development of possible tools designed to measure and control infodemic, WHO held in July 2020 the first scientific conference remotely provided on the topic, by bringing together more than one hundred experts (WHO, 2020). During this unprecedented and innovative conference, forms monitoring, information quality improving, and a public health research agenda were discussed, in order to direct the focus and investment towards this emerging scientific field.

In this context, four pillars were defined for developing "infodemiology": (1) information monitoring (infoveillance); (2) strengthening literacy in the fields of digital health and science; (3) fostering processes capable to improve the quality of information, such as fact checking and peer review; and (4) accurate and timely translation of knowledge, minimizing distortion factors, such as political or commercial influences.

From the discussions that have been developed during the conference, five currents of thought emerged about where to focus the efforts for infodemic research: (1) measuring and monitoring the impact of infodemics during health emergencies; (2) detecting and understanding of the spread and impact of infodemics; (3) responding and implementing interventions that protect against infodemic and mitigating its harmful effects; (4) assessing interventions and strengthening infodemic resilience of individuals and communities; and (5) promoting development and application of infodemic management tools.

At the end of the conference, an agenda was defined with a list of priorities: analysing evidence in each of the five streams; developing a research and practice community to promote connections; monitoring the implementation of the agenda; and developing tool repositories, resources, as well as training and educational curricula and structures.

The infodemics management agenda can be used by the WHO, different kinds of partners, research agencies, and academia, as a reference in identifying research and evidence gaps that might be able to support infodemic management interventions and their assessment.

SCIENTIFIC KNOWLEDGE AND THE INFORMATION AND KNOWLEDGE OBSERVATORIES

WHO establishes that its own guidelines should be based on the best evidence, advocating the use of scientific knowledge to improve performance of health systems among member countries (World Health Organization [WHO], 2003).

Scientific knowledge is the one generated from scientific methods and associates data collected in the field with theories. According to the Oslo Manual (2006), which provides guidelines for the collection and interpretation of data on innovation:

[...] Scientific knowledge is broadly applicable across a wide and rapidly expanding frontier of human endeavour. Science has been considered that part of knowledge which cannot or should not be appropriated by any single member or group in society, but should be broadly disseminated. Because of this, much of science is considered a "public good", a good in which all who wish can and should share if social welfare is to be maximized (p.21).

Explicit scientific knowledge can be defined as any form of codified and rationally structured knowledge, which has the possibility of being transmitted by structured communication systems or formal means of communication. It then comprises all forms of scientific literature, whether evaluated or not. Tacit scientific knowledge, in turn, refers to knowledge or skill that can be exchanged between scientists through personal contacts. This type of knowledge cannot be exposed or represented by formulas, diagrams, tables, graphs, declarative verbal descriptions or procedural instructions to conduct action (Collins, 2001).

Communication of scientific knowledge can occur through diffusion and dissemination, aiming to work, 'translate' and convey this knowledge. Just as there are points in common between these terms, there are also differences that distinguish them, such as the type of channel through which scientific information will be disseminated, the public profile for which to address, he purposes of communication to be carried out, in addition to the type of support and format to be conveyed (Bueno, 2010).

Scientific diffusion can be seen as communicating information among researchers and specialized people (Caribé, 2015; Bueno, 1985). Thus, for this audience, the main objective of scientific communication is to establish informational channels for exchanging knowledge about research and its results.

Scientific dissemination, on the other hand, is treated as a practice of reformulating or translating scientific discourse into a second form of discourse (Grillo, Giering & Motta-Roth, 2016). It is important to highlight that in the process of scientific dissemination there is "a permanent conflict between the need to maintain integrity of technical terms and concepts, to avoid erroneous or incomplete readings, and the imperative requirement to effectively establish communication" (Bueno, 2010, p. 3).

Gibson et al (1994) present a vision in which scientific research methods have been disseminated throughout society, and the consequence of this is that all research sites, public or private, can be identified as a possible origin point of scientific knowledge.

In the academic context, scientific knowledge management can be studied from two different perspectives. The first one concerns the scope of scientific communities, which are understood as the grouping of peers who share a topic of study, develop research, and dominate a specific field of knowledge, at an international level; and the second perspective is related to teaching and research institutions (Costa, 1999).

In this sense, characterizing the scientific community concept as the group of researchers who share interest in specific topics or areas can be evidenced in networks of participants. Probst et al. (2002) state that a network is a common basic interest among its members, in addition to personal guidance and voluntary participation, and their relationships are based on the principle of exchange. Nowadays, with the development of the Internet, relations between members rescue and intensify the gift principle, composed by three consecutive processes: giving, receiving, giving back (Mauss, 1925).

Sharing relationships as well as information and knowledge flows within scientific communities occur through invisible colleges. Unlike academic communities, scientific communities do not have borders or organizational characteristics.

The practices and methodologies most directed to producing and disseminating knowledge emerged in the last decade of the twentieth century, under the name of knowledge management. The effects of changes in the productive structures of society, caused by the transition from the industrial to the post-industrial economic model, led to rethinking organizations and, therefore, knowledge management studies grew in its importance.

According to Davenport and Prusak (2003), knowledge management the integration of actions addressed to the codification of knowledge, aiming to identify, manage, and share information. For the authors, organizations need to "create a set of functions and qualifications to perform the task of apprehending, distributing, and using knowledge" (Davenport & Prusak, 2003, p. 53).

Malhotra (2000) adds the technology component in knowledge management, since it encompasses processes that seek a synergistic combination of data and information processing capacity, through Information Technology, with the creative and innovative capacity of human beings.

In the definition of knowledge management adopted by authors Nonaka et al. (Nonaka et al., 1998; Nonaka et al., 2000; Nonaka, Toyama, 2002) the concept of "Ba" is presented to refer to contexts and / or environments that enable knowledge development. For the authors, knowledge would need a context to be created, a place where information is interpreted in order to become knowledge, to be shared and used. This place, with a complex and dynamic nature, is called "Ba" and it is not necessarily a physical space, as they explain:

Ba is a time-space nexus, or as Heidegger expressed it, a locationality that simultaneously includes space and time. It is a concept that unifies physical space such as an office space, virtual space such as e-mail, and mental space such as shared ideals. (...) The key concept in understanding ba is interaction. (NONAKA et al, 2000, p.14).

Capurro (2009) adds other Japanese concepts to the definition of "Ba", because according to the author the concept Ba means a place where the subject, the object, events, human interpretation of objects, and experiences meet. Thus, it would not be possible to manage knowledge, but rather to provide conditions and contexts that favor knowledge creation. Therefore, in a knowledge management program, what is managed is the "knowledge artifact, and not the knowledge itself" (McInerney, 2002, p. 1011).

It can be observed that managing knowledge does not imply exercising direct control over it, but planning and controlling the context, or the ba: situations in which this knowledge can be produced, registered, organized, shared, disseminated, and used in order to make better decisions possible.

In line with the ideas of Nonaka et al, Capurro and McInerney, the motivation for designing the Scientific Evidence Observatory COVID-19 (OECC), the very object of this study, was integrating several sources of information, sharing scientific knowledge, and external communication. The integration of these elements is aimed at all people interested in obtaining quality information about COVID-19, in order to orient themselves and make appropriate decisions based on research conducted with strict methodological criteria.

Observatories first appeared in Europe, at the end of the 20th century, because of the wide view they provide in the analysis of phenomena and events. They recognize information and knowledge as the main drivers of a country's social, political, cultural, and economic development and, as such, assume a central role in decision-making, as well as in the design and evaluation of public policies (Ortega & Valle, 2010).

The authors also highlight the role of observatories in systematizing different sources of existing information and, in particular, offering complete, integrated, reliable, and accessible sources of information, in order to facilitate access to knowledge about a sector or theme.

The observatory must dedicate itself to the mission of supporting decision-making, together with mechanisms that change different stages of the process, from collecting and treating information to reflection and co-production environments with interested actors. Usually structured through small teams that work in an articulated way, and with a wide network of external collaborators, they produce specific data sets for sectorial projects and make use of advanced methodologies for data collection, processing and dissemination (Silva et al, 2013; Vessuri, 2002).

Silva et al. (2013a) pointed out that observatories must act in favor of knowledge, thus breaking with the "syndrome of mere information", in which there is excessive valuation and diffusion of structures that only inform and do not generate knowledge; and breaking with the "repository syndrome", which is limited to the recording and reproducing of pre-existing information.

Therefore, observatories are instruments of decision support, endowed with resources to integrate different sources of information and externally communicate the results through research methodologies, to achieve information, knowledge, and critical reflection (Alabés, 2007; Costa et al., 2008).

For Pacheco and Batista (2016), observatories have three types of products and missions that complement each other in the functions performed (Type A, B and C).

The Observatory type A produces studies and analyzes for decision-making products and the corresponding missions are finding, registering, and producing studies that help decision makers in their acting upon the phenomenon of interest. The Observatory type B produces sector monitoring and follow-up, so they are monitoring centers par excellence, both including those carried out on indicators, specific to those who use these tools, as well as the systematic monitoring of a specific sector or thematic. In addition, the Observatory type C intends to produce communication of information or strategic knowledge, the corresponding mission is dissemination of information, and knowledge about the phenomenon of interest to all potentially interested social actors.

The authors highlight the growing association of increased functions, from type A to C, emphasizing that type C is the observatory that has the most complete mission, as it conducts studies and analyzes to support decision-making (type A), monitoring and following up (Type B), and assuming a commitment of communication with interested actors.

According to Alabés (2007), observatories are hardly part of the formal decision-making system, as in the scope of public policies, but they manage to develop a certain power of persuasion based on the development of articulated and strategic actions with the actors of the environment. This is because, as a stage in the structuring process of an observatory, partnerships are established, as well as articulating networks among involved social actors, considered as fundamental elements for developing its activities.

In the study carried out with the OECC, it is possible to observe that the Observatory's mission is to disseminate scientific information and knowledge, in line with type C, studied by Pacheco and Batista (2016). In the next section, the Observatory's motivation and mission as well as the results achieved in the analyzed period will be discussed.

A CASE STUDY OF THE COVID-19 SCIENTIFIC EVIDENCE OBSERVATORY

Motivation for Developing and Implementing the Observatory

The COVID-19 pandemic impelled researchers, from the most varied areas, to develop studies that sought to understand a wide range of aspects, from the virus and its mechanism of action, to the social and economic impacts generated by the measures that had to be adopted to try to contain the pandemic. This high production of studies generated a new information explosion, more precisely characterized as a new infodemic. Since then, there has been an exponential increase in scientific production, in the midst of which all scientists began to seek to disseminate their findings to contribute to the development of science. In parallel to this information blast, another movement took place. There is a huge need from the part of researchers, professionals, and the general population to get information, thus generating an increase in the search for information. Opening access to scientific production, from the part of publishers, which journals previously had their access granted only through subscription, provided the connection between these two explosions. Therefore, there was a mutual and recursive potentiation of both movements: production of knowledge, on the one hand, and demand for information, on the other side, causing positive feedback in the combination of these two processes.

On the demand side, different audiences have expanded their information needs. Health professionals, health researchers, researchers from other scientific fields, public and private managers, educators, communication professionals, lay people, all need access to high quality information. However, due to the great flow of information that was being made available through opening access, it became difficult for professionals and lay people to find out what they sought and consequently satisfy their demand. Another complicating factor was the lack of efficiency of this process, in terms of the time invested on the part of these social groups to find the desired information. In this dimension, the time taken to assimilate the information sought was an additional factor to increase the challenge. On the part of the professionals, who are on the front line and need to update themselves, tiredness and emotional exhaustion resulting from working hours make it even more difficult to allocate the necessary time to search for desired information. This constituted a fourth factor, which increases even more the overall difficulty. On the part of the lay people, the explosion of information supply, associated with the growing wave of disinformation, accentuates the negative effects of the scarce informational competence, so necessary in fields of specialized technical knowledge.

When the Observatory was created, there was no similar experience to meet the needs of different audiences. The audiences were divided into: those aimed at sources of information for the lay public,

such as hygiene habits, recommendations for the use of masks and distancing, and how to adopt personal prevention measures, from the risks of viral contagion to the possible installation of the disease and its evolution stages; and those aimed at a specialized audience with databases and scientific articles, professional recommendations and protocols, and related materials. The inspiration for the conception of the OECC came from the lack of an information and knowledge experience that would unify and meet the common demand of these two groups.

This scenario indicated to the members of the research group Information in Science, Technology, and Innovation in Health, of the Brazilian Institute of Information in Science and Technology (IBICT), the need to develop resources for information provision that could meet both the demands of professionals and the lay people.

On March 27, 2020, the researchers met with the objective of creating a project proposal, in order to give amplified informational support to these different population groups about a global collective health problem, constituted by the COVID-19 pandemic.

The project for the Scientific Evidence Observatory COVID-19 (OECC) was approved and the website link http://evidenciascovid19.ibict.br/ was then made available. Thus, a specialized team in knowledge management was created, to develop the Observatory of Scientific Evidence COVID-19 (OECC) initiatives. The team developed the website layout and its information architecture, and started to feed content that was being developed. On May 20, 2020, the site was nationally launched by the Ministry of Science, Technology and Innovations (MCTI), as part of the MCTI Science Portal to Combat COVID-19.

To meet the informational demands of both professionals and the general population, on June 11, 2020, the first scientific reviews were published on the site. Currently, they exceed 141 reviews. These works seek to provide a summary of the existing information regarding different aspects of COVID-19, saving professionals' time. In this way, they have access to information in a more extensive form than provided by the abstracts available in articles. At the same time, they can access the entire articles themselves from the links available in the references. In addition to attending professionals from several other areas other than the reviewed theme, the general population can also benefit, since the language used in the reviews is simple, based on scientific dissemination methods, and adapted to the standards of the Brazilian Association of Technical Standards (ABNT).

To expand the access to different types of users and to publicize the OECC website, on June 18, 2020, the Observatory's social networks were created: on Facebook, Instagram, and Twitter. Then, on June 29, 2020, the first post was simultaneously made on the three social networks.

In order to make the technical terms that are used in the reviews more understandable, for audiences who do not have the specialized knowledge, on June 25, 2020, the Observatory team started the construction of a glossary. In this resource, technical terms are translated into natural language, based on definitions found in specialized dictionaries, in the Medical Subject Headings (MeSH) of the National Library of Medicine, in other glossaries, and in scientific articles.

To provide access to the existing information sources on COVID-19 for the users in a worldwide scale, on June 30, 2020, the Observatory team began to develop a navigational concept that would provide the user with a cognitive and multimodal learning experience. This navigation experience was consolidated as the Kaleidoscope of Science, which allows professionals and laypeople to browse information sources according to levels of classification, in a pleasant and visually attractive way, and to access scientific information and sources of COVID-19 information in websites on a worldwide scale.

With the increasing volume of reviews, there was a need to organize this information, so that the reader's time could be saved and the user's navigability could be both effective and efficient, while

remaining attractive as well. Thus, on August 14, 2020, the Kaleidoscope of COVID-19 began to be constructed, following the same conceptual organization principles that were used in the Kaleidoscope of Science, from the perspective of a recommendation system. Its launch took place on September 22, 2020, offering users navigation through the different scientific reviews, organized by thematic categories and their associative relationships.

Feeling that the informational demand of the population was ever increasing, on August 26, 2020, the Observatory team expanded its information actions, offering live events, in partnership with the IBICT YouTube channel. They address emerging themes and count on the participation of experts who have experience in the covered topics, bringing to the site users a set of precise information, didactically exposed, with language that is understandable by different sectors and social strata.

In order to expand the user experience in this communication aspect, on October 21, 2020, the Observatory team launched its own YouTube channel. Short videos started to be offered, bringing the central message of different reviews. With this additional informational resource, the user can choose between watching the video, reading the review, and complementing this information by going to read the article in its entirety. Therefore, there are different ways of accessing quality information, such as different layers of complexity on the subject, chosen with scientific rigor and written by specialists from different areas of knowledge. Live events helped to expand the audience diversity, through the partnership with the IBICT's YouTube channel, thus adding to the offer made by the Observatory's own channel.

Methodology used for Development

Specialized Team Formation

The methodological steps for the construction of the OECC involved the formation of a specialized team of knowledge managers and a network of scientific collaborators. The team of knowledge managers curates the articles available in the scientific databases, starting from the search stage in the scientific journals, which are selected according to their quality. They then identify the articles that present assured methodological rigor and scientific quality, and proceed to offering the chosen material to scientific collaborators through a database. The network of collaborators is made up of professionals and researchers from the three major areas of scientific knowledge involved in the themes: Health Sciences; Social and Human Sciences; Technology and Innovation.

Dissemination of Science through Reviews

For defining the *corpus* of journals used in the selection of articles, a survey was carried out in Qualis-Periodicals, developed at the Brazilian Ministry of Education by the Coordination for the Improvement of Higher Education Personnel (Capes). A check was made regarding the journals that are open access. The Pubmed database of the National Library of Medicine, USA was chosen, as it indexes the journals identified after this stage.

For selecting articles, the team of managers adopts the methodological steps of the Systematic Literature Review, which includes planning and structured search process, as well as the adoption of inclusion and exclusion criteria.

Thus, with constructing semantic-syntactic search expressions, designed to answer the research questions of each selected theme, structured searches are carried out on the scientific literature databases.

To construct these expressions, the appropriate terms are searched in the Medical Subject Headings (MeSH), and all the research resources available in the Pubmed database are used. The inclusion criteria adopted are: empirical and experimental studies; most recent articles; novelty of the researched themes; breadth or thematic coverage; matters demanded by reviewers; most published themes in the media; pandemic phases. The exclusion criteria adopted are: opinion articles; restricted regional articles; case studies; narrative reviews; conceptual articles; studies without methodological rigor; and paid studies.

After carrying out all these steps, the selected articles are inserted in an article bank, built in a spreadsheet computer system, and shared with the reviewers. The bank is divided into three thematic tabs, corresponding to the major areas of knowledge: Health Sciences; Social and Human Sciences; Technology and Innovation. Each tab is divided into three column blocks. The first block is composed of a column containing an identifier, one column with the subjects of the articles, and another one with the type of study. The second block contains the requesting reviewer names, the request date, and the expected delivery date. In the third block, the metadata of the articles are inserted. Reviewers choose the articles and send the request for reservation, by using a google drive form built for this purpose.

Reviews can be informative or critical. Writing them follows a predefined standard, which involves well-defined parameters, such as having a limit between 550 (in the first type) and 600 words (in the second type), being written in clear language, using short and affirmative sentences, and whenever possible avoiding language symbols, acronyms, and technical terms. These guidelines allow the published review to be easily understood by readers from different social groups, including researchers, health professionals, and professionals in other areas, teachers, students, managers, and the general population. Everyone can thus have access to valid information that presents high scientific level, reliability, and high quality standards. Reviews also always contain the reference of the selected article, written in the format ABNT - Brazilian Association of Technical Standards (NBR 6023/2018).

After reviewers have developed their reviews, they send them by e-mail to the OECC knowledge management team. Before being published on the website, they go through a thorough review process, using the criteria of the Observatory's scientific and publishing policies, and, when necessary, modifications are made accordingly.

After this review process, the article reviews are forwarded for publication on the website. For each scientific review, a digital imagery representation is selected, which visually indicates to the reader the subject that will be approached, in an analogical way. This procedure is adopted so that the imagetic stimulus associated with the text allows a previous cognitive induction of the reader, in a specific way. By allowing the buildup of a cognitive framework, conjugating the image with an interest provoking question facilitates a consequent better understanding and assimilation of the content of each review.

Covid-19 Terminology Glossary

Technical terms that are more difficult to understand by non-specialized readers and the population in general are also identified in the review texts. The terms are registered in a spreadsheet, and then they are semantically searched by using different instruments, which include specialized dictionaries in health, glossaries, thesauri, MeSH, and the literature of the area, aiming to identify its most appropriate definition for different audiences. After this procedure, they are translated into natural language, using scientific dissemination techniques. These definitions are validated by a health specialist and then inserted in the website glossary using the Tooltip plugin. This feature allows marking inside the review texts the terms that have been defined in the glossary, so that the reader can identify the existence of each term with its

corresponding definition. By hovering the mouse over the selected term, the user can then visualize its meaning in a drop-down box, in order to seek a better understanding. Reading thus becomes easier and more fluid, whilst this Observatory resource contributes to converting information into knowledge and thus fulfilling an educational objective.

Network Science in Knowledge Management

Associated with each publication on the website, a coordinated action is carried out so that these reviews are also published on the OECC social networks. This process is implemented in an integrated and concomitant way in the three Observatory networks mentioned above. For this purpose, promotional card arts and a short summary of the review theme are constructed, aiming to serve as public calls for the reader to read the reviews. The card arts contain an image representation of the review as its background, as a kind of watermark, and an instigating question to stimulate interest in the theme, as well as the OECC logo.

As part of the development of live events, some methodological steps are taken to provide quality. Performed both through the IBICT YouTube channel and the OECC YouTube one, the stages for constructing the Live events are made up of: selection of the theme, according to its importance for society at each moment; selection of guests, who are experienced experts on the subject; thematic elaboration and organizational meeting with the guests; prior disclosure through the website and social networks; and conduction and transmission of the Live event. For selecting the theme, the issues that are present in the most researched reviews are identified through Google Analytics, the most publicized themes in the media are raised, and the evolutionary stages of the pandemic are analyzed. The selection of guests involves criteria such as professional training in the thematic area, academic experience in the subject, specialized knowledge of the topic addressed, and eventually the condition of being involved with research groups on the subject. When gathering the selected guests during the preparatory meeting, the elaboration and organization of the live event is conducted, defining the approach to be adopted, the subthemes to be covered, and the presentation dynamics, which consists in a dialogical format. For diffusing the live events, the dissemination resources of Facebook (event creation) and Instagram (timer in the story) are explored. Dissemination is also carried out on the main page of the OECC website, and after the event, the event visualization is also available in the Science in Movement website resource.

The OECC website is continuously evaluated and analyzed by means of metrics, based on data collected by Google Analytics, allowing knowledge managers to define strategies to help improve it.

Knowledge Organization and Information Architecture of Kaleidoscopes

The information architecture designed for the Kaleidoscope of Science and for the COVID-19 Kaleidoscope is based on the faceted Classification model that has been developed by the Indian librarian Shiyali Ramamrita Ranganathan, in 1933, and presented in the publication called Colon classification.

The faceted classification proposed by this classifications uses the synthetic-analytical principle. In this way, the subject is analyzed based on its fundamental, material and formal constituents and they are synthesized departing from relationships and connections that consider the content of the document. This form of organization allows new subjects to be inserted and the same document to be classified in more than one category (Maculan and Aganette, 2018; Campos, 2001), as it allows the same informational element to be apprehended and represented by its different aspects.

According to Maculan and Aganette (2018), the greatest contribution of Ranganathan's idea to the theories of classification was to divide the subjects into dimensional categories (facets) and bring them together by the same principle. This allows greater flexibility to the systems and allows a better organization of information regarding multidimensional concepts.

Facets are understood "as the part resulting from the application of a principle of division, i.e., a difference or characteristic. The facet gathers terms that have the same type of relationship among themselves" (Ferreira, Maculan & Nave, 2017, p. 287)

Ranganathan proposes this division into five fundamental dimensional categories: Personality, Matter, Energy, Space, and Time, which form the acronym PMEST. Personality for Ranganathan is the essence of each subject. It refers to what is inherently peculiar to the element whose knowledge is organized. Matter is the substance that constitutes the material, referring to its properties. It corresponds to the ontological dimension Continuant (Sowa, 2000), the elements related to the support of the conceptual unit that is to be classified. Energy is the process, the method, the operation, that is, the action that takes place. It corresponds to the ontological dimension Occurrent (Sowa, 2000), encompassing the elements related to change. Space is the topological or geographic location, that is, a street, a city, a country, a state, a continent, that is, where it happened. Time is the temporal dimension, as for instance, a century, a decade, a year, a month, a day, that is, when it happened. These last two facets correspond to the universal dimensions of a priori intellectual apprehension of the phenomena. (Kant, 2002).

According to Uddin and Janecek (2007) "A classification structure influences the design of a website information architecture, specifically on the process of organizing, searching, and browsing systems that help users efficiently find and access information" (p.219).

The use of faceted classification in the construction of the information architecture of websites allows users to search for any resource from different angles of their attributes, and from different multidimensionalities, allowing for greater navigational flexibility from the part of the person that is interested in the information.

Therefore, Uddin and Janecek (2007) emphasize that "one benefit of faceted classification, especially in website architecture, is that users often have a very accurate understanding of the domain content even though they are unfamiliar with website content" (p.252).

From that process, starting from the principle of friendly navigability and aiming to allow the user to go through the different facets of knowledge in a flexible and multidimensional way, the design of the Kaleidoscope of Science structure starts from four fundamental categories: Geographic regions; Type of institution; Information for lay people and Information for professionals. The Kaleidoscope of Science gathers and organizes scientific information and knowledge produced on an international scale, of different natures and sizes, and aimed at different types of audiences. The first category corresponds to the ranganathian facet of space. The second one refers to the personality facet. The third and fourth categories relate to the facets of matter and energy, as they include sets of declarative and procedural scientific knowledge. It is worth mentioning that the categorization of the Kaleidoscope of Science was not developed in an aprioristic way. Instead, it was conducted after the analysis of the sources and information units produced in the context of the pandemic. Each of these categories has two more levels of sub-categorization.

In the Geographic region's category, information sources are organized according to the geographic location in which they are made available. Thus, its subcategories are South America, North America, Europe and Global. In the instance below this subcategory, the sources are organized according to the

types of institution, that is, the Government Agency; Library and Database; Organization, Council, and Society; Public Research Institution; University; Hospital; and Press.

In the Types of Institution category, the sources are organized based on the nature and institutional characteristics in which each source was made available. Thus, its subcategories are Government Agency; Library and Databases; Organization, Council, and Society; Public Research Institution; University; Hospital; and Press. In the subsequent instance, the sources were organized into the following subcategories: Scientific Literature and Pre-prints; Resource; Guidance; Video; Technology and Innovation; Legislation; Tracking; Guidelines and Protocol; and News.

In the Information for laypersons category, the sources are organized according to the analysis of its content, by checking if it contained information that could be understood by the population in general. Thus, the subcategories were divided into: Video; Guidance; News; Tracking; and Resource. In the following instance, the subcategories were organized according to the Type of Institution, covering Government Agency; Library and Databases; Organization, Council, and Society; Public Research Institution; University; Hospital; and Press.

In the Information for professionals' category, the sources are also organized according to the content analysis criterion; but this time, this information is distinguished by being specialized and geared to different professional categories. Consequently, the subcategories were divided into: Scientific literature and Pre-prints; Guidance; Technology and Innovation; Legislation; Guidelines and Protocol. In the later instance, the subcategories were also organized according to the Type of Institution, that is, Government Agency; Library and Databases; Organization, Council, and Society; Public Research Institution; University; Hospital; and Press.

As previously exposed, the COVID-19 Kaleidoscope was also built. This information resource gathers scientific knowledge produced in the literature of specialized areas, and published in the most relevant journals in the major areas of science. Its information architecture was designed to organize reviews in six categories: COVID-19 Pandemic; Disease Information; Clinical care; Clinical symptomatology; Clinical consequence; Innovation and technology. The first and second categories correspond to the personality facet, relative to information about the peculiarities of the phenomenon that constitutes the central object of the COVID-19 Scientific Evidence Observatory. The third, fourth, and fifth categories refer to the energy facet, relating to different types of processes that are specific to the central object of the OECC. The sixth category is relative to the facets of matter and energy, insofar as innovation can be related to both product and process. Each of these categories has, in addition, another level of sub-categorization.

The Pandemic category of COVID-19 gathers reviews that address themes of a general scope of the pandemic. Therefore, the subcategories that comprise it are: Overview; Pathophysiology; Epidemiology; and Infodemiology.

The Disease Information category includes reviews that examine information, that is, how it circulates, how it is used, which means, which sources, which formats, and the disinformation process. In summary, its subcategories are: Source of information; Social media; Information search by the professional; Official guidelines; Disinformation.

The Clinical care category is one of the two most extensive classes of scientific production, reflecting the clinical complexity of health care at COVID-19. This category includes reviews that deal with topics on care for the treatment or prevention of the disease. Thus, its subcategories are: Medicines; Mind-Body Care; Nutritional; Ethical aspects; Pandemic Management; Vaccine; Artificial respiration; Different populations; other diseases.

The Clinical Symptom's category is also one of the two most extensive classes of scientific production, reflecting the complexity of COVID-19's clinical expression. This category gathers reviews that discuss COVID-19 symptoms in different groups of individuals. In this way, its subcategories are divided into: Symptoms in children and adolescents; Symptoms in the elderly; Symptoms in pregnant women; Symptoms in patients with other diseases; Symptoms in hospitalized patients; Asymptomatic; Symptom Characterization; X-ray images; Oxygen.

The Clinical consequence category is a class almost as extensive as the previous two, reflecting the effects that are derived from the clinical occurrence of COVID-19. This category includes reviews based on the consequences that COVID-19 can bring to patients who are infected with the virus. Therefore, its subcategories were divided into: Pulmonary; Cardiovascular; Glucose and diabetes; Neurological; Psychobehavioral; Gastrointestinal; Renal; Coagulation.

The Innovation and technology category includes in its scope all reviews that deal with the use of technology for the management of the disease. Therefore, the subcategories are: Telemedicine; Complementary exams; Individual protection equipment; Artificial intelligence.

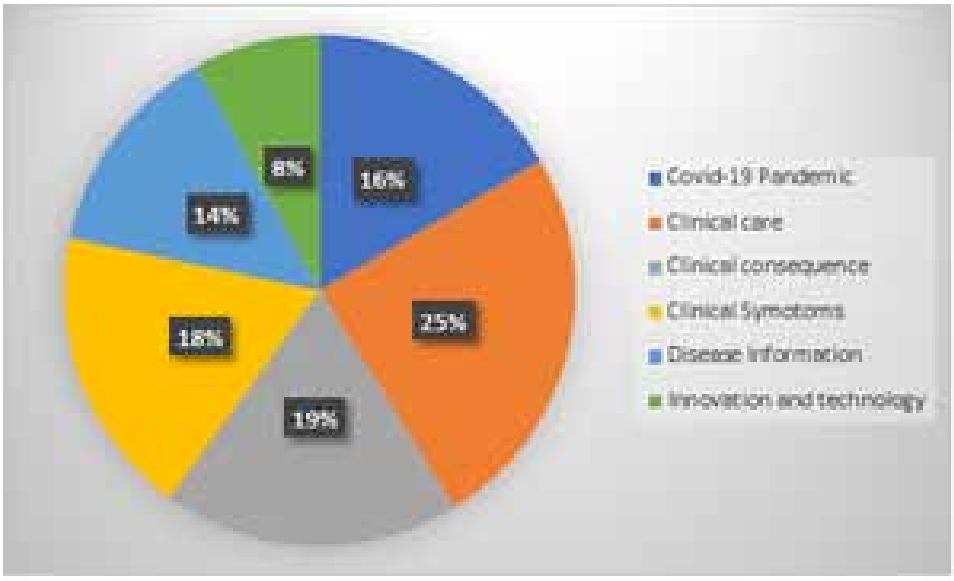
As for the quantitative aspect, graph 1 shows the distribution of reviews in the facet macro categories.

The data in Graph 1 show that the themes named Clinical Care and Clinical Consequence are the ones that add to the greatest amount of reviews.

Results developed by the Observatory

The OECC has resulted in becoming a broad and reliable source of information, accessible to different audiences, as it includes informational, cognitive, and accessibility resources. While analyzing the metrics obtained by Google Analytics, it is possible to notice that the Observatory has broadly breached the geographical barrier of its place of origin, becoming an internationally consulted website. As illustrated in figure 2, the coverage of the continents includes the Americas, Europe, Africa, Asia, and Oceania.

Figure 2.



Looking at figure 2, the areas with the strongest blue color are those with the largest number of users, as is the case in the Americas (397,414) and the areas with the lightest blue are those with the least number of users, such as Oceania (46) . Regarding the total number of users, the OECC website was visited, from May 20, 2020 to April 20, 2021, almost half a million times, more precisely 407,268. In the same period, it reached more than half a million page views, more accurately 539,484.

The OECC website is multilingual, covering twelve different languages. Thus, from google analytics data, in addition to Portuguese, it is possible to identify that the most used languages are English and Spanish; besides these, French, Italian, German have also been identified as frequently used languages.

On November 23, 2020, the OECC website was cataloged as a source of information in the Virtual Health Library - Health and Information Locator (VHL-LIS) database by librarians from the Documentation Center of the Disease Control Coordination of the Secretariat of Health in the State of São Paulo, which feed the data from the VHL - Information and Knowledge Network (VHL-RIC). The VHL-LIS is a catalog that brings together Internet sites or resources that have quality and relevance to the health area. It belongs to the VHL-Network, which is coordinated by BIREME - Latin American and Caribbean Center on Health Sciences Information, of the Pan American Health Organization / World Health Organization (PAHO / WHO).

On December 11, 2020, the Digital Library of the Federation of Industries of the State of Paraná System (FIEP System) also inserted the OECC website in its catalog. Since then, it has recognized the Observatory as a source of scientific and quality information for the health area.

Social networks, in addition to being other information resources for disseminating reviews that are published on the site, also become a source of user conversion to visit the site. From social network posts, new users become interested in visiting the site, in reading the reviews in full, and in browsing the other possibilities provided by the site as information resources, themes, sources, and other reviews.

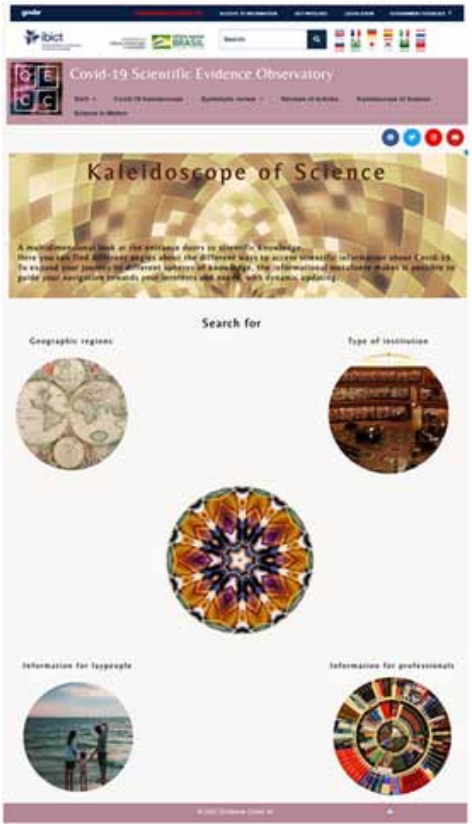
As described in the methodology, the website is composed of a network of professional collaborators from a wide range of different areas of knowledge. Researchers and professional cooperators, divided among the areas of Health Sciences (60), Social and Human Sciences (14), and Technology and Innovation (4).

The thematic contents of the site are presented based on the principle of friendly navigability, providing the user with a multimodal, flexible, pleasant experience, and facilitating meaningful learning, covering different aspects of the cognitive sphere (Margolis & Laurence, 1999). Two information resources, the Kaleidoscope of Science and the COVID-19 Kaleidoscope, represent this form of navigability.

The first one (figure 3) brings together different global information sources about COVID-19. Each navigation instance allows the user to find the information he needs. The user can navigate from different paths: geographic regions, types of institutions, and type of information source for whom it is intended (laypeople or professionals). For each page that opens up during the successive navigation stages, the visitor exercises his/her own thematic choice, according to his/her interest at the specific occasion of the navigation experience. In this process, it is always possible to proceed further on or return to previous steps, being able to make different trajectories or changes of course. This is accomplished through simply using one's finger to touch the cell phone or the tablet screen, or by mouse clicking on the computer screen, to make the choices according to one's interest at each time of navigation.

Figure 3.

Figure 4.



The COVID-19 Kaleidoscope (figure 4) gathers the reviews published on the website according to different information categories. The principle of knowledge organization, established for the classification of reviews, follows the faceted classification paradigm. In this way, one same review can be classified in more than one facet, thus expanding the perspective flexibility on the information and knowledge that they represent.

CONCLUSION

In a context of "infodemic", triggered during the COVID-19 pandemic, the OECC was created with the objective of disseminating information and diffusing scientific knowledge. It is important to note that the OECC seeks to work on two pillars of "infodemiology": (1) encouraging processes to improve information quality based on scientific evidence, such as fact verification and peer review; and (2) accurate and timely translation of knowledge, minimizing factors of informational distortion, such as educational, socioeconomic, political, ideological, or commercial influences. Since the whole process is entirely based on research that is carried out with methodological rigor and selected in a careful and explicit manner, the availability and communication of scientific evidence ensure that the information is presented in a clear, objective, useful, and applicable manner.

The continued growth of the user number accessing the OECC website has shown that the produced and published material is undeniably the result of people's demand for quality information.

The OECC develops itself through professional partnerships that allow extensive disposal of published material, which also places it in the perspective of collaborating to the informal decision-making process of different audiences. The distributed network articulation between the social actors involved in their own environments contributes to increasing its reliability. In this sense, one aspect in view of the Observatory's growth would be the progressive expansion concerning professional and institutional partnerships both inside and beyond the health environment.

The consequent increase in information produced within the scope of the OECC continually demands successive changes in the work process of the Observatory. In this sense, the OECC will continue to adapt itself in order to provide information on the evolution of the COVID-19 pandemic. To fulfill this objective, the Observatory will follow up by using continuously updated material, processes that facilitate understanding, incorporation of new information resources, in order to remain to be a reliable source of information for researchers, managers, professionals, and the population in general.

The successful experience of the OECC has pointed to the perspective of the reproducibility of the information system model. This includes the different variables of its development process. They cover aspects of its mission and its objectives, in the methodological, cognitive, informational, communicational, interactional, computational, and social spheres. The progressive expansion of the thematic scope constitutes a development stage currently underway, concomitant to the continuous improvement of the OECC.

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Chapter 3
One Health and Information Management Using Big Data in Health:
A Brazilian Case Study for COVID-19

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ABSTRACT

In an increasingly connected world, information regarding the contagion and spread of COVID-19 has been an important weapon to enable better coping with the disease. The use of information technology can assist in the prevention, care, and monitoring of patients. In addition, remote service using applications avoids the overload of health centers and contagion. This research reports the experience of a research project initiated in Brazil at the Oswaldo Cruz Foundation, with the objective of developing an application and big data for the new coronavirus in a public health clinic using information management and One Health concepts. Initially, the application requirements were defined through interviews with users and health professionals. The partial results obtained so far demonstrate improvements in the different processes of the health center with the use of the application. The use of big data for the analysis of information makes it possible to define better health policies for the population in a more precise way and in a shorter time.

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INTRODUCTION

The United Nations (UN), in the Universal Declaration of Human Rights, adopted and proclaimed in 1948, social progress and better living conditions in a broader freedom, as fundamental human rights, in dignity value of the human person and the equal rights of men and women. In this context, people have the right to life, freedom and personal security (United Nations, 1948). The purpose to study and promote the right to life, consequently to health, in 2007, the concept of One Health emerges, which brings an approach collaborative, multisectoral and transdisciplinary to achieve ideal health results, recognizing the interconnection between people, animals, plants and their shared environment. Thus, it is necessary to think about new strategies and forms of research, development, and innovation in the 'bridges' between human, animal, and ecosystem health systems, to reduce emergency risks and the spread of infectious diseases.

The world faced the Covid-19 pandemic, declared by the World Health Organization (WHO) on March 11, 2020. This new Coronavirus-derived pandemic was started by an outbreak in China in December 2019 and quickly spread throughout the world. After spreading to several countries in Asia, Europe, North America, the pandemic reaches South America and Brazil. To break the disease, it is vitally important to have accurate information for decision-making by authorities around the world (Who, 2020). To obtain this information, a large amount of data on the disease is generated daily by computer systems from around the world. This great mass of information needs an adequate organization for its understanding and decision making.

New technologies have been developed for the processing and analysis of large amounts of data, one of the most used today is the Big Data, which refers to the third generation of the information age with the characteristics of storing a large amount of information and its availability in an aggregated and organized manner, meeting the criteria of the 5Vs: Volume, Variety and Speed, Veracity and Value (Magalhães et. al., 2020). However, it is also important the need for more detailed information, aiming to deepen the analysis of data within a territory regarding the conditions of sustainability and social conditions. One Health refers to a unified view of health considering social, environmental, and animal health aspects as whole that must be analyzed (Zingsstaget et. al., 2011).

This chapter describes the case study of the project construction of Big Data analysis carried out in two stages using an electronic patient record application that occurred during the Covid pandemic 19 at the Germano Sinval de Faria Health Center (CSEGSF), a Family Health Unit (FHU). The Unit is located at the National School of Public Health (ENSP) of the Oswaldo Cruz Foundation (Fiocruz) in Brazil, in the north area of Rio de Janeiro served by the Unified Public Health System(SUS). The target audience is the population of Manguinhos of approximately 40,000 people, located around Fiocruz, which has one of the lowest Human Development Indexes in the city.

In a first stage, an application was built, called "InfoSaude", for Primary Care users to assist patients in the prevention, care, and monitoring of Covid 19. Prevention was carried out through messages sent by WhatsApp® to residents, through the application. The service was carried out in person at the Family Health Unit (FHU) and the monitoring took place through the telephone contact of the health professionals. In the service, patients answered questions about the symptoms of the disease (fever, cough, difficulty breathing, chest pain, among others), in addition to information regarding risk factors (respiratory diseases, diabetes, hypertension and others). The information collected by the application allowed health professionals to guide patients on the procedures that must be followed, as well as to assess the need for tests to confirm COVID-19.

In a second stage, a COVID-19 information panel was built with Big Data, allowing to assess the situation of the New Coronavirus in the region. Thus, it allows an analysis of the problems faced by in the community of the Manguinhos neighborhood, in the identification of necessary interventions for the planning of health actions for managers and a better definition of public policies for the community. Therefore, this chapter aims to exemplify a case study on the treatment of essential data in COVID-19, specifically, as a contribution to the management of health data information.

CONCEPTUAL FRAMEWORK

Knowledge Management in Informational Data in the Context of Big Data in Public Health

Since the dawn of humanity man sends signals to communication and informs others about something. One can imagine at the time of the "caves", two men staring, gesticulating, making sounds and even documenting their activities with scribbles and drawings on walls. Over time, these sounds and squiggles were gaining adherents, yielding improved which today we call today we call communication. Unfortunately, we cannot be sure how these sounds were, but are but through the cave drawings we speculate theories about our origin on the planet and life forms of a distant era. Obviously, there was a profound evolution of transmission and documentation of our information. The arduous task has been to get the gist of it and remove the "noise", namely, managing data for decision making correct (Magalhaes et al., 2018).

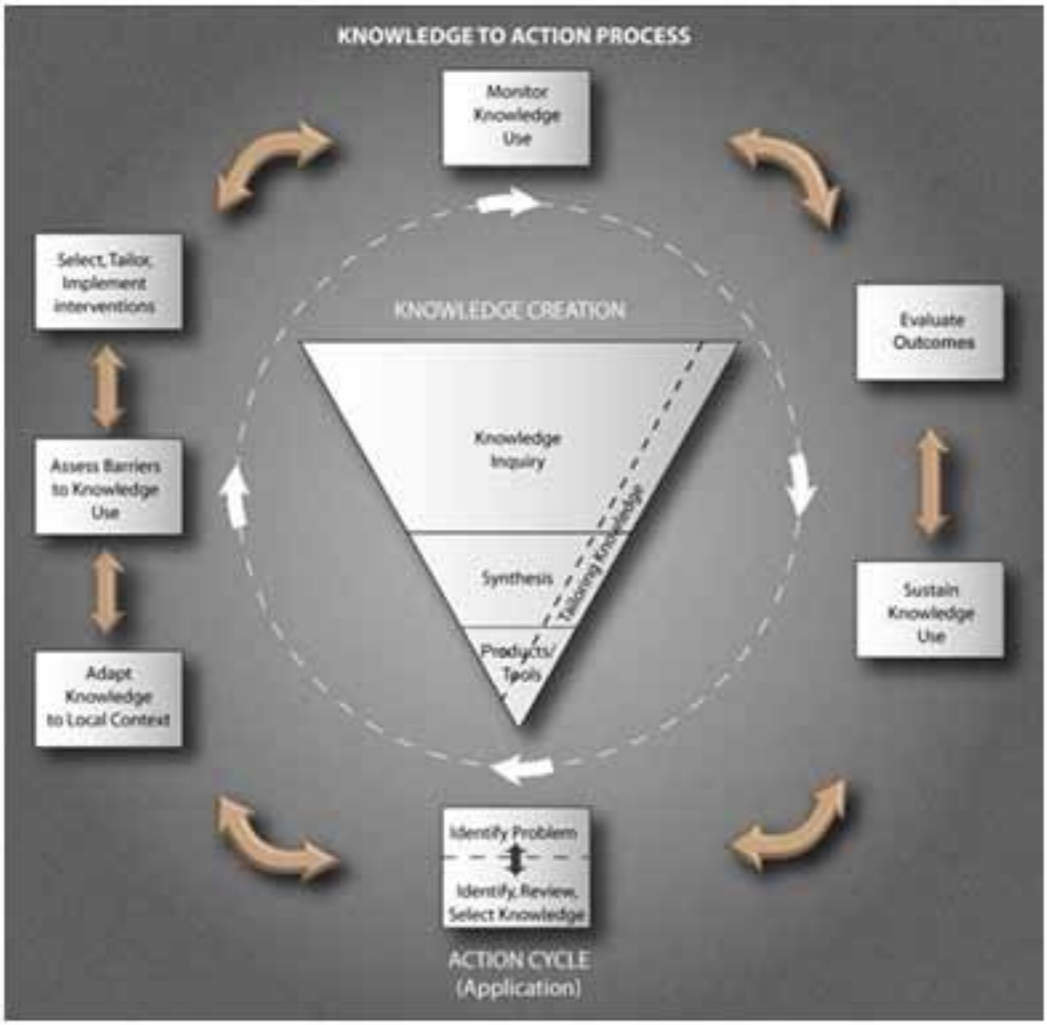
Finding true information becomes a task increasingly difficult and valuable. This fact is like a fragment which evidences the discovery of rare species was never seen. Technological advancement has made available resources that allow us to maintain the fidelity of information more efficiently, although it is virtually impossible to have a complete record (real form) with all the motivations and reactions. However, get a digital resource with limited space is possible to ensure a considerable representation of this information for a long period and without considerable losses (Magalhaes, JL & Quoniam, L., 2015).

Knowledge Management requires the involvement and support of all the company's stakeholders to preserve, transmit and develop knowledge. Indeed, it is the individuals who are at the center of the creation of value and who hold the keys to the success of such a project. The management of the knowledge and know-how of the company is therefore not universal, it depends strongly on the culture of the country in which it is practiced (Balmisse, 2006).

To motivate individuals to share their knowledge, it is important to consider cultural and human factors, and not just tools and procedures. Pesqueux *et al* (2011), define "culture" as the set of values, norms, habits, and customs specific to a society that will influence the personality of the individual.

Therefore, the Knowledge to Action Process conceptualizes the relationship between knowledge creation and action, with each concept comprised of ideal phases or categories. As shown in figure 1, a knowledge creation "funnel" conveys the idea that knowledge needs to be increasingly distilled before it is ready for application. The action part of the process can be thought as a cycle leading to implementation or application of knowledge. In contrast to the knowledge funnel, the action cycle represents the activities that may be needed for knowledge application (Canadian Institutes of Health Research, 2016).

Figure 1. Knowledge to action progress
Source:(Governmentof Canada, 2016).



According to Morin (1982), it is necessary to elevate the concept of "system" of this theoretical level to the paradigmatic level. A paradigm, for the author, is the set of fundamental relationships of association and/or opposition between a small number of "master concepts" that command/control all existing knowledge in all the speeches and theories. Thus, to sustain the action cycle (application) of the knowledge to the action progress, it is necessary to try to identify/define what are these notions, featuring the new paradigm and to resume as the (re)definition of the system where the logic of complexity in modeling the actual performance interact with a posture of the researcher and the actors involved in evaluative process (Hartz, 1997; Morin, 1982; Piaget; Garcia, 1983).

In this sense, to identify, classify, measure, disseminate and training competencies are essentials to aid strengthen to the R, D&I in Management of Science, Technology, and Innovation in health. According to Hartz (1997), evaluation and health are characterized by phases. The first, is the "systemize" and refers to a "structuralism and cybernetic" practice supported on mathematical theories which stands the

analysis of hard-systems (Le Moigne, J.L., 1994). This approach is still "analytic in nature and positivist in attitude (...). Thus, knowledge needs to be thought as a process that takes place within a complex system of interactions between researchers and knowledge users which may vary in intensity, complexity and level of engagement, depending on the nature of the research and the findings, as well as the needs of the particular knowledge user – knowledge translation (Brouwers et al., 2010).

Knowledge translation increasingly assumes critical importance for health research, since it is recognized that the creation of new knowledge, often alone, does not lead to its application or to effective impacts on the health of populations (Canadian Institutes of Health Research, 2016; WHO | Special Programme on Research & Training in Tropical Diseases, 2006).

There are several critical aspects in translating research results into best practice. These include, among others, the discrepancy between the knowledge needs identified by the communities and the work, done by the researchers during the "research" process and the gap between the knowledge produced and its incorporation into good health practices and policies (Pearson et al., 2012). Thus, there is a growing interest in the research on the mechanisms underlying the translation of knowledge, seeking to maximize and maximize the results of this process.

The 21st century presents itself as an era with 40% of the population connected to the Internet (McKinsey Global Institute, 2011). In this sense, O'Reilly (2007) suggested the term Big Data as a gigantic database updated in real time, which easily reaches thousands of terabytes of storage in different formats (O'Reilly, 2007a). Traditional relational database management systems cannot handle these large masses of data (Magalhães & Quoniam, 2013; Quoniam, L, Lucien, A, 2010). Big Data drives a new generation of methodologies developed to extract economic and strategic value from a large and varied volume of data (structured and unstructured), allowing high speed of capture and analysis (Gray, J. and Chambers, L. andBounegru, L., The Data Journalism Handbook, O'Reilly Media, 2012 - InfoVis: Wiki, nd; O'Reilly, 2007b).

Big Data technology refers to the third generation of the information age (Magalhaes, JL & Quoniam, L, 2015; Raghupathi&Raghupathi, 2014). Initially, this exponential volume of data met the criteria of the 3Vs: Volume, Variety and Speed (Laney, 2001); subsequently, 2 Vs were added: the attributes of Veracity and Value. Some authors even attribute the last 3 Vs, such as Veracity, Versatility and Viability, where the combination of all "Vs" generates the "V" of Value (Aleixo & Duarte, 2015). According to Minelli et al (2013), Big Data is divided into a perfect data storm, a perfect convergence storm and a perfect computing storm, the latter resulting from 4 phenomena: Moore's law, mobile computing, social networks, and computing in cloud computing. This data collection must be treated to present information searched in a selective and objective way to increase business intelligence, in addition to allowing an improvement in the decision-making process (Minelli, M. et al., 2013).

When we reflect on health, it is considered as a global public good: that it is not exclusive, that is, that no one or any collectivity is excluded from its possession or consumption; and that its benefits are available to everyone. There is also the apparent consensus that health is not competitive, and that there is no rivalry, that is, a person's health cannot be at the expense of excluding other people (Buse & Waxman, 2001; Haines et al., 2009; Hartz, 2012; Vance et al., 2009).

In the health spectrum, it carries challenges and opportunities in the globalization process, which is the catalyst for the evolution of the term "Global Health". Global health can be understood at the same time as a condition, an activity, a profession, a philosophy, a discipline, or a movement. However, it should be considered that there is no consensus on what Global Health is, nor a single definition, and

its field of action has inaccurate limits (Fortes & Ribeiro, 2014), however it is indisputable that we live in health in times of globalization (Koplan et al., 2009).

Thus, it is necessary to seek to identify, extract and treat the Big Data of Health in this globalized world, to focus on the essential information for the decision makers of the present century. Nevertheless, the management of this knowledge is not considered trivial since the Open Science approach is imminent. Open science is a model of scientific practice that, in line with the development of digital culture, aims to make information available in a network opposite to closed laboratory research.

THE USE OF PUBLIC HEALTH APPLICATIONS IN THE COVID-19 PANDEMIC

World Health Organization stated that, in addition to finding, testing, isolating and treating all positive cases of COVID-19, it is vitally important to "track all contacts" of individual positives with others to reduce the spread of viruses (WHO, 2021).The application technology offers a powerful tool to monitor the cases of COVID-19 that collect user data, possibly infected, so that the health agencies can identify the possible cases of the COVID-19. The cases of countries like South Korea have clearly illustrated how effective applications can be when using applications when identifying and notifying citizens who may meet infected individuals and used to combat the COVID-19 epidemic by public health (Rezaei et. Al, 2020). Mobile applications, research sites, information panels, devices for connecting diagnostics, sensors for health and applications for analyzing medical images, among others (Buddet. al, 2020).

Brazilian Unified National Health System (SUS) uses the family health strategy (FHS) as a model of primary care in health. The model in Familily Health Unit (FHU) provide health care of the neighborhood, with Community Health Worker (CHW) in collaboration with different professionals of health (Cordeiro & Soares, 2015). In this research, the "InfoSaude" application was initially used for COVID-19 patients at FHU unit locate at Fiocruz campus in Manguinhos neighborhood.

FHU plays an important role in preventing the spread of infection through information to the community through family health teams (FHT). Community health workers (CHW) can assist in the identification of families in situations of greater economic difficulty, assisting in the delivery of items in greatest need. However, the care provided by the FHU is restricted to consultations and simple medical procedures, in relation to the pandemic of the COVID-19, an action limited to the initial stages of the disease where the clinical situation of each patient is assessed. Serious cases are referred to Intensive Care Units, suspected cases should be referred for tests that allow confirmation of the disease and monitored primarily by phone, thus avoiding possible contamination of health teams and other patients (Daumas et. al., 2020).

The distance medical care can be made by phone, or video. The use of the telephone medical consultation is satisfactory for mild cases of COVID-19, as in general patients search advice on the disease. However, for more severe cases and with greater comorbidities, video call is more appropriate since it provides visual information and diagnostic clues. However, the use of these techniques is not simple due to necessary changes in the work routine and the availability of technology that allows the service to be performed (Wherton et. al., 2020). The use of distance medical care, it's also called as TeleHealth and it's not restricted of medical care and could be used for multidisciplinary healthcare consultation performed remote using applications (teleconsultation), distance monitoring of patient's health (telemonitoring), diagnostic support service at distances(telediagnosis), courses for health-related topics for patients (teleducation) and other possibilities (Caetano et. Al,2020).

In Brazil, the distance medical care for COVID-19 was possible due to legal changes, initially carried out by the Federal Council of Medicine, through letter nr. 1756/2020 (CFM, 2020), and subsequent authorization by the Ministry of Health through Ordinance MS / GM No. 467, of March 20, 2020 (MS, 2020). The routine for monitoring COVID-19 in FHU was defined by the Ministry of Health through the Coronavirus clinical management protocol (MS, 2020a). Some applications were developed for COVID-19 by the Brazilian Ministry of Health during the pandemic in 2020. The Coronavírus - SUS TM and SusCovidZap™is applications focus on the self-diagnosis of the disease, the monitoring of symptoms and the notification of cases to health authorities. In these applications, users can check whether the symptoms are compatible with COVID-19, assess the degree of severity of the disease, provide recommendations on the need to isolate the patient and even notified cases (MS, 2020b). However, these applications do not have the electronic medical record of the patient, making it impossible for healthcare professionals to provide distance medical care, representing a gap in the care of patients.

The technology for the distance medical care involves the need for patients to have cell phones or computers connected to the internet. However, patients do not always know how to use them or have access to the internet. According to a survey conducted by IBGE in 2016, 64.7% of the Brazilian population was connected to the internet. Still, 63.3 million people (37.8%) were still offline because they did not know how to use digital tools. In this sense, in Brazilian society, although noticeable the gradual developments of access to the internet at the diverse socioeconomic levels, disparities are directly outlined related to the economic power and use of the computer with access to the Internet (IBGE, 2016). The infrastructure for distance medical care is not restricted to users, medical clinics must also have an adequate infrastructure for internet access. However, the low investment in technology by the federal government makes it difficult to service applications at health centers (Sarti, 2020).

INFORMATION FOR THE NEW CORONAVIRUS WITH THE HEALTH BIG DATA

The COVID-19 pandemic was accompanied by an informational pandemic. This pandemic of information referred to as an "info pandemic" and is essentially an overabundance of information about the outbreak of the disease. This large amount of information generated the need for data to be organized by international organizations (Hamzah et al., 2020). The UN, through its headquarters in Geneva, has sought to centralize worldwide information on the disease on its website (https://COVID-19.who.int/). Several countries also make the information available on their websites, such as England (https://digital.nhs.uk/dashboards/coronavirus-in-your-area), the United States (https://covid.cdc.gov/covid-data-tracker/#cases_casesper100klast7days) and several other countries. Some international organizations publish data on the disease, including, i.e., Johns Hopkins (https://coronavirus.jhu.edu/data).

In Brazil, the Ministry of Health (MoH) started publishing information on the disease through the registry of the municipal and state health departments, this registration is mandatory and carried out in the Notification Diseases Information System (SINAN), allowing the totalization of cases by the MoH (Bastos et. al, 2020). However, in June 2020, the MoH decided to change the criteria for counting cases and deaths by COVID-19, in a clear attempt to try to reduce the impact of the numbers of the disease on society (Calil, 2020).

One of the most important and reliable information about COVID-19 is available at FIOCRUZ, at the Communication and Information Institute (ICICT), which daily updates data on the pandemic in Brazil. The data are updated at the state and municipal levels, generating graphs that facilitate the analysis of

managers and researchers (https://bigdata-COVID-19.icict.fiocruz.br/). The information is analyzed in greater depth through newsletters that are published periodically at (https://portal.fiocruz.br/documento/boletim-do-observatorio-covid-19) (Pereira, 2020). It should be noted, however, that all these databases are of secondary origin since the primary origin of the data occurs in visits to hospitals and clinics in the public and private network. The data are centralized in the Ministry of Health, from the mandatory notification in SINAM, allowing them to be collected and summarized for state and federal data.

For a deeper understanding of the disease, more detailed information about patients is needed, from primary sources of information in the clinical records, contained in the Electronic Patient Record (EPR). Thereby, another format of BIG DATA is then constructed with specific disease data, requiring greater detail of the patient data contained in the clinical record. In California, the University of California hospital in San Diego has developed an EPR for data for the New Coronavirus with real-time information panels, making the collected data available through panels, with real-time data on the number of suspected patients, infected and tested. As soon as this information becomes available, it is available the disease at the local level, identifying outbreaks of the disease in the region (Reeves et al, 2020). The detailed information about the disease its important, however individual patient information poses a risk to patient privacy (Song et al, 2020). Therefore, it is necessary to build a patient BIG DATA for data analysis, however it is necessary to protect patient data to prevent their data from being violated. The problem of underreporting in COVID-19, it is a phenomenon present throughout Brazil, which has one of the highest underreporting rates in the world in contrast to the United States, Germany, and South Korea. The rate of notification calculated in April 2020 indicates a value of 9.2% which means that the actual number of cases can be up to 11 times higher. A wide variation in the notification rate is found in Brazilian states, more populous states like Rio de Janeiro and São Paulo have worse rates than the national average with 7.2% and 8.9% respectively. Other states such as Roraima and Distrito Federal have better rates of 31.7% and 27.6% respectively (Padro et al, 2020).

Researchers at Fiocruz have analyzed data from slum in the city of Rio de Janeiro, highlighting the bulletins published by the slum situation room at the Fiocruz Observatory of COVID-19. In the second bulletin the data from the slums were analyzed and compared with the data from the rest of the city, it was observed that the wealthy neighborhoods have a greater number of cases than the neighborhoods with slums. It was observed that richer neighborhoods such as Gávea district have a higher percentage of contaminated percentages than poorer district. The analysis of the researchers is that this discrepant situation occurs because the richer districts test the disease more through private clinics and laboratories, thus being able to confirm the presence of the virus in the population that lives in these districts. This aspect calls attention to the difficulty of the poorest part of the population to have access to the test for the confirmation of the disease in public health, which distorts the data related to the infected population, demonstrates the underreporting of the disease, and the fragility of the public health system (Angelo et. al, 2020). Therefore, underreporting is just one aspect that demonstrates the need to build a Big Data for data visualization and analysis, making it possible the construction of evidence-based public health policies.

The World Health Organization calls EBP - Evidence Briefs for Policy, a short, focused, jargon-free summary for a non-specialist audience to be used in public health policies. The policy must be focused on scientific evidence to provide a decision subsidy, so that health managers can decide to adopt a public policy. The synthesis of evidence aims to convince the target audience with a simple and direct language about the urgency in adopting a public policy, based on a set of evidence that has already been adopted with satisfactory results (Toma et al., 2017).

The United Nations has used the synthesis of evidence to support public health policies through SURE - Supporting the Use of Research Evidence. "SURE" is a collaborative project, developed by an Evidence-Informed Policy Network (EVIPNet) in Africa and the East African Community Regional Health Policy Initiative (REACH). The project involves teams of researchers and policymakers in seven African countries and is supported by research teams in three European countries and Canada (WHO, 2016). In Brazil, a group of this network was created, called EVIPNetBrasil (BRASIL Evipnet, 2019).

PAHO (Pan American Health Organization), presents as a proposal for the elaboration of evidence-based policies the SUPPORT (SUPporting Policy relevant Reviews and Trials) or SUPPORT (Essays and Reviews relevant to Policies) This proposal recommended the following steps: 1 - Describe the problem that is related, 2- Describe the policy options, 3- Describe the methods used to select the evidence, 4- Discussion of the quality of the studies and their applicability, 5- Form and language that should be used in the document, 6- Review of the merits of the document (Lavis, 2019).

Therefore, the public policy document must be developed by the manager, based on relevant scientific documents that prove the efficiency and effectiveness of the adoption of the public policy. Efficiency is understood as the relationship between the products / services generated (outputs) and the inputs used, relating what was delivered and what was consumed of resources, usually in the form of costs or productivity. Effectiveness can be defined as the quantity and quality of products and services delivered to the user (direct beneficiary of the products and services) (Andrade et al, 2017).

METHODOLOGY

The methodology is an action research in primary health care, of which the researcher is part of research work. The objective of research is generating solution for a practical problem, start with clearly identification of problem, seek and implementation solution and monitor the process of changes with people involved of the study problem with engagement of practitioners (Meyer, 2000). The study problem referring to an intervention using digital technology, through the "InfoSaúde" application and data evaluation through a Big Data in health synthesized through information panels, in Primary Health Care (PHCU) unit in an uncontrolled scenario with the participation of professional's health and users.

The PHC unit is locate in Manguinhos, in the north of the city of Rio de Janeiro, and the population enrolled has one of the worst Human Development Indexes (0.726 - 122nd place among 126 regions analyzed in the municipality) and Social Development (0.473 -158th place among 158 neighborhoods analyzed) (Cavaliere, 2008). The PHC unit is composed of 13 family health teams and 40,000 patients.

To build the application, the development team met three times a week, the team consisted of a systems analyst coordinator, a system developer technologist, an information technology intern, a doctoral student in communication and health and a student at high school with expertise in graphic design. To define the application requirements, an assessment of the current situation was made, with the identification of the main problems faced by health professionals and patients. The requirements of application were carried out a group of fifteen users at the Medical Clinic, chosen at random questionnaire by the user (Appendix 1). After this step, the documents used by health professionals for the care and monitoring and notification by health team for the COVID-19 were evaluated according to questionnaire (Appendix 2).

For the evaluation of the application, weekly meetings were scheduled with the health professionals' team for tests and adjustments of the application. The final assessment of this first stage was carried out

with interviews from users (Appendix 3) and health professionals, according to the application evaluation questionnaire by the health professional (Appendix 4).

The application was developed in modules, initially the registration of users, providers and their profiles, the clinics. In a second phase, the WhatsApp® messages module, as well as the message standard, and in the third phase, the part referring to COVID-19 care by the nursing, medical teams, and patient monitoring.

The second stage of the research was the analysis of the total of Covid disease data obtained through a Big Data. Due to the emergency of the disease and aiming at obtaining data more quickly, Big Data in health, called Covid Panel, was built through panels with the data obtained from COVID-19 services in excel spreadsheets and visualized through panels built on the Google DataStudio® a free tool from Google.

RESULTS

Present Situation

The Health Care Unit installed tents in outside of the building to screen infected patients and prevent them from entering the building and contaminating other patients. The external area team is called "rapid response team" and is made up of nurses and health workers. This team asks patients questions and fills out a paper form and forwards it to the doctor's office located outside the building. The doctor after the examination of the patient makes the diagnosis of the patient, fills forms and makes tests to confirm the disease for confirmation of the diagnosis, and in severe cases, makes the referral to hospitals. The service is updated at government health software (E-SUS) and the form is forwarded to another team that fills out a control spreadsheet and finally insert data in other government software called "NotificaSUS." From two days after the first appointment, the patient is monitored through telephone calls, where the patient's clinical situation is verified. The Monitoring is performed through a form in Google Forms® and if there is a change in patient information, updates are made to the control spreadsheet. The disease prevention depends, most of the time, on the visit of CHW in the Manguinhos neighborhood and on recommendations that are carried out in person in the care of patients. The diagnosis of the present situation shows that the information related to the care is fragmented in spreadsheets and electronic forms, making it difficult to analyze the data and demonstrating the vulnerability of the information in the care of patients of the COVID-19.

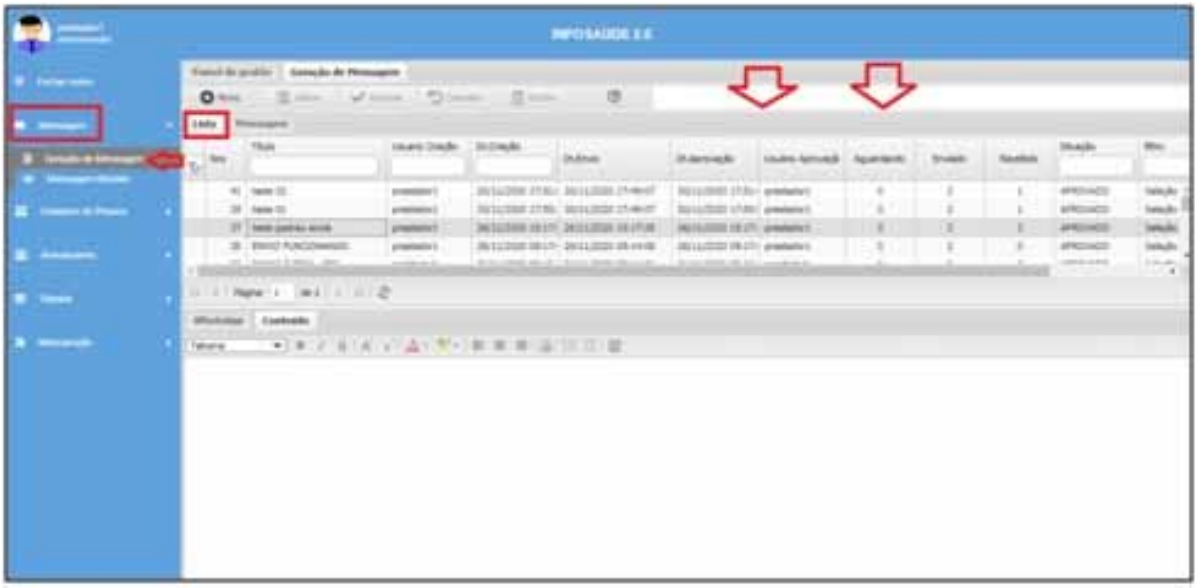
Covid-19 Application

The "InfoSaúde" project application was developed to enable the prevention, care, and monitoring of COVID-19. The application in addition to patient registration, adds information regarding transmission, symptoms, treatment, and disease prevention. The patients are evaluated through the responses to the disease questionnaire of symptoms of the disease (fever, cough, difficulty breathing, chest pain, among others), in addition to information regarding the risk of developing severe cases of the disease (diabetes, hypertension, problems respiratory diseases, among others). The patient's personal information, such as the patient's name, telephone number and address, was load from the data in the E-SUS (Electronic Health Record of SUS) registration, allowing health professionals to make patient telecare and advise on the procedures that must be followed, as well as evaluate the need to carry out tests for the confirma-

tion of COVID-19. The application was developed for access by computer and cell phone with PWA (Progressive Web Application) technology, not requiring installation, being available in the "cloud", and can be used through a link. Regarding the way of communicating with patients, it was evaluated that WhatsApp® is the most efficient way, due to the wide use of this messaging application by patients. The messages sent initially will be for the prevention of the disease (social distance, use of masks, hand washing, among others), later the application will be used for patient care and finally for the monitoring of patients. Allowing the stored information to be used to find out about the pandemic situation in the region. Despite being used now for the COVID-19 pandemic, the application will be parameterized and can be used for other pandemics, diseases, and health post campaigns in the future. This parameterization will be carried out through the configuration of the database, allowing health managers to configure the application according to their needs.

The first application module, for COVID-19 prevention, was made sending WhatsApp® messages prepared by health professionals with the objective of preventing the disease. At application, the messages was performed sending by health team to specific groups of users. Sent messages appear in a message list that allows the identification of sent, received, and approved messages, the title of the message, the sending date, the approval date, the user who created the message, and the user who approved the message. So far, approximately 4.000 messages have been sent for preventions to users. Figure 2 shows the application form on the control message.

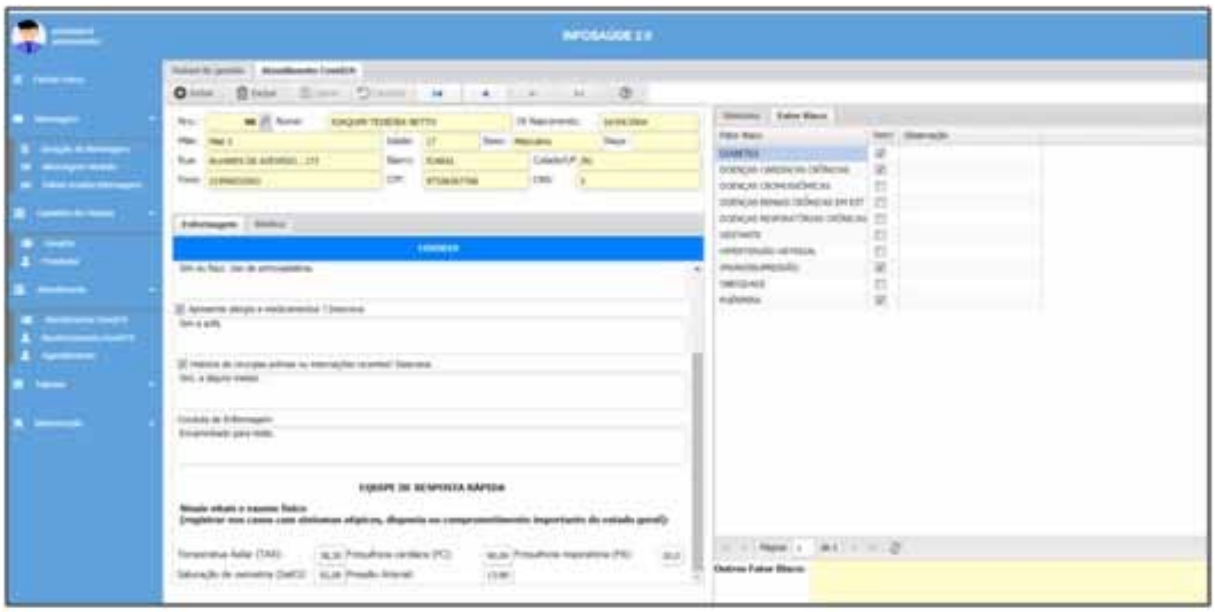
Figure 2. "InfoSaúde" control message application form



The second aplication module, for COVID-19 care, as built with questions defined by the health teams of with data relates to anamnesis of the disease: respiratory rate, heart rate, oximetry saturation and blood pressure. As well as the following symptoms: sore throat, headache, shortness of breath, absence of smell, absence of taste, cough, pain in the body. The assessment also includes the following risk factors: diabetes, hypertension, heart disease, obesity, immunosuppression, respiratory diseases.

Subsequently, the doctor assesses the patient and makes the diagnosis and medical conduct, indicating the clinical examination for COVID-19. Figure 3 shows COVID-19 application form.

Figure 3. "InfoSaúde" Covid-19 application form



There were several difficulties in using the application in the field. Initially, there was difficulty with network infrastructure and equipment. Later, it was related to human resources that were mostly outsourced by a company whose contract was coming to an end.

The infrastructure of the network and equipment was overcome, later attempts were made to use it, which resulted in the care of 100 patients.

COVID-19 INFORMATION PANEL

An initial analysis of the data results was performed in this chapter, enabling identify a pandemic situation in the Manguinhos neighborhoods. The analysis of the number of cases of COVID-19 in the Manguinhos neighborhoods was compared with other neighborhoods from city of Rio de Janeiro. For this comparison to be possible, a comparison was made with a percentage rate per 100,000 inhabitants, city neighborhoods with different population characteristics and Human Development Indexes (HDI) were chosen. A population of Manguinhos is approximately 40,000 people, the territory is located around Fiocruz and has one of the lowest HDIs with a value of 0.726. Other three neighborhood in Rio de Janeiro was chosen to compare, one is Maré neighborhood that is a community with a lower HDI with a value of 0.722, another is Cascadura neighborhood with value of HDI 0.833 and Gávea neighborhood with highest HDI in the city with a value of 0.970. The values of HDI have the source in Pereira Passos Institute that represents the city's official information (IPP, 2021).

The data obtained during the research were synthesized in Figure 4 with data of other districts.

Figure 4. Comparative frame for Covid 19 in Rio De Janeiro
Source: Covid Information Panel e DataRio.io, February 24, 2021.

Rio de Janeiro Districts	Souce	IDH	Total Cases	Population	% Cases per 100 mil hab
Manguinhos	Covid Panel	0,726	750	36000	2083
Maré	DataRio.io	0,722	1557	129770	1200
Cascadura	DataRio.io	0,833	843	34456	2446
Gávea	DataRio.io	0,97	1410	17745	7946
Rio de Janeiro	DataRio.io	0,842	205932	3304557	6232

The Covid Information Panel was developed with Google's DataStudio® a free tool available from Google company for Data Analysis built by the CSEGSF IT team and is available at: https://datastudio.google.com/u/0/reporting/1cc847ad-929f-4e20-949f-358cfacf6aec/page/hb7MB. From the data generated, an assessment will be made of the total data of COVID-19 in the Manguinhos region. The data for February 24, 2021, confirmed cases of 750 at line 1 column 4. For this comparison to be possible, a comparison was made with the percentage rate per 100,000 inhabitants. The percentage cases of Manguinhos were 2083, for the neighborhood of Maré the value of 1200, while Cascadura was 2446, Gávea 7946 and of the city of Rio de Janeiro 6232. It was observed that the percentage of infected people was higher in the neighborhood with the highest HDI value as in Gávea (7946 cases and HDI of 0.970), in second place was the average of the city of Rio de Janeiro (6232 cases and HDI of 0.842), in third place Cascadura (2446 HDI of 0.843), followed by Manguinhos (2031 cases and HDI of 0.726), in fourth place and lastly in Maré (1200 cases and HDI of 0.722). According to the data in Figure 4, it can be observed that the percentage of infected people follow up in a proportional way to the number of infected. So, neighborhoods with higher HDI values have higher rates of infection.

In fact, this result is distorted due to the difficulty in confirming the disease without taking the tests. This difficulty occurs in the poorest populations, due to the small number of tests available in the public health system. Demonstrating the need to provide health services with a greater number of tests for COVID-19 for the low-income population, so that the available data can be better evaluated.

FINAL CONSIDERATIONS

In the face of a communicable disease such as COVID-19, information technology is essential for understanding epidemiological behavior, tracking of cases, the use of preventive measures considering from diagnosis to monitoring and evaluation of the effectiveness of the measures resulting in decision making based on data. Mobile technology offers a powerful tool to facilitate this task through "applications" that collect user data. Cases from countries in Asia, such as South Korea, used digital technology as a strategy for tracking cases of COVID-19 and their contacts, and monitoring the quarantine of cases successfully.

Essential information is the great differential in the 21st century for decision makers. It translates into knowledge for innovation, when one traverses the trail knowledge that is formed by the extraction of data that generates information and, therefore, knowledge. However, the management of this knowledge is

fundamental for the scientific and technological advancement of organizations and, consequently, wealth of countries, for the well-being of their populations.

The knowledge presented in each technology promotes the continuous scientific and technological development translated into various sources, such as patents. They characterize the state of the art of innovation and present themselves as opportunities for the strategic management of knowledge.

The translation of knowledge into the global health sector has shown great dynamism in the 21st century. They present as strategic innovation of new technological trajectories of the future for the health sector. They present strong investments in R, D & I, remaining competitive for the public and private sector, constituting a great ally for One Health concept.

The implementation of new technologies to contribute to the actions and activities inherent to Primary Care such as assistance and comprehensive care is a powerful tool for disease control. The development of a friendly and effective application that aggregates, through an interface, the information with the current system, can reduce the work overload of the teams, increase the reliability of the data, could promote remote monitoring actions and evaluation for decision making. The involvement of users and health professionals in this process, in a participatory way, contributed to point out needs aiming at a more adequate service, bringing gains such as the range of actions and activities necessary for comprehensive care and reducing the risk of contagion. In addition to the development a friendly application based on the processes of daily work and joint construction with the care teams. The availability of the data through a panel, even if it does not represent a fully finalized Big Data, was important so that the data could be analyzed and visualized in a simple way, in fact today is avalilable analitical database with around 7.000 cases of Covid-19. Our plan is load the database with other sources of information in order to build an effective Big Data, with ''InfoSaude'' application.

The main barriers identified are related to the macro aspect of human resource management and technological investment, respectively, hiring by social organizations and a deficient local structure for the use of networks aimed at data collection, actions, activities, and distance learning. Currently, investment in this technological area is quite accessible and should be made by management as a priority since it is a powerful tool for the effectiveness of comprehensive care. Another relevant point is the development and applications to contribute to the analysis and monitoring of data and, consequently, to the improvement of actions related to comprehensive care.

Finally, it is important to note that through the application "InfoSaúde" and the Big Data proposed in this study, there was an improvement in the quality of information since through systematized forms, with access in real time, and integrated with the current information system decreasing the possibility of errors. Enabling health policies to be better evaluated and made available to the population in a more precise way and in a shorter time.

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APPENDIX

Questionnaires Use in Research

1. What is your assessment of the preventive measures for COVID released by health professionals?
2. What would be the best way to disseminate prevention measures through the App?
3. Should the application be installed on the cell phone or through direct access over the internet?

Questionnaire for Application Requirements for Healthcare Professionals

1. How is the prevention team for COVID informed by health teams?
2. What is the service flow of each team?
3. What documentation is used to assist each team?
4. In which system is the team notification carried out?

Application Evaluation Questionnaire for Users

1. How was Prevention information received using WhatsApp®?
2. Was the information understood?
3. From the messages do you believe that you will follow the guidelines received?

Application Assessment Questionnaire for Healthcare Professionals

1. Was the application easy to use?
2. Did the application improve the work routine of each team?
3. What would be your suggestion to improve the application?

Chapter 4
Innovations for an Integrated Approach to the 2030 Agenda:
Patent Landscape, One Health, and Sustainable Development Goals

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ABSTRACT

From the One Health (OH) perspective, the achievement of better public health results depends on effective strategies and interventions based on integrated research in diverse sectors of activity (human health, animal health, agriculture, and environment). The central topic in the United Nations 2030 Agenda aims at a world free of hunger, poverty, and severe disease through the achievement of 17 Sustainable Development Goals (SDGs). The objective of the present study is to evaluate countries and applicants of technologies patented between 2015-2020. From this methodological perspective, searches have been carried out in this study on the global patent database documents available, using specific search strategies for technologies related to challenging diseases for achieving SDGs, such as neglected communicable and non-communicable diseases: diarrhea, tuberculosis, malaria, obesity, cardiovascular diseases, diabetes, lung cancer, human schistosomiasis, and Zika.

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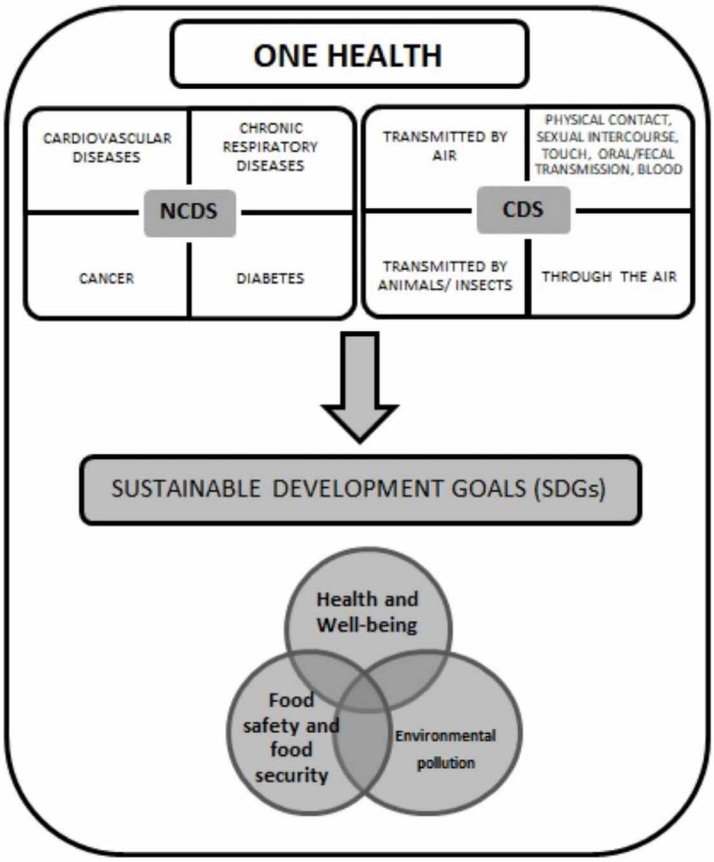
CONCEPTUAL FRAMEWORK

Figure 1. SDGs from agenda 2030
Source: United Nations – UN, WHO
Elaborated by the authors

According to the World Health Organization (2020a), the causes of death globally are grouped into three categories: 1. Noncommunicable diseases NCDS (chronic diseases) 2. Communicable diseases CDS (Parasitic and infectious diseases; nutritional, perinatal and maternal conditions) and 3. Injuries. Globally in 2019, 7 of the 10 leading causes of deaths were from NCDS – 80% of the top 10 or 44% of all deaths. Low progress has been observed in control and prevention of premature deaths, when compared with significant advances against the communicable ones (WHO 2020a; WHO, 2020b). According, to the World Health Statistics (2021) from NCDS, premature death is still the leading cause of death global. While key risk factors such as alcohol consumption, tobacco use, physical inactivity, obesity and hypertension required urgent interventions. Mainly in the COVID-19 scenario which is in the rank of the ten top causes of deaths in absolute numbers in 2020 (WHO, 2021a). On the other hand, a CD is one that can spread from person to person depending on the infectious agent or specific disease. Transmitted through the air (tuberculosis), through animals transmitting the disease or bites from insects (mosquito: malaria, Zika), contact with blood (HIV/AIDS), contaminated object/surface, water (cholera/ diarrhea) or food (diarrhea) and touch (Staphylococcus) are some ways in which they are spread by (Alameda County Public Health Departament, 2021). OH's concept includes (CDC, 2018): **1. Health and well-being:** As a broader concept, it is clear that the future of human health does not depend only on medicine, but also on multiple disciplines which must work together, such as public health, environmental studies, social science and biology. Indeed, the interconnections among **human, plants, animals and environment** must be recognized, to achieve important results on well-being and health through a trans-disciplinary, multisectoral and collaborative approach at local/national/global levels (Brymer, Freeman & Richardson, 2019; One Health Commission, 2021); **2. Food safety and food security:** Concerning the production

from livestock, it is necessary the biological improvement of all-food-producing species. The increase of biological efficiency requires vaccination to prevent diseases, intervention by therapy and diagnostics or biosecurity's application to prevent infectious diseases (Fitzpatrick, 2013); **3. Environmental pollution:** The most dynamic and, unfortunately, most vaccillating sector of OH is the environment which depends on variable weather patterns (precipitation, humidity and temperature), which influence bacterial ecosystems. Animals, human and environment's health depends on environmental issues and are affected by its adverse effects (Essack, 2018).

Figure 2. SDGS and one health in the NCDS and CDS' diseases
Source: Elaborated by the authors based on WHO 2020a; WHO, 2020b; CDC, 2018; Seifman, 2019; United Nations
NCDS: non-communicable diseases
CDS: communicable diseases



Despite OH approach is not new, it has turned recently into a paradigmatic change, supporting the notion that the crucial human-animal-environmental health interface for the global health security is strongly addressed by OH issues which can be correlated to the Sustainable Development Goals (SDGs). Aspects of vector-borne diseases, water and food safety, antimicrobial resistance, animals and human infections, and the spread of novel coronavirus or COVID-19 (which is probably originated in a bat and probably used an intermediary species to crossed over to humans), besides the high probability of a new

emerging epidemic/pandemic caused by other viruses, show the importance of OH's inclusion in the SDGs (CDC, 2018; Seifman, 2019). OH's concept and action, through the interdisciplinary communications and collaboration on health care not only for humans, but also for animals and the environment, are an advance for the 21st century. Besides that, OH's principles are considered as a *"mainstream component of public health"*: Emerging and zoonotic diseases (with complex life cycles) can be prevented and controlled, and millions of lives can be saved (One Health Initiative, 2021).

For *"leaving no one behind"*, in 2015 193 United Nations members states adopted goals (and specific targets) to ensure property for all, protect the planet and end poverty. The 17 indivisible and integrated SDGs (and 169 targets[1]) (Figure 1) faced global challenges, mainly the extreme poverty in all dimensions and forms blend the three dimensions of sustainable development: social, environmental and economic (GAVI, 2020; Plataforma Agenda 2030) what is shown below that correlates the SDGs and OH (Figure 2):

From a recent study (Queenan et al*.,* 2017), we identified and selected diseases (NCDS or CDS) which have an important impact on people lives. NCDS such as diabetes, hypertension, lung cancer and obesity and CDS such as schistosomiasis, malaria, HIV/AIDS, tuberculosis, Zika and diarrhea. Moreover, it is also important to highlight the persistent problem all over the world: the neglected tropical diseases, such as schistosomiasis, malaria and Zika, besides that, the women and children's health challenges (IFPMA), aiming at a global health where everyone can have access. Their correlation wih the SDGs can be observed (Table 1).

Table 1. One health's aspects and their correlated SDGs

One Health's Aspects	Target diseases (chronic communicable and non-communicable)	Correlated SDGs*
Health and well-being	Schistosomiasis, Zika, Malaria, HIV/AIDS	1, 2, 3, 5, 6, 8, 9, 10, 12, 15, 16 and 17
Food safety and food security	Diabetes, hypertension, obesity, diarrhea	1, 2, 3, 4, 5, 8, 10, 12, 16 and 17
Environmental pollution	Tuberculosis and lung cancer	3, 4, 5, 6, 7, 8, 9, 11, 12, 13, 14, 15, 16 and 17

Source: Elaborated by the authors based on United Nations – UN; Queenan et al*.,* 2017
(*) See figure 1

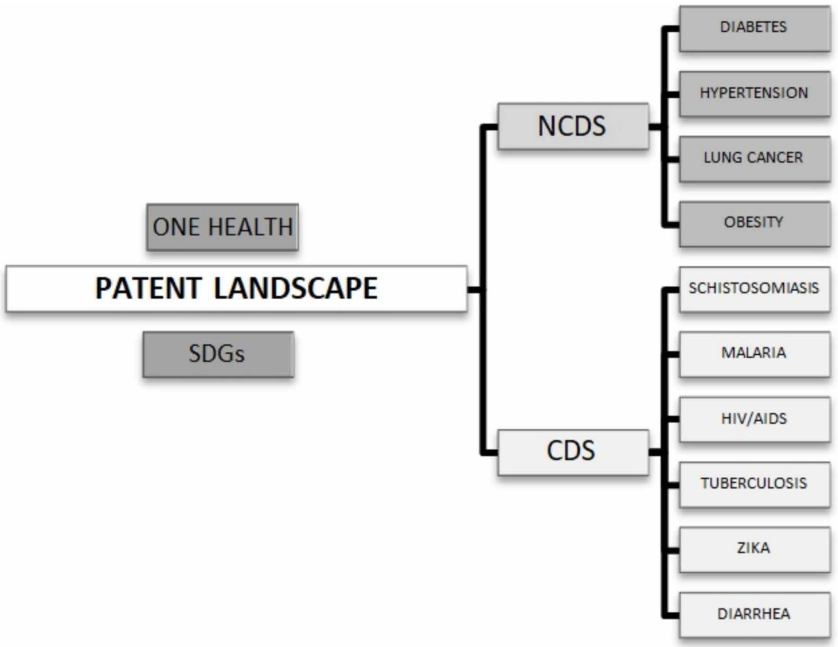
A nation´s economic growth is significantly driven by its patent system. In fact, the patent represents an agreement between the inventor and society. The State grants the inventor a monopoly and in return the inventor describes the technology in detail. In this way, the patent document analysis provides technological information about the scope of protection. To be patentable, it must meet 3 basic requirements according to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) from World Trade Organization (WTO), article 27(1) (1994): to be industrially applicable, to be novel and non-obvious. The new inventions, when made available through the patent document, have a description of the operation with technology employed's details. This published information provides, in fact, technological solutions to the challenges and difficulties that people around the world face daily (WIPO, 2020a; WIPO, 2020b). The goal of the present study is to achieve an overview of technological development related to target diseases to achieve Sustainable Development. This overview is possible through a patent landscape which offers a broad perspective on novel technologies and technological

trends retrieving and identifying the leading depositors globally in a given region or country and the developers' technologies. Furthermore, it also provides data about patent's validity and other informations.

Methodology

From the global OH concept and considering the relevance of diseases whose eradication and/or control are fundamental for the promotion of Sustainable Development for all countries and all over the world, 10 diseases were chosen for the strategy searches' development - 4 non-communicable diseases (diabetes, hypertension, lung cancer and obesity) and 6 communicable (schistosomiasis, malaria, HIV / AIDS, tuberculosis, Zika and diarrhea) (Figure 3). These 10 diseases, target of governmental and social policies, are challenging and worrying, especially in the low and lower middle countries, where the number of deaths are still at very high levels, a scenario which has become worse with COVID-19 due to reduced access to health services. For the present study, a patent landscape from published applications was carried out in the period from 2015 (the beginning year of the 2030 Agenda of the World Health Organization for Sustainable Development, adopted by all United Nations Member States) until the end of 2020. The patent search was carried out in the Derwent Innovations Index database (from Clarivate Analytics) using the terms related to each disease, mainly based on the search in the Mesh (Medical Subject Heading) descriptor used for indexing articles from the Pubmed / NCBI (National Center for Biotechnology Information) database (https://www.ncbi.nlm.nih.gov/mesh). International Patent Classification (IPC) from the World Intellectual Property Organization (WIPO) was used, besides the Derwent Manual Codes from Derwent Innovations Index Database for each search separately. From the universe of the retrieved applied documents in the study period, the main priority countries[2] (in number of applications) were chosen, and thus the documents' scopes of the main applicants/assignees according to the priority country were analysed. Thus, the figure 3 below represents the target diseases in the collection of patents' data that integrate SDGs with OH:

Figure 3. Patent landscape of NCDs and CDs: achieving SDGS in the context of One Health

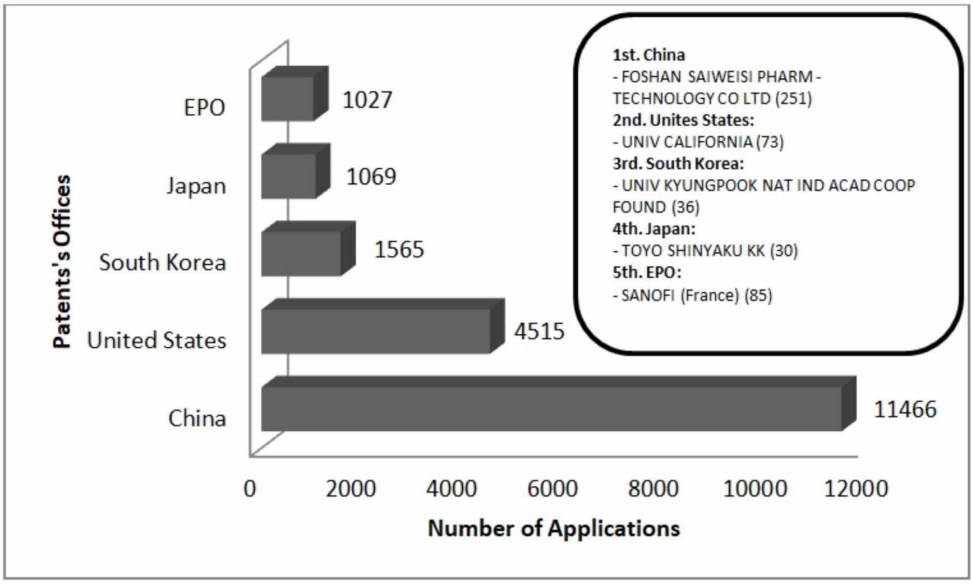


PART I. PATENT DOCUMENTS AND NON-COMMUNICABLE DISEASES

Diabetes

Diabetes type 1 (when the insulin is not produced by the body) or type 2 (when the insulin is not used properly by the body) is a serious disease which carries a high risk of premature death all over the world with a global impact for people which develop serious and life-threatening complications. It is the top 10 causes of death globally. To give an illustration for the extension of this problem, global numbers are provided: 463 million people have diabetes (1-11 adults between 20-79 years) and the most cases are from low-and middle-income countries (79%). The associated complications, stress on families, cost, need of medical care and frequent hospital admissions can reduce the quality of life of patients with diabetes of different national boundaries or socioeconomical status. Likewise, the numbers are worrysome: by 2030 10.2% of the global population (587 million) will have diabetes. And that number is expected to be greater by 2045, with 700 million people. Notwithstanding the complexity of its causes, three rising numbers for disease are in part due to the increase in obesity and overweight people (IDF, 2019; ADA, 1995-2021; WHO, 2020c), besides the higher risk for people with diabetes for severe COVID-19 disease (WHO, 2020d). Around 100 years after insulin hormone's discovery, the reduction of diabetes incidence (and other NCDs - SDG - target 3.4[3]) is still searched: a reduction by 30% has been set as SDG by 2030. Coupled with the lack of access to technologies and essencial diabetes medicines, which unfortunately, are not available in the poorest countries in the world (UN, 2016).

Figure 4. The top patent's offices (Priority Countries) for the documents obtained from the search strategy for diabetes.
Elaborated by the authors
EPO: European Patent Office
Source: Derwent Innovations Index
The analysis of applied documents leads to the following technology developers:
Note: Leading applicants in top priority countries are described in detail.



The selected search[4] results were 21.813 patent applications. From results' analysis, a key finding has emerged: China is the priority country with the highest number of applications (11466), far from the other countries, i. e., United States (4515), South Korea (1565), Japan (1069) and European Patent Office (EPO) (1027) (Figure 4).

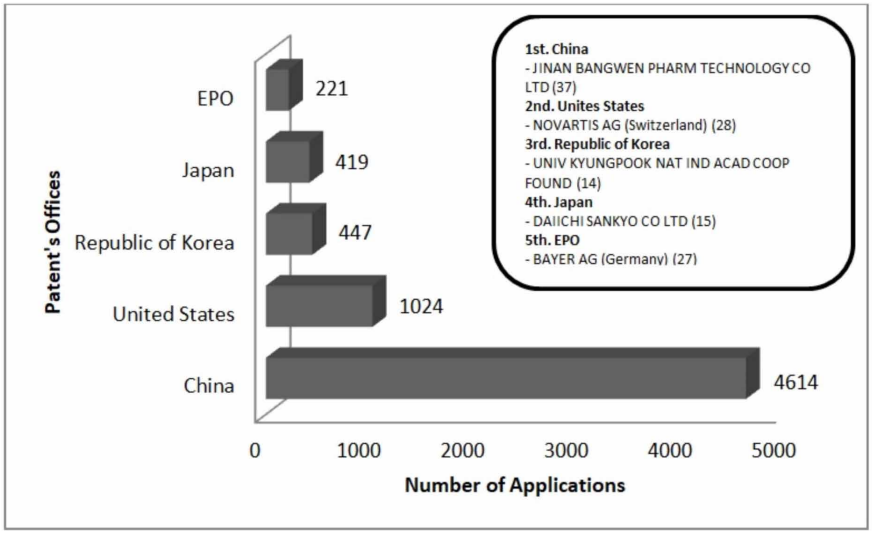
FOSHAN SAIWEISI PHARM TECHNOLOGY CO LTD is the leading applicant in China with 251 documents – all of them were applied in 2015. For this institution, the analyses of the patent documents indicated the research about new substances for the preparation of a medicine to treat type II diabetes (Patent document - PN[5]: CN104892569-A; CN104892517-A; CN104892505-A; CN104926755-A; CN104926756-A; CN104926757-A; CN104910097-A; CN104910130-A; CN104910083-A; CN104910084-A; CN104926742-A). Dipeptidyl Peptidase-IV Inhibitors used as anti-diabetic were also claimed (PN: CN104496968-A; CN104478859-A; CN104530010-A; CN104530011-A; CN104529855-A; CN104529856-A). The American documents from **UNIV CALIFORNIA** (73 applications) were analysed and our results demonstrated that there is a diversity in the scope of protection with methods and substances with different therapeutic activities, including the antidiabetic one. Such as, 1. A method to modulate diatery response by the administration of a milk oligosaccharide (PN: WO2021011905-A1), 2. The use of a human regulatory T cells (PN: WO2020223568-A1); new conjugates which comprises peptides, hydrophilic polymer, etc. (PN: US2017165382-A1); derivative substances for treatment of type II diabetes (e.g.) (PN: US2019112268-A1). Indeed, the treatment or prophylaxis of many diseases, and also used to inhibit the development of metabolic syndrome or type II diabetes (PN: WO2016144829-A1). Indeed the administration of a compound to increase the stress resistance in subjects (PN: WO2017062751-A1). From South Korea, the **UNIV KYUNGPOOK NAT IND ACAD COOP FOUND** (with 36 documents) has applied scopes of protection related to food composition which can be used (e.g.) as: 1. anti-diabetic agents (PN: KR2021032370-A; KR2021032368-A); 2. Antioxidant compositions to prevent diabetes (e.g.) (PN: KR2020040605-A; KR2020040607-A) or 3. Pharmaceutical/food compositions which are used as to prevent/treat diabetes, among other conditions (PN: KR2020040606-A; KR2020040608-A; WO2020067832-A1). Specif conditions were also observed, such as a nutraceutical (or pharmaceutical/food) composition using extracts as principal active ingredient for the treatment of disorders related of lipid or sugar metabolis, including diabetes, such as *Caragana sinica* (PN: KR2016135037-A); *Angelica tenuissima* (PN: KR2019100880-A) and ginger leaf extract (PN: KR2019100878-A). For the analysis of Japanese documents, revealed the main applicant, i. e., **TOYO SHINYAKU KK** (with 30 applications). Most of them were about antidiabetic agents through the promotion of sugar uptake in muscles cells (e.g.) (PN: JP2020115816-A); prevention of diabetes (e.g.) (PN: JP2017088616-A; JP2020138936-A) or its complications (PN: JP2017141201-A). Indeed, compositions to suppress the increase of the blood glicose levels (PN: JP2017001965-A; JP2017105728-A). The documents retrieved from EPO (European Patent Office) suggested that the multinational pharmaceutical company **SANOFI** (from France) is the most applicant with 85 documents. From the results it was clear that the development of drug delivery devices for the treatment of diabetes was highlighted: injection pen device for the treatment of diabetes (mellitus) (e.g.) (PN: WO2016113409-A1; WO2016150900-A2; WO2016180774-A1); medicament delivery system for the treatment of type II diabetes (e.g.); (PN: EP3045186-A1); *"drive mechanism for pen-type injector"* (PN: WO2016128424-A1; WO2016128425-A1) or the use of seringes to deliver the drugs (PN: WO2017089269-A1; WO2017089277-A1). These are technologies developed for the prevention and treatment of the disease with the promotion of better glycemic control, as well as convenience and comfort for people with diabetes and their families, such as the development of anti-diabetic substances, insulin injection devices and food compositions.

Hypertension

The blood pressure[6] is too high in a hypertension disease which causes damages on the tissues of the arteries over time. The disease is related to non-modifiable risk factors, like age over 65, kidney-disease, diabetes and family history of hipertension (addressed by SDG 3). Meanwhile being obese or overweight, comsumption of alcohol (SDG 3 target 3.5[7]) and tobacco use (SDG 3, including its use among women which has implications on the SDGs target 3.1[8] and 3.2[9] and it is crucial among women not only during pregnancy, but also in a post pregnancy period) and an unhealthy diet (high in trans fats and in saturated fats, low intake of vegetables and fruits and excessive salt) (SDGs 1, 2 and 3) are the associated modifiable risk factors. Hypertension gets worse due to the formation of plaque along the artery walls caused by low-density lipoprotein (LDL) cholesterol, which can lead from arrhythmia to stroke and heart attack (American Heart Association, 2016; OMS, 2017a; OMS, 2019c, UN). Globally, the hypertension numbers increased from 594 million in 1975 to 1.13 billion in 2015, mainly in low and middle-income countries. Besides that, the number of people who are uncontrolled, untreated and undiagnosed are higher in these countries when compared to high income ones (WHO, 2013; WHO, 2019c). It is a public health challenge all over the world and requires prevention, control and politicals, nor only by policymakers and governments, but also by the individuals, families, private sector, academic research community and health workers (WHO, 2013). Hypertension and diabetes is closely linked to NCDs as kidney diseases (OMS 2013-2020). According to Tadic and Cuspidi (2020), there is a consensus about the relation among the high prevalence of diabetes and hypertension and severe COVID-19 (including lethal outcomes and complicated course of the disease with the need of admission in intensive care unit). Nevertheless, our study could not associate the mortality and severity of COVID-19 with hypertension alone, despite the management of high blood pressure in these patients.

From the strategy search[10], 7269 patent documents were retrieved. From the top 5 priority countries, China and The United States have the most number of applications: 4614 and 1024, respectively (Figure 5).

Figure 5. The top patent's offices (priority countries) for the documents obtained from the search strategy for hypertension. In detail there are described the most applicants by the most priority countries
Elaborated by the authors
EPO: European Patent Office
Source: Derwent Innovations Index



From all documents considered (Figure 5), it is clear that most of them are from China. From **JINAN BANGWEN PHARM TECHNOLOGY CO LTD** (37 documents), they were claimed medicinal compositions to treat hypertension specifically or including hypertension (PN: CN105560648-A; CN105560883-A; CN105582175-A; CN105582192-A; CN105582327-A; CN105596437-A) besides the use of *"Traditional Chinese medicine composition"* for the treatment of the disease (PN: CN105560885-A; CN105687765-A). Indeed, from the American priority documents, **NOVARTIS AG** (Switzerland) has applied 28 documents, including pharmaceutical composition to treat diseases, e.g. hypertension (PN: WO2016185443-A1) or substances, such as "*naphthyridinone derivatives*" (PN: US2019263803-A1), *"new isothiazolidine 1,1-dioxide and 1,4-butan sultone rapamycin derivatives"/"eoxo-rapamycin derivatives are target of rapamycin kinase inhibitors"* (PN: WO2020194209-A1; WO2020128861-A1). Pulmonar hypertension was also in the scope of protection in some documents. From Republic of Korea, the **UNIV KYUNGPOOK NAT IND ACAD COOP FOUND**, with 14 documents, applied pharmaceutical or food compositions for the treatment of e.g. hypertension (PN: WO2020235947-A1; KR2016135039-A). Moreover, Japanese applications from **DAIICHI SANKYO CO LTD** (15 documents) were retrieved. About the inventions for the hypertension treatments, the applications also comprised substances for e.g. hypertension: (PN: WO2020153432-A1; WO2020153433-A1; WO2018151240-A1; WO2018003983-A1). Not to mention the patent applications which were filled at the European Patent Office (EPO). From the 221 documents, our results casted a new a light about the most applicant alone (without no partnership), i.e., **BAYER AG** (Germany) with 27 documents. These ones contributed to innovations in hypertension treatment, such as the development of new substituited compounds for diaseases, including hypertension: PN: WO2020254197-A1; WO2017121693-A1 and WO2016124565-A1.

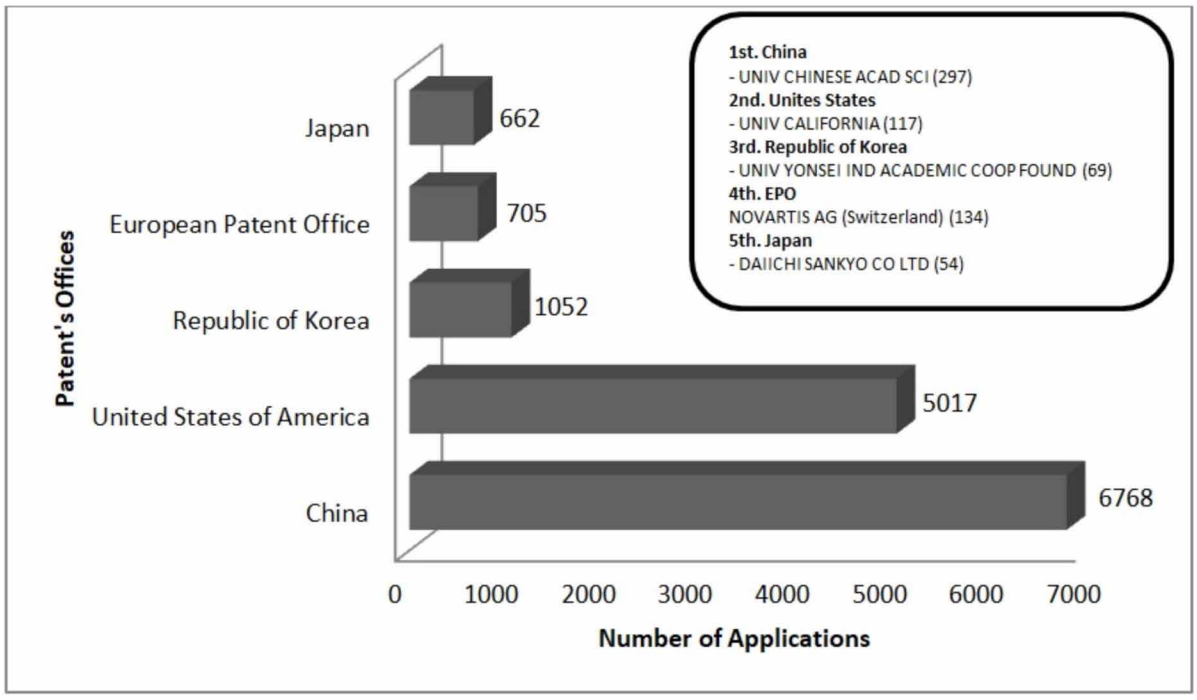
Hypertension is a disease caused by environmental and genetic factors, i.e., it has a multifactorial character. These inputs are aggravated in poorer countries, as the type of diet and tobacco use. Both can lead to an increase in cholesterol levels, hypertension and the development of cardiovascular diseases. In summary, it is a promising scenario for the development of compounds for the management of the disease in all countries of the world.

Lung Cancer

Estimates for lung cancer in the United States for the year 2021 are worrying: 235.760 new cases (116.660 in women and 119.100 in men) and 131.880 deaths from the disease (62.470 women and 69.410 men). The disease is responsible for almost 25% of all cancer deaths and with a representation of more deaths per year than prostate, breast and colon cancers combined. It is a diagnosed mostly in older people, aged 65 or over, with an average age of 70, but it can be diagnosed in people under 45. Lung cancer can be classified, mostly, into non-small cell lung cancer (NSCLC) and small cell lung cancer (SCLC), with 84% of all lung cancer type NSCLC and 13% SCLC, both of them are the most commom among men and women[11] (American Cancer Society, 2021). When we move to a global scenario, the numbers are no less worrying: according to data from The Global Cancer Observatory, it appears that the number of new cases for both sexes, at any age corresponds to 11.4% (2 206 771 new cases in 2020). The number of deaths, however, puts the pathology in first place for the year 2020 - 18%, which corresponds to 1 796 144 deaths, with very high mortality and incidence rates in Asia for both sexes (58.4% and 52%, respectively). Among the risk factors associated with the development of the disease, smoking is the first (risk factor number 1 - In the United States, 80-90% of lung cancer deaths are related to smoking): people who smoke cigarettes are 15-30 times more likely to develop lung cancer than people who do

not smoke, without removing the risks associated with pipe and cigar smoking. Other factors include secondhand smoke, exposure to substances such as radon, asbestos and arsenic; family history, HIV infection, environmental factors (addressed by SDGs 8, 11 and 12), diet, pharmacological supplementation of beta carotene in heavy smokers and particularly exposure to air pollution (addressed by SDG 13) (Cancer Research UK, 2019 ; CDC, 2020a; National Cancer Institute, 2020, UN). In relation to this, the objective until 2030 (according to the 2030 Agenda) is the substantial reduction of diseases and deaths due to the contamination of soil, water and air (SDG 3 - target 3.9) (UN). From the strategy search[12], 15238 patent documents were retrieved. China, United States and Republic of Korea are the most priority countries in number of applications (6768 and 5017 documents, respectively) (Figure 6).

Figure 6. Top patent's offices for the documents obtained from the search strategy for lung cancer
Elaborated by the authors. In detail there are described the most applicants by the most priority countries
EPO: European Patent Office
Source: Derwent Innovations Index



From the leading applicants/assignees, for the first analysis, a Chinese Institution stood out in invention's development directed to lung cancer: **UNIV CHINESE ACAD SCI** (with 297 documents): Substances/medicines to treat tumor and cancer or inhibit cancer cell growth, including lung cancer were claimed (PN: CN 108864236; CN 107753484; CN 109745324; CN 105287510). Moreover, polimeric material systems used in products for the induction of tumor's apoptosis, including from human lung cancer cells was also claimed (PN: CN 110028674) or the development of anti-cancer (including lung cancer) components (PN: CN 105726553). Furthermore, the American universities/institutions claimed about the subject. Among them: **UNIV CALIFORNIA**, with the leading number of applications (117)

in researches about cancers (e.g. lung cancer), including chimeric antigen receptor for pharmaceutical compositions (PN: WO 2020198531), besides different compositions (PN WO 2017095826), indeed composition to treat hyperproliferative disorder as lung cancer (PN: WO 2017205611). From South Korea, the **UNIV YONSEI IND ACADEMIC COOP FOUND** with 69 documents applied documents about anticancer pharmaceutical tablets, (PN: US 2020087250), complex for pharmaceutical compositions (PN: KR 2018122128) and compositions for early diagnosis (PN: KR 2020139002). Moreover an invention to predict the cancer's prognosis through mRNA's levels (e.g. lung cancer) was claimed (PN: KR 2020067419). From the Swiss companies/institutions, **NOVARTIS AG**, HOFFMANN LA ROCHE & CO AG F and IDORSIA PHARM LTD are the main applicants. Indeed, the first one has the highest number of applications (134) and claimed different scope of patents' contents: antibodies for pharmaceutical compositions to treat/prevent the disease (PN: WO 2020089811; WO 2018142322; WO 2020128620; WO 2018215936). In addition, the development of substances to treatment/reduction of cell's proliferation, including NSLC (PN: US 2019359594; US 2020017461). The Japanese documents revealed the leading applicant was **DAIICHI SANKYO CO LTD** (54 applications), such as the described antibody-drug conjugates for pharmaceutical compositions to prevent/treat cancer, e.g. lung cancer (PN: WO 2018066626; WO 2018159582; WO 2020100954; WO 2020196475; WO 2019065964). This aspect of this research suggests, that tobacco and the environment are risk factors for people from low income countries. In this scenario, technologies are used for the development of new compounds for the prevention/treatment of lung cancer, as well as high-tech antibodies and disease prevention devices such as tablets.

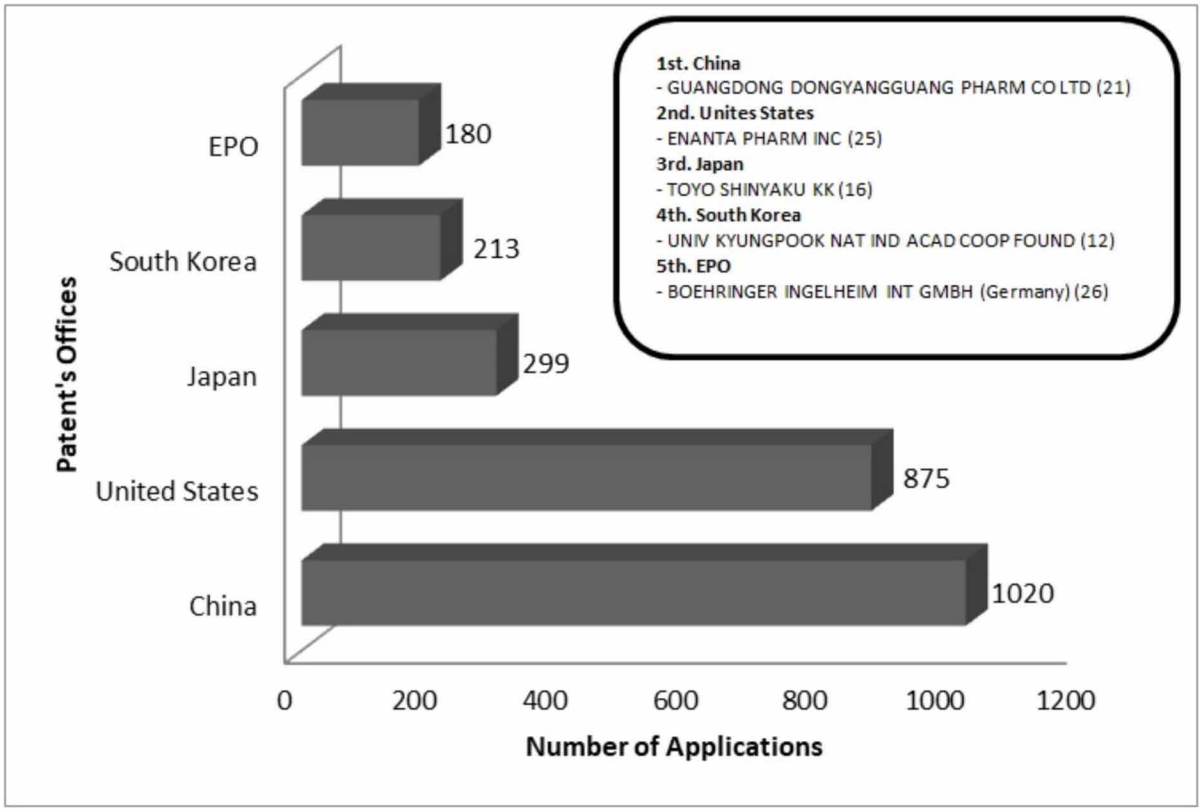
Obesity

According to World Health Organization (2020e) overweight and obesity are *"abnormal or excessive fat accumulation that may impair health"*. Prevention efforts by international partners, governments, non-governamental organizations, civil society and private sector must decrease the deaths caused by obesity: at least 2.8 million people die per year due to overweight (Body mass index - BMI[13]: equal to or more than 25) and obesity (BMI: equal to or more than 30). This number shows a concerning situation of a global epidemy, not only associated with high-income countries but also prevalent in low and middle-income ones (WHO, 2020e). For children under the age of 5 years, there is an estimative that 38.2 million were obese or overweight in 2019. Since 2000, there is an increase by 24% of overweight children under 5 in Africa. And in Asia, almost half of this age group was obese or overweight in 2019. The global causes are related to the increase of intake of foods that are high in sugars and fat, despite the sedentary way of life, including the increase of the urbanization, modes of transportation and forms of work. In fact, raised BMI is associated to NCDs such as some cancers (e.g. colon, kidney, prostate, ovarian, endometrial and breast); musculoskeletal disorder (osteoarthritis); diabetes and cardiovascular diseases (mainly stroke and heart disease) (WHO, 2020f). Furthermore, obesity, mainly severe obesity, has a strong correlation with severe COVID-19 and with the increase of disease's complications (Stefan, Birkenfeld & Schulze, 2021). The knowledge that good habits lead to a healthier life is not new, but it still important to avoid many diseases by the weight's management. It includes regular physical activity, healthy eating habits and walking more daily (CDC, 2021). Obesity has direct and indirect links to the SDGs. Not only SDG 3, target 3.4[14] (about the prevention and treatment of NCDs to promote well-being and mental health) or the SDG 2 (for the end of all forms of malnutrition, including overnutrition), but also SDGs 1 and 8 (related to poverty, income and economic growth); SDG 4 (related to education); SDGs

5 and 10 (reduction of gender inequity and inequalities); SDG 6 (access to safe water); SDGs 13 and 14 (related to planetary healthy); SGD 11 (sustainable urbanization); SDG 12 (sustainable comsumption production) and SDG 15 (land use) (UN; Ralston, Cooper & Powis, 2021).

For the search[15] of the anti-obesity agents, 2897 patent documents were retrieved. For the top priority countries, the results are shown below (Figure 7).

Figure 7. Top patent's offices for the documents obtained from the search strategy for anti-obesity agents
Elaborated by the authors. In detail there are described the most applicants by the most priority countries
EPO: European Patent Office
Source: Derwent Innovation Index



The leading Chinese applicant was **GUANGDONG DONGYANGGUANG PHARM CO LTD** with 21 applications and relationships with Chinese institutions such as demonstrated in the following patent documents about substances used to prevent/treat/ameliorate diseases/conditions including obesity associated to *"beta-3 adrenergic receptor activation"* (PN: CN109761892-A, CN109776373-A; CN109776374-A; CN109734712-A) or to *"5-hydroxytryptamine 6 receptor"* (PN: CN105367474-A; CN109232362-A), for example. The American documents revealed the development by **ENANTA PHARM INC** (25 applications) about the development of substances/their derivatives to treat/prevent conditions, including obesity, such as PN: WO2018081285-A1; US2018237471-A1; WO2018218042-A1; WO2018218051-A1 or WO2018218044-A2. Japan, as one of the top priority countries, also has documents which protect anti-

obesity compounds. From **TOYO SHINYAKU KK** (16 applications), the deposit of compositions containg digestive enzimes were claimed (PN: JP2018171044-A; JP2018171045-A; JP2018083800-A) and others with anti-obesity effects with *"excellent storage stability"* (e.g.): PN: JP6620323-B1; JP6541047-B1. **UNIV KYUNGPOOK NAT IND ACAD COOP FOUND** (12 applications) from South Korea applied documents which comprises e.g. nutraceutical/pharmaceutical compositions to treat/prevent obesity or obesity-related complications (PN: KR2019100878-A; KR2019100879-A; KR2019100880-A) or for obesity's diagnosis (PN: KR1620274-B1 and KR1594735-B1). **BOEHRINGER INGELHEIM INT GMBH** from Germany is the European applicant which stands out the most in number of applications (26). Its scopes of protection are similar, such as compounds for the treatment of conditions related to diabetes (e.g. obesity) (PN: WO2020007729-A1; WO2017042121-A1; WO2016113299-A1), indeed to treat/prevent/ameliorate diseases, including obesity (PN: US2017101411-A1; US2018208560-A1). The analysis leads to the following conclusion: nutritional education is an important factor of recognition for all populations from high-income, upper middle income, lower middle income or low-income. However, there are efforts to develop anti-obesity compounds.

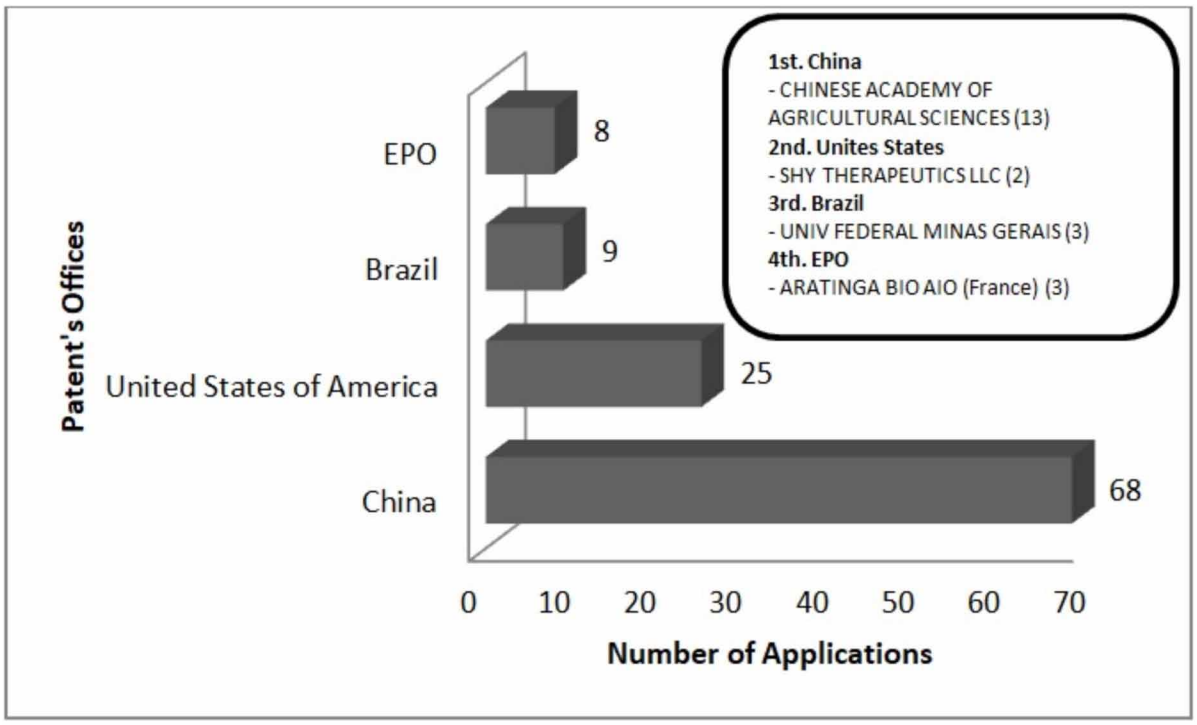
PART II. PATENT DOCUMENTS AND COMMUNICABLE DISEASES

Schistosomiasis

Schistosomiasis (it is characterized as a disease from poor countries) is an infection that affects almost 240 million people worldwide, with more than 700 million living in endemic areas, mainly in subtropical and tropical ones and causes severe morbidity in millions of people. It is caused by *Schistosoma guineensis, S. intercalatum, S. mansoni, S. japonicum* and *S. mekongi* (intestinal schistosomiasis) or by *S. haematobium* (urogenital schistosomiasis) and has a strong relationship with the lack of adequate sanitation and drinking water (WHO, 2021b). As a neglected tropical disease, the fight against schistosomiasis is also a target of the SDGs (SDG 3, target 3.3[16] - By 2030, end of the epidemics diseases, including schistosomiasis – neglected tropical diseases) (UN). Globally, schistosomiasis mansoni is registered in 54 countries (mainly in Africa, Eastern Mediterranean, Egypt, Sudan and regions of the Nile Delta). In the Americas, South America stands out, in countries such as Venezuela, the Caribbean and Brazil. For the last one, it is estimated that 1.5 million people live in risk areas, mainly in some states in the Southeast and Northeast regions of the country. The parasite species are distributed differently according to the region, for example, *S. mansoni* that occurs in regions of Brazil, Africa, the Caribbean, the Middle East, Venezuela and Suriname (Brasil, 2020; WHO, 2020g). The control of the disease can be done with the use of anthelmintic drugs (including preventive chemotherapy), in addition to interventions for the control of helminthiasis transmitted by soil, onchocerciasis and lymphatic filariasis (WHO, 2021b). It is a pathology that incapacitates more than it kills, promoting important impacts on the economy and health. In its chronic form it can affect the ability to work and can lead to death. And in children it can cause growth retardation, learning difficulties and anemia. Adding to the female genital schistosomiasis can cause bladder cancer, ectopic pregnancy and kidney and liver failure (WHO, 2020g). For this item, patent data referring to drugs / substances for the control of schistosomiasis in the world in the last 5 years were examined, using a validated search strategy[17]. Based on the strategy described, the documents deposited in relation to the applicants (institutions) and priority countries were analyzed in general. 113 patent documents were found. It can be seen below (Figure 8) that the countries with the largest number

of deposits are China, with 68 documents deposited, followed by the United States of America, with 25 documents. And third, Brazil, with 9 documents deposited. And finally, for EPO, 8 documents were retrieved. Not outstanding partnership was observed between the depositing companies / institutions.

Figure 8. Top patent's offices for the documents obtained from the search strategy for schistosomiasis
Elaborated by the authors. In detail there are described the most applicants by the most priority countries
EPO: European Patent Office
Source: Derwent Innovations Index



From the analysis of patent documents, key findings emerged: the very low number of deposited documents on schistosomiasis, which is characteristic of a neglected tropical disease. **CHINESE ACADEMY OF AGRICULTURAL SCIENCES** (with 13 documents) have applied preparations for medicines or the use of recombinant technology to treat/prevent schistosomiasis (PN: CN 105816421; CN 106554968, respectively) or substances or their derivatives as anti-schistosomiasis to prepare drug/medicine (PN: CN 110856722). Moreover, the use of a small interfering RNA (siRNA) for the preparation of drugs, medicines or vaccines (PN: CN 108795934; CN 108795935; CN 109971762; CN 110016477; CN 110564724; CN 111321145; CN 111705057; CN 111808856; CN 111979239) for the same purpose. For the prevention and treatment of e.g. schistosomiasis, a substance derivative (PN: US 2017174699; WO 2020132071) was claimed by the American Institution **SHY THERAPEUTICS LLC** (2 documents).

Brazilian patent documents have specific scope of protection for schistosomiasis, **UNIV FEDERAL MINAS GERAIS** (3 documents) claimed for a vaccine composition against schistosomiasis (PN: BR 102016017335); the use of a recombinant protein to prepare vaccine and/or a diagnostic kit against schis-

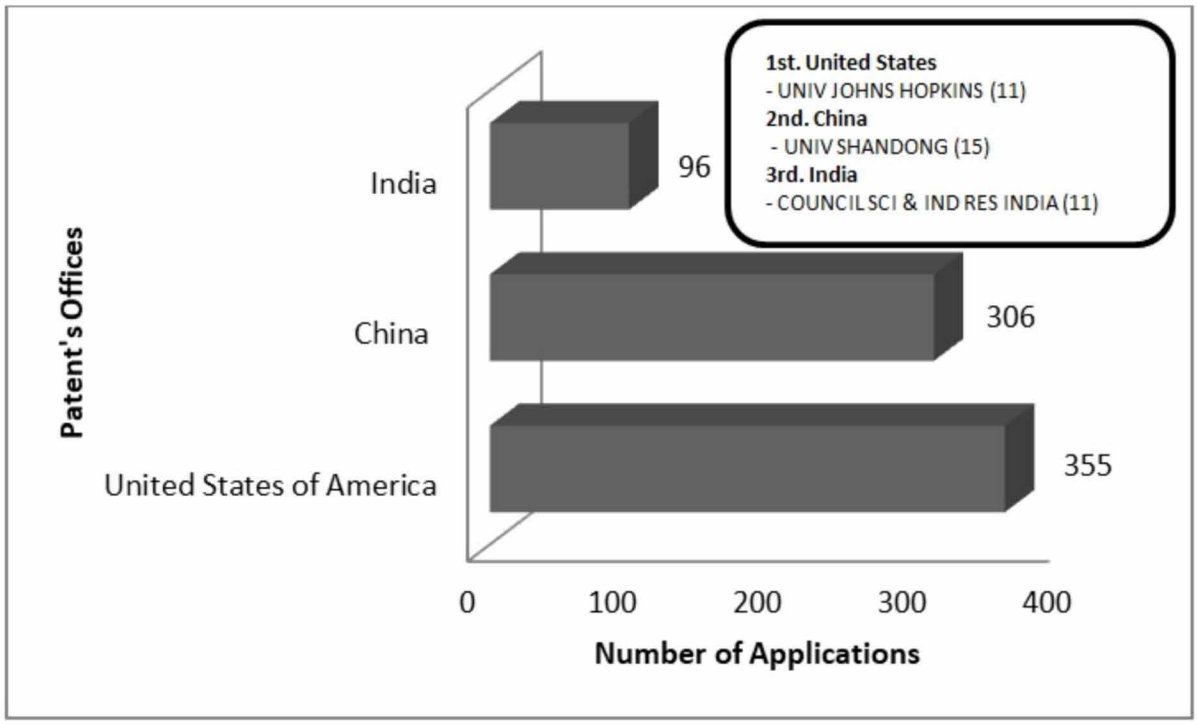
tosomiasis (PN: BR 102015027298). Moreover, a vaccinal composition to treat/prevent schistosomiasis. This document was applied in a partnership between FAPESP FUNDACAO AMPARO A PESQUISA ESTADO and **UNIV FEDERAL MINAS GERAIS** (PN: BR 102017026852). From **ARATINGA BIO AIO** (France) (3), he following documents were applied about a specific scope of genetic immunotherapeutic agents (viral vectors) to treat/prevent e.g. schistosomiasis (PN: WO 2019106432; WO 2018096399; WO 2018096395). The main conclusion that can be drawn from the documents analysis is that the lack of adequate sanitation and drinking water are the main factors for disease's development. For this reason the understanding of the tecnologies' use for development/production of anti schistosomiasis vaccines and new compounds is fundamental for the diseases'management.

Malaria

According to the World Health Organization's World Malaria Report (2020h), the estimated number of malaria cases in 2019 in the 87 endemic regions of the world is 229 million (a lower number than that observed in 2000 - 238 million). Of these regions, 29 account for 95% of cases worldwide, in particular Niger, Mozambique, Uganda, Democratic Republic of Congo and Nigeria. The situation is so serious in some regions of Africa that the forecast is that in Sub-Saharan Africa (Kelland, 2020). However, a reduction in the number of deaths was observed: in 2019 409.000 were documented in contrast to 736,000 in the year 2000. The drop was also observed in the percentage of deaths in children under 5 years old, with 67% in 2019 comparing them at a high rate of 87% in 2000. It is a disease transmitted by the bite of the Anopheles mosquito infected by a parasite of the genus *Plasmodium* (*P. malariae, P. falciparum, P. ovale* or *P. vivax*). The main preventive measure of the disease is the control of the Anopheles vector (including the control of larvae and the reduction of mosquito outbreaks) together with the supply of medicines for the management of infections. It is a pathology that puts half the world's population at risk and as a negligible disease it is within the goals of the WHO Agenda 2030 (SDG 3, target 3.3 - By 2030, end of the epidemics diseases, including malaria) (Doctors without Borders, 2018; UN). Measures to contain the disease are also related to the reach of other SDGs, especially the elimination of poverty (SDG 1); ensuring quality education, promoting learning for all (SDG 4); promotion of gender equality (SDG 5); promoting sustainable growth (SDG 8) and reducing inequalities (SDG 10). Without prejudice, efforts to combat malaria in accordance with the Millennium Development Goals (MDG), with a reduction in child mortality rates in the world and in Africa (MDG 4) and a decrease in the global incidence of malaria until 2015 (MDG 6 Target 6.C: *"to reverse the incidence of malaria and others major diseases"*), which prevented the deaths of approximately 6.2 million people (WHO, 2019a).

The search strategy[18] used in the methodology was restricted to patent documents deposited from the first year of launch of the Sustainable Development Goals (SDGs), 2015. A total of 1031 documents were deposited in that period. The number of deposits taking into account the country where the first deposit took place and its analysis reveals that deposits took place mainly in the United States and China, with 355 and 306 deposits respectively (Figure 9).

Figure 9. The top patent's offices (priority countries) for the documents obtained from the search strategy for malaria
Elaborated by the authors. In detail there are described the most applicants by the most priority countries
Source: Derwent Innovations Index



The American patent documents (**UNIV JOHNS HOPKINS**, with 11 applications) were about drugs (atovaquone) to prevent fungal/parasitic infection and malaria (PN: WO2018204563-A1) or a fusion protein/molecule to treat cancer or infectious diseases, including malaria (PN: WO2018218215-A1). Indeed, antibody/fragmente to identify Plamodium (PN: WO2016205585-A1). From the analysis of the patent documents of the main applicants, it is clear that the Chinese documents (**UNIV SHANDONG** with 15 applications) have a scope of protection directed to the development of new substances and medicines used to treat or prevent diseases, including malaria (PN: CN104529933-A; PN: CN104592114-A; PN: CN105153163-A or PN: CN110950897-A). Finally, the documents which were applied by **COUNCIL SCI & IND RES INDIA** (11 applications), revealed specif and general objects of the invention: antimalarial agents (or including other diseases) (PN: IN200600891-I1; PN: IN201711008388-A; PN: IN201711017655-A; PN: IN201711017656-A) or PN: IN201711019070-A). We can also describe the result of nanotechnology's advantage: a *"polymer-lipid nanocomplex"* with many uses - treatment/ prevention of diseases including malaria, drug delivery, and aqueous absorption and solubilization's increase (PN: WO2020229971-A1). Another point to highlight is that due to the fact that the largest number of registered malaria cases has occurred in the African continent, a complementary search was carried out in order to identify patent documents that had been filed in that continent. The Derwent Innovations Index database used in this research retrieves only patent applications filed in South Africa. Therefore, searches were carried out in two Espacenet databases, from the European Office, and in the

African Regional Intellectual Property Organization (ARIPO). Documents relevant to the topic were found, but were outside the period defined in this research. Although applied patent documents were not specific for malaria, broadly translated our findings indicate that malaria as a negligible disease mainly for the low-income countries. For this disease specifically, the eradication of the Anopheles mosquito is an important control measure.

HIV/AIDS

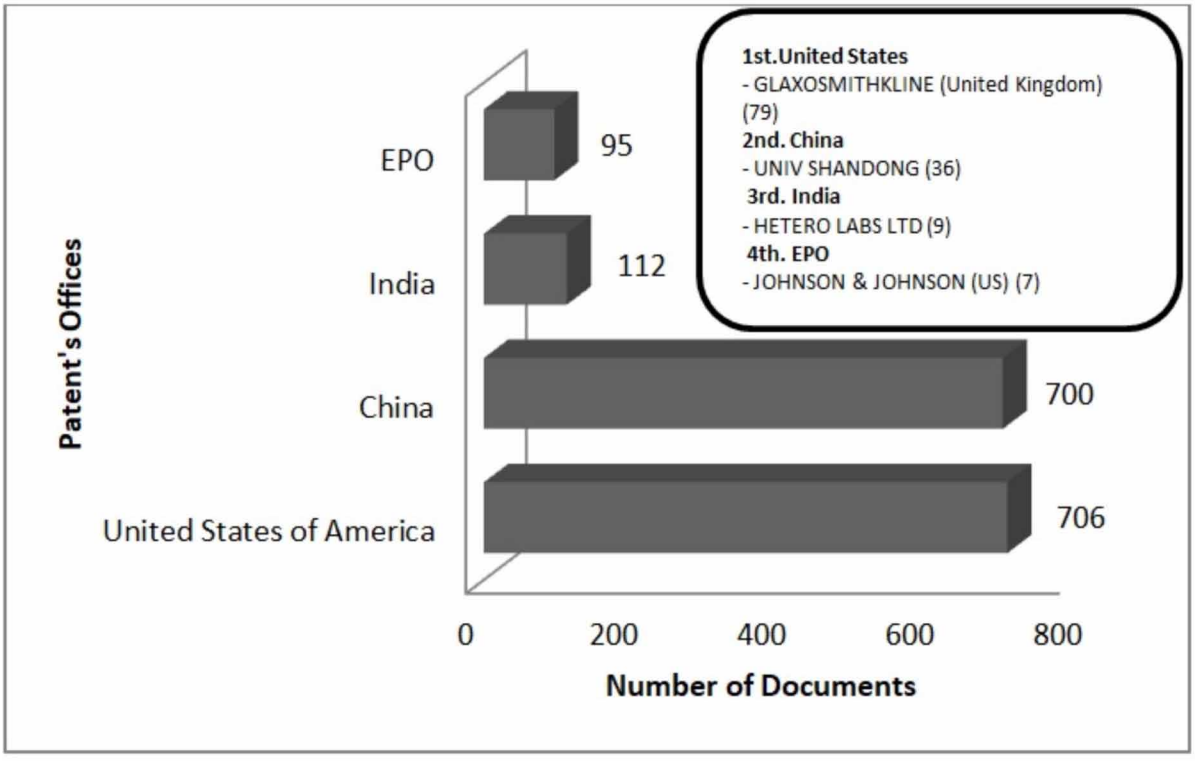
First identified in 1981, HIV has been one of the humanity's most persistent and lethal pandemics. In 2019, an estimated 38 million people were living with HIV and an average of 1.7 million people was infected in the same year. The number of deaths from AIDS is also worrying: an average of 690.000 in 2019 (UNAIDS, 2020). The human immunodeficiency virus (HIV) attacks cells that are responsible for the body's immune defense, leaving the infected person more vulnerable to other diseases. If left untreated, HIV can lead to Acquired Immunodeficiency Syndrome (AIDS), for which there is still no cure. However, currently there are several drugs capable of controlling the disease - the so-called Antiretroviral Therapy - ART, which allows transmission to be prevented and people to live their lives, like so many other chronic diseases. Contagion prevention can also be performed through post and pre-exposure prophylaxis therapies (PEP and PREP, respectively). As of June 2020, more than 26 million people worldwide have accessed ART (HIV.ORG, 2020; UNAIDS, 2020). Despite great advances in the fight against HIV, the epidemic remains a serious public health problem (addressed by SDG 3) worldwide, especially middle-income countries, where about 70% of people with HIV live. As well as low-income countries (SDGs 1 and 10) need funding to maintain essential services for the treatment of HIV (WHO, 2016). The epidemic will never end without people with HIV and their vulnerability being addressed. The disease, which is still stigmatizing, affects many more people who live in fragile communities and who are affected by instability, inequality and prejudice. Efforts to overcome these barriers have promoted advances in relation to human rights (SGD 16), social protection, employment (SDG 8), gender equality (SDG 5) and certainly, more right to health. Thus, the fight against HIV / AIDS is also related to the vulnerability to which people are exposed, and so it is relevant in SDGs not only related to health and well-being (SDG 3), but also to fight against poverty (SDG 1), and against hunger (SDG 2), promoting economic growth (SDG 8), reducing inequality (SDG 10), safer and more resilient cities (SDG 11) and promoting more peaceful and inclusive societies (SDG 16) (UNAIDS, 2021) .

From the strategy search[19] used, 1863 documents were recovered. Once again The United Stated and China were the main applicants with 706 and 700 documents respectively. The British Multinational Pharmaceutical Company **GLAXOSMITHKLINE** is the most applicant with 79 documents (Figure 10).

From its American patent's documents, **GLAXOSMITHKLIN**E (United Kingdom – 79 documents) combinations for HIV treatment were claimed: PN: WO 2018051250; WO 2018042332; WO 2018042331; WO 2019016679; WO 2018044852; WO 2018044853; WO 2018044838; WO 2019069269. The development of new formulations was observed for HIV's treatment (PN: WO 2019074826). Considering the evolution of HIV treatment with new antiretrovirals, our results have demonstrated the great number of new drugs/substances for the treatment and/or prevention of HIV infection, specifically when it is considered the scenario of lifelong therapy: PN: WO 2020157692, WO 2021024114; WO 2020044257; WO 2020031112; WO 2018203235; WO 2020121161; WO 2018127801), including specific HIV integrase inhibitors (PN: WO 2017025914; WO 2020003093; WO 2017029631; WO 2019244066; WO 2017195112; WO 2017195113); nucleotide reverse transcriptase inhibitors (PN: WO 2020222108) and

capsid inhibitors (PN: WO 2020084492). Chinese documents from **UNIV SHANDONG** were also the top in number of applications (36). Concerning the scope of protection, new compounds which are specific for HIV treatment/ prevention or used as anti-AIDS medicines are also claimed (PN: CN 109824756; CN 111285859; CN 111647034; CN 109796418; CN 109369623; CN 105294550; CN 104876860; CN 108586482; CN 111875548), including integrase inhibitors (PN: CN 105418609), *"human immunodeficiency virus-1 ribonuclease H-IN dual target inhibitor"* (PN: CN 108299428) or reverse transcriptase inhibitor (PN: CN 111205287). **HETERO LABS LTD** (9 Indian documents) developed formulations to treat HIV: PN: IN 201841012398; WO 2019130341; IN 201741045372 and WO 2018029561; IN 201841028923 and IN 201741033906. **JOHNSON & JOHNSON** (US) with 7 documents claimed e.g. a "new recombinant HIV envelope protein" to treat/prevent HIV infection (PN: US 2018072777) and a vaccine combination against HIV (PN: US 2019321462). An important finding in the understanding of the applied documents is that China and the United States are the leaders, as the technological developers for the treatment and prevention of the disease which is still stigmatizing and affects many more people who live in fragile communities and who are affected by instability and inequality.

Figure 10. The top 10 patent's office (priority countries) for the documents obtained from the search strategy for HIV/AIDS
Elaborated by the authors. In detail there are described the most applicants by the most priority countries
EPO: European Patent Office
Source: Derwent Innovations Index

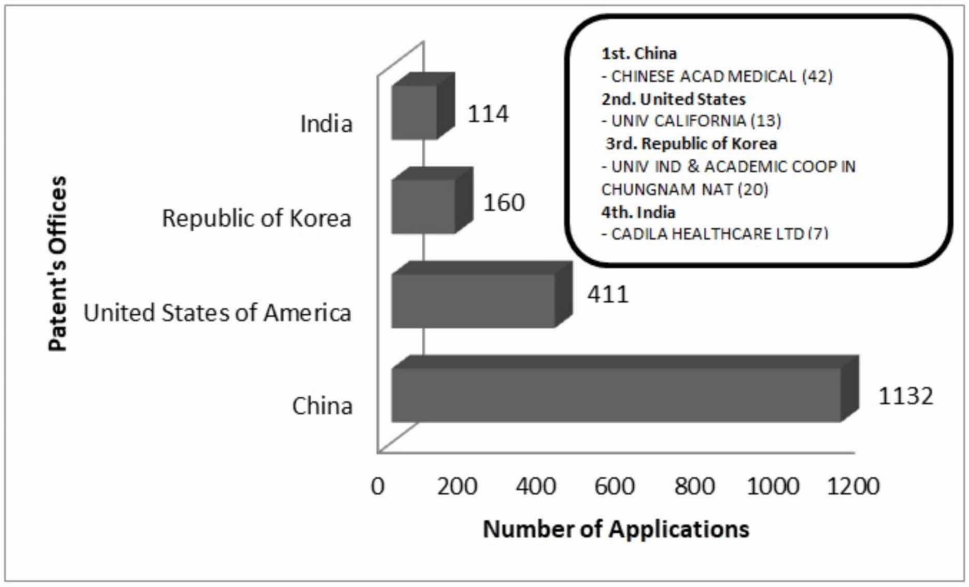


Tuberculosis

The fight against tuberculosis is also within the goals of the WHO Agenda 2030 (SDG 3, target 3.3 - By 2030, end of the epidemics diseases, including tuberculosis (UN). It is the main cause of infectious death in the world: 1.4 million deaths each year and also the main cause of death for people living with HIV[20], which explains the preventive treatment for tuberculosis of people with HIV: 1.8 million of people in 65 countries in 2018, as this protocol decreases tuberculosis mortality rates and also the risk of developing the disease by 40% (UN, TB ALLIANCE, 2021; UNAIDS, 2020). Not only are people with HIV the most vulnerable, but also women (SDG 15) and children[21]. It is a disease responsible for the cycle of poverty (SDG 1), economic devastation in several countries (SDG 8) and also for frightening morbidity and mortality numbers around the world. It is transmitted through the air and caused by the bacterium *Mycobacterium tuberculosis*. The development of strains that are more resistant to drugs is caused by long-term therapies, abandonment of therapies or incorrect administration. These factors generate multidrug-resistant tuberculosis and extensively drug-resistant tuberculosis - XDR-TB, which is present in over 131 countries worldwide. Resistant types make treatment more difficult, time-consuming and have worse results, in addition to significant social and economic costs: The estimated global cost of MDR-TB is $ 16.7 trillion by 2050). Therefore, rapid treatments and the development of diagnoses for resistant tuberculosis are necessary (TB Alliance, 2021; WHO, 2021c). The impact of COVID-19 was another challenge for this very challenging scenario: 0.2-0.4 million deaths from tuberculosis in 2020 alone, with rates of drop in both detection and treatment around 25-50% in one period of 3 months. The declines in the number of diagnoses in January-June 2020 occurred in countries that account for more than 44% of tuberculosis cases in the world: India, South Africa, Philippines and Indonesia (WHO, 2020i).

From the document patent strategy[22], 2079 were recovered main applicants are described below (Figure 11).

Figure 11. The top patent's offices (priority countries) for the documents obtained from the Tuberculose's search strategy
Source: Elaborated by the authors based on Derwent Innovations Index



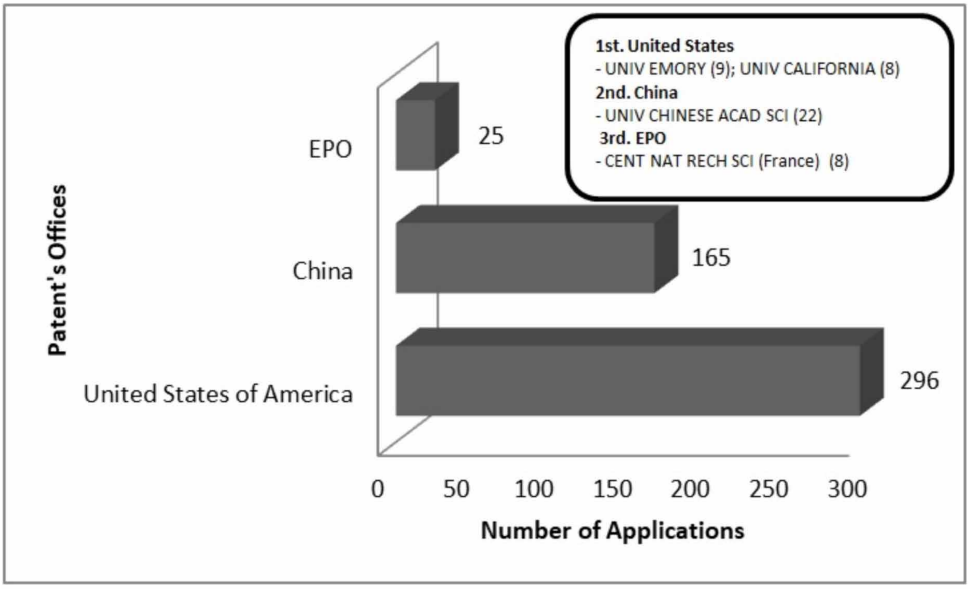
Patent document's analysis highlights the scope of protection, described for main institutions from China, United States, Republic of Korea and India. The documents from the leading applicant (42 applications), **CHINESE ACAD MEDICAL SCI**, revealed a scope related to the development of substances/medicines and their derivatives for treatment/prevention of infectious diseases, including tuberculosis. The examples can be listed in the following applications: PN: CN 106518964 and CN 106167464). Moreover, to treat/to prevent infectious diseases which are caused by *Mycobacterium tuberculosis* substances are claimed (PN: CN 108239098; CN 110759889; WO 2018214639; CN 108947952; CN 109293681; WO 2018177302; WO 2019042267). Substances for *"active tuberculosis, single-drug resistant tuberculosis, multi-drug resistant tuberculosis, extensive multidrug-resistant tuberculosis, extrapulmonary tuberculosis"* were also claimed (PN: CN 110204546; CN 109503631; CN 106543106). Another scope to highlight is the use of reagent to prepare a kit for tuberculosis' diagnosis (exprapulmonary or pulmonar tuberculosis) through reagentes to detect *"expression level of the molecular marker ring finger protein"* (PN: CN 112143792) *or "detect the expression level of molecular marker"* (PN: CN 112143797). The American documents revealed that the leading applicant, **UNIV CALIFORNIA** (13 documents), claimed different scopes about the disease, such as a pharmaceutical composition to treat tuberculosis (PN: WO 2018191628) or an intranasal vaccine against *Mycobacterium tuberculosis* (PN: WO 2019147509). **UNIV IND & ACADEMIC COOP IN CHUNGNAM NAT** has applied 20 patent documents. Among them, stand out the applications on anti-tuberculosis pharmaceutical compositon to treat/prevent tuberculosis (PN: KR 2019082571; KR 2018121191; US 2019321368) or other diseases, including tuberculosis (PN: KR 2016130706), specially *"multidrug-resistant tuberculosis, pulmonary tuberculosis, lymph node tuberculosis, breast tuberculosis or spinal cord tuberculosis"* (PN: KR 1884770). Besides the development of vaccine to prevent the disease, including kidney tuberculosis, skin tuberculosis and ocular tuberculosis (PN: KR 2020065257). Indian patent assignees, **CADILA HEALTHCARE LTD** has applied 7 documents: the scope of protection is mainly about derivatives compounds to treat diseases, including tuberculosis (PN: WO 2019239382; IN 201821049820; WO 2020234636; WO 2019145919; WO 2020021468). From the second one, new drugs/substances to treat tuberculosis were claimed (PN: IN 201502838; IN 201503433; IN 201711010231). Results provided a basis for the continuity of efforts in the development of compounds for diagnosis and treatments, especially of resistant strains, since tuberculosis is still a great challenge as one of the main causes of death from infectious disease.

Zika

First discovered in 1947 and identified in 1952 in humans, the Zika virus (name from the Zika Forest in Uganda where it is first identified in monkeys) is a flavivirus that can be transmitted by mosquito bites of the genus *Aedes*, by vertical transmission (pregnant woman to the fetus), sexual intercourse and probably by blood transfusion. Although the symptoms related to the disease (joint pain, headache, skin irritation, muscle pain, fever and red eyes) do not lead in most cases to hospitalizations and deaths, it is a disease of particular concern in pregnant women due to the risk of microcephaly[23] in babies (reported in Brazil on October 2015), in addition to other serious brain problems, despite the Congenital Zika Virus Syndrome[24] (CDC, 2019a; CDC, 2020b; WHO, 2018). Guillain-Barré[25] Syndrome (GBS) has also been reported in areas that have had Zika outbreaks and are strongly associated with this disease in a small proportion of people (WHO, 2018; CDC, 2019c). For mosquito-transmitted diseases, as caused by Zika virus, it is important to control the vector (use of larvicides, destruction of larval breeding sites and inseticides) due to the absence of treatment (Sarkar & Gardner, 2016). In 2007 it was first reported an

outbreak of Zika virus disease in the Island of Yap. In 2013, French Polinesia (and other regions in the Pacific) and in 2015, a worry outbreak was reported in Brazil (WHO, 2018). According to World Health Organization (2019b), there are 87 countries/territories with previous or current Zika virus transmission, most of them from Americas (49). In the territories/countries Barbados, Brazil, Colombia, Ecuador, El Salvador, French Guiana, Guatemala, Guyana, Haiti, Honduras, Martinique, Mexico, Panama, Paraguay, Puerto Rico, Saint Martin, Suriname and Venezuela. it was confirmed the autochthonous circulation of Zika virus[26] (February 2014 – January 2016). In 2015 Brazil has reported 76 patients in the state of Bahia with neurological syndromes: 55% (42 patients) were diagnosed with GBS, and among them 62% (26 patients) has symptoms of Zika Virus Infection (ZIKV Infection). Above all, it seems that there is a correlation between the circulation of Zika virus and the increase of autoimmune and neurological syndromes, including, GBS and congenital anomalies (PAHO/WHO, 2016). To describe the scenario of the patent documents, a strategy search[27] was developed. From it, 592 patent documents were recovered. Most of them, according to priority country were from United States (296 documents) and China (165). It was noted a relationship among the leading applicants, i. e., **PEOPLE'S LIBERATION ARMY**, **UNIV CHINESE ACAD SCI** and **UNIV FUDAN**, were all amongst Chinese Institutions) as showed below (Figure 12).

Figure 12. The 10 leading patent's offices (priority countries) for the documents obtained from the search strategy for Zika
Source: Elaborated by the authors based on Derwent Innovations Index
EPO: European Patent Office



Leading American educational institutions were identified with documents about new substituted substances/compounds to prevent/treat disease as viral infections, including ZIka (PN: WO 2017155923; WO 2017156255; WO 2017189978; WO 2019133712) from **UNIV EMORY** (9 applications) and (PN: WO 2019070709) from **UNIV CALIFORNIA** (8 applications). From Chinese priorities, **UNIV CHI-**

NESE ACAD SCI (22 documents) has applied documents about substances and their derivatives used for the preparation of anti-Zika virus inhibitor medicine (PN: CN 108619133; CN 108619133). Moreover, to treat general viral infections, including Zika virus, diverse patent document were applied (PN: WO 2018210149; CN 108619164, CN 108498528). Indeed, the use of antibodies to be used as Zika virus detection antibody/ to produce a vaccine and/or to develop an antibody drug against Zika virus (PN: CN 109081868; CN 110172095; CN 110066333; CN 106589116) was also claimed. EPO patent documents were represented by the relationship among **CENT NAT RECH SCI** (France) (8 documents) and other institutions with applications related to anti-viral against diseases including Zika (PN: WO 2017102014 - CURIE INST, INSERM INST NAT SANTE, RECH MEDICALE and UNIV AIX-MARSEILLE or WO 2019185579 - INSERM; INST RECH DEV and UNIV REUNION SAINT DENIS). On this basis, it was concluded that it is important to control the vector (use of larvicides, destruction of larval breeding sites and insecticides) due to the absence of treatment. Ongoing developments include vaccine.

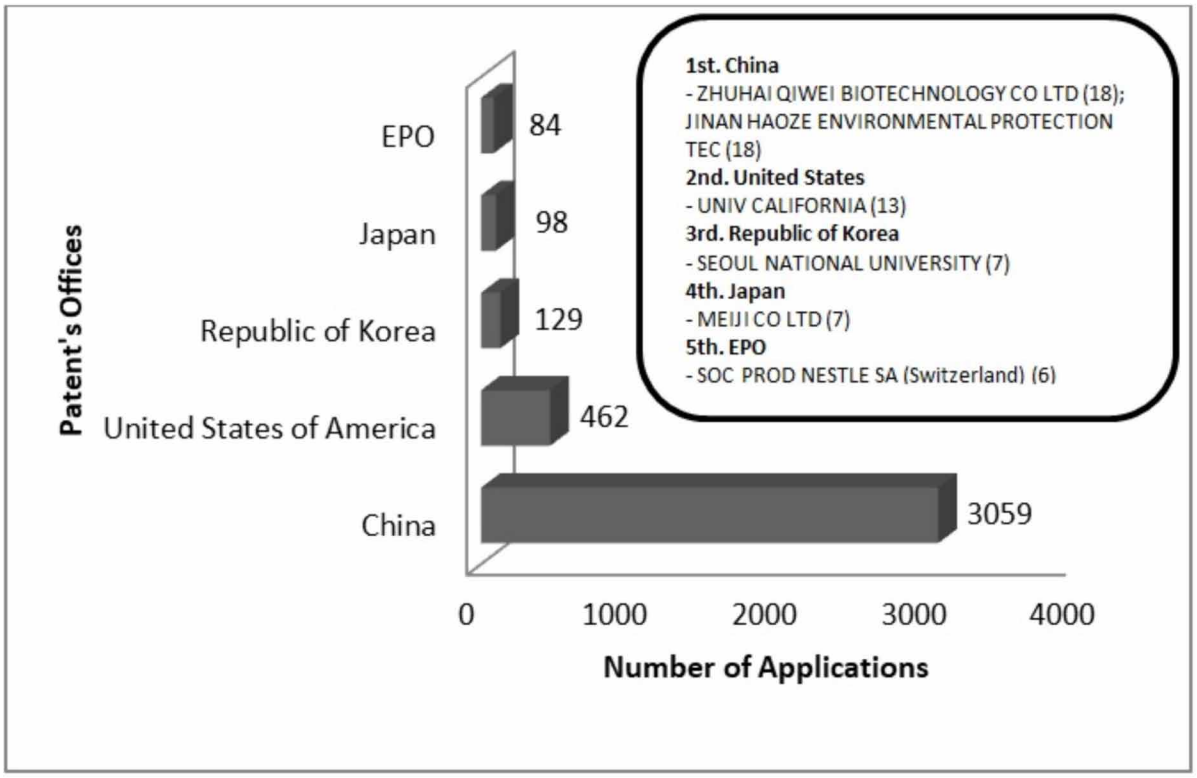
Diarrhea

According to WHO (2017b), "*it is the passage of three or more loose or liquid stools per day (or more frequent passage than is normal for the individual)"*. The disease, which can leave the organism without salts and water is responsible for the second major causes of deaths in children under 5 with 525 000 deaths by year. Diarrhea is usually related to malnutrition, ingestion of contaminated water with animal and human faeces, an intestinal infection caused by parasites, virus or bacteria (*Escherichia coli* and Rotavirus are commom etiological agents), and can be spread from person to person or contaminated water or food. To prevent it, measures as vaccine against rotavirus, health education, personal and food hygiene, hand washing with soap, improved sanitation and access to safe drinking water (WHO, 2017b). According to The Global Burden of Diseases (GBD) Diarrhoeal Disease Collaborators (2018), in undernourished children, people without access to health care, sanitization and safe water, the situation is more worrying and need faster and more effective actions to fight the disease. Primary interventions to reduce its incidence can accelerate the reduction of case numbers in the most vulnerable populations, as universal access to oral rehydration and to the rotavirus vaccine, besides the primary interventions. In conclusion, diarrhea, as an intestinal infection caused by parasites, virus or bacteria, is usually related to malnutrition, ingestion of contaminated water with animal and human face. Education and hygiene are the best precautions to prevent. Development of nutritional compositions to prevent/to treat and vaccines has been done.

The interventions/risks factors of diarrheal disease can be related to susceptiblity (oral rehydration therapy, micronutrients – vitamin A and Zinc deficiency), related to support nutrition (addressed by SDG 2); short gestation, low birthweight, suboptimal breastfeeding, underweight/undernutrition; unsafe sanitation, childhood stunting, underweight and wasting, all related to poverty or hunger (adressed by SDGs 1 and 2), low coverage for rotavirus vaccine (addressed by SDG 3), handwashing with soap, safe drinking water (addressed by SDG 6) (UN; GBD, 2017; International Bank for Reconstruction and Development, 2017).

From the results obtained in the strategy search[28], veterinary deposits were removed from the analysis, resulting in a sample of 4084 patent applications. The numbers of deposits taking into account the country where the first deposit was made (Figure 13).

Figure 13. The top 10 patent's offices (priority countries) for the documents obtained from the search strategy for Diarrhea
Elaborated by the authors
EPO: European Patent Office
Source: Derwent Innovations Index



Among the main depositors, the presence of several individual depositors was verified, especially in deposits with Chinese priority. Therefore, for this analysis, these depositors will not be considered. Medicines/substances/plants to treat diseases related to disturbances in intestinal flora (to regulate intestinal miccroorganisms), including (chronic) diarrhea were claimed. From the Chinese documents, the institution **ZHUHAI QIWEI BIOTECHNOLOGY CO LTD** (18 documents) has applied different preparations such as: Panax notoginseng (PN: CN110404076-A); Angelica (PN: CN110403965-A); cogon grass rhizome (PN: CN110522860-A); Astragalus root (PN: CN110522789-A); rhizoma polygonati (PN: CN110522843-A); rhubarb charcoal (PN: CN110522797-A) or radix curcumae (PN: CN110575517-A). Moreover, from **JINAN HAOZE ENVIRONMENTAL PROTECTION TEC** (18 documents), Traditional Chinese medicines were also observed to treat diarrhea associated to other clinical conditions, such as "*stagnation type diarrhea"* (PN: CN105288437-A); "*upper and lower heat and cold type diarrhea"* (PN: CN105267846-A) or treating "*kidney failure-type diarrhea"* (PN: CN105343849-A). From the American documents, **UNIV CALIFORNIA** (13) applied different objects of protection: subunit vaccine or pharmaceutical composition against astrovirus infection which causes diseases, including diarrhea (PN: WO2016149089-A1; WO2016149103-A1); indeed, the use of "*recombinant or isolated polypeptide"* for its treatment/prevention (PN: US2020087360-A1) or the treatment of bile acid diarrhea

(PN: WO2020251906-A1). Other findings were from the South Korean documents (**UNIV SEOUL NAT** - 7 documents in partnership), such as the applications from **UNIV SEOUL NAT** R & DB FOUND: diarrheal agents (PN: KR2020073665-A); new lactobaccillus strain with antinorovirus activity (PN: KR2017058197-A) or composition to treat diseases, including diarrhea (PN: KR2016119520-A). From Japan, **MEIJI CO LTD** (7) claimed e.g. compositions to the treatment o diseases, including persistent diarrhea (PN: WO2018190407-A1). The analysis of European Patent documents found clear support for the importance of the institution **SOC PROD NESTLE SA** (6 documents) (Switzerland): the application of nutritional compositions to prevent/to treat *"non-rotavirus diarrhea"/*diarrrhea (PN: WO2018024870-A1; WO2018024440-A1) or with at least one fucosylated oligosaccharide (PN: WO2016139330-A1; WO2016139333-A1).

FINAL CONSIDERATIONS

Our results indicate that despite their great relevance to vulnerability to COVID-19, innovations and new developments for both NCDS and CDS have been scarce. This global patent protection landscape constrasts with the unprecedented and accelerated investments in COVID-19 vaccines and drugs.

Nowadays, in the current severe global pandemic scenario, there is a new challenge: people with pre-existing NCD, as diabetes and hypertension seem to have a higher risk of severe COVID-19 disease and death if they are infected. Moreover, the disruption of health services has placed these patients in great vulnerability due to lack of adequate medical resources, mainly in low-income countries. Not only intensive care for life-threatening conditions is needed but also essential care is also urgently required (UN, 2020; WHO, 2020b; WHO, 2020d). In addition, it is important to highlight that communicable diseases, such as **HIV/AIDS**, **Tuberculosis** and other, also deplete the immune system and dramatically increase vulnerability to the COVID-19 pandemic. Our results indicate that in many documents the target disease (NCDS or CDS) was not clearly presented as the only scope of protection.

The analysis of the patent documents revealed relevant characteristics related to the selected (NCDS or CDS). With the understanding that Individual Health is related to Global Health in all its aspects and that everyone has the right to access health services, and especially therapies to control / cure diseases, we focus on the OH / SDG approach.

First, the number of patent deposits of new technologies for prevention, treatment and control of neglected CDS in tropical countries is much lower when compared to NCDS d, which are mainly chronic-degenerative and affect the global population as a result of changes in life style in the contemporary world. Second, these are diseases with a huge consumer market and usually do not rely on government aid programs, contrasting with neglected communicable diseases affecting mainly the poorest populations. And third, in view of this scenario and based on the novel funding and incentive mechanisms for Research, Development and Innovation (R&DI), we can consider some important issues for these NCD: **- Diabetes**: we observed that both companies and universities develop new technologies for the treatment of diabetes, failing however to cooperate in extensive partnerships, which is a basic condition and logical strategy to leverage a technology; **- Hypertension:** As a disease that affects the global population as a whole, and as an important risk factor for cardiovascular disease, among increasing vulnerability to other diseases, both in kidney or brain new drugs and other innovations contributing to its prevention and management have emerged as the target of research by many companies and universities; **- Lung cancer: we** also observed several research projects by several universities and companies,

for the development of new drugs / formulations for the inhibition of tumor growth; **- Obesity:** usually related to lifestyle and also related to the development of technologies for "food safety", it has a large market aimed by multinational pharmaceutical companies and universities; **- Schistosomiasis, malaria and Zika:** neglected diseases, from tropical developing countries, transmissible, with low number of deposits contrasting with other diseases, such as **HIV** and which have deposits (of the main depositors) via PCT (Patent Cooperation Treat) of companies whose countries are not endemic areas, such as the French companies ARATINGA BIO AIO (**schistosomiasis**) and CENT NAT RECH SCI (**Zika**). In addition, they are also subject to research by Government Agencies (e.g. **malaria**: COUNCIL SCI & IND RES INDIA) to the control in many countries. **Tuberculosis** is a severe disease, especially for people who live with **HIV**. For HIV, the number of drugs / therapies is quantitatively much higher, in addition to a variety of drug therapies in different pharmacological targets. However, we observed that both are object of technological development by companies and universities. For **Diarrhea**, we identified novel developments in drugs, nutritional and traditional compositions are the object of research not only for therapies, but in food safety's's field with an important consumer market.

Finally, our results indicate that a paradigm shift based on One Health and SDG approaches is urgently needed to a better understanding of the impact of CDS and NDCS, which became more urgent and serious with COVID-19's pandemic. This will require transdisciplinary research supporting a more integrated health response to these diseases, besides prevention, treatment and control, and adequately understanding and responding to their diverse related co-morbidities, which are dramatically contributing to increase populational vulnerability all over the world. In this neglected area, new incentives to innovation such as "patent pools", prizes and awards, will be thus key for more effective control strategies, supported by comprehensive and integrated One Health and Sustainability approaches.

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ENDNOTES

1 The 169 targets associated to the 17 SDGs can be found in the document from the United Nations: https://sustainabledevelopment.un.org/content/documents/21252030%20Agenda%20for%20Sustainable%20Development%20web.pdf

2 The priority countries search indicates the first deposit with the location of the technological development.

3 Target 3.4: *"By 2030, reduce by one third premature mortality from non-communicable diseases through prevention and treatment and promote mental health and well-being"* (UN).

4 The search was carried out on the Derwent Innovations Index Database using the following terms from MESH Database: Diabetes, Antidiabetic, Hypoglycemic Agents, Antihyperglycemic Agent, Hypoglycemic Drugs in combination with the International Patent Classification A61P 3/10 (*drugs for hyperglycemia, e.g. antidiabetics*) and the Manual Code of Derwent B14-S04 *("Diabetes -This code is used when a drug targets the symptoms and associated disorders"*) and B14-S04A *("Type II diabetes Also known as adult onset diabetes or non-insulin dependent diabetes"*).The search period was 2015-2020. The search was carried out on April 9th, 2021.

5 In the present work, Patent Document (PN) refers to the document which was applied between 2015-2020.

6 Blood pressure is the force of the blood which pushes against the walls of the blood vessels (American Heart Association, 2016).

7 Target 3.5: "Strengthen the prevention and treatment of substance abuse, including narcotic drug abuse and harmful use of alcohol" (UN).

8 Target 3.1: *"By 2030, reduce the global maternal mortality ratio to less than 70 per 100,000 live births"* (UN).

[9] Target 3.2: *"By 2030, end preventable deaths of newborns and children under 5 years of age, with all countries aiming to reduce neonatal mortality to at least as low as 12 per 1,000 live births and under-5 mortality to at least as low as 25 per 1,000 live births"* (UN).

[10] The search was carried out on the Derwent Innovations Index Database using the following terms: Hypertension, High Blood Pressure, Antihypertensive, Anti-Hypertensive, Anti Hypertensive, Diuretic, Adrenergic beta-antagonist, Adrenergic beta-receptor blockader, Beta-adrenergic blocking agent, Adrenergic alpha-antagonist, Alpha-adrenergic receptor blockader, Alpha-adrenergic blocking agent, Adrenergic alpha-receptor blockader, Angiotensin-converting enzyme inhibitor, Kininase II antagonist, Angiotensin-converting enzyme antagonist, Kininase II inhibitor, Calcium channel blocker, Ganglionic blocker, Ganglioplegic agent, Ganglionic blockader, Ganglionic blocking agent, Vasodilator agent, Vasodilator, Vasorelaxant, Vasoactive Antagonist in combination with the International Patent Classification A61P-011 ("disorders of the respiratory system"); A61P 9/12 ("Antihypertensives") and the Manual Codes of Derwent B14-F02B ("Hypotensive genera"), B14-F02B1 ("Angiotensin converting enzyme inhibitor, angiotensin antagonists"**). This code covers renin inhibitors when used as hypotensives; B14-F02B2 ("Calcium antagonists/entry blockers"**) (**These codes are also used for antagonist/inhibitor or receptor antagonist/inhibitor activities.). The search period was 2015-2020. The search was carried out on March 25th, 2021.

[11] Without considering skin cancer. Separately, in women, breast cancer is the most common and in men, prostate cancer (American Cancer Society, 2021).

[12] The search was carried out on the Derwent Innovations Index Database using the following terms from MESH Database: Pulmonary Neoplasm*, Lung Neoplasm*, Lung Cancer*, Pulmonary Cancer*, Cancer of the Lung, Cancer of Lung in combination with the International Patent Classification A61P* (*"specific therapeutic activity of chemical compounds or medicinal preparations"*) and the Manual Code of Derwent B14- H (anticancer drugs). The search period was 2015-2020. The search was carried out on March 19th, 2021. (*indicates the word's variation).

[13] Body mass index (BMI): It is an index that is used to classify in adults obesity or overweight. It is defined as *"the weight in kilograms divided by the square of the height in meters (kg/m2)"* (WHO, 2020e).

[14] Target 3.4: *"By 2030, By 2030, reduce by one third premature mortality from non-communicable diseases through prevention and treatment and promote mental health and well being"*(UN).

[15] The search was carried out on the Derwent Innovations Index Database using the following terms from MESH Database: Obesity, Overweight, Obese, Anti-Obesity Agents, Anti-Obesity Drugs, Antiobesity, Weight-Loss Agents, Weight-Loss Drugs, anorexigenic, anorexiant agent, appetite suppressant, Anorexic, Appetite-Depressing in combination with the International Patent Classification A61P 3/04 (Anorexiants and Anti-obesity Agents) and the Manual Code of Derwent B14-E12 (Anorectic, obesity treatment - appetite depressant)). The search period was 2015-2020. The search was carried out on April 5th, 2021.

[16] Target 3.3: *"By 2030 end the epidemics of AIDS, tuberculosis, malaria, and neglected tropical diseases and combat hepatitis, water-borne diseases, and other communicable diseases"* (UN)

[17] The search was carried out on the Derwent Innovations Index Database using the following terms from MESH Database: Schistosomias * or Bilharzias * or "Katayama Fever" or "Schistoma Infection *". The terminology "snail fever" was also used. The International Patent Classification code used was IPC = A01P * and the Manual Code Codes of the Derwent Innovation Index base used

were B14-B02 or B14-B03 (European Patent Office - EPO). The search period was 2015-2020 and the search was carried out on February 23, 2021 (* indicates the word's variation).

18 The search was carried out on the Derwent Innovations Index Database using the following terms: Plasmodium Infection, Remittent Fever, Marsh Fever, Malaria, Antimalarial in combination with the International Patent Classification A61P 33/06 and the Manual Code of Derwent B14- A03B both referring to antimalarials. The search period was 2015-2020. The search was carried

19 The search was carried out on the Derwent Innovations Index using the following terms: HIV, Human Immunodeficiency Virus, AIDS, Acquired Immunodeficiency Syndrome Virus, Acquired Immune Deficiency Syndrome Virus associated to the terms Anti-HIV, Antiretroviral, Antiretroviral Therapy, Inhibit*, Reverse Transcriptase Inhibit*, Protease Inhibit*, Nucleoside Reverse Transcriptase Inhibit*, Non-Nucleoside Reverse Transcriptase Inhibit*, Fusion Inhibit*, CCR5 Antagonist, Post-Attachment Inhibit*, Integrase Strand Transfer Inhibit*, Integrase Inhibit*. They are used in combination with the IPC A61P 31/18 and the Manual Code of Derwent B14-A02B1 both referring to drugs against HIV. The search priod was 2015-2020. The search was carried out on March 9th, 2021. (* indicates the word's variation).

20 1 in each 3 children deaths related to AIDS are from tuberculosis: from 10 million people with tuberculosis, 9% were HIV positive: (UNAIDS, 2020).

21 1 million children get sick with tuberculosis every year (TB Alliance, 2021).

22 The search was carried out on the Derwent Innovations Index Database using the following terms from Mesh: tuberculos*, Kochs disease, Koch's disease, Koch disease in combination with the International Patent Classification A61P-011 (*"disorders of the respiratory system"*); A61P-031* (*"antiinfectives"*) and the Manual Code of Derwent B14- A (*"pharmaceuticals activities"*). The search period was 2015-2020. The search was carried out on April 2021 (*indicates the word's variation).

23 Microcephaly is a congenital malformation in which the baby's head is significantly smaller in size than expected and usually with impaired brain development (CDC, 2019b).

24 Congenital Zika Virus Syndrome - Five features are only observed in this syndrome that is so rare in other infections: hypertonia with restriction of body movement, damage to the back of the baby's eyes; congenital contractures, decrease of the brain tissue in a specific pattern and the severe microcephaly (CDC, 2020b).

25 It is a sickness of the nervous system where the nerve cells are damaged by the person's own immune system. It is uncommon and causes muscle weakness and in more severe cases, paralysis (CDC, 2019c).

26 The autochthonous circulation: the disease is transmitted within the state itself) of Zika virus was first confirmed in Americas in Chile (February 2014) (PAHO/WHO, 2016).

27 The search was carried out on the Derwent Innovations Index Database using the following terms from MESH: Zika or ZIKV in combination with the International Patent Classification A61P * or the Derwent Manual Code B14-A02 (for antiviral agents). The search period was 2015-2020. The search was carried out on February 22nd, 2021.

28 The search was carried out on the Derwent Innovations Index Database using the following terms from MESH: antidiarrhoeal, diarrhoeal, diarrhea, antidiarrheal, antiperistaltic agent, antiperistaltic drug in combination with the International Patent Classification A61P 1/12 or the Derwent Manual Code B14-E02 (for Antidiarrhoeals). The search period was 2015-2020. The search was carried out on March 18th, 2021.

Chapter 5
Events, Evolution, Controversies in the Implementation of a Health Surveillance Qualification Program

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ABSTRACT

The objective is to describe the implementation and development of the Training Program for Health Surveillance Actions (2013-2018), which focuses on improving the performance of health surveillance. It is an evaluation research with a qualitative method. Key informants were interviewed, and documents and literature were analyzed. The analysis enabled the construction of the timeline, the retrieval of the chronology of the events that marked the development of the program, its implementation, and the identification of innovations and controversies. The authors identified three organizational axes: conception/formulation, implementation/monitoring, evaluation/communication. They found that the program went beyond the traditional approach to surveillance and met regional diversities. There were controversies about the responsibility for monitoring the program's actions, whether they belonged to the technical areas related to the indicators or to the management of the program at the Ministry of Health.

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INTRODUCTION

In this chapter we will show the outcome steps of an evaluation research about the Health Surveillance Actions Qualification Program (PQA-VS), which was done to the Health Surveillance Secretariat (known in Brazil by the initials SVS), a branch of Brazilian Ministry of Health. The study was conducted by the Laboratory of Evaluation and Analysis of Regional Endemics Situations (known as LASER) – a branch of Samuel Pessoa Department of Endemic Disease, Sergio Arouca National School of Public Health (ENSP)/Oswaldo Cruz Foundation (Fiocruz), in a partnership with Health Evaluation, Monitoring and Surveillance Laboratory from Aggeu Magalhães Institute (Fiocruz) and the State Health Secretariat of Pernambuco.

PQA-VS was settled in 2013 (Brasil, 2013) with the aim of improving the performance of health surveillance actions (VS) in the country through financial incentive as an inductor of actions improvement processes. The program has the purpose of reaching favorable results in fourteen indicators, with established goals which are annually revised, related to the country's most prevailing health problems, being the object of health surveillance actions (VS).

The chapter describes the PQA-VS timeline from its origin up to 2018, identifying the relevant events throughout the period, considering the actors, the organizations and the involved context dimensions (Joly *et al*., 2015); and presents an analysis of challenges and potentialities to the full development of the federal manager role as an inductor of VS actions improvement and qualification.

In order to achieve it, a participatory evaluation was carried out with the involvement of stakeholders, aiming to qualify the management processes institutionally developed by the applicant, in this case, the Ministry of Health. When conducting participatory evaluations, different stages of the decision-making process are shared between evaluators and stakeholders. The most regular steps include involving the joint accomplishment of the evaluation design, definition of questions, collection and analysis of evidence, as well as the preparation of reports with their recommendations. The level of participation of the actors or stakeholders will depend on the interests involved and on the context factors which may favor or hinder adherence (Cousins, Whitmore, 1998; Cardoso *et al.*, 2019).

After deciding the type of evaluation to be articulated, relevant research questions and field work, investments were made in the development of evaluative technical capability of the involved individuals, based on a discussion of evaluative methodologies and their main stages in each moment of this construction, as a way of contributing to the incorporation of continuous monitoring and evaluation practices, favoring the proposal appropriation by those involved.

The Timeline that had been traced, besides promoting the understanding of the events implied in the referred program implementation and evolution, served as an instrument of approach between the team of researchers and the team who was demanding the study; furthermore, it allowed the analysis and achievement of the results expected by the program. The reconstitution of this trajectory filled with present contextual elements throughout the implementation period favors the comprehension of how and why the program has worked in certain given context.

BACKGROUND

Monitoring and Surveillance Systems to Improve Health Surveillance Actions

The meaning of the term surveillance has been modified over time, and new paradigms have been discussed in the sense of developing methods which connect the individual to collective levels (Monken, Barcellos, 2005). Due to the changes concerning the socio-sanitary profile and the incorporation of noncommunicable diseases and injuries, as well as the emerging and reemerging diseases and public health emergencies, surveillance model started acting not only on risk factors, but also on the promotion, protection, control and prevention of risks, diseases and injuries (Freitas, 2009).

Regarding the changes in Brazilian population morbimortality pattern associated with the aging process amid huge inequalities, and the establishment of the Unified Health System (SUS), it is observed the reorientation and reorganization of services in addition to a wider view of surveillance (Monken, Barcellos, 2005). Furthermore, the concept of health surveillance emerges, aiming to expand the health services responsibilities, besides dealing with damages and controlling certain risks, which includes the improvement of living conditions and environmental determinants of the health-disease process. Such focus can contribute to the update of concepts which guide the health practices reorganization at the municipal level and review the main methods and techniques to be used in it (Monken, Batistella, 2008).

Since the 1990s, Brazil has been implementing and operationalizing VS actions, considering a wider approach as a space for health practices whose continuous and systematic work processes seek to intervene on the determinants and on the conditions of health problems and needs in a delimited territory. This approach requires the adoption of a health and a health surveillance expanded concept, which enabled a greater capacity of services to act on health problems that imply a risk of dissemination (Carmo, Penna, Oliveira, 2008), helping to redefine its scope, particularly regarding the integration of Epidemiological, Sanitary, Environmental and Occupational Health Surveillance Systems.

The health surveillance attributions are in the center of the 'health situation surveillance' and serve as a foundation for monitoring and evaluation, contributing to a more comprehensive and effective action (Silva, Teixeira, Costa, 2014). The systems for monitoring health policies, programs, and actions, as well as other social interventions, aim to produce continuous and systematic information for guided and convenient actions, searching the achievement of desired results (Garcia, 2015; Jannuzzi, 2016). Once data quality is kept and analyzed and the information is produced in a systematic and relevant way to meet the needs of organizations, the surveillance systems become able to follow up the health indicators, which are the object of interventions/programs, and to promote the efficiency and effectiveness improvement of public health systems (Groseclose, Buckeridge, 2017; Bensyl, Greene-Cramer, 2021).

Defined by the World Health Organization (WHO): '*as the continuous, systematic collection, analysis and interpretation of health-related data needed for the planning, implementation, and evaluation of public health practice*' (WHO, 2017), VS is responsible for recording and analyzing data from public health events designed to produce and use knowledge to provide timely and appropriate response. Variations in its practices are observed in different countries also, in continental dimensions countries, like Brazil, which embodies very distinct living conditions and health systems organizations. In order to be faithfully implemented to their purposes, ensuring the necessary flexibility in different contexts, it is expected that the *public health surveillance systems* accurately define their objectives and the results they aim to achieve. In order to get aligned with such goals, their processes and action mechanisms must be defined to provide valid information for operational effectiveness (Groseclose, Buckeridge, 2017).

The complexity of health problems and the possible solutions in a continental country with deep inequalities reverberate in great variations in public health programs, systems implementation and results which, therefore, require their periodically performance evaluation (CDC, 2011). In the current socio-sanitary scenario, characterized by the triple burden of diseases (acute diseases, diseases due to chronic conditions and external causes), it is observed the demand for health management based on timely actions which expand the system's response capacity (Oliveira, Cruz, 2015). The development of strategies and tools to monitor the performance of VS actions aim to contribute to their improvement, it has been useful to respond to the current needs of VS management in the three governmental spheres (Costa *et al*., 2015).

INCENTIVE MODALITIES FOR IMPROVING HEALTH ACTIONS AND RESULTS IN BRAZIL

Among the programs for improving public health actions designed to VS practices, PQA-VS presents itself as a financial incentive modality, with characteristics of Result-based financing (*RFB*) or Payment for performance. Such incentives consist of resources or material goods being transferred to service providers, conditioned to measurable actions or predefined execution goals achievement, which are increasingly observed in both public and private health systems (Barreto, 2015).

The adoption of this type of proposal emerges as one of the main management strategies implemented in Brazil since the 1990s to promote changes in the quality of public services (Ditterich *et al*., 2012). This management modality aims to turn the management process more flexible and increase the public administration accountability by keeping records of results; and to propose the establishment of agreement mechanisms with clearly defined goals, indicators and charging instruments, enabling the State and the society to have greater control. Thus, management by results has been stood out as an approach typically marked by: (a) the search for effectiveness, reaching the social results desired by the society, which includes social interest services offer compatible with its needs in terms of extension, quality and prices; (b) effectiveness: committing politically and institutionally to competent planning and responsible compliance with its execution; (c) efficiency: using public goods and resources with economy, care and dedication (Barreto, 2015).

Although different models are used in the transfer of resources, offering incentives to produce 'desired behaviors' in managers and professionals with the aim of improving health outcomes remains being a basic premise (Barreto, 2015). By observing the public sector, the management agreement in health services intends to: encourage the decentralization of management; give more responsibility to local managers and teams; control the quantitative and qualitative performance of providers; assist in local planning, encourage the use of information tools and technologies; improve clinic management, pathology management and case management; focus on health needs of the territory population; seek the involvement and commitment of the entire team to achieve results, stimulate the culture of negotiation; induce improvements in processes and expected results; provide more transparency within social control. Methodologies related to management agreements have been widely used in primary health care as an instrument of commitments/agreements/pacts between administrators and municipal services managers, as well as health teams, bringing effective results (Costa, Silva *et al*., 2014).

Among the most common types of payment for performance in public health services, we have the incentive for evaluated performance based on process indicators and health outcomes (institutional

goals); the incentive for evaluated performance using programmatic indicators (individual goals); and a composition of institutional and individual goals. The ways of financial incentive can go directly to health professionals or to the federated entity involved (institutional transfer); or both (professionals and institution). As for the kind of transfer, it can be fixed or variable (Ditterich *et al*., 2012).

In Brazil, management agreements (contractualization among public entities) or management contracts (contractualization with private or nonprofit institutions) and management by results represented the main instruments of the management reform since 1995 (Pereira, 2017). Both contracts and agreements are instruments used to agree or contract institutional objectives and goals between the entity responsible for executing the health actions and the institutional maintainer (Barreto, 2015).

In the VS case, the funding coming from the federal level has this mixed composition, in which there is the Fixed Floor for Health Surveillance (known in Brazil by the initials PFVS) and the Variable Floor for Health Surveillance (known in Brazil by the initials PVVS). The aim of this study, PQA-VS, which is described below, integrates the PVVS, corresponding up to 20% of the annual value of the fixed floor that each Municipal or State Health Secretariat receives as systematic transfer from the federal level (Brasil, 2009b).

PQVA-VS Characteristics and Functioning

PQA-VS was implemented by the Brazilian Ministry of Health in 2013 and regulated in 2017, with the objective of promoting, through a federal financial incentive, the improvement of the health surveillance actions performance (VS) at state, district and municipal ranges. Its guidelines are based on the improvement of actions that involve management, the work process and the results achieved; management based on commitments and results expressed in agreed goals and indicators, and voluntary participation (Brasil, 2013).

It is a panel of indicators that annually evaluates the achievement of goals for the fourteen selected indicators. Since its conception (2013), the indicators and goals have been submitted to reviews with modifications and adjustments in the calculation methods or in the indicators and goals published by annual ordinances. When the present study was being conducted, the indicators in force used to supply it were SIM, SINASC and SI-PNI (three indicators) information systems; samples analyzed for the disinfectant agent residual in the water used for human consumption (one indicator); timely closure of cases at SINAN (one indicator), timely treatment of malaria cases (one indicator); coverage of properties visited for vector control of dengue (an indicator); examined contacts of new leprosy cases (one indicator); examined contacts of new tuberculosis cases (an indicator); amount of syphilis tests per pregnant woman (one indicator); amount of HIV tests taken (one indicator); filling in the 'occupation' field with notifications of work-related diseases and injuries (one indicator); filling in interpersonal and self-inflicted violence field with notifications of 'race/color' (one indicator); and proportion of vaccines selected from the national vaccination calendar (one indicator) (Brasil, 2016).

The number of goals to be achieved varies according to five strata of population size. Cities and Federal District-DF receive a financial incentive of up to 20% of the respective Fixed Floor for Health Surveillance (PFVS) annually, according to the number of goals achieved for their population strata. The State Health Secretariats (known in Brazil by the initials SES) also receive a financial incentive being up to 20% of the respective annual PFVS, according to the percentage of cities which could reach the defined goals strata. Furthermore, at the time of accession, 50% of the incentive value is transferred. SES participation is conditioned to the minimum accession of 60% of the cities in their territory. The federal

and state spheres systematically follow up the indicators according to their level of action, identifying opportunities for improving and providing technical support (Brasil, 2016).

The indicators collected by the official Information Systems of the Unified Health System (SUS) and the databases of the Ministry of Health (known in Brazil by the initials MS) are kept in a computerized application developed specifically for this purpose by the Executive Secretariat of Health Surveillance (SVS/MS), which generates state and municipal reports. The application also provides an action programming tool (available at: http://portalms.saude.gov.br/acoes-e-programas/programa-de-qualificacao-das-acoes-de-vigilancia-em-saude-pqa -vs). By using these computerized systems, the agreed indicators are monitored every four months, allowing timely interventions in ongoing actions.

This first stage of the program performance evaluation study was developed to understand the context, the interests and the process of the PQA-VS implementing to elaborate the intervention design used in the evaluation. This stage also contributed to the identification of the changes and innovations occurred in its evolution, pointing out the main strengths and weaknesses aiming at its development and qualification.

Study Ways for Exploring the PQA-VS Evolution

In the period from April to May, 2018, the research and analysis of official and technical documents (Table 1), and of documents from the literature review on the evaluation of VS programs were conducted, besides individual and collective interviews with key informants, who were responsible for the PQA-VS implementation and management at the Ministry of Health (MS). The evidence sources used in the study allowed the collection of data on the origin and trajectory of PQA-VS and its related policies. The empirical and secondary material analyzed contributed to the elaboration of an auxiliary instrument to work in the identification and systematization of relevant events of the program's trajectory during the study period: PQA-VS Timeline.

The arrangement of these events in a Timeline allows the identification of the main events over a given period, expressing the actors and the context involved, as well as the "turning points" related to the history of an intervention (Joly *et al*., 2015; Figueiró *et al*., 2016). As it has been demonstrated in several studies, comprehending how programs are implemented and evolve makes possible to take actions which promote their sustainability (Oliveira *et al*., 2017; Cazarin *et al*., 2019). The analysis of events related to the development of interventions is particularly important to capture the dynamics of the process, as well as the time gap between the implementation and obtaining its results (Joly *et al*., 2015).

It is also recommended building the Timeline progressively during the case investigation, since the delimitation of the necessary events to explain the maintenance of the programs and the production of their results are not given *a priori* (Joly *et al*., 2015). Thus, as the data was being analyzed, the Timeline was being revised, producing the final design of the PQA-VS trajectory, containing relevant events to its evolution and the contextual aspects involved.

Semi-structured interviews with managers (two), coordinator (one) and technicians (three) were conducted, being six interviews in total. The material was collected and analyzed by the research team, considering the categories initially identified and those which emerged. As categories of analysis for the material exploration, the political and institutional context prior to the program (management models, types of financing, pre-existing programs), the actors and interests (internal VS actors, internal MS actors, regarding other Brazilian health system management spheres) and the consequences (initial strategies, changes in routes, products).

Table 1. Documents used to build the PQA-VS timeline.

Document	Goals
Health VIGISUS Project. Ministry of Health; National Health Foundation, 1998.	It intensifies the structuring and the technical capability of Municipal and State Health Surveillance Systems.
GM/MS Ordinance No. 1,399, of December 15, 1999.	It regulates Basic Operational Norm (NOB) SUS 01/96 regarding the Union, states, cities and the Federal District's competences in the epidemiology and disease control area, defines the funding system and takes other measures.
GM/MS Ordinance No. 64 of May 30, 2008.	It establishes the Health Surveillance Actions Program (PAVS) as a planning tool for defining a guiding list of health surveillance actions which will be operationalized by the three management spheres and takes other measures.
Decree no. 6,860, of May 27, 2009.	It approves the Ministry of Health regulatory structure, establishing the powers of the Health Surveillance Secretariat (SVS/MS) as the National Health Surveillance System manager and as the Health Surveillance Policy formulator, together with the National Health Surveillance Agency
GM/MS Ordinance No. 3,252 of December 22, 2009.	It approves the guidelines for the execution and financing of Health Surveillance actions by the Union, States, Federal District and Cities and takes other measures.
Presidential Decree No. 7,508, of June 28, 2011.	It regulates Law No. 8,080, of September 19, 1990, in order to provide health planning, health care and inter-federative articulation for the Unified Health System - SUS organization, and other measures.
Brazil. Ministry of Health (MS). Health Surveillance Secretariat. Health Surveillance	Guide for programming the actions of the National Health Surveillance System.
GM/MS Ordinance No. 1,378, of July 9, 2013.	It regulates responsibilities and defines guidelines for the execution and financing of Health Surveillance actions by the Union, States, Federal District and Cities, related to the National Health Surveillance System and the National Health Surveillance System.

Source: Created by the elaboration.

The literature review used an integrative approach (Reis *et al*. 2015), following a research plan based on the recommendations contained in the *Cochrane Handbook* (Higgins, Green, 2011), which includes: the definition of the review question; the databases for consult; keywords and search strategies; selection criteria; critical evaluation of studies; data collection and synthesis; interpretation and conclusion.

Literature reviews are considered secondary studies in which methodology based on a defined research question is used, by this question, it is intended to identify, evaluate, select and synthesize evidence from empirical studies that meet predefined eligibility criteria. In the conduction of this type of study,

methods aimed at minimizing bias are used in order to produce more reliable findings which can be used to inform decision making (Galvão, Pereira, 2014).

It is a kind of research which uses the literature on a given topic as data source. This type of investigation provides a summary of evidences related to a specific intervention strategy, through the implementation of explicit and systematic methods of searching, critical appraisal and synthesis of the selected information (Sampaio, Mancini, 2007).

The review was guided by the following research question: What strategies (models, techniques and indicators) for evaluating health surveillance interventions are described in literature, from January 2013 to December 2017?

For this purpose, a bibliographic search of scientific articles published in the last five years was conducted, from January 2013 to December 2017, with themes related to: evaluation of health surveillance interventions (actions, programs and services), published in Portuguese, English or Spanish languages. The study period was selected from the year the program was instituted (2013) to the end of the last year.

The search for publications was conducted in May and June 2018. Guided research was conducted in the databases: LILACS (Latin American & Caribbean Literature in Health Sciences) and SciELO (*Scientific Eletronic Library Online*) with terms related to health evaluation and surveillance which are part of the Health Sciences Descriptors (DECS) list, available on the Virtual Health Library portal (http://decs.bvs.br). Boolean operators (AND/OR) were used.

After pre-tests, the following keywords were identified: 'health evaluation' 'performance' and 'health surveillance'. The publication language (English, Portuguese and Spanish) and the publication period (2013 to 2017) were used as a filter in both databases.

At the end of the survey, duplications were excluded, followed by the reading of the title and author (s) of each article. The selection of texts was conducted in two stages. The first stage consisted in reading the abstracts of each work, which was done by two independent examiners, based on inclusion and exclusion criteria (Table 2).

Table 2. Inclusion and exclusion criteria for articles selection.

Inclusion	Exclusion
Scientific articles.	Gray literature: theses, dissertations monographs, research reports, etc..
Articles published from 2013 to 2015.	Articles published before 2013 anc after 2017.
Articles published in English, Portuguese and Spanish languages.	Articles published in languages othe than English, Portuguese and Spanish
Articles with abstract.	Articles which do not contain abstract.
Articles which provide health surveillance evaluation of actions or programs.	Articles which provide evaluation o other health interventions. Articles which provide professiona evaluation, individual care o medical/biomedical technologies.
Articles which explain the definition of evaluation or the type of evaluation or the criteria for value judgment (included in the second stage).	Articles which do not explain the definition of evaluation or the type o evaluation or the criteria for value judgment (included in the seconc stage).

Source: created by the authors.

Having concluded this phase, the texts with the abstracts that met the inclusion criteria (Table 2) were selected for the second stage, in which it was proceeded the complete texts reading, with another inclusion criterion being considered in this stage: the explanation of the evaluation definition or the type of evaluation or criteria for value judgment.

The included texts had their content analyzed and systematized by a data extraction matrix, containing general characterization items (author/title; publication year; publication country, evaluation type; evaluated intervention and its objectives, evaluation method, criteria and value judgment parameters); structure, evaluated process and results indicators; main study findings (negative and positive) and whether the findings are related to PQA-VS indicators.

The present study was approved by the Research Ethics Committee from Aggeu Magalhães Institute (IAM/Fiocruz-PE) under the registration No. 2,806,465. It met all the Resolution 466/2012 of the National Health Council recommendations.

For all individuals involved in the proposed methodology, the Informed Consent Form (ICF) was obtained, leaving it clear, in the opportunity, the reason, objectives and procedures used in the research.

PQA-VS Timeline Description

The program trajectory can be observed in two phases: its antecedents and the period of implementation. From this exploration point it was possible to elaborate the timeline design presented at the end of the narrative. The antecedents made it possible to understand the active political-institutional context in the phase of the program elaboration and implementation, with the interventions which gave rise to PQA-VS proposal.

PQA-VS antecedents came in the context of the discussion for implementing management tools aiming at Brazilian federal government results, an integral model of the governmental political project from the 1990s and which is in force until the present day. The Managerial Reform of the government promoted constitutional changes to make management more flexible and decentralized, leading to greater regulation and autonomy (Pereira, 2017).

VS decentralization started in 1999, with the publication of the Basic Operational Norms of the Unified Health System (NOB-SUS) (Brasil, 1999). The financing system through agreements and transfer of resources from the federal level to states and cities included resources directly designed for epidemiology and disease control actions. This first agreement modality for health surveillance actions (VS) anticipated a transfer ceiling amount per federative unit according to population strata, being operationalized by the Integrated Pact Program for Epidemiology and Disease Control (PPI-ECD), in force from 1999 to 2004. Subsequently, PPI-ECD was reformulated for Integrated Health Surveillance Pact Program (PPI-VS) (2005-2007).

These inter-federative transfer modalities represented a milestone in the management of VS actions, meeting the needs of states and cities by defining activities and parameters for action program. Concomitantly, the federal level started to invest *in local* actions under VS technical supervision. With the creation of PPI-ECD the process of VS management decentralization was implemented, with the definition of competences in the three levels of management, as well as certification of VS actions for states and cities.

In the same period, in 1999, phase I of the VIGISUS project (VIGISUS I) was set, and in 2004, phase II of the mentioned project (VIGISUS II) was implemented. This project aimed to intensify the technical capability of Municipal and State Health Surveillance Systems. VIGISUS I was restricted to capitals and cities which belong to metropolitan regions and it was an important source of funds to promote

the implementation of VS activities (Oliveira, Cruz, 2017). In 2003, the National Health Surveillance System (SNVS) was settled. VIGISUS II (in force from 2004 to 2009) focused on modernizing SNVS, on strengthening VS management and expanding the operating capacity of state and municipal departments (Brasil, 2004).

A new management device was implemented in the health system after the publication of the Health Pact, in 2006 (Brasil, 2006). It proposed that state and municipal managers took on the management and execution of health actions, including VS ones. The interface with primary health care was equally planned. Accession to the Health Pact promoted important changes, which boosted the process of decentralizing VS actions (Oliveira, Cruz, 2017).

PQA-VS was also influenced by other instruments idealized for monitoring and evaluating health actions at local level, with emphasis on the Evaluation of the Quality Improvement of the Family Health Strategy (AMQ), launched by the Ministry of Health (MS) in 2006 (Brasil, 2009). AMQ, and later AMAQ/PMAQ-AB, despite the differences in terms of guidelines and operationalization, they also aimed at improving the performance of health actions at local level.

Two inter-federative devices for programming VS actions took place from 2007 to 2011 (Programmed Health Surveillance Actions Pact - PAP-VS, 2007-2008; Programmed Health Surveillance Actions- PAVS, 2009-2011). Both worked as instruments for programming VS actions to the inter-federative spheres, considering the local reality, in an increasing and agreed planning (Brasil, 2012). Furthermore, PAVS was linked to the Health Pact (Brasil, 2006) in the achievement of goals settled in the Pact and in other VS priorities and programming process which occurred without interruptions until 2011, with this instrument.

Significant changes in VS management happened with the publication of Presidential Decree No. 7.508/2011 and brought a new management dynamic in the inter-federative relations to SUS institutional scenario (Brasil, 2011). MS was in charge of developing new normative and operational instruments for its implementation, such as the Regional Planning Guidelines and the Organizational Public Health Action Contract (COAP), including the review and the subsequent extinction of the PAVS. Within COAP, although it was not fully accomplished in the country, the creation and qualification of regional thematic care and surveillance networks (urgency and emergency, 'rede cegonha' — assistance from family planning to 28 postpartum days, puerperium, plus the first two years of a child's life - SUS, mental health care, among others) was implemented (Brasil, 2011). With PAVS extinction and the need for strategy to induce improvement in the performance of VS actions in the states and cities, the reason for elaborating and implementing PQA-VS was justified.

Qualification Program of Health Surveillance Actions (PQA-VS) Implementation: Events, Controversies and Consequences

In order to conceive PQA-VS, there were debates with internal and external actors of the Health Surveillance Secretariat and of the Ministry of Health from 2012 to 2013. Among the external actors, the representatives of the National Council of Health Secretaries (known in Brazil by the acronym Conass) and of the National Council of Municipal Secretaries (known in Brazil by the acronym Conasems) stand out; they also actively participated in the VS guidelines and their new conformations since the publication of the Health Pact in 2006.

The review of documents plus individual and group interviews made it possible to identify the political and institutional antecedents which shaped the PQA-VS implementation. Search in literature identified 870 scientific articles, of which 33 were included for final analysis. About 80% of the selected refer-

ences were related to some of the PQA-VS indicators. Tuberculosis control program, health surveillance management and information systems were the most frequently analyzed. The main findings of these studies have been incorporated to the description and analysis below.

During the period, important events were identified, and they are represented in the Program's Evolution Timeline (Figure 1), regarding its beginning and duration. There was an attempt to express how the emergence of events and their consequences acted on other relevant events; on the practices; and on the importance of the program context, which influenced its evolution. The happening of one event caused by another, or others, is represented by the circles and arrows between them (Figueiró *et al*., 2016).

From the relevant events similarity and temporality points, they were grouped, and three structuring organizational axes of the program were recognized. Then, they were reformulated and after being presented and discussed with stakeholders, the following axes were defined: 1. Conception and formulation; 2. Implementation; and 3. Monitoring, Evaluation and Communication.

PQA-VS Timeline design made possible the identification of fifteen events (Figure 1). The Conception and Formulation axis includes events related to institutional regulation and to the legal framework of the program, being considered its axis of institutional structuring. The Implementation axis refers to important events in the development of the program. Eventually, the Monitoring, Evaluation and Communication axis identifies events which relate to the development of monitoring and evaluation (M&E) instruments, besides the program and its results dissemination. The events and their relationship with the context by axis of the Timeline are described below.

Axis 1- Conception and Formulation

PQA-VS was conceived in 2011 and officially implemented in 2013, through GM/MS Ordinance No. 1,708 (Brasil, 2013), being considered an important legal framework of the program, as it delimits its objectives and action scopes. Its general aim is to (Brasil, 2013):

Promote health surveillance actions improvement at state, district and municipal levels and comprises the Accession Phase and the Evaluation Phase.

Before its conception, there was a change in the SVS management, which started counting on a manager with technical-political profile. In that period, it was proposed to qualify public management through measurable results with guaranteed access and quality of health care. Moreover, it was necessary to regulate responsibilities regarding the execution and financing VS actions by federative entities (Brasil, 2013). In this sense, PQA-VS design was created in accordance to VS technical-political project, which in the beginning, was considered as favorable to the implementation of the program.

It was also interesting to reassure the cities autonomy regarding the use of resources, leaving them less conditioned to federal requirements and with greater flexibility of use, considering each region's specificities. It was then presented, as a clear objective of the program, how to change the manner of resources transfer and how to implement basic health surveillance actions which could be conducted by all the cities or, at least, by most of them.

Its funding logic was based on voluntary accession, considering regional differences by defining the achievement of goals according to population strata (Brasil, 2013). Some consultants were hired to assist in the construction of its regulatory and technical framework.

From the publication of the Ordinance that implemented the program, there was a significant municipal accession: almost all cities joined it (97.3%). This process demanded some effort of the internal team to monitor accessions and the initial transfer of resources, which were provided for in the moment of joining it.

As initial criteria for selecting indicators, according to the interviewees' opinion, those considered 'basic' in VS, which could be extracted from official health information systems and which fit three out of four VS axes (once health surveillance is run by another institution): epidemiological surveillance, occupational health surveillance and environmental surveillance. The initial list counted on approximately 40 indicators, presented by the SVS technical and programmatic areas, for the 14 indicators proposed in their implementation, which underwent some adjustments throughout the program implementation.

By the interface between VS and primary care, whose approach has been narrowed since the publication of the Health Pact, the indicators chosen by PQA-VS have great connection with actions developed by PHC teams and endemic community agents (ACE), being mostly process indicators.

In general, the indicators include the quality of main health information systems, vaccination coverage, early detection of some tracer diseases (HIV, syphilis, leprosy and tuberculosis), vector control of arboviruses, opportunity for tracer disease treatment (malaria), water quality (residual chlorine) and filling in specific fields in notification forms (Brasil, 2013).

Besides flexibility, in order to turn the process of transferring financial resources possible, by reaching indicators according to municipal stratification, PQA-VS has added value to cities and states indirectly, once they are able to choose their priorities for action within a list of indicators according to regional specificity.

One year after its implementation, there was a need for regulation and revision of the program. According to the interviewees, the process of building the indicators qualification sheets generated discussions and the need of revising the form of calculation, indicators and goals. During the revising period, new ordinances containing a review of the targets and evaluation methodology were published (2014), besides other two which were published in 2016, proposing changes and adjustments in some indicators.

Information systems supply, being one of VS pillars, which qualification must be implemented, can be ratified by the quantity of PQA-VS indicators in this theme (four), as well as in the studies identified by the literature review on the evaluation of interventions in VS, in which nine of the 33 studies regarded this theme (Fiocruz, 2018). The latter covered issues related to the quality of filling in the variables (n=6), coverage, agreement and implementation (Guimarães *et al*., 2013; Abath *et al*., 2014; Girodo *et al*., 2015; Oliveira *et al*., 2015; Rocha *et al*., 2015; Paula Júnior *et al*., 2017). Among the systems, SINASC was the most frequently evaluated (Guimarães *et al*., 2013; Girodo *et al*.; Oliveira *et al*., 2015).

The legal framework anticipated by the previously mentioned Ordinances (Brasil, 2013; Brasil, 2009) was considered a consolidation component of the program at federal level and also important for its legal establishment, regulation and institutional insertion, although it was insufficient for its internal and external recognition as management policy for VS results.

Axis 2 - Implementation

PQA-VS development had, internally, the guiding role of SVS management mechanisms, such as the expanded (monthly) and executive (weekly) collegiate of managers and technicians, in force until mid-2015. The most representative program indicators were monitored by participants of the collegiate bodies weekly.

The debates promoted in the conception of PQA-VS were submitted to agreements within the Health Surveillance Technical Group (GTVS) and the Tripartite Interagency Commission (CIT) scope. This forum keeps monitoring the program execution and implementation, having less active participation though. As mentioned, the decrease in the representative technical profile in these forums have brought possible losses in the quality of the discussions.

It was also mentioned the scarcity of spaces for discussion between the area responsible for the PQA-VS coordination and other technical areas involved in the execution and implementation of the programmatic actions followed by the suggested indicators. The forums happen annually, however there is little involvement of the SVS internal actors. The SVS collegiate groups deactivation, according to the interviewees, brought unfavorable repercussions to the internal articulation of the program follow up.

Meetings with states and cities happens occasionally, being a weakness observed in the program implementation. The representation of these federative entities, with a hand of the National Council of Health Secretaries (Conass and Conasems), is perceived as being more interested in the transfer of resources and less active in technical discussions and in the qualification of VS actions.

The intense initial accession (approximately 94% of the cities) and the continuity of new accessions, year after year, can be explained by the stimulus of the state sphere being close to the cities, as well as by the current financing format of the actions within the Unified Health System scope. This format of financing spots some municipal dependence on federal financial resources for the execution of actions, which makes managers quickly join the existing induction proposals. In addition, the receipt of the 20% corresponding to the incentive value at the time of joining may also explain the high number of participations.

It was observed that the institutional political instability experienced in the country from 2014 to 2016 did not have any negative influence on the continuity of the program. Throughout that period, there was no reference to reduction of resources programmed for transfers to states and cities, according to the PQA-VS rules. On the other hand, the implementation of the program in the scope of states and cities was penalized in that period due to the contingency of expenses suffered by these entities, unlikely from what was observed at the federal level, which occurred more intensely in 2015. It is pointed out that among the negative aspects related to the VS qualification identified in the literature review, the structure dimension was often the worst evaluated, with emphasis on the insufficiency of human resources, which results in work overload (Fiocruz, 2018).

Being one more contextual reason, the turnover of municipal managers in 2016 (municipal elections) was pointed out as a negative consequence in the continuity of actions and interinstitutional articulation at the time.

Axis 3- Monitoring, Evaluation and Communication

Following up the indicators was one of the most important actions of the program in connection with cities and states, as well as the federal level, while the SVS/MS management collegiate was in force. There were investments in monitoring and programming tools, with the availability of a PQA-VS application for programming actions and reports by those involved (2014), as well as partial monitoring reports, from 2015 on.

However, weaknesses in the monitoring practices were detected, mainly from 2015, when the primacy of the PQA-VS discussions with the management collegiate was extinguished. Both cities and states have stated insufficient federal return regarding the qualification of actions inducing. Technical areas

responsible for programmatic actions in the Ministry of Health have pointed out the same weakness, depending on the profile of the coordinators in SVS different sectors; besides the insufficient achievement evaluation of the PQA-VS goals. However, the possibility of communication between cities and the responsible individual, at the central level, is remarked for clarification on the published results.

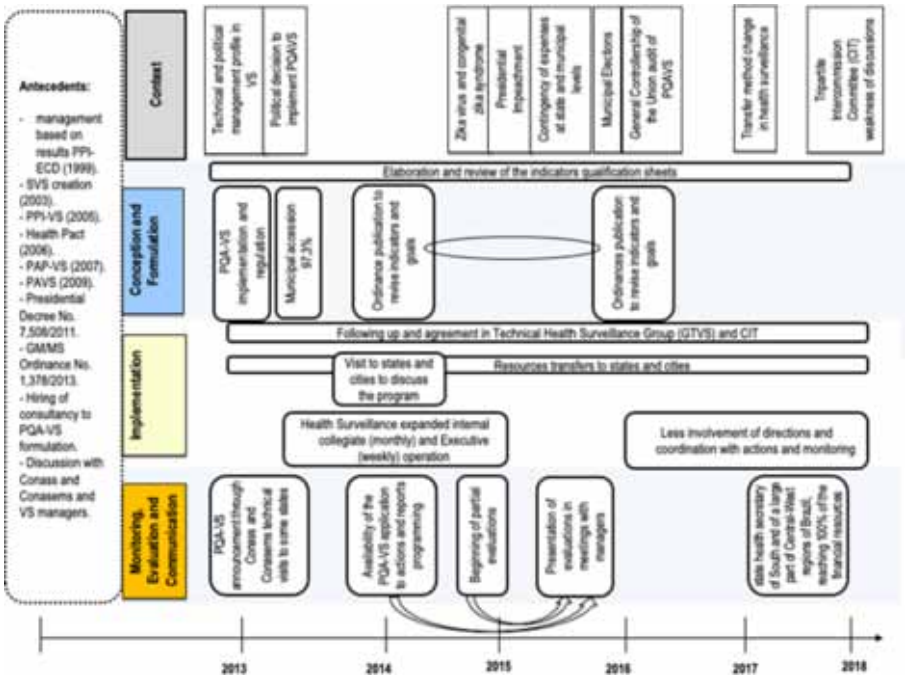
Studies identified through the literature about VS management evaluation were unanimous in pointing out the importance of involving the entire management body in the follow up processes and the co-responsibility of people involved, reinforcing the importance of this axis in the qualification of VS actions (Fiocruz, 2018).

In terms of communication, it was recognized that the investment in institutional dissemination for the program was limited since its conception. Technical visits were conducted in some states, besides visiting five cities in 2013, according to the study empirical data. In the initial phase of the program, by a federal administration initiative, communication happened through official letters to states, alerting them about a problematic situation identified in the data analysis. However, the main way to advertise the program was through the partnership established with Conass and Conasems.

There have been investments in states and cities response capacity over time, with the promotion of technical qualification of professionals by conducting *lato and stricto sensu* training courses in VS, a corroborative action of the federal management. This investment in capacity did not reverberate in researches about PQA-VS, with little scientific production on the subject (Fiocruz, 2018).

However, the duration of the program at the time of this study, which has been five years, may be considered insufficient to produce the expected results and publications (Fiocruz, 2018). Some internal productions and successful livings coming from municipal and state experiences have been presented in forums, congresses and seminars on VS and public health, as well as the dissemination of actions and results achieved by the program.

Figure 1. Timeline of events related to the Health Surveillance Actions Qualification Program performance, Brasilia-DF, 2013 to 2018.
Source: created by the authors.



SOLUTIONS AND RECOMMENDATIONS

Reflections and Learnings Acquired with the Construction of the PQA-VS Timeline

The more general institutional political context favorable to the PQA-VS implementation was due, in its antecedents, to the experiences of VS in planning and strengthening actions at the three management levels. These propositions followed the political project guidelines of the federal sphere focused on management by results, turning to the formulation of methodologies and instruments for M&E of the health system. These experiences counted on the cooperation of education and research institutions in the elaboration of methodologies, such as: AMQ- Evaluation of the Quality Improvement of the Family Health Strategy (Brasil, 2005); PNASS - National Policy for Health Services Evaluation (Brasil, 2007); the PROADESS - Health Systems Performance Evaluation Project (Viacava *et al*., 2004) and the ID-SUS - SUS Performance Index (Oliveira *et al*., 2013).

The SVS internal context presented favorable facts to the PQA-VS implementation, mainly in the previous years and in the first years of the program, such as: filling some gaps that the previous instruments did not anticipate; alignment with the government project (management by results) and the new VS technical-political management project, which occurred from 2011 to 2015.

The VS technical-political management profile and the decision to implement a transfer of financial resources connected with the qualification of actions; linked to some political and institutional experience were identified as being essential for the program implementation. The literature pointed out the role of leaders in the implementation and sustainability of interventions (Oliveira *et al*., 2017; Cazarin *et al*., 2019).

In this context, in which political support and technical competence were allied, the development of strategies for monitoring VS assignments within federated entities in their areas of activity were advantageous. Moreover, the financial award for the fulfillment of goals considered 'basic' in VS was implemented, pointing to the performance praise in reaching goals (meritocracy).

Differently from the traditional focus on VS strategies, which are generally oriented to epidemiological and health surveillance, raising the criticism of efforts focused on the search for information, on the routine of notification and investigation of cases (Carmo, Penna, Oliveira, 2008), PQA-VS innovated by incorporating representative indicators of the main areas in VS (occupational, environmental and epidemiological).

It was also observed that the proposal narrowed the actions between VS and PHC, by contemplating indicators that could be monitored by family health strategy. Along with it, there was the attempt to attend, even if insufficiently, the national diversities with the possibility of focusing on actions according to the regional socio-sanitary profile, by directing efforts towards the most important indicators with a minimum proposed list.

In the following period, national events with the potential to weaken the strategy implementation were observed. Among them, it is stood out the externalities that occurred during the 2015-2017 period, such as: public health emergencies (like the Zika virus epidemic and congenital Zika virus syndrome), which demanded focused efforts; and the country's political and economic situation, with expenditure restraint in states and cities. Moreover, internally, there was a reduction in discussion spaces with the deactivation of management collegiate bodies who were responsible for monitoring the program.

Internally, there is a controversy regarding the sector responsible for the PQA-VS implementation and monitoring. While actions to control diseases and injuries based on the program's indicators should be SVS technical areas' responsibility, a lack of definition of which sectors should hold the indicators monitoring and the dialog between those in charge of the three federal entities remains.

The Timeline analysis until the present study period indicated that the national program is relatively recent (five years of existence), making it difficult to evaluate this intervention in its different implementation contexts. The complexity of the intervention, combined with the adopted implementation model, brought difficulties in the articulations between the intervention (PQA-VS) and its results (long term). In the opinion of Champagne *et al*. (2011), the questions answered by M&E processes must correspond to the development stage of the intervention.

According to Scheirer *et al*. (2012), effective programs aiming to produce the desired results begin with a prolonged period of problem analysis and development of interventions, which means having a test phase before its large-scale implementation, which may require two to five years until reaching the expected results. This period will be extended the more time the product delivery cycles and the iterations necessary for revisions and adjustments take. In addition, as Mark (2012) points out, an extensive program may suffer with changes in context that alter the positive route of its implementation, such as the loss of leadership and team demotivation, situations observed in PQA-VS.

CONCLUSION

The analytical process revealed three organizational axes for implementation: Conception and Formulation, Implementation and Monitoring, Evaluation and Communication. The collected data suggests that the Conception and Formulation axis contributed to the strong insertion of the program, promoting an institutional rooting. The Implementation axis expresses mainly the financial transfers maintenance, even in periods of instability, the indicators revisions and the weakening of SVS internal processes led to critical reflection on the program. As for the Monitoring, Evaluation and Communication axis, the presentation of the program data analysis stands out at specific moments, both internally and externally to SVS, besides the innovation in the construction and availability of the PQA-VS application.

As exposed in the methods item, it is proposed that the present PQA-VS Timeline should be dynamic and, therefore, undergo revisions throughout the continuation of the data analysis collection period. The information produced until the present moment has been analyzed, allowing the definition of events. However, there are gaps in the intervention trajectory, with the accomplishment of new interview turns.

It should be pointed out that the period of the program formulation and implementation (five years), considering its anchoring in different interventions (such as programmatic actions under the responsibility of specific technical areas and other federative entities) and the dependence on different contexts (states and cities), lead to the need of considering the difficulty in achieving the desired results and impacts. Furthermore, the internal changes in the SVS management and the instability of the country's political-institutional context consisted of an important period of its implementation.

However, as a contribution to the improvement of actions and practices, formative evaluations and participatory evaluative processes aim to make the use of their findings easier, they can become allies for the reflection of potentialities and limits, pointing at lessons learned to be observed in the effort of the intervention success.

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Chapter 6
Challenges and Opportunities in the Study of Innovation Ecosystems in the COVID-19 Pandemic Context:
The Role of Open Science in Vaccine Development

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ABSTRACT

The process of knowledge construction, widely discussed in the literature, follows a common structure that encompasses transformation of data into information and then into knowledge, which converges social, technological, organizational, and strategic aspects. The advancement of information technologies and growing global research efforts in the health field has dynamically generated large datasets, thus providing potential innovative solutions to health problems, posing important challenges in selection and interpretation of useful information and possibilities. COVID-19 pandemic has intensified this data generation as results of global efforts, and cooperation has promoted a level of scientific production never experienced before concerning the overcoming of the pandemic. In this context, the search for an effective and safe vaccine that can prevent the spread of this virus has become a common goal of societies, governments, institutions, and companies. These collaborative efforts have contributed to speed up the development of these vaccines at an unprecedented pace in history.

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COVID-19 PANDEMIC CONTEXT: HISTORY, CONFRONTATION STRATEGIES, COLLABORATION AND SCIENTIFIC PRODUCTION

The COVID-19 pandemic[1] that plagues humanity has had impacts on a number of aspects, mainly those related to individual and collective health arising from the severity of the disease and the high transmission capacity of the virus. Besides, other noteworthy aspects are the indirect impacts related to the mental health of the populations, and worsening social inequalities, which increase in this scenario of low economic activity and high world unemployment. In the midst of this crisis, it is possible to identify positive aspects in tackling the pandemic, ranging from solidarity initiatives of humanitarian aid to accelerating strategies for the development of vaccines, supported by actions in science and technology. Open science has become one of the main success factors in speeding the development of these innovations, thus becoming the main hope in solving this challenge of global order, thanks to open access to scientific knowledge, data sharing, and rapid use of information by the ones involved in the technological development of COVID-19 vaccines, as well as their treatment.

The world has surpassed the mark of 130 million infected by SARS-CoV-2, the causative agent of COVID-19, and 2.8 million deaths from the disease, reported to the World Health Organization (WHO) since the beginning of the outbreak that soon became a pandemic[2]. While exposing the seriousness of this crisis, the concept stated by WHO that "no one is safe unless everyone is safe" points to the need for coordinated actions to cope with this pandemic, which should be faced as a global health problem (World Health Organization [WHO], 2021a) that evolves in a frightening way in a highly connected world.

On December 31st, 2019, WHO was alerted to several cases of pneumonia in the city of Wuhan, Hubei province, in the People's Republic of China. It was a new strain (type) of coronavirus that had not been identified in humans before. A week later, on January 7th, 2020, Chinese authorities confirmed that they had identified a new type of coronavirus. A few days later, on January 11th, 2020, the genetic sequence of SARS-CoV-2 was published, thus triggering an intense global activity of Research and Development (R&D) and a race to develop a vaccine against the disease (Pan American Health Organization [PAHO], 2020a; Le et al., 2020).

On January 30th, 2020, WHO declared that the outbreak caused by the new coronavirus (COVID-19) constitutes a Public Health Emergency of International Concern (PHEIC) - the highest alert level in the Organization, as provided by the International Health Regulation. This regulation was approved in 2005 and provides for its application in situations of extreme risk in the spread of diseases on a global level. The PHEIC statement triggers networks, processes, and information flow coordinated by WHO related to notification, monitoring, consultations, risk verification, and WHO cooperation with intergovernmental institutions as well as international organizations (World Health Organization [WHO], 2005).

This was the sixth time in history that a Public Health Emergency of International Concern was declared. The other five were: H1N1 pandemic (2009), international spread of poliovirus (2014), Ebola outbreak in West Africa (2014), Zika virus and increased cases of microcephaly and other congenital malformations (2016), Ebola outbreak in Democratic Republic of the Congo (2018). On March 11th, 2020, COVID-19 was characterized by WHO as a pandemic (Pan American Health Organization [PAHO], 2020b).

In this context, data and information are essential for decision-making and actions to mitigate the risks of spreading the agent that causes PHEIC. Collaboration and sharing of information become strategical and driving factors for evidence-based policies, as well as for the advancement of scientific research, thus contributing to the knowledge of the agent's natural history, diagnoses, and treatments in a situation of great need for a coordinated response.

In this context, in 2014, during the Ebola outbreak in West Africa, difficulties in the collection and sharing of data were reported, even though the disease was considered a Public Health Emergency of International Concern. As pointed out by the World Health Organization (2015), the need for global rules and norms for the sharing and opening of scientific data in such situations became evident. Genomic and epidemiological data as well as those generated through clinical studies and essays were crucial, as well as the publication in preprints, increasing the speed of circulation of information resulting from research. (Jorge & Albagli, 2020, section "The case of the Zika virus").

In October 2020, Tedros Ghebreyesus Adhanom, WHO's head, together with Michelle Bachelet, High Commissioner for Human Rights, and Audrey Azoulay, Director-General of UNESCO, the organization for science, culture, and education launched a joint appeal in favour of "Open Science" as a "fundamental human rights issue" thus ensuring the right to universal access, scientific progress as well as its applications. Open science facilitates scientific collaboration and the exchange of information for the benefit of science itself and society, thus creating more and better scientific knowledge and disseminating it to a wider population.

The exploration of data and information can also be analyzed with the support of knowledge management tools (Maier, 2007; Robson, 2020). The use of current interaction methods with the World Wide Web makes it easy to collect knowledge through different open data sources for science. In addition, these knowledge management tools promote cooperation between researchers with content sharing thus enabling the creation, application, organization, formalization, and knowledge refinement (Nonaka & Takeuchi, 1997; Anand & Singh, 2011). These processes are encompassed in a set, therefore creating new knowledge and expanding the capacity for incremental[3] and radical innovation[4] of researchers from the worldwide network to face the pandemic of COVID-19.

It can be highlighted that in the field of organizational innovations, the adequacy of workflows, and the adoption of optimized practices by regulatory agencies in relation to the evaluation processes for approval of clinical studies and sanitary registration of inputs and products intended to combat COVID-19 was extremely relevant. Added to this, the cooperation initiatives between these agencies seek to harmonize procedures, in addition to sharing of data and assessments, allowing a quick response to society, especially in the context of pandemics.

On the other hand, the availability of data and information on the network, thus characterizing an open science practice, culminating in the rapid process of developing vaccines for COVID-19 among other benefits, setting an example of radical innovations, based on innovative platforms, that were not configured in the field of vaccines until then. New technologies related to the process of genetic sequencing, artificial intelligence and the use of large databases, supported by industry 4.0 corroborated this innovative environment. As examples, initiatives aimed at epidemiological surveillance, with data available in relation to the number of infected and deaths can be cited. Such initiatives, added to other repositories and databases, drive innovation in this sector. Such an environment allows both the scientific community, governments, and organized civil society, quick access to data and strategic information for decision-making, exploring the identified knowledge almost in real-time.

This set of innovations, combined with the rapid sharing of data and networking and added to other factors, enabled the offer of immunizers to the world population in less than a year from the beginning of the fight against the pandemic. This topic will be addressed in detail throughout the chapter. It is noteworthy that the single concept of global health requires actions encompassed beyond the management of health information, in a shared and collaborative way. Global cooperation efforts between all subjects

involved in combating the pandemic and demands for equitable access to strategic inputs, especially vaccines, are necessary to achieve this objective.

This chapter aims to explore the main initiatives and practices adopted by institutions, governments, and society, in the context of combating the COVID-19 pandemic to contribute to the field of health information management, especially in the use of open science principles and concepts, data sharing and networking for technological development.

In order to prepare for the next pandemics, special focus is given to efforts to develop a vaccine to contain the spread of this disease. In this way, this chapter is organized into four sections, which begins with the presentation of the context of the COVID-19 pandemic and its main coping consequences. In sequence, the factors that accelerate the development of vaccines for COVID-19 and the role of open science in this process are explored. Section three presents the challenges and opportunities in information management, given the intense scientific production in this pandemic context. In the final considerations of section four, the importance of open science and data sharing in technological development is emphasized, with a special focus on reaching vaccines in an environment of incentives, cooperation, and public policies.

VACCINES AND ACCELERATING FACTORS: OPEN SCIENCE PRACTICES AS A DRIVER IN TECHNOLOGICAL DEVELOPMENT

The conventional process of developing a vaccine encompasses a number of highly complex technical steps. Until reaching the complex and expensive clinical studies for a new vaccine, such steps include the existing knowledge about the target (pathogen), the selection of the most appropriate antigen, bioprocess and formulation development, stability studies as well as proof-of-concept studies in animal models. In the clinical stage, the vaccine under study must prove to be safe (Phase I), which normally takes from 6 to 12 months of data collection after administration to all the patients. Phase II trials provide an understanding of the most appropriate dosages and administration scheme to proceed to Phase III, which comprises the complete efficacy study, with the consolidation of the safety assessment. As companies gain more confidence that vaccine development will be effective, they begin to prepare for a commercial launch. The entire process usually takes five to ten years (Boston Consulting Group [BCG], 2020; Lurie, Saville, Hatchett & Halton, 2020; Defendi, Madeira & Borschiver, 2021).

Unlike the usual process, the overall scenario for developing COVID-19 vaccines has been accelerated at an unprecedented pace, evidenced by reaching the emergency use authorization in less than a year of the epidemic's emergence as well as the high number of vaccine candidates in advanced clinical development. In April 2021, one year after the characterization of COVID-19 as a pandemic, 273 candidate vaccines in development and 87 in the clinical phase can be identified, of which 24 are in the advanced clinical phase (Phase III) and about 5 vaccines already approved for commercialization (WHO, 2021b).

A great effort of research and global coordination resulting in a rapid process of vaccine development is noticeable. It is important to note that we live in a context of growing competition and limited resources, in which companies need to seek competitive advantages over their competitors in order to survive. Radical changes that took place in the working world, from the end of the 19th century until the end of the 20th century, caused humanity to evolve rapidly from an artisanal society to an industrial society, and gradually to a society of knowledge. The end of the 20th century and the beginning of the 21st century is increasingly characterized by production based on cognitive administration, with an em-

phasis on thinking and learning, on data and information management for the production and exchange of knowledge. Such dynamics intensively improved communications, and rapid development in information technology. Information technologies are reducing the time available for effective organizational decision-making (Santos, 2017), becoming even more evident in the COVID-19 pandemic. Data sharing and intensification of open science practices have provided support for rapid scientific and technological advances in the field of vaccines.

Open science is a broad action involving several practices. According to Albagli, Appel and Maciel (2014), open science is an umbrella term that comprehends multiple levels. As examples, we cite free access to scientific publications, the opening, and sharing of research data, open educational resources, open peer review, and use of free software, open hardware, citizen science, and other initiatives that facilitate the approximation of different actors in scientific practice.

The open science proposal comprises more transparent and collaborative scientific processes, which facilitate reproducibility and enable debates and citizen participation. Such engagement will take place through communication and scientific dissemination actions, aiming to shorten distances between society and scientific knowledge as well as its overall practices. In this way, open science proposes the dialogue and approximations of groups that often act separately, but still that have a lot to advance when they act together.

Based on the work of Defendi, Madeira and Borschiver (2021), this section aims not only to explore the innovation ecosystem, which has enabled the rapid development of COVID-19 vaccines, but also to address the main accelerating factors that have promoted this phenomenon, leveraged by open science practices and recognized as a transversal factor that has supported this rapid technological development process. The acceleration factors identified and explored by Defendi et al. (2021) come from the analysis of the strategies adopted by the developer companies of COVID-19 vaccine candidates. The performance of the main players involved in this process, as multilateral organisms (WHO, UNICEF, Gavi, CEPI), regulatory agencies, and governments were also considered. This analysis was carried out by the monitoring and follow-up of the initiatives and projects led by these players in addition to a bibliographic review on the theme.

Based on the work cited, this section presents three major acceleration factors that hold an important relationship with open science practices, namely: 1) Technological base factor; 2) Factor of R&D strategies and regulatory flexibilities, and; 3) Global coordination, financing, and strategic alliances factor for the production and equitable supply of approved COVID-19 vaccines.

Technological Base Factor

In relation to the technology-based acceleration factor, especially with regard to vaccine development, it is important to consider the accumulation of knowledge developed and acquired over time as an aspect of preparation for combating epidemics, as evidenced in the case of COVID-19. In this sense, some components and underlying aspects that help explain the speed at which companies are advancing in the development of their candidate vaccines against COVID-19 can be highlighted. Such components are the accumulation of technological knowledge and evolution of disciplines and sciences linked directly or indirectly to the field of vaccines; the emergence of innovative development and production platforms; knowledge acquired in the fight against other pandemics and the use of previous studies as a scientific basis.

In the biological sciences, advances in the segments of biotechnology and molecular biology have boosted the capacity for technical understanding and processing of biological analyzes, together with the rapid progress of computing, automation, and evolution in data science. This progress generated a shift in terms of time and cost of genetic sequencing, allowing the identification and sharing of the SARS-CoV-2 genome to the world in about a week. In the SARS epidemic in 2002, this sequencing process took a few months. The sharing of the genetic sequence of a new virus can be considered as the initial stage of the scientific and technological development efforts of candidate vaccines based on innovative platforms, which use the technology of recombinant DNA, such as nucleic acids and viral vectors (Mckinsey, 2020).

Currently, many databases of genomic content accumulate metadata of epidemiological nature from the studied cohorts. An example is UK Biobank (UKB), a major research project that investigates the health and genetics of 500,000 Britons. Launched in 2000, this database has provided many studies and scientific findings that ratify its potential on the knowledge generated through an open access approach (Kaiser & Gilbson, 2019). It would be no different in the COVID-19 pandemic.

The vaccines based on technological advancement in genetic sequencing techniques along with the increasing capacity of nucleic acid synthesizers have proven to be of rapid development. These were the first vaccines to enter clinical studies and receive an emergence use authorization. Based on the knowledge of the virus genome, the development strategies in this type of platform start to focus on the study of genes that encode proteins considered immunogenic, followed by the synthesis of these genes on a larger scale. The validation and production processes are considered simpler and faster, as they are not cell-based. Some limitations are related to the lack of installed capacity and higher production costs (Callaway, 2020).

The platform of vaccines based on viral vectors are considered technological approaches already used in the development of vaccines for other epidemics, as in the case of MERS (Middle East respiratory syndrome coronavirus), Chikungunya, Influenza, Zika, Meningitis B, among other diseases. This platform consists on the insertion of genes (that express immunogenic proteins of the pathogen that causes the disease) in a known and very well characterized virus.

With regard to the establishment of a viral vector as part of the vaccine development process, the structural characterization, quality control, safety and effectiveness profile, once validated to one vaccine, can be considered transposable to other vaccines that use the same vector. Such practice allows greater flexibility and speed in the process of new vaccines or adjustments to combat variants (Le et al., 2020; Callaway, 2020; Defendi et al., 2021).

Another important aspect to highlight is the previous knowledge acquired in the fight against other epidemics of international importance and the use of previous studies related to other etiological agents. More specifically in relation to other viruses of the SARS-CoV-2 family, the pathogens that cause the SARS (severe acute respiratory syndrome) and MERS epidemics caused outbreaks of severe respiratory syndromes associated with high mortality rates in the last 20 years and have stimulated the development of vaccines to contain these diseases (Koirala, Joo, Khatami, Chiu & Britton, 2020). Most COVID-19 vaccine development projects were produced based on these previous studies, which despite being considered different technological platforms, all aimed at protein spike (S) as a target of immunogenic potential. Therefore, the discovery process, phase in which different targets are tested and the first proof of concept *in vitro* is carried out has been shortened. This was possible since the gene that encodes the SARS-CoV-2 protein S is quite similar to the SARS-CoV / SARS protein S gene in sequence and

structure, thus sharing a global protein folding profile similar to that of protein S of the MERS-CoV / MERS virus (Smith et al., 2020).

These examples reinforce the importance of open access to scientific knowledge, especially in emergencies. Since the Zika virus PHEIC in 2016, statements are signed for rapid data sharing and first results in public health emergencies. The first statement was in 2016, followed by the Ebola PHEIC in 2018, and in 2020, during the COVID-19 pandemic. Releasing of results counted with the support of funders, scientific journals, research institutions, multilateral organizations, private companies, societies, and scientific consortia. In the 2016 declaration, the signatories highlighted that:

Journal signatories will make all content concerning the Zika virus free to access. Any data or preprint deposited for unrestricted dissemination ahead of submission of any paper will not pre-empt its publication in these journals. Funder signatories will require researchers undertaking work relevant to public health emergencies to set in place mechanisms to share quality-assured interim and final data as rapidly and widely as possible, including with public health and research communities and the World Health Organization. (Wellcome Trust, 2016, Statement on data sharing in public health emergencies).

In the COVID-19 pandemic, guidelines for open access to publications continue to gain strength, as observed during previous PHEICs. According to Bermúdez-Rodríguez, Silva, Spatti and Monaco (2020, p. 6) the results of studies carried out on scientific production showed that the average monthly growth rate for the period analyzed is of 166%. Such growth occurs both in publications with open access and in closed access, with a greater number of publications within the first set. The authors complement their analysis by explaining that open access to published articles promoted a greater impact of the citation by area of knowledge and a greater diffusion of knowledge when compared to closed access articles. Specifically, open access articles are cited almost 26 times more than the average of articles in the same area of knowledge, and closed access articles are cited almost 10 times more (Bermúdez-Rodríguez, Silva, Spatti & Monaco, 2020, p. 7).

In the field of scientific communication, scientific journals, whether of open or closed access, establish editorial process stages such as screening, peer review, approval, and editing, with deadlines established at each stage, taking an average time until effectively become available to readers, endorsing these publications as reliable and valid. In the case of preprints, the authors submit their research findings on platforms intended for this type of publication, which go through a screening process, made quickly available to the reader, who can comment and suggest revisions directly on the platform. It is a version that has not yet been peer-reviewed and has not gone through the flows of traditional editorial processes.

The use of preprint platforms for quick access to scientific information aimed at the development of vaccines for COVID-19 and underlying innovations, combined with the initiatives to provide access to most international scientific journals, enable a rich environment of technical information, especially concerning innovations in research methods and procedures, as well as its errors and successes. As an example, the two main preprint platforms (medRxiv and bioRxiv) represented a scientific production of 13,377[5] (10,370 in medRxiv and 3,007 in bioRxiv) publications on the COVID-19 theme in less than a year from the beginning of the pandemic.

A preprint posted in April on bioRxiv2 found that many medical-research journals had drastically speeded up publication pipelines for COVID-19 papers. The analysis, which included 14 journals, found that average turnaround times had fallen from 117 to 60 days. (The study omitted several influential journals,

such as JAMA, The Lancet and The New England Journal of Medicine because of a lack of appropriate data). Some journals went from submission to publication in two weeks or less. (Kwon, 2020, p. 131).

R&D Strategies and Regulatory Flexibility Factors

The rapid advance of the development process of COVID-19 vaccines candidates is strongly related to the regulation of the pharmaceutical sector and must be considered. The role of regulatory agencies and international harmonization institutions has been fundamental in combating the COVID-19 pandemic, how they guide vaccine developers in providing support and thus taking action to accelerate the clinical trial approval process, as well as marketing authorizations. This responsibility is accompanied by great pressure, placing regulatory agencies in complex circumstances. While it is expected to accelerate the stages of vaccine development, these agencies must strive for caution and rigor in evaluations of efficacy and especially safety, before moving on to studies in humans and licensing for commercialization (Defendi et al., 2021).

In response to the challenges of the COVID-19 pandemic, many countries, under the leadership of their respective regulatory agencies, such as the European Medicines Agency (EMA), Food and Drug Administration (FDA), and the Agência Nacional de Vigilância Sanitária (ANVISA) have established greater flexibility in the regulatory pathways as well as prioritizing analysis. Such dynamics improve existing processes and mobilize their internal workforce. The processes of rolling submission of data by the developers, the triggering of emergency routes, and the reorganization and internal mobilization of the agencies through task forces, have provided an accelerated response time for the advancement of studies related to COVID-19 vaccines (Lumpkin, 2020; Defendi et al., 2021).

Moving forward in discussions on sharing regulatory data bring numerous advantages, especially in relation to the more harmonized approval process between regulators and pharmaceutical companies. As highlighted in an editorial of Nature Journal, "by assessing the same data, regulators could more easily compare their findings and analyses with those of others, and their decisions would not only be more robust, but also be seen to be more robust" ("COVID vaccines: the world's medical regulators need access to open data", 2020, p. 145).

Organizations and schemes aimed at harmonizing regulatory agencies, such as ICH (International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use) and PICs (Pharmaceutical Inspection Co-operation Scheme) enable the exchange of information between the member agencies of these programs. Such exchange provided diffusion of improvements in regulatory practices and in the sharing of data and opinions, thus resulting in a faster assessment in the process of granting marketing authorization for strategic products to combat pandemics, such as vaccines.

Due to the cost and high failure rates, drug developers generally follow a linear sequence with little overlap between the main stages of development, with several breaks for data analysis or checks on the development of the manufacturing process. The accelerated development of a vaccine in pandemic situations requires a new paradigm in the R&D process. In this sense, companies that develop COVID-19 vaccine candidates adopted R&D strategies that accelerate the development process, such as conducting adaptive clinical studies and phase parallelism (Defendi et al., 2021).

In global crises such as the COVID-19 pandemic, where great amounts of data are generated almost instantly, wide varieties of distributed and decentralized entities are involved in the production and data collection processes. These entities include local and regional government officials, technology developers and suppliers, healthcare institutions, private organizations, as well as local citizens.

As mentioned throughout this section, data and information related to the COVID-19 pandemic and initiatives to overcome it are being generated in an intense and dynamic way, enabling the governments of all levels to tackle the pandemic with effective measures. Thus, the early identification of SARS-CoV-2 infection, the tracking of cases and the transparency of data for the whole society has been an important factor in this process.

According to Tinoco and Borschiver (2020), the fact that the first cases of COVID-19 were identified in China triggered a process of local and regional scientific production, at first more significant in this country, followed later by a global effort by the scientific community. Through a prospective study of scientific articles carried out between February and June 2020, these authors identified that of the total articles produced in that period, 28% were from China, 16% from the United States, and 11% from the United Kingdom. In this sense and joining the spirit of open science at the beginning of the COVID-19 pandemic (February 2020), the Taiwan community promoted collaborative research in support of the development of detection methods, therapies, and a vaccine against COVID-19, by sharing sources, and data to promote progress in academic research (Yong, Su & Yang., 2020). Subsequently, numerous data collection and sharing initiatives were launched around the world with the aim of subsidizing the fight against the pandemic.

In May 2020, Alamo, Reina, Mammarella, & Abella (2020) surveyed several open data initiatives and listed their repositories, demonstrating a rapid effort by institutions and governments to share data on the local, regional and global situation of the pandemic, mainly regarding parameters of infection, transmission, morbidity and mortality. This survey allowed decision-making in terms of measures to control the epidemic by authorities, but also strategic decisions by developer companies of tests, vaccines, and treatments.

Zastrow (2020) also cites some experiences in relation to data. The Nexstrain project, an open-source platform, tracks the spread of viruses through genetic variations in the sequences found. Another situation implies health workers and Chinese researchers who shared the first SARS-CoV-2 virus genome sequence on the online repositories virological.org and GenBank. Even in the face of initial tension and subject to the limits of the Chinese government on what information could be released; Chinese researchers shared the virus sequences, essential for various scientific works, controls, and alerts. The author also cites several datasets on COVID-19 available on the code-sharing GitHub site, including the data underlying various panels and views available worldwide, such as the Johns Hopkins University tracking panel of COVID-19 cases widely available (Zastrow, 2020).

Data sharing projects contributed to the development and availability of vaccines for the population, but also equally important for monitoring the evolution of the virus, such as the "databases of genetic sequences of animal isolates of coronaviruses can be used to model the evolutionary emergence of the viruses" (Koff & Berkley, 2021, p. 758). In the genomics area, there is data sharing in consolidated databases, showing how fundamental the guarantee of access, continuous and real-time exchange is fundamental in these cases.

Sparc Europe, a Dutch foundation is committed to delivering on the promise of open access, open science, open scholarship, and open education, has listed some initiatives that make COVID-19 datasets and data tools available, such as ELIXIR support for SARS-CoV-2 research[6], The COVID Tracking Project[7], Wikidata - WikiProject COVID-19[8], Human Coronaviruses Data Initiative[9] and COVID-19 Open Source Dashboard[10].

In addition to the fast track and open access provided by scientific journals and preprint platforms, another initiative of open data of great importance is formed by the set of clinical trial registration

platforms, such as ClinicalTrial.gov, thus enabling vaccine developers to better understand the mistakes and successes in conducting research conducted concurrently across the world by groups of scientists.

These platforms currently encompass a rich repository of information on the strategies and designs of clinical study protocols developed by several companies around the world. As a good practice of ethics and research in human beings and in addition to transparency and strategic collaboration, the mandatory registration of clinical studies carried out on open access platforms has provided the monitoring and evaluation of the designs and strategies adopted by companies in the accelerated clinical development of COVID-19 vaccine candidates. The analysis of this information is also an important source for studies in the scope of innovation and accelerated drug development process in preparation for future pandemics (Defendi et al., 2021).

Many clinical studies on COVID-19 are being planned, developed and executed at an accelerated pace, with the challenge of always maintaining a focus on scientific rigor.

Clinical trial protocols are already open on thematic platforms such as Clinicaltrials.gov. However, the pandemic showed that data sharing of clinical trial could be advantageous for research; whether to increase transparency, secondary analyzes, Meta-analyzes, reproducibility and confidence of clinical trials results; or even to identify risk profiles and predictors of treatment success. They can assist in evidence-based decision-making and decrease the politicization of decisions during the pandemic, as was the case with (hydroxy-) chloroquine.

A large trial on COVID-19, RECOVERY, announced that it stopped recruitment in the hydroxychloroquine arm because the drug did not show any benefit, consistent with findings of no benefit of hydroxychloroquine in a recent observational study in patients with COVID-19 reporting, and no preventative effects of the drugs in a randomized controlled trial. (Ewers, Ioannidis & Plesnila, 2021, p. 145).

Another important issue for the clinical development of COVID-19 vaccine candidates, considered strategic by the developing companies, concerns access to information related to the epidemiological parameters of the disease in the world, such as the rate and dynamics of territorial infection and transmission, mainly for the conducting efficacy studies (Phase III). This occurs when clinical studies evaluate vaccines for viruses considered new, with no existing protection correlates, that is, biomarkers that can infer protection, as are generally the protective antibody titers for known diseases (Defendi et al., 2021).

These analysis parameters are fundamental for the quick decision-making of companies that develop the COVID-19 vaccines, as well as where the Phase III clinical studies will be carried out. Such studies were accelerated by the joining of several initiatives from institutions, governments and even consortia formed by the media in the daily sharing of data and updating the evolution of the pandemic worldwide.

Global Coordination, Financing and Strategic Alliances Factor

Regarding the global coordination factor, the initiative led by WHO called the ACT Accelerator (The Access to COVID-19 Tools Accelerator) stands out in fighting the COVID-19 pandemic. Since April 2020, the ACT-Accelerator partnership was launched and coordinated by WHO and partners (Bill & Melinda Gates Foundation, CEPI, FIND, Gavi, The Global Fund, Unitaid, Wellcome, and the World Bank). It is a groundbreaking global collaboration to accelerate development, production, and equitable access to COVID-19 tests, treatments, and vaccines supporting the fastest, most coordinated and successful global efforts in history to develop tools to fight a disease. With significant advances in research

and development by academia, private sector and government initiatives, the ACT-Accelerator is on the cusp of securing a way to end the acute phase of the pandemic by deploying the tests, treatments and vaccines the world needs (World Health Organization [WHO], 2021c).

This initiative is based on four pillars of action, three of which are aimed at accelerating the process of development, production, and distribution of vaccines, medicines, and diagnostic tests, and a fourth dedicated to the strengthening of the health system. With regard to the vaccine pillar, the initiative known as the COVAX facility is led by CEPI (The Coalition for Epidemic Preparedness Innovations) and GAVI (The Vaccine Alliance).

The creation of CEPI in 2017 was a global coordination response to tackle pandemics using a strategy based on promoting innovation and the development of vaccine candidates to fight diseases with great potential to cause epidemics, according to the WHO. In 2018, this organization was already promoting the research and development of vaccines based on innovative technologies, such as nucleic acids and viral vectors (Gates, 2018), which became a reality in the fight against COVID-19. The role of this organization in the COVAX facility (the COVID-19 Vaccine Global Access) is to establish a development pipeline funded with donations from various actors, such as governments, private initiatives, and organized civil society. These vaccine development projects are subsidized financially and technically by CEPI support and are diversified in the most varied technological platforms (The Coalition for Epidemic Preparedness Innovations [CEPI], 2021).

Based on the successful development of these vaccines supported by CEPI, the Alliance on Vaccines (GAVI) acts in the process of allocating financial resources for the purchase of immunizers and its equitable distribution, prioritizing the low and middle-income countries with no negotiating conditions to purchase vaccines. Part of GAVI´s (https://www.gavi.org/our-alliance/about, recovered in 4th of July, 2021) mission is to save lives, reduce poverty and protect the world against the threat of epidemics. It has helped to vaccinate more than 882 million children in the world's poorest countries, preventing more than 14 million future deaths.

Concurrently with the development acceleration programs, the production and equitable distribution of COVID-19 vaccines, WHO has been diligently practicing open science and data sharing on the most varied fronts in a collaborative and networked way. Such initiatives include individual and collective health guidelines, contingency plans and social distance, thus offering support to companies that are developing strategic inputs focused on COVID-19, such as vaccines, medications and diagnostics. The R&D Blueprint group and the monitoring of the COVID-19 vaccine development landscape are among the other prominent initiatives led by WHO, which openly informs society about the scientific progress around the world.

The work developed in the R&D Blueprint group strategy aims to respond promptly to outbreaks, preventing epidemics by the gathering of knowledge assimilated by this structure through the actions carried off in past epidemics. Aiming at guiding the efforts of vaccine developers, this group is reactivated as epidemics of international importance emerge, developed a Global Target Product Profile (TPPs) for COVID-19 vaccines, and made it public in March 2020. The TPP describes the minimum and desired attributes required for safe and effective vaccines (World Health Organization [WHO], 2020).

As a by-product and future perspectives, it is expected that these factors, arising from the global emergency in public health, can redirect the Research and Development processes for new drugs, including new vaccines. Additionally, as explained, the role of open science as a transversal factor in scientific and technological progress has been proven, not only in the Zika and Ebola epidemics, but also in the COVID-19 pandemic. In addition to the factors explored here, the rapid process of develop-

ing COVID-19 vaccines highlighted the potential of the combination of intense scientific production, collaboration and data sharing practices. However, for the best use of this potential to generate and use data and technological information, it is necessary to apply tools, methods and approaches that facilitate and guarantee the integrity of the research, discussed in the next section.

CHALLENGES AND OPPORTUNITIES FOR SCIENTIFIC AND TECHNOLOGICAL INNOVATION ECOSYSTEMS USING DATA AND INFORMATION IN THE POST-COVID-19 SCENARIO

Accelerated technological advances to data and information access, transformed into global health knowledge in a short time in the pandemic COVID 19, pointed to the importance of networking in the era of the Knowledge Economy (Castell & Cardoso, 2005). From the cases that started in China at the end of 2019 to the first quarter of 2021, the large volume of data generated needed to be treated and organized for the structuring of scientific knowledge in health.

Currently, there are many technologies and tools that collect and/or generate health-related data, such as cell phone applications that record health habits and routines, medical equipment for exams or treatment of diseases (e.g., pacemakers) that have been in our daily lives for some time, in addition to health services and other information systems. In addition, large amounts of location-based data are collected from IoT (Internet of Things) platforms, social media applications, and mobile devices (Ting, Carin, Dzau & Wong, 2020). In this context, it is essential to use and organize this data ecosystem in order to make it useful for all entities involved in the effective fight of the pandemic (Pan & Zhang, 2020).

The evolution of processing capacity, such as the recent dissemination of sensors and IoT, in addition to new models of data organization, allowed data and information to be quickly accessed, combined, compared, and analyzed in this process, be they images, texts, sounds, posts on social networks and other types of formats

The increase in the processing of the volumes of data generated has been discussed in studies on big data, bringing together reflections on the treatment, analysis, and obtaining of information from data sets too large to be analyzed by traditional systems. Scholars cite 7 “Vs” to define big data, namely:

1. Volume: large volumes of data, usually around Petabytes;
2. Velocity: speed of data capture, processing and availability;
3. Variety: more than different data sources, dealing with different formats and media;
4. Veracity: accuracy and reliability of the information incorporated;
5. Variability: different from Variety, it deals with the understanding and interpretation of data, based on its context;
6. Visualization: how data is presented, interpreted and consumed;
7. Value: generating value from the application of the lessons learned in the analysis and interpretation of data

In addition to reflections on big data, there is also a need to recognize opportunities in the use of technologies, such as artificial intelligence (AI), data mining, machine learning and deep learning, and IoT in scientific responses, making them more accurate, robust and fast. The development of algorithms,

analysis and data processing for the generation of new knowledge related to the prospection of the researched subject and its technological applications.

In the COVID-19 pandemic, there are examples of research being developed with the help of tools linked to AI and machine learning, such as the study by Wardeh, Baylis and Blagrove (2021) that uses AI to detect where the next *new* pathogenic coronavirus could arise. The researchers deployed a meta-set of similarity learners from three complementary perspectives (viral, mammal, and network), predicting which mammals are hosts for multiple coronaviruses. Also developed an algorithm that predicted more potential hosts for new virus strains than those previously detected, identifying species at high risk for coronavirus surveillance (Wardeh, Baylis & Blagrove, 2021).

Another example of the importance of using data can be observed in research that linkage large volumes of information, bringing scientific evidence to complex issues in society. Researches carried out with limited databases can bring different results when compared to the results of researches that linkage numerous databases (Harron et al., 2017). There are countless initiatives to facilitate data linkage in the world, such as the work developed by the Centro de Integração de Dados e Conhecimentos para Saúde (CIDACS) from the Fundação Oswaldo Cruz in Brazil (FIOCRUZ), which allows the linkage of different administrative databases from a research question.

In this context, it is also important to highlight the potential of using different types of data as a source of information on technological innovations used in Technological Prospecting studies, such as patent documents registered in free access databases available at intellectual property offices worldwide (Madeira, Borschiver & Pereira, 2012). Patents need to meet three requirements to be considered an innovation, being necessary to have novelty, inventive activity, and industrial application. Patents are rich in technological information, however, depending on the country, they comply with a confidentiality period after being deposited, and can reach up to 18 months, as in Brazil. In the context of a pandemic, such as COVID-19, this time delays access to information and may hinder the development of new technologies, with a need for quick and effective actions in order to access information.

In the case of the coronavirus pandemic, the majority of patent filings are taking place at the office of the People's Republic of China, where the country's Intellectual Property Law does not provide for a confidentiality period. There are some patent filings available in other countries, such as the Sputnik V vaccine, developed by the Russian state-owned Gamaleya Center, where depositors probably requested the document not to undergo a period of confidentiality. In cases of compliance with the confidentiality period, access to the content of the patent is possible when the scientific article is published after the filing date. In doing so, intellectual property rights will be maintained and the information will be disseminated quicker to the scientific community.

In this scenario of using data and information for scientific and technological development, it is necessary to mention some challenges involving technical, cultural, ethical, and legal aspects.

Despite the inclusion of opening and sharing of data in contracts for scientific cooperation and research funding, Jorge and Albagli (2020) recall that "in situations of public health emergency, requirements for fast access to health data is necessary but collecting data and information from different systems for exchange and sharing is often impossible given the lack of interoperability of data". There are countless types of data such as those produced in genomic, clinical, social, and epidemiological studies. In addition, the records produced in the various health service information systems provided by governments can serve as a source of research. They are heterogeneous data, produced under different business rules and that often cannot be reused. It is necessary to harmonize data collection protocols, with respect to the

principles and guidelines for data management, in addition to observing the ethical and legal principles of the health area for the responsible opening and sharing of data.

In a PHEIC it is important to ensure that rights of access to information and the right to the research of collective interest are respected, in line with the protection of personal data and intellectual property rights, in such a way that one right does not overlap the other. In the context of open science, the proposal is for research to be "as open as possible, as closed as necessary" (European Commission, 2019).

Consider all these demands, the open science movement emerges from the need for an alternative to the numerous challenges and barriers faced by researchers during the research process. Since the 90s of the 20th century, the movement has advocated open access as a way of reducing the barriers between information, researchers, and society, as well as the democratization of knowledge and scientific progress, debating the role of the great scientific publishers that act commercially by monopolizing and controlling the flow of scientific communication. At this point, PHEIC times are exemplary to strengthen these arguments, but on the other hand, they illuminate problems developed from the open access movement, when journals started to charge high values for subscription and publication in open access, with rates known as the Article Processing Charge (APC). Publishers argue that publishing comes at a cost. In this way, subscription journals recover publication costs by charging a fee to access the content.

There are still processes to be discussed and developed so that open access is actually implemented as described in the manifestos launched by its creators, such as the Budapest Declaration (2002), Bethesda Declaration (2003), and Berlin Declaration (2003). Since 2018, Plan S, an initiative supported by cOAlition S, an international consortium of research funding and performing organizations, whose slogan states, "Making full and immediate Open Access a reality", have been debating the issues highlighted here, thus settling the fundamental principles for future open access publications.

Numerous studies emphasize the importance of access to data for research development (Organization for Economic Co-Operation and Development [OECD], 2007; 2021; Murray-Rust, Neylon, Pollock, Wilbanks, & Open Knowledge Foundation, 2009; European Commission, 2012; Pampel & Dallmeier-Tiessen, 2014). Data and information are cumulative elements (do not decrease over time), not rivals (do not oppose each other) and can be non-exclusive (they can be shared, facilitating cooperation between people). The more exclusive, dependent, and commercialized, the greater the concentration of power, the incentive to scientific asymmetries, and therefore situations of inequality perpetuate.

Specifically on the development of the vaccine, the document "Developing and Delivering COVID-19 Vaccines Around the World: An Information Note About Issues with Trade Impact" stands out, raising issues of commercial impact that need to be considered along with the chain vaccine value thus providing a non-exhaustive list of useful resources to help decision making (World Trade Organization, 2020).

In what they called step 1 for the development of the vaccine, this document identifies possible issues of commercial impact to be considered, highlighting those related to data sharing:

Are there policies and regulations in place that promote an effective, timely cross-border exchange of scientific information, data and physical samples both at the research and development stage and at other steps of the vaccine trade value chain?

- *What actions can be taken to encourage the exchange of data about COVID-19 vaccines (e.g. studies, clinical trial data, database access) in order to facilitate international R&D collabora-*

tion? For example, do domestic laws include public interest clauses that allow clinical trial data to be disclosed?

- *How are "legitimate commercial interests" protected with respect to any confidential information submitted to regulators?*
- *How can access to investigational products (e.g., drugs, plasma and other medical supplies) needed in COVID-19 vaccine research be facilitated, and how can the quality and safety of these products be assessed promptly?*
- *How can access to the technical know-how (including as embodied in international standards) needed in COVID-19 research be facilitated?*
- *What information exists about the IP, data and knowledge relative to the development of vaccines, and how can this information be accessed? What mechanisms are available to incentivize development and support IPsharing? Do IP laws provide for research exceptions? What policies apply to IP ensuing from publicly funded research? What forms of intervention may be needed to curb or limit IP rights to ensure necessary access and use? What, if any, access and benefit-sharing regimes for pathogen materials apply?*
- *Are the results of inspections for quality assurance (e.g., good laboratory practices/good clinical practices and other relevant standards or guidelines) shared?* (World Trade Organization, 2020, p. 13).

The questions presented by the World Trade Organization (2020), reflect on access to data and information not available in open databases. In order to continue the development of a vaccine, to seek to minimize its risks, and to support the decision-making of continuity or discontinuity of this process, many of the answers are still in the commercial databases. Consequently, this can be a limiting factor for the laboratory network of developing countries engaged in research, development, and providing high-quality vaccines for the population, as they need access to data and information from paid databases for vaccine production[11].

In Latin America, specifically in Brazil, FIOCRUZ's public laboratory uses more than one commercialized base and specific software for the recovery and treatment of data obtained, thus optimizing the time of accomplishment of some steps through the automation available by software not offered for free, however, this might implicate in manual data cleaning. As they streamline the decision-making process, delineating and testing possible and desirable horizons for today and contributing to the elaboration of the future, the data and information collected, during specific technological processing, must be saved outside the base.

Due to the nature of public procurement, these bases are classified as services offered by specific suppliers, and their purchase may be renewed each year, depending on budget approval. Its high cost, coupled with the bureaucratic procurement process of the public sector, renewal can be time-consuming. In view of this uncertain scenario, this factor may generate a gap in the gathering of new knowledge.

This delay makes it impossible to use commercial bases immediately after the license expires, thus limiting access to more data and information about vaccines, and affecting knowledge on the technological chain.

As noted in the examples covered in this chapter, sharing information and data on the treatment, diagnosis, and prevention of COVID-19 and other product lines brings equitable access to the world population.

In this sense, open science with its data repositories, facilitated the structuring and organization of this data for its sharing and support to knowledge management, making decision-making faster in health in times of pandemic (Magalhães, Hartz, Quoniam, Pereira & Antunes, 2020), and thus promoting the rapid innovation of processes and products globally.

In view of the issues presented here, the COVID-19 pandemic showed the need for a global effort for data governance, essential both for surveillance and political measures to contain the disease, as well as for the development of medicines and vaccines. With data made available, it is possible to develop numerous and different researches in favor of rapid responses to emergencies, that expose the health and life of populations to high risks.

FINAL CONSIDERATIONS

The COVID-19 pandemic raised the importance of open science for a quick response and an effective return to society; a science that is inserted in a context of technological structure, R&D strategies and regulatory flexibilities, programs and initiatives of project financing, and the establishment of collaborations and strategic alliances between the ones involved.

In this sense, a global effort is needed to guide the adoption of new practices, which, although not so recent, was not so common in Science until then. Advances in diverse knowledge such as biological sciences, biotechnology, and molecular biology, computing, automation, and data science are noted, thus showing the importance of cooperation for technological development. Information technologies, which support technological development, combined with the rapid data sharing and networking, in addition to other factors, enabled the offer of immunizers to the world population in less than a year from the beginning of the pandemic.

Since the beginning of the pandemic, the United Nations has been calling for reliable research and scientific information to be made available free of charge in order to accelerate the search for effective vaccines against the SARS-CoV-2 virus and help contain misinformation and "that science can do all the work in its full potential."

According to Unesco, open science is a true "game-changer". By making information widely available, it allows more people to benefit from scientific and technological innovation. Thanks to international collaboration, scientists improve their understanding of the coronavirus with unprecedented speed and openness, adopting the principles of open science in the face of this global health emergency. Journals, universities, private laboratories and data repositories joined the movement, allowing open access to data and information. More than 120,000 publications related to the virus and the pandemic and over 80% are freely available to the public (United Nations, 2021).

The present study pointed out several factors of a technological base such as R&D strategies and regulatory flexibilities, programs and initiatives for financing projects, establishment of collaborations and strategic alliances among the ones involved in the development of these vaccines, but also factors related to global coordination for production and equitable supply of COVID-19 approved vaccines.

The overview of the development of COVID-19 vaccines has shown that the time of development has been accelerated, catalyzed by the sharing of data and intensification of the practice of open science, with more transparent and collaborative scientific processes. This acceleration process is mainly due to factors related to technology, R&D, Regulation, Financing and Cooperation. Global cooperation

efforts are needed between all actors involved in fighting for equitable access to strategic inputs during the pandemic, especially vaccines.

Finally, the global health crisis, which began in 2020, highlighted the urgent need to bring science closer to decision-making and society as a whole. Fighting COVID-19 and disinformation for promoting decision-making based on evidence supported by well-informed citizens have proved to be extremely important in ending the pandemic that has plagued the world for over a year. While collaboration and global exchange of research data have reached unprecedented levels, the challenges remain. There is still an absence of specific standards, coordination and interoperability in world data and this can be considered a major bottleneck in the development and trust of open science. Adequate data governance models, involving the public, private and civil society within a scenario of incentives for researchers with sustainable infrastructures, must be guaranteed.

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ENDNOTES

1 COVID-19 is the disease caused by the SARS-CoV-2 virus, a new virus of the Coronaviridae family, identified after the alert on December 31st, 2019 to the World Health Organization (WHO) about several cases of pneumonia in the city of Wuhan, Hubei province in the People's Republic of China.

2 Information from April 3rd, 2021.

3 Incremental innovation is one that incorporates new elements in products, without changing the basic function of the product.

4 Radical innovation is one in which the element incorporated into the product brings about drastic changes, which may be in the product, process or change in the market.

5 Accessed on February 22nd, 2021.

[6] https://elixir-europe.org/services/covid-19
[7] https://covidtracking.com/
[8] https://www.wikidata.org/wiki/Wikidata:WikiProject_COVID-19
[9] https://about.lens.org/covid-19/
[10] https://towardsdatascience.com/covid-19-open-source-dashboard-fa1d2b4cd985
[11] Developing Countries Vaccine Manufactures Network (DCVMN).

Chapter 7
Modelling Business in Healthcare:
Challenges on Emerging Technology Adoption for Innovative Solutions

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ABSTRACT

The appeal for new business models is at high level nowadays in all market sectors involving all economic agents. Dealing with classical, non-responsive, bureaucratic structures, traditional organizational arrangements impose delays on management, ineffective control features, and, more critical, limitations to innovate. In this chapter, the authors analyze the proposition for new business models with the consideration of two huge pressuring motivations: to innovate in the healthcare sector and adopt emerging technologies. Both dimensions brought opportune facts for business models development and application, but, with an immense and uncontrolled dynamicity, also produced a confused, turbulent scenario where the academic and scientific knowledge, always demanded, was not developed and communicated efficiently. To address this imperfect scenario, the authors present their reflections around perspectives on building and applying business models supported by emerging technologies for the healthcare sector, offering a background to foster these discussions in further studies and decision-making contexts.

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INTRODUCTION

Designing new business models has been both a challenge and a victorious experience for entrepreneurs in the last years. Some of the successful solutions, usually related to modern businesses, such as Uber, AirBnB, Netflix, Soptify, digital banks, among several others, even changed progressively the way companies evaluate, think, and practice their strategies.

In this chapter, we pay attention to business models design in modern times, specially looking for Healthcare sector and emerging technologies application. In this evolving context, both market demands, and fast-moving emerging technologies play a contributive role, as, at the same time, answer tough competition, with intensive rivalry and the offer of solutions which will demand a significant work to answer organizational needs to answer competitive requirements.

Business models are a conception for how one organization will perform, to answer their strategic needs (Osterwalder, Pigneur and Tucci, 2005; Osterwalder and Pigneur, 2012). They are part of the most essential decisions taken by strategists when evaluating value positioning in markets (Magreta, 2002; Casadesus-Massanel and Ricart, 2007; 2011). It is a rich, dynamic background, which is being reviewed along time, with remarkable events in last years, as function of several economic opportunities, together with emerging technologies put available, which supports their design (Jamil and Berwanger, 2019).

Contemplating two ways to advance from the strategy formulation to strategy design, it is opportune to relate the works of Michael Porter (2008) and Henry Mintzberg (2009), when reflections were issued, resulting in different, complementary views for the strategic planning process. In a first glance, it is possible to think about a process – strategic planning – which allows organizational strategists to structure their ideas and those strictly corresponding to a plan, which will be executed. Additionally, however, a continuous monitoring, inserted in this planning process, must also result in an evaluation, which will both continue to address execution characteristics and perspectives and making it possible to learn from the plan operation itself, reaching a learning level (Porter and Magretta, 2011).

As an opportune supporting alternative, several technological tools and their associated methods were put available in the last years, when the information technology market gained abilities on the availability of newest infrastructure, this way offering more and more information and communication technologies (ICT) (Lacerda and Jamil, 2020). Their relationship with organizational management is still on study, and this chapter intends to contribute with this chapter, as to launch an observation to the Healthcare sector.

For the Healthcare sector, it is undeniable that it was already looking for business model (BM) solutions based on cost management, productive chain optimization, information technology insertion, strategic design, productivity, among many other aspects when the Covid-19 Pandemic emerged as, likely, the most dramatic event in the mankind´s history. With severe impacts because of hundreds of thousands dead victims and the economic downturn, the Pandemic exposed the Healthcare sector and pressured it to adopt more flexibility, under a terrible wave of circumstances.

This is the scenario where we will update our previous findings in IGI publications, noticeable Jamil, Vieira and Xavier (2019), where analytics data treatment, to produce knowledge, was analyzed by authors regarding information architecture. In this seminal work, authors launched some observations and analysis about information technology resources being applied in a similar context where this chapter now focus.

Information and communication technologies can foster and impact business models design (Jamil and Berwanger, 2019; Lacerda and Jamil, 2020). This way, it is important to consolidate this thinking on choosing a competitive sector, as Healthcare, to identify and address real potentialities on evaluation new business models propositions. About these propositions, they can be considered new if they present

changes to stable, used paradigms and, obviously, if brand new ideas are defined towards its implementation. As stated by authors such as Schumpeter (1934) and Utterback (1996), business models can be not only a source of competitive innovation, but even a dimension for innovative platforms, where ideas and proposals can emerge as one of the most reliable and potential management relationships, both for applied innovation and BM design.

This way, it can be affirmed that in this chapter we address a good opportunity as to appreciate how business models design, answering to innovation requests by Healthcare organizations, could be understood and conceived. An initial view for innovation – business models – management – emerging technologies is searched by authors, corresponding both as a conceptual leverage work and an understanding on how it can be practiced in further studies and real implementations.

The following text is organized in the following sections. We started mainly affirming the potentials of this study, detailing the opportunities where we intend to promote the planned discussion. After this introduction, an applied conceptual background review will be worked, to leverage the expressive set of concepts approached in this study and, in the after, how they relate to each other. Interestingly, this theoretical review opens one discussion regarding the conceptualization itself and allows, in progress, as it is desired by the authors, a continuity of this discussion, as to develop more analysis regarding the concepts and how they can form a base for additional works.

After these two initial sections, a practical view of this concepts is practiced, inviting the reader to understand that conceptual network in practical terms, followed by some case studies discussions and a conclusion where this chapter work is summarized.

CONCEPT THEORETICAL BACKGROUND

This section has the objective to define a formal concept base to enable the chapter development. Here the main and accessory concepts will be discussed and affirmatively enunciated, granting chapter intended legibility, theoretical and practical works and, at last, the conclusive results.

Business Models

Business models are high-level conceptions which produce a consolidated organizational view, integrated to fulfill customers' requirements, adjusting all components to a perfectly managed operation. One organization execute their activities under plans, specific structural designs (which encompass communications, for example), directions, decision-making processes, systems (including information and technology-supported ones), methods and other business components which must be aligned to a strategic objective. This alignment results in the adopted business model. It will define how the organization performs internally and, mainly, how it produces, offers its results, and interacts with external players and related organizations. BMs are not a simple plot, not a mere design or documented principle, but stable relationships, formal and informal agreements, goals definition and achievement methods, human resources specifications and managerial implications, technological platforms design, processes definitions and project design methodologies.

As conceived by Casadesus-Massanel and Ricart (2007;2012) and Zott, Amit & Massa (2011), business models are potential strategic choices, becoming another recent factor to be evaluated in the modern scenario strategic planning. In the following, we cover some usual definitions, just presenting them as

a possible outcome for this chapter, as, even considered as stable ideas, they are, at most, starting to be efficiently adopted by companies and organizations around the world, always demanding a better reflection for their successful adoption.

Known as a case of success, marketplace model is regarded as one strategic solution as to develop an alternative communication platform which connects the potential owner of an idle or available resource to an interested customer (Eyring, Johnson & Nair, 2011; Mullins, 2014). This model can be found in the solutions provided by several of the actual competitive leaders of the known "shared economy", like Uber, Spotify, AirBnB, etc. and is adopted by companies which also compete in the B2B arena or even offer their products and services using a formal, presential shop. Some offers in Healthcare are found, as websites and "apps" which provide specialized services, such as physiotherapists, fitness and wellness professional works, nursing for elderly, among others, using the contemporary fashion of "choosing the best professional who matches user´s need from a catalog". It is possible to state that, even based on a classical principal, quite simple to adopt, marketplaces are supported by an information technology platform, which serves for value addition in the overall offer, promoting better interface, easiness of procurement and choice, from other possibilities.

For example, the Waze platform, for traffic information and management is a potential platform which helps entrepreneurs on integrating a distribution and delivery commercial feature, bringing more flexibility for users and transparently integrating its services in a marketplace designed application. Usually, resources like big data and analytics are also available, becoming a two-way advantageous business model, as it can be used to improve provider-customer relationships, improving choices by the users and customized answers from the provider (Tennant, 2018; SAS, 2020).

Marketplaces, however, present some strategic risks. In the case of Uber, for instance, the resource was rapidly adopted by competitors and even replaced competitors (as taxi companies), becoming a factor of leveraging, not for difference, as its mere reproduction was possible. Moreover, biases introduced in the resources owner's database, favoring a specific provider – driver, host of an apartment, etc. – can be perceived by the user as a reliability damage, this way, avoiding platform´s further usage. Obviously, this lead to an inevitable conclusion: marketplaces, as to becoming a well-known business model, is turning to become a standard, not producing essentially expressive competitive advantage, faced by the market as a way to provide a typical service, adopted as a patter for all competitors. However, none of these factors are motivations to deny its application in Healthcare services and even as a source of competitive advantage – if it is well monitored and updated – of strategic innovation for these organizations.

Another family of business model conceived and adopted nowadays is those identified with the acronym's IaaS, SaaS and PaaS (this list usually receives more conceptions and contributions). The main principle in these models, as discussed by Jamil (2018) and Jamil and Berwanger (2019) is the "as a service", referring to the possibility to align, dynamically, business components to serve a specific need from a customer. These designs resemble the original definitions for client-server computer services configurations, addressed by Tannembaun and Wheterall (2010), where these authors mentioned this adaptation and alignment considering the main demands from an external user of a computer network.

Those three initial definitions relate to what is to put available to be served, to be implemented, completing the platform already in use by the customer. This way, IaaS, infrastructure as a service, where the user has more ownership and isolated resources, define a composition where the collective provision will answer for adaptable functions, as, thinking about a distributed computer model, servers and associated services, storage and networking. For the intermediate level, we have the PaaS, or platform as a service, where the user solely have to manage his or her own applications and data. Finally, the model SaaS,

software as a service, or "serving" as a service, encompasses all the information or basic technological services, allowing to be shared or distributed for interested users.

SaaS, for example, is the model which propels several of "media streaming" services, as video and audio sharing platforms, such as Netflix, Deezer, Amazon Prime, SoundCloud, Spotify, among many others. For these platforms, the user must only access it directly or through a partner website or app, as an embedded application, and interact with the effective platform. Some of the most successful cloud service providers, on the other hand, adopt the IaaS model, enabling the address of their services by an interested user and, this way, with the responsibilities to provide remaining layers of governance, networking, interfaces, etc (Mullins, 2014; Interoute, 2018).

Based on information technology-based services, these models were adapted by businesspeople, to encompass more or lower number of resources, encapsuled by the original owner and accessed or served for the final user, becoming a business model definition, way above than a regular IT implementation for a computer networking. These conceptions are adopted, for example, by digital banks, some operating completely integrated through an app environment, just operated by the final user, the bank customer, whereas other solutions are operated through a partnership website, demanding more configurations and cost management for the customer base direct company (Pilcher, 2019).

Another model which had expressive adherence in the last years, was the "signature", or frequent demand. This model is characterized to provide a regular service for customers of products and / or complementary services, corresponding to a periodical fee or monthly installment. Some popular alternatives are the wine clubs, sophisticated high-value added products and services – as luxury hotels or cars rental services – magazine and newspapers (in online form, indeed) offered by several companies. Alternatively, signature models resulted in two other popular implementations:

- Entertainment and information services, as those provided by independent bloggers and social media entrepreneurs, who offer a regular paid service where users receive special contexts – like consolidated e-books, courses, and other informational pieces – along with "premium content" services. Provider budget is also supplied by immediate payments during an informational session, as the streaming of a movie analysis, sportive event, rocket launch, journalist analysis, among many others.
- B2B implementations of signature models, which relate providers to users, also implementing an alternative for continuous supply of a raw material or supply, anticipating any need of bureaucratic interaction between an industrial or process-oriented customer and the effective supplier. This way, the same structure for the signature model is adopted by companies, offering a continuum which tends to benefit both sides of this commercial relationship.

Interestingly, because of its simplicity to adhere and negotiate, signature models are one of the most adopted by individuals, small and medium entrepreneurs, among other businesses which are frequent in the World. This fact assures its continuous development, platform availability among many other perspectives of increased adoption (Sako, 2012; Mullins, 2014).

Some interesting reflections arise when evaluating the value offering balance, continuous adaptation, innovation, classical business substitution, among other strategic thoughts around signature models. As a successful option, this business model is provoking these questioning continuously, serving also as a base for study of the BM implications and impacts in modern businesses promotion.

As the last conceptual approach for business model, not intending to exhaust its discussion, but indeed just to exemplify how they can be adopted for modern business, another successful case to be approached is the platform.

The "platform" concept evolved and increased in the last years, following some perspectives around entrepreneurship and business development. As an integrative solution, platforms recall information technology used to involve different businesses and, eventually, this simple approach must not be disregarded anyway. It is also recommendable to recall, in an immediate metaphor, that platforms are engineering-based components which serve to receive and connect different system elements, as those in industrial plants and / or transportation sites. Platforms, as business models, will also permit this integrative perspective, connecting different businesses elements, such as costumer communication and payments services, provided by different companies or partners, in a transparent way for the final customers (Gautatis, 2017).

According to Gautatis (2017), platforms are, nowadays, ways to connect groups of people, as teams and complete organizations, also networking resources, such as communication systems, storage resources, intelligent and automated machinery, informational components, and even other platforms. In a historical approach, platforms evolved from the industrial conception, physical, structured and material to an association with modern and even routinary technologies, as e-mail services and instant messengers. One typical platform infrastructure is the popular social media network Instagram, where one entrepreneur can offer his or her service – let us exemplify with a hairdressing expertise – supported by the connectivity and openness of the Instagram base to publish media, such as audio, video and images, together with personal customized communication provided by the specialist. This way, the platform will integrate its own resources, the components developed by the entrepreneur and, finally, other tools and technological implements offered by other partners, connected to the same platform, as social media analytics tools, communication and payment services, among many others, all integrated to a composed value offer for the customer.

This is the same principle adopted by industrial platforms, as those being tested, configured and proposed for industry 4.0 implementations, where, instead of end-user friendly environments, robotics, automation and middle software elements are connected to configure a business model of one immense, huge process environment, to be integrated with other environments, in a platform which offers a consolidated business model for the final customer (Kenney & Zysman, 2016; Gautatis, 2017).

The list of business models, fortunately, is as far to be completely analyzed as the strategic alternatives they offer to envision scenarios for organizational future. It is possible both to compose new ideas, completely, different from these original here discussed, as other models could be composed by adhering or mixing these original models – for instance, implementing two complementary signature models together, forming a new SaaS one – to produce a new, singular one. These are real strategic choices, conceptions and different implementations, to promote businesses with a supporting conceptual framework provided by business models (Magretta, 2002; Zott, Amit & Massa, 2011; Ovans, 2015).

Innovation

As one of the most challenging and debated concepts in modern times, Innovation was considered as one definition, turned to be a process conception and, nowadays, it is a management principle, strictly related to organizational life cycle and competitiveness (Jamil, 2018). Remarkably defined by Joseph

Schumpeter, innovation can be understood as the product of changes in a product or service, as a real solution, or a brand-new proposition to solve a practical problem (Schumpeter, 1934; OECD, 2005).

Regarding innovation, authors always looked to two main implications: first, how to relate innovation to a strategic process, aiming to produce a radical and perpetual organizational change, as to produce a different culture, which will motivate the organization to a continuous innovation search. Additionally, innovation sources, as to produce a definition on how factors such as market perceptions, technology emergence, competitive demands, customer requests and data availability could lead to ways to innovate. Are these factors related? Potentially, they can feed each one in the search for innovation projects? How these sources are produced, controlled, and shared? These are some provocative questions that arise when studying and planning to adopt innovation as a strategy in organizations (Nonaka, 2008; Open Innovation, 2016; Jamil, 2018).

As we observe these sources, two important factors, or dimensions – as built from several different variables and perceptions – emerge: technology and business models (Schumpeter, 1934; Utterback, 1996). It is important to explore these two dimensions in the following, attempting to reinforce innovation concept and its relationship to such strong conceptual sources like these.

Technologies can be understood as a set of tools, techniques, and apparatus, developed by mankind to solve problems. Since our ancestors looked for tools to identify and control how to simply manage food for their survival, ranging to the space rockets, wireless communication devices and medicine drugs, mankind always have our development supported by technology. This way, as technology integrate materials and its associated processes to offer new products and devices, from simple to complexes, it is possible to identify how these tools changed our way of life, offering new perspectives to human beings to solve problems and to implement new levels of evolution. This way, it is possible to identify technology as a source of innovation, in its own proposition and in the changes produced for associated processes (Teece, 1986).

For business models, however, innovation is not always so apparent, so perceived (Saren, 1984; Saren, 2012). Business models can be understood as the overall arrangement of competitive business components of one organization, as adjusted for customers answering and organizational dynamic market relationships (Magretta, 2002; Jamil and Berwanger, 2019). Business models can be designed as to become choices for strategists, when these managers think and plan different levels and ways to offer values to the market (Casadesus-Massanel and Ricart, 2007; 2012).

As propositions which can become different ways to serve customers and organizational arrangements, business models potentially offer new ways for companies´ offers and strategic positioning. Several remarkable cases in the market, such as Facebook – as one communication agency without physical infrastructure to communicate – AirBnB – as a housing rental company without real estate properties – Uber – a car rental company which operates without own cars – show, among many others, the strength of business models.

BMs are proposed in different ways and as discussed by Jamil and Berwanger (2019), these conceptions can be adopted in isolated fashions, combined, changed, or implemented in related configurations, which can result in modified businesses models. Models, according to Silva (2008) are conceptions of the reality, idealized to express all phenomena and processes of that specific environment, enabling the complete understanding of all analyzed context (Berenzoi, 2014). To produce the effective implementation, one can base his or her practical specifications for a real case, adopting the modelling production as a guideline, as a contextual framework. This way, a modelling technique, adopted to produce the conception offer to implementers a generic, complete, and wide view of the reality, in a comprehensible

fashion, aiming to allow practical configurations which will reproduce its suggested alignments in real resources, such as project and processes delimitations, technological tools definitions, risk management details, among many others (Teece, 2009; Sako, 2012).

Talking about innovation, we can comprehend modelling techniques as the primary orientation towards both innovation creation and production itself, as a production recommendation. Moreover, these conceptions which are based in the model, will allow also defining an associated process – in our case, the innovation management process – which, at the end, could foster an innovation culture for the company (Saren, 1984; Sommer *et al.,* 2015).

Good examples on how this paradigm is implemented is presented by corporative startups (Ries, 2011). With these implementations, innovations can be, initially, comprehended as actions to fulfill customer´s needs – usually refer by practitioners as a "customer pains" – and then, providing the corresponding "relief", startups productions and / or services focus their formulation towards solving objectively that user´s problem. As this entrepreneurial effort is conducted with these perceptions, the startup itself, as a model component, can be understood as a precise solution, a functional innovative unit which can be aggregated to one corporation business, aiming to, as it implements what the modelling technique offered at its best, be an integrated solution for a problem.

Conceiving a permanent, resilient process, however, is a bit more difficult and demands also strategic considerations by entrepreneurs (Sommer *et al.,* 2015; Jamil and Berwanger, 2019). With this intention in mind, not only a successful solution is produced, but the process in which this solution was conceived, is integrated, and managed by one organization. In here, a conception for a more complex, wider view of the organization implications and business – generally speaking, the organization strategic fundamentals – must be considered, to promote a better evaluation on what is being offered to customers.

So, in this situation, an innovation management process is searched, reached and integrated, resulting in a planning achievement for the corporation (OECD, 2005; Sako, 2012; Jamil and Berwanger, 2019). As one of the most frequent signals of this need, we can cite the fact that some companies achieve a momentary success when launching a specific product or service, "forgetting" the effort in an average period ahead, due to several factors and lack of priorities (Sommer *et al.,* 2015). It is possible and advisable that one organization evaluates the reasons, motivations, risks, resources, and phases which an innovation was proposed, to understand and implement a solid innovation process, aligned to its overall management strategies (Jamil, 2018). Without these actions, it is plenty possible for any innovative entrepreneur to become just a "single hit" case, not being able to reproduce or even to advance the learnings achieved during that innovation positioning.

Finally, innovation must be the starting point of a cultural change for companies, as its management can be changed by a process which continues to evaluate the market to produce and offer innovative solutions (Birkinshaw, Hamel, G. and Mol, 2008; Berenzoi, 2014). With this in mind, we are reaching the final point of this important way, where one organization not only can produce one innovative solution, not only achieve the learnings from this rich experience, as to implement an innovation process, but, more important, changed forever its view regarding innovation (Jamil, 2018). This is the point where we can consider this organization as to have gained and shared the innovation culture.

The innovation culture will enable one organization as to improve their innovation process continuously, reaching more results from innovative solutions, understanding different levels of organization and corresponding innovation possibilities and how these innovation-related efforts will result in benefits for customers and associated partners, fulfilling strategic goals through rigorous and managed plans (Albernathy and Utterback, 1978; Jamil and Berwanger, 2019). This cultural change is a lasting

modification on the organization´s market understanding, bringing conceptual framework to redesign its processes, mainly the organizational strategic planning process, this way, interfering with all tactical and operational processes.

This is the context where we intend to present innovation fundamentals for Healthcare organizations, based on business models conceptions and discussions: achieving a potential for a change of culture.

Information and communication technologies

It is important to state, initiating this approach, that we consider almost impossible to present a "final" version of a theoretical background regarding information and communication technologies. This apparent awkward affirmation has three different sources: (1) This field presents a difficult contour, as it is embedded with services and products, with the interference of practical signs and phenomena which blurs a traditional way to define concepts in a solely manner; (2) It is not regarded as a scientific field *per se* by several researchers, becoming a view of implementation of solutions based on Science. This way, just "tools"; (3) As the field – for us it is a scientific field, a context – does not stop to be updated, it is almost impossible to keep a theoretical background regarded as closed for a long period of time. This way, answering these questions, we admit that our references are just presented to form a base for this chapter production, they are scientifically valid and can produce a singular perception for each one of the technologies presented. It is important to define that we keep our focus for the goals of this chapter, as we produced an oriented review.

Initially, we must consider the huge amounts of data available in Healthcare environment. It is possible, thinking in a usual service for a regular patient, to understand dialogues, data collection by instruments, measurements, calculations, sample analysis and several other contents produced as to show data and information and, as a result, to produce more data, information, and knowledge. As we think about structured and unstructured data, it is possible to recall several of IT tools and methods available for its collection, organization, and analysis. We start our conceptual approach from this point.

Big Data is strictly conceptualized this way: tools, platforms, and methods to analyze structured and unstructured data, as to search for a level of understanding for a wider view about a phenomenon, a practical case (McKinsey, 2021). As combining these contents, from different sources and contextual formats, Big data services implement a new level for analysis regarding the interpretation and association from a contextual point of view, producing a more consistent scenario for a problem (Jamil and Silva, 2021). Social Media applied artificial intelligence software platforms, systems of instant communication and web services are among ways to create these data and information, leading to difficult contexts to be analyzed without an implementation such as Big Data (Jamil and Silva, 2021; SAS, 2021).

Big data, nowadays, are emerging as one of the predominant technologies to be used, as a standalone item or embedded with other systems, reactivating the perspectives of use for large sharing data warehouses (Kimball and Ross, 2013) and data mining support (Jamil, 2018). This constitutes a data analysis platform which, supported by a consistent level of conceptualization, serve for organizations to gather data and information spread throughout productive chains and, this way, to optimally produce knowledge for decision-making. There is a reasonable chance these tools can be defined and implemented to update and differentiate the information system conceptual background, bringing a new perspective for studies around these environments, as knowledge creation contexts for organizational planning and decisions (Jamil, 2018).

Another way to frequently produce analysis from data is Analytics. Analytics became an associated, front-end tool applied by several website hosting providers, such as Amazon, Google and Microsoft, to allow users and managers to understand the basics of traffic access in these sites (El-Gayar and Timsina, 2014). With this aim in purpose, these services were progressively adapted and updated, serving to implement functions towards artificial intelligence-based programs and environments, helping on more sophisticated functions. Nowadays, these tools support complex implementations, supplying improved levels of networked knowledge for decision-making, specially regarding website and webhosting services. Interestingly, Analytics are also implemented in end-user terminals, monitor and appliances, such as smartphones, TV sets and domestic utilities, becoming a de facto data and information monitor applied even in homes and small offices (Yonce, *et al.,* 2017; Jamil, 2018).

Another actual strong trend is artificial intelligence (AI) applied techniques. For these, as approached by Jamil and Silva (2021), we have two main contextual resources: Machine Learning (ML) and Deep Learning (DL). Machine learning is an applied way for AI which intends to promote a possibility on how automata will reproduce human movements, operations, and basic, repeated actions (Jamil and Silva, 2021). It is an affirmation of the first practical studies of artificial intelligence scientific field, which resulted in an intention, by researchers and practitioners, of a robotized solution which could repeat human actions without mistakes and undefined number of times. It is based on "training" the automata by coding, data supply, video sampling and recording or even a "follow-up" way as one human operator guides the machine through controls for it to "learn" how to do one routinary operation. This training and implementation led to its usage for simple answering machines for small offices, which interact with end-users and customers in an improved way than a simple answer machine, and with the perspective of learning – building new rules and contexts – gradually becoming more trained and able to "sample" new answers by itself. It is found in these simple implementations, but also in industrial robots, and even in sophisticated spacecrafts, like the landing crane of the Perseverance rover, which is exploring Mars since the beginning of 2021.

Deep learning advances these ML implementations as to add some perspectives of rules association development, contextual rules categories and this way, also advancing the comprehension around some phenomena and implementing a higher level of decision (Jamil and Silva, 2019). In DL implementations, it is typical to learn from a situation where a robot "took notice" of something – an industrial alarm, a meteorological condition, a traffic situation – and decided to act to stop, modify or improve it, using its own contexts of analysis. This apparent futuristic implementation can be found in auto-driven vehicles, combining ML and DL. As ML serves for the machine to identify, through intensive patter recognition, traffic management elements as semaphores, street signals, traffic signals and more important, human transit, DL implements progressively new rules to manage risk and improve safety in these scenarios. This way, ML and DL make it possible to define new and increased levels of auto-driving facilities as they are trained, used, and improved.

Defined by Pessoa *et al.* (2019), Internet of things is a way where we can connect almost any device to Internet, attributing it to a valid Internet (IP version 6) address. This way, that specific object can be associated to commands, measurements, actioning, and other processes. Through various layers of software platform, it is possible to associate IoT "things" to command-enabled networks, ranging from simple "on / off" commands, to connections monitored by artificial intelligence-based algorithms, which will allow intercommunication of these devices, as to provide interoperation, governance, risk management and, above all, complete intelligent automation. IoT is a way to connect devices to automate functions like repetitive operations – this way recalling the definitions for Machine Learning, described

above – and complete monitoring of operations, integrating regular or smart processes for industrial and services purposes. IoT is completely open to integrations, allowing that smart objects could be integrated to supervisory systems, which could perform through integration provided according to big data sampled and analyzed.

Cloud services can be considered initially as data and information storage resources, in a simple way to understand it, adopted for several years. As this important service evolved, nowadays, cloud computing is regarded to a modern context where, beyond the usual and regular transparent storage services, it can also store virtualized machines and networks configurations, emulating real solutions which can be configures and used by any interested organization, with easiness and practical decisions at hand, such as cost, risk and schedule management (Jamil and Silva, 2021). Huge IT players, such as Amazon / AWS, Microsoft, Oracle, Facebook and Google, among many others, offer, nowadays, integrated solutions for cloud computing, enabling entrepreneurs as to adopt a virtual IT installation, instead of a physical one, implying in an expressive change of computer sites design, implementation and development.

Finally, as resources of visualization – a trend in modern study and simulation systems – augmented reality (AR) and virtual reality (VR) must be addressed, as a base to build new Healthcare solutions. AR is a way to superimpose simulations over the reality you see, as to insert or include details and information on a photo, animation, or real context, captured from a real context (Abbasi and Ali, 2021). Additionally, Zaveri and Amin (2019) present virtual reality to idealize something completely new, based on existing reality, but which can present a new scenario for the user, as, for example, inserting this user is a specific game or case simulation. AR is an expansion of a real context, while VR is a creation of a new context, which can be completely idealized, maybe based on a real scenario.

These references and concepts here discussed will help when we advance for the contextual relationship and modelling Healthcare perspectives on offering new organizational business models.

Working on supporting concepts: strategy, knowledge and information

Strategy, according to Porter (2008) and Mintzberg, Ahlstrand and Lampel (2009) is defined as a composed view for future scenarios where one organization will survive, develop its relationships, plans and actions. For market organizations, strategy defines mainly the value positioning for competitiveness, detailing the relationship for goals and actions and tactical and operational tasks. Porter and Magretta (2011) addressed the rich context for the business model design and strategic planning, reinforcing the contributions of Casadesus-Masanell and Ricart (2007, 2011) affirming business models as strategic choices for corporative planners. Thinking this way, business models conception are potential definitions to be taken by strategists to implement successful and disruptive strategies along a period, executing a strategic plan.

The relationship between strategic planning and business model is one of the main pillars where our ideas are affirmed, as a powerful two-way path to maturity to be reached by one organization, as it evolves from initial phases of knowledge on how to plan its strategy, raging to a level where the plan, overall, implements, through a business model definition and practice, a new way to offer value and interact with customers and other economic agents on its competitive way.

Knowledge is another concept to be examined briefly and aligned to other contextual components: data and information. These concepts are essentially the elementary base of disciplines and scientific areas. Information Technology, Computer Science, Information Science, Management Information Systems, Supply Chain management, among many others, can be listed as examples. Interestingly, we

witness, in the last years, the emergence of the Data Science field, as data became massive available, and attention started to be paid to tools, techniques and methods to treat it to produce information and knowledge. This relationship, nowadays, is stronger than ever (Jamil, 2018).

It is important, for this sake, to start to understand the nuclear concept of data. Data is conceived, as exposed in Jamil (2005) and Jamil (2018), as value or symbol, which is easily produced, communicated, and registered, referring to a usual perception about a phenomenon. Although abundant and easy to treat, data itself does not retain any high level for decision-taking, usually needing a better development to produce a real sense of comparison or a deeper perception. For example, 150 Km is precisely comprehended, but it is not more than a numeric expression, as the user does not know, essentially, even in a superficial analysis, if this is a huge or small distance. More context must be added, to complete the user´s analysis.

Authors used to define data, information, and knowledge not separately, but based on their relationship and implementations. This is a typical approach, for example, adopted by Data Science discussions. Turban, Mc Lean, & Wetherbee (2002), Turban, Rainer & Potter (2007), Ackoff (2003) and Lucas Jr. (2005) discussed how information technology (IT) solutions are precisely related not only to the basics of these concepts, but with its dynamic relationship, addressed also by Stair & Reynolds (2009). In this latter, we understand how this strong and powerful composition can lead to successful implementations for information systems. It is possible to refer to Davenport & Prusak (2000), verifying these definitions in the way to understand what information and knowledge management is. In Tuomi (2000), as an apparent controversy, a "reverse" thought was studied, as the author examines data production from knowledge when developing models and database schemas for application in software development. This attempt to develop an alternative comprehension for the data – information – knowledge relationship is, at the end, a support for the contextual difference here reported.

Information is defined as a collection of homogeneous, related data (specially aligned to a specific phenomenon, for example a process), combined with context framework where and when it was produced (Ackof, 1989; Davenport and Prusak, 2000; Jamil, 2018). With this conception, we can assess a content – information – which, implicitly, provide more decision power, comparative perceptions, and overall comprehension of an environmental issue. For Turban, Rainer and Potter (2007) and Stair and Reynolds (2008) it is possible to reach the definition of information systems – an aggregate of components, such as business elements or units, put together to treat information – collect, compose, register, share, etc. As an alternative approach, the definition of information not only as "a thing", but also as a process is presented by Allen (1995). Information as a process is important for businesses model propositions, as we can even understand some organizational proposals, such as marketplaces and SaaS business models as information systems by themselves. This way, this BMs can be understood as specific business conceptions as to manage information and produce knowledge for a specific business proposal (Buckland, 1995.

Another conception, which is useful to address the potentialities of this relationship, is the proposition of information services organizations, such as information sharing, brokers or even retailers, observing how some real companies are proposed from a business model indeed consolidated through information management (Marchand & Davenport, 2000; Marchand, Kettinger and Rollins, 2001). Information services is another conceptual framework which can be applied for this chapter motivations, as Healthcare organizations produce and need information to implement efficient business models to answer their challenges.

As a top-notch concept, knowledge is defined as a collection of related information, including definitions of the processes which treated that information. Knowledge is a more complex matter, being

difficult to delimit, understand, obtain and organizationally manage, but it represents a higher level of detail and comprehension about the organizational business environment (Ackoff, 1989; Jamil and Berwanger, 2019). Knowledge allows more precise and skilled decision capabilities, enabling even competitive scenario predictions (Davenport, 2000; Akbar, 2003; Nonaka, 2008). This way, knowledge management can be understood as a complete view on how it is possible to coordinate a set of actions to produce, store, convert, communicate, and share it in a manageable fashion. (Choo, 2003; Kearns & Lederer, 2003; Jamil, 2005; El-Bashir, Collier & Sutton, 2011).

As presented by Jamil (2018):

The perspective of integration of these fundamental concepts already offers the chance of a process: knowledge generation from data. Examining the conceptualization above, it is important not to forget that information plays a critical role in this transformation, as it is in the middle of the conceptual relationship, implicating in its decisive participation in practical issues also. In here, for instance, it is possible to understand the application of information systems and their associated, "layers", applications that will allow the organizational generation of knowledge. Cycles of data and information gathering, processing and communication can lead to knowledge formation, to be further treated by companies and professionals, reaching the knowledge management process level. As an organization matures in these cycles, it is possible to expect its evolution towards a better application of knowledge for strategic decisions and competitive comprehension, directly influencing its managerial capabilities (Jamil, 2001; Jamil, 2013; Dimitrios, Sakas & Vlachos, 2013). (Jamil, 2018).

Considering studies from the last twenty years, it is possible to comprehend the fastness, flexibility and agility which transformed the relation of data, information, and knowledge. Nowadays, in one simple, usual smartphone, with a simple and usable app, a transaction can occur in a small number of seconds, resulting in this transformation as fast as we can use any service. For example, through a car sharing app, it is possible to understand the usage of customers´ data, the association to other users´ data, producing information – as to calculate a fair price for the transportation service – and knowledge which will produced by the user when he or she evaluates the offer and its associated results. With this knowledge, the car sharing company can produce more knowledge, regarding customer preferences, price practices, driver's performance, app usage, etc. This way, an intense exchange of data, information and knowledge dynamically occurs, serving to reinforce exactly this innovative business model (the marketplace business model, as defined in the specific conceptual section of this chapter).

One conundrum that challenges researchers and practitioners for many years is the possibility of managing information and knowledge. For some, these are contexts impossible to be managed, as they pay attention specifically to restrictions such as "controlling" every aspect of their production. As one considers "controlling" by the strict aspect of limitation, continuous rigor and restrictions, somewhat relating to classical ways of management. Our point of view, however, is to consider information and knowledge management as processes for modern organizations, focusing an "optimistic" fashion of control: knowing what to do in all critical aspects of these two valuable contents (Lang, 2001; Gal, 2004; Jacobson & Prusak, 2006). This way, actions such as the following are taken as basics to define both processes:

- Understand and develop information sources, as emerging from data sources aiming to produce knowledge.

- Relate information and knowledge to continuous decision-making improvement in organizations.
- Information and knowledge can be update frequently, timely adjusted to organizational demands, for example, from data sources.
- Specify, plan and adequate information systems and associated technology to serve for information and knowledge management, becoming a de facto base for these processes to exist and be considered in one organization and, finally:
- Integrate information management to knowledge management, favoring a continuous which will lead to both contents to be used in an optimal way (Gal, 2004; Cristea & Capatina, 2009; Haslinda and Sarinah (2009).

These aspects are discussed in the above references and, additionally, by Davenport and Prusak (2000), Choo (2003) and Jamil (2005, 2018).

To manage information and knowledge is, for these and several other aspects and factors, a strategic activity for organizations. Discussing information systems, for example, as conceptualized above (Ackoff, 1989; Stair and Reynolds, 2008), it is possible both to identify that some business models can be conceived as entrepreneurial adaptations of ISs, and, beyond, being regarded as information systems themselves. If, for example, we understand a marketplace or a IaaS implementation as one immense resource composed to manage information and knowledge, supporting their collection, optimal and retrieve-oriented storage, process, sharing and protection, it is possible to face these modern competitive arrangements as information systems. This way, the theoretical framework which was developed and under constant review for information systems will also help on evaluating benefits and opportunities to understand better new business models, producing an interesting relationship for this study (Ries, 2011; Jamil and Berwanger, 2019).

Generally observing, information and knowledge management can be understood as composed from the following sub-processes:

- Production: considers the creation, collection or capture of information and knowledge, both from external and internal sources, considering organizational limits. Information technology integration, systematic collection about customers' behavior towards information and knowledge sources, catalog, emerging modelling and others are to be done in the after, as a result of a stablished production sub-process.
- Retention: Methods to record, store and keep information and knowledge treated by the former production sub-process. Information technology infrastructure, knowledge codification and tagging, artificial intelligence algorithms application, "big data" classification, among many others, are aspects of study.
- Valuation: approaches organizational ways to value these two productions – information and knowledge – and to appreciate works related to their processing for expected results. This valuation can be related to former implications, as to award professional works, share and sell information and knowledge adopting models such as "brokerage", among many others.
- Sharing: actually, one of the most impacting processes is sharing – putting these contents available for those who need them. For projects stakeholders, investors, decision-makers, customers with routinary demands about products and services, business partners and others, sharing the correct content and evaluating its usage is critical for information and knowledge management.

As a last remark about these processes, it is interesting to address the "control" which must be exerted, as to keep record and effectively manage them. These contents are valuable, can be produced from several sources and ways, parts of this process can be automated – as implementations of artificial intelligence algorithms and resources – can be sold, negotiated and, more relevantly, adopted as bases to define, detail, design and implement business models. This is the path for the next sections, where we will explore business model development and usage for Healthcare services.

AN APPLIED EXERCISE FROM THEORETICAL REVIEW – CONCEPTUAL RELATIONSHIP

After the work on connecting a theoretical background, this section aims to develop an essential relationship among the concepts approached in the previous sections, reaching one of the main results of this chapter. As our focal proposal, the discussion of ideas for Healtchare business models conception, through the application of information technologies, answering to organizational strategies.

It is possible to start this development, as observing that a business model can be regarded – as its best definition – as a strategic option, a choice to be addressed by one strategist. So, to compose a scenario for a business model, the strategist must understand how the eventual innovation proposed by the business model can be addressed and proposed in a strategic plan. This business model, as to propose an innovation, must consider data sources, knowledge consolidate through managerial processes which served the end-user and effectively were monitored and governed by the organization, as to deepen the customer factors domain – such as reactions, behavior, degrees of satisfaction, among other.

These signals can be produced by a big data platform, supported, and automated together with data warehouses and applying data mining programs, as to refine the data and information collected, becoming an opportune of customer knowledge regarding his or her demands for new products and services. Once this level is reached, a business model design can be started or objectively reviewed, allowing a better degree of success. Interestingly, this simple technology application makes the essential relationship strategy – business model real, producing a tuned and based way for the organization to produce its results.

But technological appliances and resources can continue to be applied, when the strategy – tactics – operation start to operate, in a coordinated level. As the organization really puts the business model to function, implementing its directives and starting to obtain the first results, technological features can collect data, form databases and data contents – warehouses and, after, big data contents – creating a platform to develop more sophisticated applications and, overall, implementing strategic monitoring and governance.

With these principles in mind, technology can become a component of an information system, as it helps to collect data and information, manage it, answer business decision needs, monitor the strategy execution and, this way, perfect the business model adopted, indicating if it demands any review, adaptation or simply must be kept around the sector competitiveness. The integrated operation, through the application of user-oriented interfaces, such as augmented reality and virtual reality, Internet of Things and networking facilities, enables the organization to collect data and valuate it versus the expected results. Aligning these functions, the organization can implement a strategic planning monitoring service in a fast and precise way.

For example, the actual demanded dynamicity for segmentation, as the phase of marketing planning which relates to Strategy, can be reached when the association of several levels of data, information and

knowledge are perfectly connected with the capacities and abilities of one organization as to answer if its strategic needs are being reached or not. This allows an unprecedented way to manage one organization, acting over the business model, with adjustments really being made "on the fly".

This is a risky two-way process, though. When one organization learns to adapt quickly and receives immediate answers to its planning needs, a false sensation of low requirements for planning can be observed and mistakenly understood. In this undesirable level, although wrongly comfortable, plans are seen as open to frequent corrections, with no observation for the quality of planning itself. This way, the organization can start to improvise again, putting their abilities to manage at risk, as the answers are frequently obtained easily and fast.

But, fortunately, the association of information and communication technologies with strategic risk management is powerful and one of the most adopted solutions for enterprises, as we have implementations from the basic level operations – as, for example, control and automate purchases of supplies of raw material – to integrate strategic dashboards for immediate analysis by managers. As one evidence becomes a risk and implicates in a real fact which will imply in a problem – with different degrees of damage for businesses – automated sampling techniques can be used to collect precise data, compare to trends (organizational and sectorial) and, overall, allow to implement process alternatives.

In another example, it is possible to think that as one risk factor increases, artificial intelligence machine-learning platforms can follow these signals, immediately "learning" from it as to activate alarms, call safety procedures and specific personnel and, moreover, include this fact in the risk manage database, following the auditing scheme adopted by the organization. An integration of three levels of risk management can be achieved: The first level of emergency signals analysis, comparing to trends, identified the real potential of the risk, associating it to the source factors in the first level, to be checked after for a complete design of the risk evidence. At the second level, this association, if confirmed – detailing why, how, how much, when and what questions for the risk were answered – can be defined as a rule, to be integrated in the automated risk database. This way, we are allowing the corrective and preventive plans to be associated. After all, we reach the third level, producing a consistent entry for Auditory process, as this new rule was established strictly in function of a real occurrence, was completely identified and turn out to be a new rule, improving the risk management process. The usage of technology in this process can result in a more precise, "intelligent" and safer way to put all the risk management process to function, enabling a more secure strategic plan execution.

Connecting these concepts is a tough but compensatory thinking, as new organizations, innovative business models can be proposed, both going in a different way or implementing a new way to make things work. Remarkably, this is a moment when technologies found base on new hardware and infrastructure available to be put in work. Also, new business models were favored by economic flexibility and market entering from new customers. Although risks are immense – protectionism, isolationism, pandemic effects among others – there are good opportunities to explore and to produce, as knowledge is available in an unprecedented way.

REFLECTING ON HEALTCHARE BUSINESS MODELS DEMANDS

In previous chapters and papers, referenced in this text, authors already presented some contributions around emerging technologies, and its associated management, for the Healthcare sector. In here, to finish our chapter, we just introduce a potential business model, integrating aerial transportation, vaccine

supply and distribution, which was used to respond to Covid-19 crisis and probably has to be kept in mind by strategists, governmental agencies and entrepreneurs to assure a fast reaction in, although not desired, potential similar crisis in the future.

As already mentioned in a notorious speech by the entrepreneur Bill Gates, few years before the Covid-19 outbreak, the world would not be prepared for a possible pandemic scenario. Although not uncommon in history, the Covid-19 crisis has entered history as one of the most contagious and dangerous phenomena. There are many factors that contribute to its spread, as in most contagious diseases, which makes the analysis of each disease more individual. However, considering a scenario of a circulation of a virus with high virulence, able to sustain a transmission rate above 1 over more than one year in several countries in the world, in an increasingly interconnected world, it is safe to say that this is one of the most dangerous disease the human species has ever faced.

In addition, the estimated fatality rate around the world is between 2% and 3%, according to (WHO, 2020) which is high enough to end lives of millions of people but seems far below of the same rate the deadliest pandemic reported, the Black Death, for example. Each disease was spread considering many variables and its own characteristics that contribute to the determination of infection and fatality rates (the Covid-19 is caused by a virus and the Black Death, by a bacterium, which is enough to distinguish many characteristics of each pandemic). The aim is not to compare both diseases. However, it is possible to observe that a respiratory infection due to a viral disease which combines the potential of transmissivity as observed in SARS-CoV-2 and a mortality potential of the bubonic plague, could severely endanger the human species.

The quick development of the Covid-19 disease from an epidemic perspective to a pandemic one highlighted the human lack of ability to contain its spread. Despite the scientific evolution of the society over the last centuries there is still room for improvement of techniques capable of restrict the development of such diseases and other harmful events for the entire society. In the specific case of viral diseases, these techniques pursue as primary objectives the contention of its spread and its scientific understanding with the view to provide base knowledge for development of prevention and treatment, as enhanced by the Covid-19 pandemic panorama.

Although pandemics are not unprecedented, many individuals have never been exposed to such scenery and the newness effect could hamper even more the development of techniques in response to these events. However, a form of reaction that could prove beneficial in the face of the novelty effect is to adapt recent developed technologies with a perspective of a new objective of pandemic reaction and containment, so the society has at its disposal support knowledge to reach it.

A specific case of analysis evolves the aviation industry around the healthcare system. In recent years, many inventions and new technologies were created and introduced in the aviation market such as new concepts of maintenance, data acquisition and further development of cargo aircrafts. One example is predictive maintenance, that has been consolidated itself as the part of the future of the aviation (Adhikari, 2018), basing itself in real-time data acquisition by sensor devices that monitors an aircraft's component's operation condition and predicting when its required maintenance. In other words, this is a smart and integrated system capable of monitoring conditions of operation and preventing a failure (Adhikari, 2018).

A common world's need to combat the Covid-19 pandemic is the mass vaccination of the society, which faces the challenge of distribution, considering the number of vaccines that must be transported and that difficult access areas must be reached. In addition, the vaccines have a required storage condition, such as a temperature range, that it must be kept under the whole course. There are regulations

for the control of the conditions of the vaccines during air transportation (WHO, 2019), including the requirement for data loggers, as observed in modern maintenance of aircraft's components.

However, the predictive maintenance evolves a more sophisticated system of integration between computers and data processors, in the form of Internet of Things (IoT) and Artificial Intelligence (AI), which can simplify the analysis and tasks of the maintenance process. The two main innovations concerning the new form of maintenance are the self-diagnosis of problems and probability of failure and the system's self-feedback and self-corrections, developments, and updates of its own analysis method. It must be taken into consideration that it a process that evolves a great amount of data generation in the context of an increased usage and dependance of computer aid and digital technology, which requires and promote Machine Learning (ML) and IoT to develop the system integration that compose the predictive maintenance process, as described by (Adhikari, 2018). This is one of the mentioned examples that the healthcare system could benefit from the knowledge structure of other domains, in this case the aviation industry: the integration of systems and computers for data analysis and conditions monitoring of the vaccines during transportation, using the predictive maintenance of aircrafts as the base know-how.

Besides the applicability of aviation industry technology for prevention, it could also be proven effective for treatment. Many airplanes were left on ground since the pandemic has started, due to the decrease of the demand for commercial air travel and increase of its restrictions, to contain the spread of the virus, and some of these planes may never fly commercially again, considering the crisis affecting the airlines. These grounded planes could instead be adapted to serve as air ambulances or transportation of patients, and the aircraft manufacturers have a new area of action that had its demand increased due to the collapse of the healthcare system in many countries around the world. There are projects for conversion of commercial aircrafts, when they are assumed not suitable anymore – often due to its age – for this purpose, into cargo aircrafts, so this could be a base knowledge for conversions of commercial aircrafts into air ambulances, considering the suitability of the aircraft for the healthcare system (Martin, 2020).

CONCLUSION

This chapter was proposed to address a perspective of new business models design for Healthcare organizations. We adopted, as our main support, the emerging technologies to discuss and evaluate how these business models can be adopted by one Healthcare organization, going from the conceptual approach to the practical observation, as to present study cases at the end of our discussion.

Concepts are being reviewed every day, as their bases and association in dynamic relationships are also being questioned, demanded, and revised according to new businesses scenarios. Segmentation, for instance, always a challenging and required process, nowadays, must be dynamic, fast, precise and allow the organization to "discuss" with the process, interacting more content, producing alternative views, and retaining the produced knowledge for further decision-making. From a detailed picture of one important action in a strategic marketing plan, now a definition of a continuum, a strategic process which will be a factor of competitiveness and a strategic tool to perform a competitive advantage.

Technologies are not to be seen as an end, as the last definition to be analyzed, but, indeed, also dynamic, and flexible connections to foster new unfolding for the strategic planning process. Governing a dynamic organization is risky, as we described earlier, control can be lost when we, without the demanded coordination, pass from a fast-planned organization to a confuse, unstable context. This way,

solid comprehension on business models is key to prevent this loss of control and to keep the strategic relationship, as we described.

Modern times demand innovation. Innovation is understood easily, but it is tough to implement, as we must address several strategic conditions and implications. As the innovations are put on the market, offering new contents for value to our end customers, business models support the offer, producing a strategic coordination which can be effectively managed by the application of information technology tools and resources. This interesting and unique panorama was addressed here, with a view for motivation, as the actual moment deserves and is benefitted for an observation like this.

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Chapter 8
Knowledge Management in Big Data Times for Global Health:
Challenges for Quality in One Health

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ABSTRACT

The 21st century brings an information revolution unprecedented in human history. The knowledge management of the data generated daily is a constant challenge for organizations and in all areas of science. Nevertheless, it is extremely relevant to the health area since it promotes the individual's well-being and health. In this sense, the quality of data, information, processes, and production of products and healthcare for the populations of the countries have increasingly become global concerns. Therefore, thinking about health only as a burden is a short-sighted thought. The new era of big data requires innovative knowledge management for global health, where quality is also guiding the new times. This chapter presents a reflection of the new times and management challenges for quality in global health and One Health.

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INTRODUCTION

According to the Organization for Economic Co-operation and Development (OECD), 55% of global wealth is knowledge (OECD, 2008). Drucker (2006) point out that generating more of this knowledge will occur in parallel to an increase in knowledge management (Drucker, 2006).

In the age of knowledge, intellectual capital has played an important role in economy and business, a key factor for competitiveness and, therefore, for economic and technological development. In high-density areas, such as pharmaceutical, aerospace and telecommunications, among others of equal weight and impact, knowledge becomes the most important asset (LASTRES, ALBAGLI, 1999).

New trends influence the industrial development of a country, such as knowledge, a main resource, and learning, a central process. Therefore, it is essential to broaden the base of expertise in human resources and hence, increase the potential of innovation (Lastres, HMM & Sarita, A, 1999b).

Nevertheless, public health issues and problems are immense and require a multidisciplinary workforce. They must be considered and analyzed in the context of the real conditions of each culture, developed using Research, Development, and Innovation strands (P, D&I), and through cooperation networks to disseminate the knowledge generated to achieve local development and create innovation. Working with Information Science, any application in the field includes a highly structured network. Due to the fact that the processes involved in "P, D & I drugs" are increasingly complex, it is necessary, as a first step, to form multidisciplinary teams to establish a systemic vision (QUONIAM, LUCIEN, 2010). In this sense, this involves significant effort and knowledge to achieve a precise match between Information Science and Knowledge Management, given that we live in the information era of the 21st century (Magalhaes et al., 2018).

This deluge of data in the 21st century, known as Big Data, requires a different analysis. This analysis is already used successfully in several countries, such as the United States. They incorporated the concept in almost all their productive sectors. In 2014, the American government presented the report "Big Data: Seizing opportunities, Preserving values ", with the objective of consulting the main American stakeholders such as Apple, IBM, Google, Bank of America, amongst others, on questions about opportunities and values in the use of Big Data, and, thus, evaluate how it will change relationships between government, citizens, businesses and consumers (The White House, 2016).

In this new era of knowledge, the data available for Global Health are immense and must be considered considering global health situations that are unprecedented in history. Global health is the understanding of health care in an international and interdisciplinary context. It includes the study, research, and practice of medicine with a focus on improving health and health care equity for populations worldwide. Global health initiatives consider both medical and non-medical disciplines, such as epidemiology, sociology, economic disparities, public policy, environmental factors, cultural studies, etc. (WHO, 2021).

One of the most prominent agencies focused on advancing global health is the World Health Organization (WHO), but this agency is not alone. Researchers and leaders in a variety of fields are spearheading initiatives that form alliances between historically disassociated fields. There is no doubt that our global environment is changing – from the hottest years on record, to the worldwide disappearance of pollinators, to the global collapse of fisheries, and to our use of about half of the planet's livable surface to feed ourselves.

It is worth highlighting the interdependence of humans, animals, plants, and their social environment throughout humanity. This scenario highlighted by past and recent pandemics demonstrates the relevance of understanding and facing threats to the ecosystem. The Covid-19 pandemic presents itself

as a characteristic of a syndemic - a phenomenon of complexity of several levels that interact synergistically at everyone, social and environmental level. Thus, it is urgent to study these contrasts and observe the existing gaps. Thus, the collection of Big Data in healthcare, its analysis and processing of these data to help decision makers in solving humanity's ills.

In this context, it is urgent to join the knowledge management effort in the informational era of Global Health, Quality Management in all its concept, specifically the 5th era of Quality, Quality 4.0. In times of Knowledge Management in Big Data for Global Health, combining Quality with the whole process, provides a competitive and innovative differential for companies, enabling them to stay at the forefront. It is based on the strategic thoughts that precede thinking, identification and extraction of data, data processing to derive essential information, thereafter, acting upon it to produce expected results.

Therefore, this chapter presents a reflection of Scientific Knowledge Management in the informational age of data, in the face of Big Data for Global Health and Quality in the 21st century. The method adopted for the research was exploratory and contributory.

GLOBAL HEATH AND ONE HEALTH

Global health is an area of study, research and practice that has as priority the achievement of equity in health of the world population. In addition to the priorities of the Sustainable Development Goals, it includes others linked to fundamental aspects of health, such as chronic diseases and non-communicable diseases (cardiovascular diseases, diabetes, etc.), which represent the high burden of disease worldwide, the social determinants of health, climate change, and the poor distribution of human resources in health. These aspects are nowadays particularly relevant for several reasons because we live in a world of global (medium) connectivity, with high mobility (global citizen), with epidemics (HIV, Ebola) and pandemics (flu). In this context, it is essential to have an approach not only based on the disease, but also on social, economic, and cultural aspects. Therefore, the area of global health is distinct from public health, international health and tropical medicine, with broader objectives in achieving equity in health (Oliveira & Magalhães, 2016).

The United Nations, concerned to improve public health, held the assembly of the United Nations in 2000, with 191 countries at the Millennium Summit. They pledged to fulfill the following objectives of the Millennium Development Goals by 2015: eradicate extreme poverty and hunger, achieve universal primary education, promote gender equality and empowerment of women, reduce child mortality, improve maternal health, combat HIV/AIDS, malaria, and other diseases, ensure environmental sustainability, and promote a global partnership for development (United Nations, 2018).

It is estimated that in 2030, aging of the population of low and middle income will cause 75% (¾) of all deaths. Over the next 20 years the proportion of death for non-communicable diseases will have a significant global growth. Deaths from cardiovascular disease will increase from 17.1 million to 23.4 million and cancer will increase from 7.4 million to 11.8 million. It can be concluded that deaths due to cancer, cardiovascular diseases, and traffic accidents will represent 56% of deaths, in a total of 67 million (WHO, Control of Neglected Tropical Diseases, 2013).

Global health is about the improvement of health worldwide, the reduction of disparities, and protection of societies against global threats that disregard national borders. It is essential that academic institutions reach across geographic, cultural, economic, gender, and linguistic boundaries to develop

mutual understanding of the scope of global health, and to create collaborative education and research programs (Macfarlane et al., 2008).

Koplan et al (2009), from the Executive Board of the Consortium of Universities for Global Health, point out that without an accepted definition of global health, it will be difficult to agree on what global health is trying to achieve and how progress will be made (realized) and monitored. This is particularly important given the recent global crises in climate change, economy, food, and energy that make global health efforts even more challenging (Beaglehole & Bonita, 2010).

The Health Care area is now in a new era of open communication. A decade of digitalizing medical records has already passed and pharmaceutical companies, and other organizations, who have accumulated years of research and development data in electronic databases, are established. Stored data is usable, searchable, and can be acted upon, as the federal government and other public stakeholders have increased data transparency. The health care agencies are currently able to access unlimited amounts of data. This increase in data liquidity, together with the development of open communication, has brought health care to the tipping point. Stakeholders can now access the promising new threads of data. This data is called Big Data, identified only for its sheer volume, complexity, diversity, and timeliness. Suppliers, clinicians, providers, pharmaceutical-industry experts, and other stakeholders are currently beginning to investigate Big Data usage to gain further insights. These insights, although still in the early stages of utilization, could collectively assist the healthcare industry with variability in quality and reduction of the escalating spending that it is known for (Alexander & Wang, 2017).

In this sense, thinking about Global Health, requires thinking about the One Health concept in a Planetary Health. By almost any measure, human health is better now than at any time in history. Life expectancy has soared from 47 years in 1950–1955, to 69 years in 2005–2010, and death rates in children younger than 5 years of age have decreased substantially, from 214 per thousand live births in 1950–1955, to 59 in 2005–2010. But these gains in human health have come at a high price, due to the degradation of nature's ecological systems on a scale never seen in human history. A growing body of evidence shows that the health of humanity is intrinsically linked to the health of the environment, but by its actions humanity now threatens to destabilize the Earth's key life-support systems (Whitmee et al., 2015).

One Health focuses heavily on antimicrobial resistance, food safety, and infectious diseases, whether they "spill over" from animals to humans or vice versa and how the emergence of infectious diseases are associated with changes in land-use and human activities, such as agriculture, food production, travel, and trade. Over 60% of emerging infectious diseases—including Ebola, HIV/AIDS, and Avian influenza—derive from animal hosts. It is estimated that over 15 million people succumb to emerging infectious diseases each year (Zinsstag et al., 2011).

William B. Karesh, EcoHealth Alliance's executive vice president for Health and Policy, coined the term One Health as reported in a 2003 newspaper article on Ebola. The term is meant to spotlight the nexus between human health, animal health, and ecosystems, and to bridge the silos between ecology, and human and veterinary medicine (Destoumieux-Garzón et al., 2018). In this sense, One Health is a collaborative, multisectoral, and transdisciplinary approach - working at the local, regional, national, and global levels - with the goal of achieving optimal health outcomes, recognizing the interconnection between people, animals, plants, and their shared environment. CDC's (Centers for Disease Control and Prevention) One Health Office leads the agency's efforts in the United States and abroad.

BIG DATA, INFORMATION AND KNOWLEDGE FOR HEALTH

Big Data refers to the third generation of the information age (Magalhaes, JL & Quoniam, L, 2015; Raghupathi & Raghupathi, 2014). Initially, this exponential volume of data addressed the criteria of the 3Vs: Volume, Variety and Velocity (Laney, 2001). Further on, 2 more Vs were added: the attributes of Veracity and Value. Some authors even attribute 3 other Vs, Veracity, Versatility and Viability, where the combination of all "Vs" generates the "V" of Value (ALEIXO & DUARTE, 2015)

The creation of the World Wide Web is one of the greatest examples of radical technology in recent times. According to O'Sullivan (2008), it is possible to have and offer disruptive products, services and processes in most industrial sectors (O'Sullivan, D. & Dooley, L., 2009). The Web has evolved in line with its progressive socialization, mainly due to the rapid growth of the population that uses the Internet. Thus, its focus has changed from business-centric to user-centric. In 2004, Tim O´Reilly called this change of scenery "Web 2.0" (Lee, In., 2011; O'Sullivan, D. & Dooley, L., 2009). The social and technological environment of participation and positive user interaction, defines Web 2.0 (Lee, In., 2011) (Nova Spivack, 2013).

The Web provides the bonds that unite the global economy and allows more and more global trade to be carried out electronically, currently representing 50% of services and 12% of product sales. A new frontier in the face of reduced communication and transaction costs, in addition to customization in view of the consumer profile. Along with saving time, these changes create economic value, increasing innovation, competition and productivity (Magalhães et al., 2017; Piet J.H. Daas et al., 2015).

As a result, the concept of globalization changes over time. Before, the image of globalization was the approximation of nations through the movement of goods, services, and finance, whilst today the flow has a different dynamic, with a focus on the data transmissions that are generated at high speed, volume, and variety. The effect of the growing phenomenon of data, called Big Data, is accelerated globalization, redefined by data flows that incorporate ideas, information and innovation (McKinsey Global Institute, 2011).

Thinking about new practices in applications for the value of information, the health area is no different, making it completely applicable and essential for innovation and technology trends for global health of the new century (Lawrence & Giles, 2000). In this sense, it is important to have a general overview about the history of public health.

Human history has been marked by great discoveries and/or ideas as economic events, measures seeking to prevent diseases, the mobilization of social classes and working. But another factor that makes it possible to measure milestones in the history is the epidemiology. This means diseases affecting the population, like for example the Spanish flu in the late nineteenth century. This disease, at the time, devastated about 50% of the humanity. Also noteworthy are the wars, which were factors in the spread of epidemics in Antiquity (Magalhaes, JL et al., 2012). The most recent example is the Covid-19 pandemic in the year 2021.

The perception of the information value was already taught about 400-300 BC by Sun Tzu in his book "The Art of War", which reads: "If an enlightened sovereign and his commanding victory whenever they get into action and achieve extraordinary feats, it is because they hold prior knowledge and can predict the course of a war " (Sun-Tzu, 2000).

Therefore, information may be seen as a condition for survival, and it broadens their communication context with the redemption narrative for preservation of social memories. Its value becomes intangible resisting all oblivion mechanisms and destruction, seeing that the acquis of informational reconstruc-

tion enables cognitive assessment and knowledge of reality. In this sense, continuity of information may indicate the result of the human capacity to act together and pursue a common course of action for the political transformation of society (Castro, 2002)

The information became a remarkably interesting word in this knowledge era, while its role in every side that could be change with data and became an intangible important commodity. There are so many perceptions about this, e.g., on the digital free encyclopedia that very dynamic's, there are several categories about information. From the viewpoint technical sense, information is a sequence of symbol that can be interpreted as a message, and information can be recorded as sign, or transmitted as a signal, and information is any kind of event that affects the state of a dynamic system. Another conceptually point of view, information is the message, utterance or expression being conveyed which the meaning of this concept varies in the different context (Floridi, L., 2010).

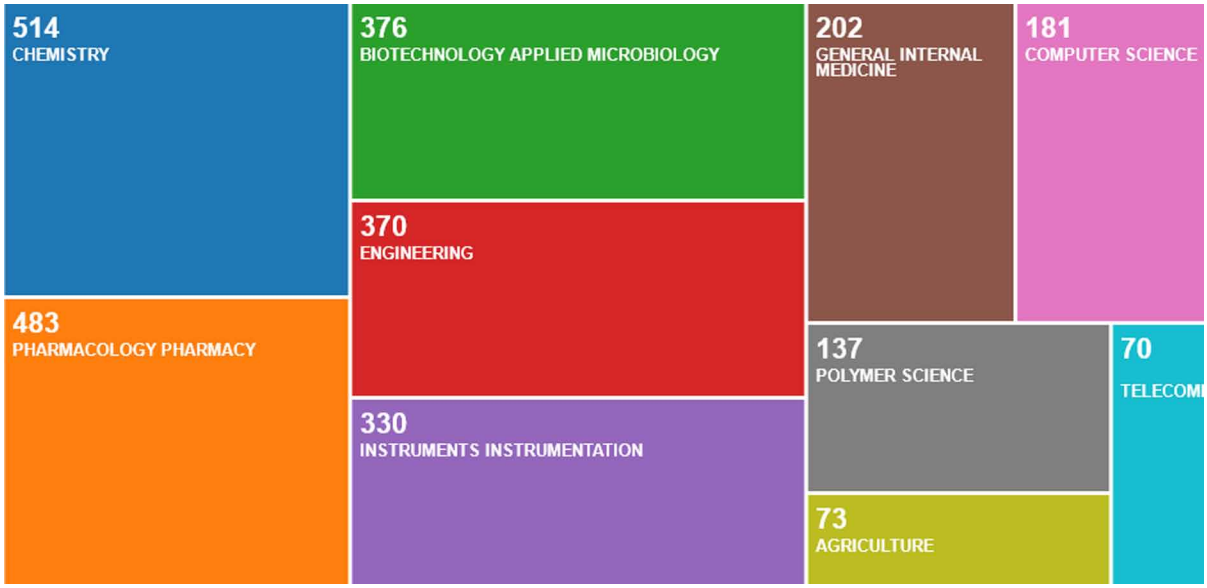
Thus, thinking about the value of information to the global level, it is difficult to define the complex cultural, social, political, and economic aims implied by the word's peace and sustainable development. We know that peace is not merely the absence of war, but a condition of living where everyone can enjoy tolerance and respect. The achievement of sustainable development has become a rallying policy goal, but the specific measures to achieve it and the interpretations of the objectives differ among various interest groups. Consensus in these areas in real situations can only be reached through democratic debate and this requires freedom of expression as well as freedom of information («UNESCO-Knowledge Society Report Draft -11-February-2013 - UNESCO-Knowledge-Society-Report-Draft--11-February-2013. pdf», 2013). Thought by United Nations Educational, Scientific and Cultural Organization (UNESCO), the information value should be focused on recalling and revisiting the aims of knowledge societies, it relies on an intuitive interpretation of peace and sustainable development as globally positive values - respect for human life and for the environment. Development policies within knowledge societies should consider the protection of the environment, social equality, and economic welfare.

Thus, it is worth considering that scientific knowledge needs to be translated into technology, such as patents and, consequently, this technological Big Data potential exploited through the transnationality of research can be translated for the good of humanity, that is, the appropriation of innovation by society (Lean et al., 2008; Possas et al., 2015). According to the National Institute of Industrial Property (INPI), a patent is a temporary property of an invention or utility model granted by the State to inventors, authors or other natural or legal persons with rights over creation. There are two types of patents: a) invention patents (PI) - they must be innovative and have a duration of 20 years; b) utility model (MU) - lasts for 15 years. With the expiry of the patent, the invention can be reproduced by third parties, thus providing generic reproduction to the brand. Expected to end the patent term, the generation of more accessibility for the population, in view of more accessible prices (Magalhaes, JL et al., 2014; MDIC. INPI - Instituto Nacional de Propriedade Industrial, 2016).

As a practical example of Big Data in health, when examining only one database of the literature with respect to Covid-19, in this case the Derwent Innovations Index, it was possible to find in the directory, on May 15, 2021, 777 studies related to Covid-19 (Figure 1). It should be noted that in just one and a half years of a pandemic decreed by the WHO, 777 patents were registered in the area. It is an unprecedented volume in the history of informational data generation. The management of this knowledge is not trivial. New times of global health, new times of multidisciplinary professionals and management tools. Identifying this data manually and analyzing it would be an arduous task. However, with the information science expressed based on Dewrent, it was possible to process them quickly and with a practical Data Visualization generated for decision making. It is noted that the database itself has

already processed the health data, "mining it" and visualizes the areas of knowledge involved, namely: chemistry (514 documents), pharmacology pharmacy (483), biotechnology applied microbiology (376), engineering (370) e instruments instrumentation (330).

Figure 1. Patent knowledge areas for Covid-19
Source: Created by the authors in Dewrent Innovation Index.



Translational research, the translation of knowledge, has its beginning in basic science, that is, in basic or laboratory research, in clinical research and, finally, its conclusion in the practical application of the learned knowledge. It is through knowledge management, with non-trivial tools, that the link of these researches allows to eliminate the gap in the stages and, consequently, favoring the appropriation of existing knowledge by the population, resulting in innovation itself (Woolf, 2008). Therefore, a translation of knowledge enhanced by collaborative research networks aided by the neglected health scientific and technological Big Data, can assist decision makers in fostering innovation for various areas of science. (Hartz, 2013; Magalhaes, JL et al., 2015; WHO | Special Programme on Research & Training in Tropical Diseases, 2006). Jiang (2021) shows that with support from the government and acceptance by the public, online health care services could develop at a fast pace and greatly benefit people's daily lives (Jiang et al., 2021; Zhou et al., 2020)

According to the Editorial of Science magazine (2016), although there has been progress in recent years, most of the data for health, e.g., clinical, and genomic data are still collected and studied in isolation, in silos - compartmentalized by disease, for example. institution, by country etc.. (Nature News, 2016). The first sharing efforts have allowed to develop treatment for rare diseases and some forms of cancer. However, this benefit will only reach the entire population when doctors and researchers can access and compare data from millions of individuals. (The Global Alliance for Genomics and Health, 2016).

Therefore, challenges for the health area have always been on the agenda of the scientific and technological community. In this sense, with the advent of the information technology revolution in the 21st

century, multidisciplinary cooperation is crucial to guarantee the advancement in science in all areas. The health area has interfaces with several areas of knowledge, including chemistry, pharmacy, medical, engineering, information science, etc.

Thus, it is necessary to understand Health from its social dimension and as a source of wealth, configuring a CEIS that links highly dynamic industrial segments and the provision of assistance services. This complex incorporates the new technological paradigms that determine the dynamism and long-term competitiveness of national economies, such as fine chemistry, biotechnology, microelectronics and new materials, nanotechnology, the sustainable use of biodiversity, among others. Practically all segments included in the third technological revolution, fundamental to the Brazil of the future, have a critical space in their development in health (Costa et al., 2012).

So, thinking of health only as a burden on the public budget is a short-sighted perspective. The segment contributes to citizenship and to the generation of investments, innovations, income, employment and revenue for the State (Gadelha et al., 2012; GADELHA, C.A.G. et al., 2020). Likewise, for the One Health concept in the face of society's ills and, especially, in times of pandemic.

In the face of the global public health scenario, One Health, technological developments, and Big Data in health, it is necessary to think about better plans for the translation of knowledge in health, to combat the problems that affect humanity. Better management of knowledge and technology is needed with non-traditional means, such as enhancement of collaborative networks for the dissemination of knowledge and respective development, effective innovation.

QUALITY FOR GLOBAL HEALTH IN THE 21ST CENTURY

The concept of quality applied to products and processes was developed along the time. Lopes (2014) shows the evolution of quality in four ages: of inspection; of statistical quality control; of quality assurance and of strategic quality management (Calarge et al., 2007; Cordeiro, 2004; Lopes, 2014; Silva & Machado, 2011).

- The age of inspection begins in 1920, after Industrial Revolution, where machines brought the possibility of large-scale production, but with final inspection on 100% of the products manufactured. Thus, the inspector as responsible for the quality of the products has become essential in this context, however, the obligation to inspect all the items produced has led to an increase in production costs (Cordeiro, 2004; Paladini, 2011).
- The age of statistical quality control begins in 1930, and the main feature was the recognition of variability as a normal attribute of the production process, therefore it was revolutionary to control the quality through statistical methods (Cordeiro, 2004; Paladini, 2011).
- The age of quality assurance begins between 1940 and 1950, but only made official in 1970 in the United States. In this period, a series of tools have been developed to demonstrate the costs of quality could be reduced through prevention. The main characteristics developed in this period were: possibility of quantifying prevention costs, possibility of choosing suppliers, give attention in hole the production chain with the contribution of all groups to prevent failures from occurring. An important landmark observed in this era (1970) was the structuring of Good Manufacturing Practices (GMP) for the Pharmaceutical Industries in different countries. Thus, at the 28th World Assembly of Health, promoted by the WHO, carried out in 1975, the Guide to GMP (Cordeiro,

2004; Ferreira, 2004; Paladini, 2011). These industries must have this certification to manufacture and sell the medicines. The purposes of GMP are ensuring the final product is free from contamination, that its manufacture has been well documented, well-trained personnel, manufacture consistent, and checked product for quality more than just at the end phase.

- The age of strategic quality management persists to nowadays, using the view of quality as a differentiation from the competition, based on meeting the needs of the market and the client in search of business excellence, it can be said that in this age, quality has a strategic character.

Thus, the evolution of the "quality" concept has influenced and guided relevant changes in its management. In this process, quality isn´t more a problem to be solved and now is considered an opportunity for competitive advantage (Lopes, 2014).

Now, we are on Fourth Industrial Revolution. Faced with the Fourth Industrial Revolution, the organizational environment will undergo profound changes in scale, connection, and complexity of the value chain. In this scenario, quality management takes a central role due to rising customer expectations, global competition, and digital transformation as part of organizational objectives, strategies, and policies (Santos et al., 2018). This phase that is generally about automation and exchange of data in factory technology, robotic and artificial intelligence. The phase that ultimately results in "Smart Process". In the Smart Process modular, algorithms, physical-cyber systems monitor physical processes, create copies of the physical world virtually, and make decentralized decisions (*A Quarta Revolução Industrial | Amazon.Com.Br*, n.d.; Etzkowitz, 2014; Santos et al., 2018).

The concept of 21st century quality, in the pharmaceutical industry, is aimed at ensuring that the drug has safe, effective, and good quality. The pharmaceutical industries are regulated heavily by regulatory authorities. The Drug must have manufactured about the requirements stipulated by regulatory agencies, and medicine´s registers is a precondition for the almost drugs to get marketed for sale. The medicine´s dossier was submitted to the regulatory agency, needs to have a lot of documents about quality, scientific and regulatory. For example, of quality documents: description of manufacturing process and process controls, control of critical steps and intermediates, process validation, characterization, elucidation of structure and other characteristics, impurities, control of drug substance, stability, batch analysis, description and composition of the drug product, pharmaceutical development, manufacture, control of excipients, and microbiological attributes.

In this context, Regulatory system for medicines should provide effective treatments for patients, safeguard patient safety, and should encourage research into new treatments. Government, regulatory agency, patients, and pharmaceutical industry share a common interest in ensuring that the system is transparent and efficient. All regulatory agencies in the world have three main objectives:

a) Encouraging R&D, flow of new innovations and preserving the incentives;
b) Assuring or ensuring public safety when drug is consumed; and
c) Monitoring new drug quantity and quality (Sai Kumari et al., 2016).

In this sense, the pharmaceutical industrial segment, due to the criticality of its processes and the consequent risks that it can offer to its different types of clients (patients, health professionals, employees, etc.), deserve and have been adopting, throughout its history, duly rigorous measures and to obtain, more and more, the control and the technical / sanitary domain of these activities (VOGLER, M. et al., 2017).

Due to globalization, the pharmaceutical industries have undergone major changes in recent years, with their standards harmonized, for a medicine to be produced in one country can be marketed more quickly in another country. A Global Perspective provides the status of the complex and broad phenomenon of cooperation in Pharmaceutical Regulations.

The International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) is unique in bringing together the regulatory authorities and pharmaceutical industry to discuss scientific and technical aspects of pharmaceuticals and develop ICH guidelines. These guidelines provide minimum requirements that a manufacturer must meet to assure that their products are consistently high in quality, from batch to batch, for their intended use.

ICH's mission is to achieve greater harmonization worldwide to ensure that safe, effective, and high-quality medicines are developed, and registered and maintained in the most resource efficient manner whilst meeting high standards. Since its announcement of organizational changes in October 2015, ICH has grown as an organization and now (2021) includes 17 Members and 32 Observers (ICH, 2021). The most important regulatory agency are members of ICH, for example: The European Medicines Agency (EMA), United States Food and Drug Administration (FDA) and Health Canada.

In the ICH, the EMA is providing the Commission with its technical and scientific support and is coordinating the scientific expertise put at its disposal by the EU Member States, notably through EMA's main scientific committee, the Committee for Medicinal Products for Human Use ('CHMP') (ICH, 2021).

The only Latin American regulatory agency that is a member of ICH is National Health Surveillance Agency (ANVISA – Brazilian term). The Brazilian Health Surveillance Agency was created in 1999, starting a new regulatory environment. Several reviews have been conducted in the process of registering new drugs, with new requirements being introduced that have influenced the criteria for registering new drugs in the country in very particular ways. With the regulatory framework for the creation of ANVISA, a series of regulatory reviews for the registration of medicines began. Thus, a process of deepening, optimizing and specializing this regulation was obtained, marked by the introduction of new requirements that occasionally improved the criteria applied to the registration of medicines in Brazil (Couto et al., 2017). This Agency was approved in PIC/S (Pharmaceutical Inspection Co-operation Scheme) since 2021.

The Pharmaceutical Inspection Co-operation Scheme (PIC/S) is a non-binding, informal co-operative arrangement between Regulatory Authorities in the field of Good Manufacturing Practice (GMP) of medicinal products for human or veterinary use. It is open to any Authority having a comparable GMP inspection system. PIC/S aims at harmonizing inspection procedures worldwide by developing common standards in the field of GMP and by providing training opportunities to Inspectors. This is reflected in PIC/S' mission which is to lead the international development, implementation and maintenance of harmonized GMP standards and quality systems of inspectorates in the field of medicinal products. In this sense, is to be achieved by developing and promoting harmonized GMP standards and guidance documents; training competent authorities, in particular Inspectors; assessing (and reassessing) inspectorates and facilitating the co-operation and networking for competent authorities and international organizations (PIC, 2021).

FINAL CONSIDERATIONS

The 21st century has brought new challenges and opportunities due to the growing volume of new data added to the Web every day. The situation is no different for scientific and technological development,

especially in the field of health. Thus, it is important to constantly develop new methodologies for identifying, extracting, and processing data to obtain essential information.

Considering that more than half of the global wealth is knowledge, it is imperative that the decision makers of the nations, dedicate themselves to global health policies, that are, really, universal for better quality of life. These policies run through better information and knowledge management practices, since, intrinsically, quality is, subliminally, at the heart of the processes through health legislation.

The health of populations is expressed through their cultural evolution, health laws, economics, etc. Therefore, public health actions such as attention, promotion, research, development, and innovation, must be thought in the light of the concept of One Health for Global Health.

The mining of Big Data in Health is an urgent and emerging issue, as it is expected that it will elicit greater agility in the decision-making processes in the face of global health. A possibility of assistance to organizations in this process is provided by the availability of tools such as software to assist in the extraction and treatment of Big Data in Health. In this way, knowledge management occurs more reliably, quickly for decision makers in the face of information essential identified.

The quality in 21st century is especially important for production in the pharmaceutical industry and, in the harmonization of technical requirements as an opportunity in competitive advantage.

Importantly, the limits of the research and implications for practice and theory must be observed. At each evaluation cycle of the research, it must be confronted with Big Data interactions considering the One Health concept; since all areas of science have constantly updated data.

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Chapter 9
Perspectives for Interdisciplinary Methodological Approaches for Technology Research in Healthcare:
Impacts of Emerging Resources and Tools

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ABSTRACT

In this chapter, the author aim to approach new ways to understand how emerging technologies can better be applied in organizational contexts. For this purpose, collaborative methodological approaches were addressed—multi, inter, and transdisciplinary paradigms—aiming to promote a better level both of comprehension and adoption of technologies, paying special attention to the healthcare sector and to the One Health initiative, just defined as an interdisciplinary front. As an overall goal for the chapter, the adoption of those methodological principles is advised to the reader, enabling a better understanding of those technologies and their way to be effectively implemented.

INTRODUCTION

Information technology professionals, as any workers in tech fields, perceived fast moving changes in the markets they work several times. It occurred with the distributed processing introduction, commercial Internet availability, mobile information systems, graphical interface platforms and operational integration software, just to mention the more remarkable and widely noticed changes. These and other changes cannot be disregarded as organizational pressures, determining strategy formulation modifications and their consequent impacts (Lacerda and Jamil, 2021).

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Remarkably, in the last years, several factors contributed to promote another wave of technology insertion for professionals and organizations, as a new set of technologies emerged in the continuum of social media dissemination, sharing economy evolution and the incessant economy movements, which demanded quick answers for companies, NGOs, governments, and any other human associations. Worryingly, these changes are sometimes implemented without the needed study development, a solid theoretical background exploration and, even, the simple historic follow-up of some unfolding, like those cited above, as a source of best practices.

Unfortunately, this is a scenario which could lead to wrong decision-making, as to privilege only the tech view for investments and implementations, repeating some mistakes that happened in the previous failures of plans and projects, originally designed to provide insertion of technologies in organizational tasks. Observing the business context, with lack of objective definition for goals and scenario studies, as it happens with the "Startup economy" facing the Covid pandemic, it is expected that these competitive arenas can be more troubled even in the sake of economy retake, after the deep crisis faced in the period of 2020 (Lacerda and Jamil, 2021).

In this chapter I offer my points of view regarding the validity and need to observe and study such contexts from multidisciplinary, interdisciplinary, and transdisciplinary methodological approaches. This posture is advised because of technological insertion, implication and impacts in modern organizations structures, processes, and projects. As it has been discussed, becoming a motto for this chapter, technology research and applied studies tend to be benefited and turn out to be more applicable, if the central theme - technology itself - it is not kept alone, as the dominant objective, except for specific studies, focusing internal and fundamental aspects of technological development, prior to a potential usage (Jamil, 2005; 2021a, McKinsey, 2021).

As a motivation, it is possible to expect, for a study or observation where different fields are called to cooperate in one context, that these different experiences, results, stories, behaviors and overall conceptions can lead to a richer way of analysis, producing not only a deeper outcome, but, more, fast and robust results, which can be appreciated by practitioners, for their usage of tools and methods, answering the fast consumption behavior usually adopted nowadays.

Thinking this way, multidisciplinarity, interdisciplinarity and transdisciplinarity are comprehensible postures for methodological choices, building up techniques and tools, allowing a research base which can produce for practitioners, allowing research continuity and open relationship with several other fields (Zaman and Gachin, 2010). But, for this promise to be fulfilled, these approaches must be comprehended (Ribeiro and Medeiros, 2015; Noll-Minor, 2019).

The choice made for this chapter development was to present a discussion about these three methodological principles, their associations, and relations, briefly evaluate emerging technologies trends and consider them as applied in the Healthcare arena, in an intended contribution for this book reading and applicability.

This chapter is structured as the following: An Introduction which presents the isolated focus on technology, observing recent facts which unfolded in the market and the possibilities of risk management and problem solving in these cases, a section which will evaluate the emerging technologies panorama, succeeded by other section, where multi, inter and transdisciplinarity concepts are developed. Finishing, a view of application of these methodological approaches for healthcare studies which will consolidate the chapter proposition and intended results.

Evolving this study in such alignment, the point of reinforcing the need and application of methodologies which will promote the essential and undisputable technology application in a better and more

robust way is welcomed both by researchers and users, as it is possible to expect a clearer context for planning businesses processes and projects.

TECHNO WAVES AND THEIR IMPACTS

Business professionals, at least the most experienced ones, witnessed, in a few decades, some remarkable "waves" of technological resources market insertions. Generally, these promising revolutions came with an avalanche of advertising announcing the rupture with the old models, new levels for immensely improved results, no costs and effort discussions (Jamil, 2013a, 2013b). Followed by an avalanche of seminars, lectures, books published among other euphoric events, a brand new of technologies were introduced, ready to be implemented. At the end of each wave, no less than unprecedented results were also offered. The excitement and immediatism reflect on organizations, some even changing their structures and processes to accommodate these new paradigms, full of expectations (Lacerda and Jamil, 2021; Jamil and Silva, 2021).

Scientific analysis could lead these happenings to a more reasonable aspect, as to study organizational effects, changes, perspectives, and overall management, always reviewing the real possibilities of tools and techniques, their scope and fundamental objectives. But it always emerged such a pressure, from the information technology media, market competition, old model stability and the appeal on developing something really innovative, uniquely positioned (although the resources, by itself should not result in any substantial difference, instead its application would promote this difference) called the attention more than a "theoretical background".

As a predominantly technological view, for instance, smaller and personal computers were massively introduced in corporations, with the lemma "computing power over the table". Some IT brands started, in the end of 1980s and beginning of 1990s, to become as famous as automotive and financial logos, known by everyone who worked in an average-sized company. Not rare, it was possible to count more than a thousand desktop computers in a firm in which, years before, there were just dozens of "stupid" computer terminals, connected to a mainframe centralized network, compose just by expensive sets of monitors and keyboards (McAfee and Brynjolfsson, 2012). No friendly interface, no personal printing or mouse, just a terminal and the conceded software usage - limited - which was installed in the mainframe infrastructure. "Let us turn the mainframe off" and other campaigns were announced to promote the "informatics" insertion in the organizational environment.

Here we are, almost forty-five years after and, not only we still have mainframes but, if you take a careful look at the "center" of your computer network, you will probably identify the same focal point concentration of the former mainframe-based arrangement, as the infrastructure design did not change (Davenport and Prusak, 2000). Some problems with that imprecise, sudden and expensive process of replacement where processes were not redesigned, tools chosen to process decentralized data did not have power beyond domestic budget databases and spreadsheets, loss of the culture of centralized control of information and, lastly, the data security, which started to become a really worry for the market (Davenport and Prusak, 2000; Choo, 2003; Davenport, 2014).

One remarkable bad effect was the loss of control over data and information: as any user, "above his or her table" could create a database or spreadsheet, the download of former contents resident in mainframe disks became a common procedure. As the user processed that data locally, emitting results for a decentralized decision, a good result was perceived (McAfee and Brynjolfsson, 2012; El-Gayar and

Timsina, 2014). But it was a temporary win, as when the organization attempted to produce an inter-departmental study, collecting data from all departments, and producing a collective analysis, some of these contents were locally updated, not changed in the central registers. So, two or more versions for a reality were available resulting in indecision and lack of authorship or change management. Closing a market share analysis or analysis of competitive performance based on indexes and variables became an internal dispute regarding "in what version should we rely?".

With a wider view, analyzing a process as a multi and interdisciplinary context, approaching all involvement of different company agents, eventually approaching external application of analytical results - for example when setting a strategic goal and searching for its achievement, receiving data from supply chain partners - it was possible to build a richer view, business process-oriented with all areas and disciplines precisely observed and approached. Lack of multidisciplinary previous analysis, before the hardware purchasing and installation (Hoffman, 2013).

Tech wave to continue, these desktop wonders were also interconnected in networks, "thousands of points", few results beyond printing optimizations achieved, again no conceptual study was previously made, generally a technological project was - not written, formulated - executed, connecting boards and cables.

In these cases, a point is reinforced: the global, integrated view for the solution, with all disciplines and subjects involved should be approached, composing a project background with solid management principles, toward a solution based on technology. If this was the case, probably, the volume of data contents, those expected answers for the analysis, integrated reports and composed management would be studied and correctly inserted into plans, resulting in a more comprehensible and manageable situation for these installations (Johnson, 2012; Kimball and Ross, 2013; Jamil and Magalhães, 2015).

Another remarkable case, which still produces a lot of mistakes and painful corrections, is the adoption of ERP - Enterprise Resource Planning - platforms. Here, we consider both the entitled ERP as from the companies which offer these products named specifically and other software combinations which result in an integrated tech-based process aiming to compose all steps of operations in one company, both as a process standardization platform and consolidated, integrated database.

In a series of events, which started in the beginning of new millennium, promising even to deal with problems that arose at that time, as the "Millennium bug" (a lack of rounding when date fields in database registers would be changed from "99" to "00", inducing mistakes on calculations) and the implementation of Sarbanes-Oxley law enforcements towards data and information tracking and governance, the operation integration platforms, identified by providers as ERP, Enterprise Resource Planning systems, emerged as a dominant and mandatory information technology background and backbone.

No doubt the problems various companies were facing at that moment really demanded such platforms and several qualified products were also offered by reliable and reputable players. What called attention, again, was the speed, lack of study, concept formation, analysis and background composition which could allow the correct management for this intricate project - implementing an ERP platform. Without a fair level of multi-aspects, multidisciplinary observations, registering and classification of operational events, these complex and expensive tools were implemented as "software", likewise an Office suite. Some "priority" tasks were coded on rules and integrated interfaces, becoming eligible for an automation which, sometimes, did not correspond exactly to what was really being treated or dealt with at the operational level.

Results? An expected level of awkwardness, unexpected steps and phases, somewhat like a new process, replacing a culture-based one, without the supporting change management approach. Not rare, we

saw - and still observe - companies dealing with these adaptations *after* the implementation occurred. So, emergency actions, after investments, time spent and a lot of reviews to do, with the software being used and processes in operation. Some of these actions last for several years, becoming a task for dedicated teams. The implementation project becomes an implementation - maybe endless - process (Jamil, 2021a; 2021b).

Why Multidisciplinary, Interdisciplinary, and Transdisciplinary Views?

This last scenario depicts exactly what is intended to be approached in this chapter: the lack of an integrated, multi and interdisciplinary organizational view of processes which will be operated by different departments, organizational structure members and units, which should result in a perspective of different views, methods, specifications and expected results. This overall observation is recommendable for a global, associated interpretation, as it should be provided by those methodological approaches (Rascão, Jamil and Marques, 2021). With those, a comprehensive conception for operational processes could be obtained, resulting in a wider and detailed view, allowing a better understanding for organizational operation to be automated and optimized with ERP platforms.

Unfortunately, as several results showed, some implementation, taken as isolated business projects, without correctly observing and analyzing all related context, produced disappointing results.

For this purpose, it will be discussed in this chapter the application of multi, inter and transdisciplinary approaches as the methodological paradigms which will sponsor fast, conclusive and, moreover, embracing views, as other scientific fields are brought upon to, in a scientific approach, promote a better understanding of these phenomena.

Why Healthcare?

As an organizational sector, populated with data and information and subjected both to social, market and management demands for knowledge production for decision-making, regulatory issues and technological pressures, Healthcare is a sector where these problems emerge, occur and, essentially, deal directly with critical decisions, regarded immediately to human life.

It is an intense, immersive, dynamic, and pressured sector, with huge supply chain management issues, requirements for urgent technology application, ranging from Medicines to Corporation arrangements and adjustments. In this panorama, clearly, conditions to develop and execute plans, both strategic, tactical and operational, are far from the desired level. Along with highly skilled professionals of Medicine, Nursing and other emergent fields, such as Biomedicine, Bioengineering and other life enhancing and caring formations, top level management is needed to provide the alignment for all these processes to integrate and perform not below than the optimal level.

It must be stated that one of the principles of OneHealth initiative, exactly one of the main topics for this book proposition, is interdisciplinarity. As we will approach the theoretical background to be developed further, interdisciplinarity aims to build a collaborative fabric of conceptual networks resulting in a broader and participative way to understand problems, propose questions and research methods which will attempt to provide answers and directions to study solutions.

The picture presented above, of mistakes or incompletions in technology adoption, conceptual availability of traditional, although not completely applied, methodological approaches and a sector where

all risks of precarious planning and impulsive technology adoption, results in an adequate scenario for this study.

INTERDISCIPLINARITY, MULTIDISCIPLINARITY AND TRANSDISCIPLINARITY RELATED TO INFORMATION SCIENCE

Interest in widening scientific studies, opening a context for other researchers, other principles of practice and ways to collect, treat and analyze data and events related to phenomena, can be found in the realm of research for centuries (Nicolescu, 2014). Perceptions of cooperative perspectives, complex views of each reality, results sharing, among many others, motivated researchers, and academic communities to practice and communicate combined, interviewed proposals, objectives, and results in various academic fields (Max-Neef, 2005; Choi and Pak, 2007; Bresciane, 2015).

Alvargonzález (2011) approaches the requirements, skills aspects, and practice behavior for researchers as these initiatives were considered positive, and the challenges over scientific fundamental studies aimed to solve problems which were each time more complex and related to several aspects.

Setting a starting point for this study around these three methodological postures, Multidisciplinarity will be discussed in the following. As contextualized by Zaman and Goschin (2010) and Alvargonzález (2011), Multidisciplinarity proposes a combined view of a subject, with associated, related and joined contributions, although each field keeps its individuality, "personality" and original conventions. A fact or phenomena is analyzed through various lenses, adding up experiences, different and complementary views, building a more solid and wide model of what is being studied. Questions are answered, typically, in separate ways, with different applied analysis, reaching a common point where the dialogue is produced, issuing a result which is the added, accumulated experience for those cooperative fields. There is no compromise to produce a set of tools or techniques, which result in a new research scope for analysis, as each field follows its original way, receiving the benefits of being working with another trend or scientific arena.

As stated by Max-Neef (2005): *"Multidisciplinary teams of researchers or technicians are common and frequent nowadays. In them, the members carry out their analyses separately, as seen from the perspective of their individual disciplines, the result being a series of reports pasted together, without any integrating synthesis*".

In Healthcare, as a typical area where the cooperation of different disciplines and subjects is practiced, Multidisciplinarity seems to be the immediate approach to be adopted, as it produces less impacts - some of them are indeed desired - and changes in the methodological background, not demanding a huge dedication on explaining new ways to study, analyze and produce results from research. Each contributing field reaches the objective and takes the results, detailing it in their own methods and words. Importantly, Multidisciplinarity is practiced also when conditions to put Interdisciplinarity and Transdisciplinarity are not favorable, sometimes being regarded as a frame where practical overhead is tolerable.

Unfortunately, sometimes, the work on combining separate results in Multidisciplinary studies, coming from different fields, can become difficult, as in terms of production or even in the field expression itself. For instance, Finance is a topic which usually drains all study answers and associated applications, overshadowing the other fields' participation (Bazeley, 2015). Usually, Finance, as an example, calls more attention in Management studies as its results and working issues are to be done immediately. This

way, the researcher must take care for the study balance (Alvagonzález, 2011; Loureiro and Guimarães, 2019; Bogdanova, 2020).

In this brief explanation, we just can check a potential relationship among these three methodological approaches, relating it both in theoretical and practical terms. Multidisciplinarity can be understood as a first-level approximation to collaborative research, to a base or alignment to allow a discussion among different, eventually not close, or related fields, which have - on their researchers´ mindset - conditions to cooperate (Flores and Rocha Filho, 2016). This can be seen, in a simple and superficial view for Healthcare assistance, when different specialties and specialists are called to examine a patient with a complex condition, and issue their complementary opinions, to be consolidated as a unique, although signaled in a separate way, to produce one analytical synthesis for the problem, enabling the solution.

Interdisciplinarity, thinking this way, emerges as the next step on building formal, scientific-supported knowledge from a research project (Loureiro and Guimarães, 2019). This posture will result in a deeper combination of different fields which will lead to a combined evidence collection, analysis, and communication. Interdisciplinary works are characterized when a combined way to sample data, not strictly based on one only discipline or research field, reaches one subject. For example, a citizen is contacted to be researched regarded garbage collection with a questionnaire (or other ways of data collection), composed by insights and questions which came from different fields - such as Economy, Demography, Production Engineering, Environmental Engineering, Biochemistry, among others - consolidated in one single research instrument for evidence collection.

As stated by Zaman and Goschin (2010):

Interdisciplinarity emerges from the process of combining and integrating various disciplines, along with their methodologies and assumptions. It involves crossing the traditional boundaries between sciences and mixing their techniques in the pursuit of a common goal. Methodologies and assumptions belonging to different disciplines are connected and modified in order to adapt to the needs of the research, creating new tools which allow for the investigation of difficult subjects that surpass the possibilities of a single discipline. In the field of economy, for instance, complex topics such as inflation, labour market, credit, stocks or exchange market imply various approaches that combine economics, mathematics, geography, politics, sociology, biology, physics and others.

Interdisciplinary is powerful, as it is simple, reachable, consolidated by several years of practice. Engineers, especially those who work in complex projects, such as specialized buildings or infrastructures, use to apply Civil, Electrical, Environmental, Architectural, and other knowledge bases to create single analytical tools and methods, applied in field examinations, corrections, and evaluations. As it is interesting to perceive how interdisciplinarity really works, we can observe how these disciplines of the Engineering context are, nowadays, congregated in BIM environments, allowing an advanced practice, supported by 3-D printing, virtual and augmented reality, simulation, and plan projection systems. This is, undoubtedly, interdisciplinarity in practice (NCSU, 2020).

Other cases encompass association of Astronomy and Environmental and Climate analysis, which supported mankind comprehension of our planet´s inclusion in the Solar System and, this way, enabling Universal mechanics and related disciplines. Pharmaceutical and Chemistry have, also, a long way of collaboration towards solutions for healthcare problems. Geography is a scientific field which evolved in the last decades with wonderful dialogues with Sociology, Economy and Demography, resulting in

a deeper understanding about our existence on Earth, through interdisciplinary studies (Noll-Minor, 2019, NCSU, 2020).

It is indisputable that interdisciplinarity results in a combination in which participant fields have potentially more voice, more expression and tend to be more stimulated to continue to cooperate, aspects that lead to interesting ways to combine efforts for many years, this way contributing for improvement for all cooperative fields. This is a way that results in an attractive fashion of work for all cooperative workers.

Comprehending this first step of evolution between these two approaches, one can understand that interdisciplinarity collaboration could evolve after some periods and successful explorations of multidisciplinary studies, which reached good objectives and fulfilled project estimates and goals. As a result, it is possible to advance in comprehension, exploration, and analysis about the two or more fields which were researched as separate, although contributive, contexts (Sakao and Brambila-Macias, 2018).

Transdisciplinarity can be understood both as an evolution of this relationship and a real disruption towards a new paradigm. Adopting a transdisciplinary approach, we aim to produce a new combined field, extending the collaborative, although isolated approach from multidisciplinarity and the composition of tools and practical arrangements, as predicted by interdisciplinarity. Thinking in multidisciplinary terms, we search for a new field, a new level of comprehension, towards problems conception, studies and analysis (Nicolescu, Morin and Freitas, 1996; Nicolescu, 2000 and Nicolescu, 2014).

A beautiful conception, a tough objective indeed. There are several issues on combining two or more fields to understand a research context which had been appreciated by one, isolated leadership of one field, or even with its patronship, when this leading field acts as the center, calling the collaboration of others, as we can conceive in transdisciplinarity (Nicolescu, Morin and Freitas, 1996).

In transdisciplinarity thinking, eventually, some fields and their associated contexts could be involved in a creation of a new way of understanding which can, at the end, calls more attention than the original contextual sources, a development that can be favored by the fast need of answers, as we face in any kind of scientific research today. This way, original and relatively stable scientific fields could face the creation of a future competitor or substitute, if not total, at least partial, replacing it for the leadership in exploring a problem scenario.

As presented by Nicolescu, Morin and Freitas (1996):

The recognition of the existence of different levels of reality governed by different types of logic is inherent in the transdisciplinary attitude. Any attempt to reduce reality to a single level governed by a single form of logic does not lie within the scope of Transdisciplinarity. (NICOLESCU, MORIN and FREITAS, 1996).

Overlooking formations and associated research terms, we can perceive the emerging of such a new interesting, opportune, and well-segmented context, such as, for Engineering, for example, with Automation, Robotics, Aerospace, Materials research, and several others. A conservative question could emerge: About these topics, were they not previously inserted (or "owned") by some Engineering conceptions, such as Mechanics, Electrical, Chemical, and others? What to say about Environmental Engineering? Some could even argue if it is not a principle, which should be taught and practiced by all specialized engineers. Robotics and Aerospace are not specializations or branches from Mechanics? Were their scientific tools, techniques consolidated also, or these new propositions will grow from what we learned and practiced from those original sources?

No doubt that several questions arise, issues, limits and extensions when thinking in this collaborative way to produce not only a new way to study a particular problem, but also to develop a completely new context to approach problem families in this quest to research.

As for Healthcare, it is recognized the emergence and success of new paradigmatic contexts, such as Biomedicine, Bioengineering, Biochemistry formations and its related research and analysis paradigms, as undeniable signals from change and insertion in this classical, essential, and strict arena. Healthcare offers a situation that will happens frequently from now on, when classical contexts will not encompass all leadership, trends, topics and demands for analysis, leading to a pressure, both from communities and already related fields - as external - and from professional and practitioners - as internal - to carefully observe some specialties, details, emerging topics and deeper analysis on some facts. This will be a situation faced by all classical scientific fields, which will likely push for a Multidisciplinary approach.

But, as a conclusion of the conceptual rationale about multi, inter and transdisciplinarity, it is important, considering these last considerations regarding the expectations and issues faced when approaching multidisciplinarity, that it is not easy to develop, conceive and implement such a new field. Although expected, probably the interest on the new study context will surpass, by far, the fundamental construction of the methodological bases for this new paradigm. This will take a long time to be offered, comprehended, tested as complete research projects and, finally, practiced and adjusted, as the field research returns inevitable signals, as cost, time and resources restrictions (Nicolescu, 2014; Flores and Rocha Filho, 2016; NC State-RDU, 2020).

So, for the survival of these three conceptual schemas, successful and fundamental bases which we are conducting our research over time, discussed by scientists from centuries, practiced developing all essential solutions for our lives, it is not easy to adapt, change and combine, although these actions are needed and desired. Multi, inter and transdisciplinary studies and practices, this way, are not to static bodies. We must understand it as dynamic, evolving, flexible and adjustable contexts, which will compete and adhere to each other, demanding researchers´ comprehension all the time.
It is important to pay attention to Alvargonzález (2011) words, as he stated:

Strict sciences, such as Euclidean geometry or Newtonian mechanics, not only can become disciplines but, as they are not transmitted by heredity, should be taught and learned if they are to be kept alive. However, strict sciences, while giving rise to disciplines, are not only disciplines: teaching and learning are moments of scientific activity, but they are not necessarily the moment of constitution of scientific theorems but the moment of their transmission. The idea of discipline is generic with respect to science because there are many non-scientific disciplines. Therefore, 'disciplinarity' is not a specific characteristic of science. As we have pointed out, the core of the idea of discipline is a social relation between the teacher and his or her disciples. Sciences are social institutions but, once more, there are a lot of social institutions that do not give place to sciences. (ALVARGONZÁLEZ, 2011, p. 389)

Validating our points of view in this applied conceptual view, observing the "discipline" characteristic of these three methodologies.

As for Interdisciplinarity, we reach a level where there is a demand and expectation for different fields integration. This concept produces a requirement on producing combined and co-joint efforts for evidence collection, data analysis, combined methodological practices and, eventually, result analysis (Choi and Pak, 2007; Zaman and Goschin, 2010; Bogdanova, 2020). In practical terms, a unified research instrument or tool can be produced, to widen the analysis object perception, evaluation and resultant

analysis. Also, combining different fields together, it is possible to define this research operation as a practical aspect to be adopted, producing a composed methodological practice, which will potentialize future collaborations from the scientific fields which worked together in a previous analysis (NC State-RDU, 2020). There is no commitment, however, on generating essentially a new research paradigm, a new composed research platform and a unified context which will assess and compose ideas from different epistemological sources. As an evolution, Interdisciplinarity produces a better level of analytical perception, an evolution from Multidisciplinarity, but demands a tougher research coordination, worries about different field research contents and contexts avoiding any dominance or partiality, as increased complexity, research costs and complexity.

EMERGENT TECHNOLOGIES REVIEWED - AN APPLIED CONCEPTUALIZATION

As it is our goal with this chapter to perceive how one can perceive emerging technologies impacts on the Healthcare sector. This way, we evaluate the application of consolidated methodological approaches, such as multi, inter and transdisciplinary, to analyze such potential changes. It is opportune to state that our book focuses on the OneHealth initiative, defined at OneHealth (2021) as an "interdisciplinary approach for complex topics, involving interactions among different sectors of global Healthcare". It will be attempted both to leverage a conceptualization and analysis about potential usages of emerging technologies implements and demands for an associated multi, inter and transdisciplinary views. Associating this way, it is possible to produce a better rationale on how these concepts can be exerted in practical fashion in the Healthcare industry.

In a complex scenario, both disciplinary views and associated technological applications are welcomed. Researchers and practitioners face tough problems, difficulties, complex questions, and issues, needing to process a significant number of signals, from different sources and formats, aiming to produce answers and objective decisions (Choo, 2003; Akbar, 2003; Alteryx, 2021).

For a primary overview, it is indispensable to consider Healthcare context as full of data and information. Along with this fact, decisions which must be supported by these contents have also to be taken all the time and, critically, usually approaching aspects of human life (Badia, 2014; Nimaku and Kruk, 2021). For this purpose, modelling scenarios through data analysis evolved from a perspective to a tough demand for this sector (Rogers, 2017; Dash *et al.,* 2019). First perceptions on how to structure data contents as to produce organizational knowledge focused Healthcare sector for several years, but as demand and complexity grew, data and information contents were also reevaluated, to admit faster and more precise production of answer to demands (Markovitch, Steckel and Yeung, 2005; Inmon, Strauss and Neushloss, 2008).

Concepts of Big data and analytics emerged as to produce knowledge, composing contents from data collection and application, ranging from structured reports to social media postings, resulting in a possibility to understand precisely the "why" questions associated with "how much" or "yes / no'' traditional requisitions. As defined by authors like Marchand, Kettinger and Rollins (2001), data services were reorganized and offered not only as a final service, but combined with hardware implementations, such as robots or another layers of software as a service, producing consistent views of reality, allowing better decision-making and advance scenario projections. Some of these new services have their fundamentals on long-time researched theories, which now can be regarded as the bases of distributed or cloud-based

systems, as conceived formerly by authors like Buckland (1995), Kearns and Lederer (2003), O'Brien and Marakas (2008), Rogers (2017).

Considering Healthcare analysis, this knowledge could be considered by private managers, as to observe endemic events and prepare their services, by public agents in the same contexts, with another view, of prevention and public assistance. For professionals who work at the operational, patient-level, the preparation for any intervention, artificial intelligence available to support an exam during a critical procedure, like surgery in emergency. For planners, all managerial issues, ranging from Financial, to Marketing, enabling a Strategic view. This complex, competitive, sometimes aggressive, and undeniably critical scenario constitutes a real challenge to apply technology (Dash *et al.,* 2019).

One concept which can be reviewed, as taking the new scenario of cloud computing support, is the information system (IS). One IS was previously conceived as a set of oriented components composed together to solve a problem dealing with information (Turban, Mc Lean and Wetherbee, 2002; Turban, Rainer and Potter, 2007; Stair and Reynolds, 2008). In a cloud environment, a network of computer resources is promptly available through an internet connection, accessed via one easy, integrated interface, as those provided by commercial browsers, where the user can work with a computer or network emulated from a configuration (Jamil, 2013a; AWS, 2020; Jamil and Silva, 2021).

In this new perspective, data, information, and the software platform itself could be put available in a cloud system, performing one easier, more intuitive, safer and model-supported data processing infrastructure, as IT managers can also provide faster solutions to final users, allowing Healthcare center to use computing resources through a simpler configuration task (Stein, Campitelli and Mezzio, 2020; NIST, 2020).

As cloud systems and supporting structures make it easier to put resources available for any user, data collection - an essential task towards information consolidation - can be done and provided by several technologies. But this can be seen as a multidirectional collection, something conceptually innovative, as allowing to concentrate signals, symbols, and values from several sources, improving what was defined by remarkable authors such as Saracevic (1996), Taylor (1996), Nonaka (2008), Russel and Norvig (2009) and Welsh (2020).

RFID implementations could be regarded as the simplest way to integrate data collection to a device or artifact, when "smart" tags are added to these objects, becoming a source of position, status (open, close, used, empty, etc.) and safety, allowing not only to identify these objects, but also dynamically understanding their status regarding any usage or operation (Pessoa, Batista and Marques, 2020).

One special evolution of this concept is achieved, in a truly higher level of implementation and services, when we think about Internet of things (IoT) devices, sensors and platforms. These implementations correspond to devices with a superior degree of integration, through Internet Protocol standard IPv6, enabling the complete identification of that specific device. Usual apparatus and domestic resources, such as thermometers, doorknobs, levers, showers, faucets and several other, related to our daily usage, can be efficiently connected to the Internet (Evans, 2011; Pessoa, Batista and Marques, 2020).

Immediately, a concept of useless connection of things like those emerge and we can turn to disappointment as facing a "do-nothing" technology, used only to check if scissors are closed and if we just put all spoons in the correspondent drawer. But IoT goes far away. For example, an automated platform, connected through IoT devices could allow us to design and implement a system where objects inside a container can communicate with a concentrator for this container and this device, for its turn, can communicate to a docking management robot. With these connections provided, objects can signal to the container they need to be collected in a period of six hours, due to health conditions and the container

will be served by the docking system, for a transportation, as the system finds a way to allocate it in a safe space to be installed on a truck (this truck, by its turn, can also be a "robot", which will come to collect the container, answering all the system requirement). This platform, which can also be adopted to transport medicine drugs, devices, and support, is nowadays available in semi-automated areas of ports.

IoT systems will expand overall data collection capabilities and processing, as providing possibilities to associate internet connection and interaction among systems to real, planned, and programmed actions, through a powerful interrelationship with other tools, such as big data processing, analytics and even blockchain open register structures (Qiu *et al.*, 2016; Jebran, 2020).

This aspect could be expanded by artificial intelligence implementations where we aim, as thought by John McCarthy at the Dartmouth College Seminar in 1956, when he and his research team announced they were looking for "automata" who will "behave and act like humans" (Moor, 2006). As these ideas evolved, artificial intelligence was implemented mainly in two ways: Machine Learning, related to the repetition of human actions, registered in the computer memory as coordinates, or obtained through a data collection from the real world, using any way of computer interconnection (for example, through IoT devices), or modelling scenarios from massive data collection, or finally, through a human follow-up, using devices or even image processing (Jamil and Berwanger, 2019; Jamil and Silva, 2021; McKinsey, 2021). This way, this AI computer system could collect data, model it through a sequence of operational rules, which can grow as the computer perceives new events regarding the same context and, finally, composing new rules or reinforcing those already existing.

Deep Learning is another fashion of artificial intelligence systems which can be understood as an evolution of machine learning. DL contexts can allow intercommunication among scenarios and, this way, provide a conception on how they relate. For example, a system equipped with ML code can process several X-ray exams, corresponding to their results dynamically, associating, by a large repetition of analysis from data, diagnostics. A DL "machine" can, in an evolved effort, attempt to establish a cause-effect rationale, associating some diagnoses as if they are health problems which occur in function of others (Courtney, 2013; Al Jarrah *et al.*, 2015; Dash *et al.,* 2019).

Examining all these technologies, it is possible to plan their applications adopting a strict view, just based on their functionalities and immediate contribution. But this is, undeniably, a risk method which this chapter text presents recommendation on not applying, as the traps regarding "technology wonders" were shown in the motivational section, at the beginning. After we consider all these technological aspects, from a managerial leverage point of view, strategic plans can be proposed or reviewed, allowing the best application of tools, techniques, and methodological contexts, in order for these emerging resources to be applied based on known and controlled contexts. This will be explored in the following section, considering the methodological overview for its better organizational usage.

RELATING METHODOLOGICAL APPROACHES FOR EMERGING TECHNOLOGIES ADOPTION IN HEALTHCARE

Strategic planning offers the guidance for an organization to plan its development, from surviving a competitive context to becoming a real innovative leader (Porter, 2008). Strategic plans are to be started, formulated, and reviewed in a dynamic organizational process, which will consider technology not only as a help, but also as an advantageous point, if it is suitably applied in plans, projects and execution (Mintzberg, Ahlstrand and Lampel, 2010; Rogers, 2017).

Starting this observation regarding the overall planning capabilities of one organization, it is opportune to bring to the main scenario those three methodological postures - multi, inter and transdisciplinary methodological fundamentals - both to understand how plans are designed, how they relate to Healthcare management as a context of technology application for real cases.

For instance, when thinking about data analysis and processing, it is possible to understand the "life-cycle" of data, towards producing information and knowledge, to become applied for decision-making, as some situations pictured above for Healthcare (Davenport and Prusak, 2000; Choo, 2003, Jamil, 2005; Jamil, 2013). This cycle can be used, in a interdisciplinary approach, at a first glance, to apply artificial intelligence implements, relating it to a data collection structure, from RFID or IoT, expanding from the simple situation of directly contacting a typical user. Machine Learning can be understood as a process which will allow a typical information production, along with the knowledge generation by Deep Learning. Understanding it from an interdisciplinary point of view, we can observe how different disciplines, such as, typically, managerial (Accounting, Logistics, Strategic planning, Marketing, Commercial, etc.) would relate to user-answering ones, such as those practiced by the Healthcare workers, as Medicine, Biomedicine and Nursing.

Understanding this way, the corpus addressed by an interdisciplinary approach of all these main scientific and practical fields will be comprehended as a collective base, an interconnected and applied platform, which allowed knowledge production from data and information, using a supporting technology not only for operational automation, but, in extent, to produce decisions, even aiming to learn from its executions.

This is a way which could lead us to think in a "platform" business model to integrate "Industry 4.0" solutions, for example (Schwarb, 2018, 2018b). As integrative frameworks, these business models' propositions encompass not only the insertion of one business itself, considering just its structures and processes, but offering an additional condition on connecting them to other businesses and solutions in the market (Jamil and Berwanger, 2019). This can promote both integration and overall complexity increase, as we can understand these new connection as one effective market to user interaction, presenting another level of demand for consistent methodological approach to be applied.

Interestingly, this simple alternative can also be understood as a first step to a transdisciplinary framework, where all these topics can be considered together, beyond a leverage comprehension, but examining their supply for automated and intelligent environments, also upgrading towards a real new context of data, information, and knowledge composition, as to create a real strategic "Blue Ocean" front, of a pioneering, analytical subject (Kin and Mauborgne, 2015).

Another way to understand the methodological application to bring more fundamentals for emerging technologies projects, would be to pay attention to cloud-based structures and blockchain. It is easy to note that people and organizations tend to evaluate cloud computing as just "backup" facilities and structures, but, going beyond, it is plenty possible to observe how this concept is a minimal, insufficient view for this technology. Aiming to implement cloud-based virtualization, we can reach the level of a virtual computer network, and all its related potentialities and services, to be applied in one organization.

As another integrative platform, ideal for a cooperative environment, implemented with safe and easy, supported access, Blockchain is also misunderstood and, this way, not well adopted by several different types of organizations. Sometimes, it is only regarded as a cryptocurrency support, with a smaller, stricter view.

Thinking in an isolated, incomplete way, it is possible to embark on an idea similar to that of "one computer for each employee" (or above its table), as it was mentioned in the beginning of this chapter.

Potential risks, as discussed before. In a multidisciplinary approach, starting an overview of a better methodological analysis, each one of the Healthcare organization main processes, related to services, interventions, management, and other factors, can become an active actor, responsible for parts or components for a solution planning, regarding the usage of cloud or even Blockchain. This way, each service or process would have its "action" element designed, operating individually, aiming at the organizational result. This can be thought of, for example, when analyzing logistics and supply chain of a hospital or clinic, relating the external environment ("suppliers") with internal demands ("internal logistics").

Extending this comprehension, interdisciplinary - strictly recommended! - approach for a cloud or Blockchain-based projects could be adopted, interpreting the collective expected answers and data sources along with analytical projections and studies, to be developed as the result of a collaboration among different and participative fields. A Doctor, for instance, could understand how his or her registering, in a patient´s follow-up procedure, could lead to a logistics planning review, using Blockchain registering for immediate data supply and, moreover, cloud-based applications to analyze it and publish for managers, allowing a perfect domain of this essential process.

Finally, it is possible to investigate the association of emerging technologies and methodological support when we simply pay attention to the main item: data. As we intend to impulsively collect data adopting coding schemas, provided by modern platforms, such as "R" and Python programming and understanding how this content can be valued as an active element to produce information and knowledge, it is possible to leverage the perspectives of applying Big Data and Analytics tools and associated methods.

With these techniques, it is possible to produce the intended levels of analysis, resulting in composing information and knowledge from data, associating this process to an improved comprehension of organizational phenomena one Healthcare installation is associated with. For instance, the usage of critical resources such as emergency-related apparatus and facilities can be programmed with anticipation, analyzing data and information occurrences improving the success for the knowledge on using these organizational resources in an optimal way.

Typically, it is an evolution of a multi to interdisciplinary comprehension of resource allocation - this way thinking this could be a research problem, a business-related base for decision - when this scheduling is critical for the results and answers to be produced by the Healthcare organization. This optimization will lead to a better operational performance, fast answering to customers and related management-oriented tasks, promoting a clear way as an interdisciplinary approach benefit for facilities administration.

Relationships like these will allow to completely address emerging technologies "on the field", promoting a better way to comprehend how they are not only "punctual" problem solvers, as usually announced by market resellers (for several decades, as the reader took notice from this chapter initial provocation about the incidents of naive technological adoption), but potential multi, inter and transdisciplinary agents, with unprecedented level of analytical answers, knowledge production that could lead even to a new managerial paradigm. Considering these scenarios, the application and integration of emerging technologies remains highly recommendable, with the adoption of these classical, elegant and efficient methodological approaches.

CONCLUSION

Emerging technologies, although we are living in a surprising scenario, it is not a new fact around organizational strategic thinking and planning. As it was mentioned, we faced, on the market, some waves

of technological redefinition and innovation, some really new, a rupture potential against old managerial models, other just new ways to understand something which was already being negotiated and implemented but offered in a new fashion.

However, technology usage is another step, as several professionals and organizations, during large periods of time, discovered. Delivering products and services for final users, customers and citizens, even with the most updated technological resources demands a level of comprehension and conscience about user-organization relations, contexts and interactions which can offer new challenges for implementers, as tools demand methods and, by its turn, these methods must be solid, based on strictly science fundamentals, as to allow they can be adopted in a clear way of thinking.

Talking about technology, it is interesting to observe that, from the several launchings and proposals, all of them are being defined - not strictly conceptualized - as integrative, collaborative, engaging and fast-answering enabled. As is cited, these concepts are usually, as perceived in other "waves", pressured from the market towards organizations, pretentiously defining these technologies as to be related and participative as is, not demanding excessive care, precaution, risk management and planning to receive those enlisted benefits. As before, we can be in the face of naive, intuitive only and precarious ways to insert a massive technological order in our lives, by just believing in their answers, productions.

Yes, these recent technologies are changing our way of life, and have served to significantly help in crisis periods, like the Pandemic which exploded in 2019 - 2020 around the World, with terrible results. Without all technological implementations, for sure, all our businesses, production and help would be impossible, and this is our view of Technology: indispensable to think about our lives without it! But, they demand careful study, comprehension and solid methodologies to provide their best results and, moreover, planned control.

In this chapter an overlook of the potential association of multi, inter and transdisciplinary methodological postures, contributed by Research Methodologies scientific field, long-time practiced, discussed and practiced by researchers with the emerging technologies, were considered. As a motivation to produce a provocative panorama, the Healthcare sector was considered as the arena for the knowledge treated by these technologies to be applied, literally, for essential human life survival and improvement.

As discussed, an introduction to these methodological fundamentals was held, proposing it as a framework to propose plans to adopt, use and review emerging technologies in the Healthcare scenario. It was opportune to remember that, even the OneHealth initiative, one of the front topics of this book, is regarded as an interdisciplinary proposition, becoming a platform for knowledge production for the sector.

This way, a perception was developed to show how these approaches can result in better ways for successful implementations for these complex but rewarding technologies, as a base to better guarantee their answers for businesses and organizations of any type.

This way, technology, represented here by these fantastic new tools and resources, can impact our lives positively for long periods, supported by solid planning abilities.

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Section 2

Intellectual Knowledge Management as a Contribution to Global Health

Chapter 10
Anvisa's Prior Consent as a Contribution to Global Health and the One Health System:
An Analysis Based on the Kingdon Multiple Streams Model

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ABSTRACT

The participation of the National Health Surveillance Agency (ANVISA) in the granting of patents for pharmaceutical products and processes in Brazil took place since 2001, giving this sector of the Ministry of Health unprecedented legal competence, until then exclusive to the entity of the National Institute of Industrial Property (INPI). This chapter proposes to analyze the technical and legal aspects inherent to patenting combined with the ability to make political decisions in favor of implementing flexibilities in the patent examination of medicines that may be favorable to public health. John Kingdon's Multiple Flows Model was the methodology chosen to understand the most relevant factors that influenced the government's agenda for the creation of Anvisa's prior consent. The results allowed to outline the political window that materialized the formulation of the public policy in question, as well as to call attention to the fundamental importance for the protection of the current needs of humanity and of its future generations inserted in the concept of One Health.

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INTRODUCTION

The importance of the patent system in a globalized world is undeniable; both for science and technology, as well as for the industrial and economic development of the different countries. Regarding public policies in the health area, the granting of pharmaceutical patents started to provoke innumerable debates focused on access to medicines and the right to health (Marques, 2000). In Brazil, the right to health is a fundamental individual right inscribed in the Federal Constitution (Brazil, 1998) in force, and universal and equal access to actions and services for the promotion, protection and recovery of health is a duty of the State (Law no. 8,080 of 1990) (Brasil, 1990).

Attempts to expand the population's access to medicines are not recent and among the main attempts we highlight the creation of the Central de Medicamentos (CEME – Brazilian term), the importance of the sanitary movement and the promulgation of the Generics Law, Law 9,787 of 10 / 02/1999 (Loyola, 2008; Lucchese, 2001).

Loyola (2008, 2010) points out, first, that CEME was an organ directly linked to the Presidency of the Republic, which since its creation aimed at the same time, on the one hand, to invest in the production of raw materials and in research to reverse dependence the pharmaceutical sector; and, on the other hand, to operate as a central purchasing agent for medicines from national or foreign pharmaceutical companies. Unfortunately, due to intra and extra-governmental pressures, the performance of this body ended up being restricted to a buyer and distributor of medicines, being formally extinguished in 1997. Secondly, as the author shows, regarding pharmaceutical assistance and medication policy, the sanitary movement, either formally through the National Health Conferences (CNS) started in the 1980s, or in several other areas of its action, achieved important achievements such as the creation of the Unified Health System (SUS), by organic law n ° 8080/90. Led by sanitary doctors and supported by several professional segments of the health sector, the sanitary movement was of paramount importance in the constitution of the first program to fight AIDS, the Reference, and Training Center for the Fight against AIDS (CRT), in São Paulo. Finally, the enactment of the Generics Law, Law No. 9,787 of 1999 (Brasil, 1999), can be attributed to a complex of factors, with emphasis on this work: the actions of health workers; the reaction to a neoliberal policy on the part of the state; the new Brazilian patent law; the national capacity for the production of essential medicines, observed since the 1980s and which continues in the case of AIDS (Cassier; Corrêa, 2003, 2007); and the participation of civil society in the fight against AIDS (Villela, 2010).

In fact, the authors emphasize that the introduction of generic drugs is simultaneous with the development of a public policy for the control of AIDS, which was characterized by not being limited to preventing the transmission of the disease but also addressing treatment. The high cost of purchasing patented drugs can threaten the viability of some government programs, such as antiretrovirals (ARVs). This was what led the Brazilian Government to adopt strategies to control the AIDS epidemic that associated, in the late 1990s, prevention programs with industrial ARV reverse engineering copy programs as a way of guaranteeing access to treatment; either by the local production of medicines, or by the negotiation of prices, backed by the demonstrated ability to reproduce the molecules against HIV / AIDS (Cassier; Correa, 2010).

Before that, since the 1980s, the proposition of a system of tax and financial incentives has favored the reverse engineering by Brazilian public and private laboratories, of several essential medicines, including 1st generation drugs against HIV / AIDS. The copying of medicines invented until 1996 and, therefore, not patentable, generated a learning process that allowed the development and improvement

of the research capacity of national laboratories. This is because the process of reproducing molecules by reverse engineering does not constitute a simple "copy", precisely because the patent documents do not describe the critical points of the synthetic routes. (Cassier; Correa, 2003, 2007, 2008, 2010).

The debates on pharmaceutical patents and public health, within the scope of public policies on access to medicines, in developing countries have become more intense since the signing of the Trade-Related Aspects of Intellectual Property (TRIPS) Agreement, because of the results of the Uruguay Round of Multilateral Trade Negotiations of the General Agreement on Tariffs and Trade (GATT), in 1994. The Uruguay Round, one of the longest multilateral GATT negotiations, resulted in the creation of the Organization World Trade Organization (WTO) to replace GATT (Guise, 2007).

According to the TRIPS Agreement, each member country must recognize and protect intellectual property rights (patents, trademarks, trade secrets, etc.) in an effective and appropriate manner in relation to other WTO members. This agreement defines the minimum protection standards for each area of intellectual property, that is, the obligation to recognize intellectual property for all technological fields, including the pharmaceutical sector (Barbosa, 2003).

Since the signing of TRIPS, issues involving pharmaceutical patents had an impact in the most diverse sectors: economic, technological, and social, with emphasis on the importance of debates on pharmaceutical patents and public health, within the scope of public policies on access to medicines, developing countries. This is a controversial issue since, on the one hand, we have issues that involve the importance of patents for therapeutic innovation in the pharmaceutical industry and, on the other hand, the harmful effects regarding the imposition of barriers to access to medicines (Meiners, 2008).

These debates are quite heated, particularly in developing countries since the vast majority did not grant patents for pharmaceutical products and processes. Historically, many developed countries also did not grant patents for pharmaceutical products until the second half of the twentieth century. For example, Germany until 1967, Switzerland until 1977, Italy until 1978, Spain until 1992 and Japan until 1976 (Núcleo ..., 1991).

In fact, the internalization of TRIPS by developing countries has compromised the sustainability of national public health programs in these nations. During the year of implementation of LPI, in Brazil, the average cost of ARV therapy jumped from US $ 3810 to US $ 4860 (Teixeira; Vitória; Barcarolo, 2003). As a result, civil society entities, especially non-governmental organizations (NGOs), started campaigns to defend access to antiretroviral treatment as a measure of social justice and protection of human rights (Loyola, 2008). In this context, the largest international humanitarian aid organization in the health field in the world stands out, the organization Médecins Sans Frontières (MSF), which has been operating in Brazil since 1993 (Villela, 2010).

The negative evidence of the effects of pharmaceutical patents on access to medicines sparked legal discussions about the relationship between TRIPS and public health that culminated in 2001 in the promulgation of the Ministerial Declaration on the TRIPS and Public Health Agreement, known as the Doha Declaration . The Declaration recognizes the seriousness of public health problems, especially those resulting from AIDS, tuberculosis, malaria, and other epidemics, which affect developing and least developed countries (Correa, 2005). The Declaration reaffirms the right of WTO members to use, to the fullest extent, the provisions of the TRIPS agreement that provide the necessary flexibilities for the protection of public health (Bermudez; Oliveira; Esher, 2004). For Correa (2000), the greater or lesser flexibility in the application of patentability requirements varies from country to country, which must interpret and apply the provisions of TRIPS to achieve a balance between public and private interests, as well as to avoid abuses and excesses of rights that erode the credibility of the patent regime.

While it defines the minimum parameters of protection, TRIPS determines measures that can be adopted by the member countries aiming at the promotion of the economic and social well-being of the population (article 7), for the protection of public health, nutrition, and the public interest in areas of paramount socio-economic importance (article 8.1) and the prevention of the abuse of intellectual property rights by the owners (article 8.2). Therefore, the Agreement provides for flexibilities or safeguards that can be included in national legislation, which depending on the scope may favor or hinder the implementation of health policies. The main flexibilities related to public health are: 1) the transition periods, 2) the parallel import, 3) the bolar exception, 4) the experimental use, 5) the performance of the health sector in the analysis of patent applications for products and pharmaceutical processes and 6) the compulsory license (Chaves et al., 2007).

Articles 65 and 66 of the TRIPS establish deadlines for member countries to incorporate the provisions of the Agreement into their national intellectual property laws, depending on the level of development. Developed countries had up to one year (until 1996) to reformulate their legislation, while developing and less developed countries had between five and eleven years, 2000 and 2005, respectively, to reform their industrial property legislation (Chaves; Oliveira, 2007) .

Parallel import allows a country to import a patented product, provided that this product has been marketed in the exporting country by the patent holder or with his consent (Guise, 2007).

The Bolar exception, on the other hand, represents a mechanism applied to pharmaceutical products that allows the use of the invention - copy and studies, in the laboratory plan to produce generics - aiming at composing the dossier necessary for the registration of commercialization, even before the patent expires, authorization from the holder (provided for in article 30 of TRIPS) (Chaves; Vieira; Reis, 2008).

Experimental use refers to the possibility of exploring the patented object for experimental purposes, related to scientific research. It is a flexibility that guarantees the use of the information made available by the holder for research and development purposes (Correa, 2002).

The participation of the health sector in the process of analyzing pharmaceutical patent applications (implicit in article 8 of the TRIPS) refers to the work of professionals from the Ministry of Health around industrial property (Chaves, 2005).

The compulsory license, which is an authorization for third parties to exploit a patented product or process, without the consent of the patent holder and can be triggered, for example, in cases of national emergency and public interest. It is considered a crucial element of health policy in WTO member countries as it serves to limit the rights of the patent holder when collective interest prevails (Chaves, 2005). In Brazil, compulsory licensing is regulated in the Arts. 68 to 74 of the LPI.

In Brazil, in 2001, the imminence of issuing compulsory licenses was an essential instrument in the price negotiation of some antiretroviral drugs, such as drugs: efavirenz and nelfinavir (in 2001 and 2003), and, in 2005, kaletra (Loyola; Guimarães; Villela, 2010).

Although the threats of compulsory license in 2001, 2003 and 2005 have not been finalized as such, since the price negotiation was considered satisfactory by PN DST / AIDS managers every time, this safeguard ended up being used by Brazil in 2007 for efavirenz. Through Decree No. 6,108 / 07, of May 4, 2007, the President of the Republic signed the compulsory licensing of efavirenz, a measure supported in the public interest, for non-commercial use by the Ministry of Health (Loyola; Guimarães; Villela, 2010). Initially (May 2007), to supply PN-STD / AIDS, the generic version of efavirenz was imported from India while local production was being prepared in public laboratories in Farmanguinhos and the Pharmaceutical Laboratory of the State of Pernambuco (LAFEPE) (Cassier; Correa, 2008).

Efavirenz was produced in Brazil through a public-private partnership between the official laboratories (Farmanguinhos and Lafepe) and the companies: Globequímica (SP), Cristália (SP) and Nortec (RJ). The production of the active ingredient was the responsibility of the three private companies forming the consortium, while the development of technology and the final production of the drug is the responsibility of the official laboratories.

Brazil joined the TRIPS agreement in 1995 and thus had to reformulate its industrial property legislation to be in line with it. Consequently, in 1997 Law 9279/96, the new Brazilian Industrial Property Law (LPI), came into force, which started to grant the granting of patents for pharmaceutical products and processes.

Regarding the patenting of medicines, the starting point for industrial property legislation in Brazil is the Alvará Régio (Brazilian term) – April 28, 1809 (BRAZIL, 1809). Then, some decrees were enacted to consolidate the industrial property legislation in the country. During the period of the military regime started in 1964, Decree-Law No. 254 of February 28, 1967 (BRAZIL, 1967) and Decree-Law No. 1005 of October 21, 1969 (BRAZIL, 1969) were issued. And in 1971, Law No. 5,772 (BRASIL, 1971), which instituted the Industrial Property Code (CPI). In its article 9, paragraph c, the Code states that *"[...] substances, materials, mixtures or food, chemical-pharmaceutical and medicinal products, of any kind, as well as the respective processes for obtaining or modification* " (Malavota, 2006).

Thus, it appears that in the recent history of Brazil, for a period of 25 years, the granting of patents for pharmaceutical products and processes was prohibited. The enactment of Law 9,279, of May 14, 1996 (LPI) changed this situation: patents for the pharmaceutical sector became liable to be granted, starting with the new LPI (Epsztejn, 1998).

It should be noted that Brazil not only gave up the longer term to adapt its legislation to the minimum conditions established by TRIPS, but also implemented the pipeline in its legislation: a patent revalidation device, contrary to national interests and which subtracts from the domain public, knowledge that was there under the law in force until 1997 (Bermudez et al., 2000; Guise, 2007).

The introduction of the pipeline device in the Brazilian legislation was an imposition of the great economic powers, mainly the United States, under the argument that the pharmaceutical laboratories would be afraid to invest in Brazil, claiming that the protection of intellectual property in the country is very fragile (Tachinard, 1993). The introduction of the pipeline in Brazilian legislation was criticized by several segments of society, as it corresponds to a revalidation device, since the concession criterion for these cases was only the following: having been granted in the country of the first deposit, the patent it would be automatically granted in Brazil, as granted in the country of origin. Thus, due to the pipeline device, Brazil allowed interested parties to deposit, between 01/01/1995 and 05/14/1997, patent applications in this area that had been accepted in their respective countries of origin (Barbosa, 2006).

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The Declaration reaffirms the right of WTO members to use, to the fullest extent, the provisions of the TRIPS agreement that provide the necessary flexibilities for the protection of public health (Bermudez; Oliveira; Esher, 2004).

For Correa (2000, 2002), the greater or lesser flexibility in the application of patentability requirements varies from country to country, which has the right to interpret and apply the provisions of TRIPS to achieve a balance between public and private interests, as well as avoiding abuses and excesses of rights that erode the credibility of the patent regime.

It is in this context that the Intellectual Property Coordination of the National Health Surveillance Agency (COOPI-ANVISA) arises from the legal requirement provided for in Law 10.196 / 01, which amended Art. 229 of the transitional and final provisions of the industrial property law, Law 9,279 of May 14, 1997 (LPI) and created the legal figure of prior consent for patent applications in the pharmaceutical area. Art.229-C provides that "The granting of patents for pharmaceutical products and processes will depend on the prior consent of the National Health Surveillance Agency (ANVISA)".

Anvisa was created in 1999 inserted in a context of international economic reorientation, review of the functions of the state and radical restructuring of the health system. With the creation of ANVISA it was possible to: a) restructure federal health surveillance, b) create competence to monitor prices of medicines and other inputs, which would not be a typical function of health regulation, c) prioritize the registration of medicines, among others (Machado, 2005).

According to Lima (2004), at the end of the 1990s, the national pharmaceutical assistance policy of the Ministry of Health needed a generic drug program to meet the health needs of the population and, as a result, price monitoring was essential practiced by companies in the pharmaceutical market. In addition, it was necessary to associate the expertise of the health area in the examination of patent applications for the work of the INPI. Thus, ANVISA's participation in the granting of patents for pharmaceutical products and processes was instituted as it understood that the state should benefit from a more careful and technically competent examination, since the health of the population was at stake, ultimately the reason for being of the existence of the State itself.

Thus, in Brazil, in 2001, patent applications in the pharmaceutical area also began to be examined by COOPI-ANVISA, whose analysis until then was carried out only by the National Institute of Industrial Property (INPI).

COOPI-ANVISA's role in examining patent applications for drugs through the prior consent device has raised several points of discussion and controversy both by Brazilian individuals, entities, and associations, as well as by international bodies. Some negative arguments against ANVISA's entry into the industrial property area revolved around the idea of violation of the TRIPS Agreement, the lack of definition of criteria for granting prior consent and the even longer delay in granting drug patents. On the other hand, the agreement was also defended by a diversity of actors. The statement in favor of COOPI-ANVISA's action lay, for example, in the fact that the role of this agency is to defend the public interest, and that the flexibilities and safeguards of the TRIPS Agreement, as well as the Doha Declaration, allow developing countries guarantee the protection of public health and access to medicines (Guimarães, 2008).

The insertion of a health agency in the patent examination, at that time, is unprecedented in the history of patent regulation in Brazil and very rare in the world. It signifies an advance of the country about the application of the flexibilities provided for in the international agreements regarding intellectual property and was studied in detail by Guimarães (2008, 2010).

As a result, the objective of this study is to understand how the theme of Anvisa's prior consent was introduced in the set of concerns of public policy makers.

The analytical framework used in this investigation is composed of the multiple flow model developed by John W. Kingdon, in 2003.

The objective is to advance in clarifying the following question: why do some problems become important for a government? How does an idea fit into the set of concerns of policymakers, becoming a public policy? (Capella, 2012; 87-88).

THE MULTIPLE FLOW MODELS

The multiple streams model was proposed by John Kingdon (2003) in his work Agendas, Alternatives and Public Policies.

According to Capella (2006), an issue becomes part of the government's agenda when it awakens the attention and interest of policy makers. Analyzing the formation of the agenda allows us to ascertain causal, relational, and contextual mechanisms that introduce a certain theme to the government agenda in a plural environment and under pressure from certain groups. In this way, it is possible to understand the dynamics of politics and the role those political actors play in the formulation of a given public policy. The governmental agenda represents the set of themes on which the government and its agents are concerned at a given moment. Undoubtedly, a certain issue becomes part of the agenda when it arouses the interest of public decision-makers.

Kingdon's model is basically concerned with two processes, called pre-decision-making: agenda-setting and alternatives for the formulation of public policies: policy formulation (Capella, 2007).

Due to the complexity and volume of questions that are presented to formulators, only a few are considered at any given time and become part of the decision agenda (a subset of issues on the government agenda that are about to become political).

Kingdon's theoretical model (2003) highlights the agenda formation process because of the convergence of three decision flows, which follow independently and permeate the entire organization: problem stream; flow of solutions or alternatives (policy stream) and political flow (political stream).

In the problem flow, the model seeks to analyze how certain issues are recognized as problems and how they come to occupy the governmental agenda. Government action would take place according to three basic mechanisms: indicators (point and measure the magnitude of a situation), events and crises and symbols and feedback (the result of monitoring the budget, costs, and expenses).

Indicators represent a quantitative part of the analytical model in which the formulator seeks to identify possible evidence to guide his interpretation of a particular problem: such indicators are many in the world of politics, as both governmental and non-governmental agencies routinely monitor various activities.

The events and crises and symbols highlight the influence of events of great magnitude that accentuate the attention around a given issue, reinforcing its characterization as a problem: "Sometimes, this pressure is caused by an event understood as a crisis or catastrophe that calls attention to the problem, a powerful symbol that arises, or the personal experience of a policy maker" (Kingdon, 2011, p. 94-95).

Feedback consists of the return of information about other policies that can bring new problems to the center of attention of policy makers.

The chances of a particular proposal or issue being highlighted on an agenda are greater if they are related to a major problem. After the problem is recognized and defined as relevant / important, some alternatives and / or solutions gain strength while others disappear. In this perspective, it is worth mentioning political entrepreneurs (policy entrepreneurs) who are people who invest their time and resources to convince public authorities about the existence of problems, in addition to presenting a set of solutions to them. Political entrepreneurs located in the government (in the Executive Branch, occupying

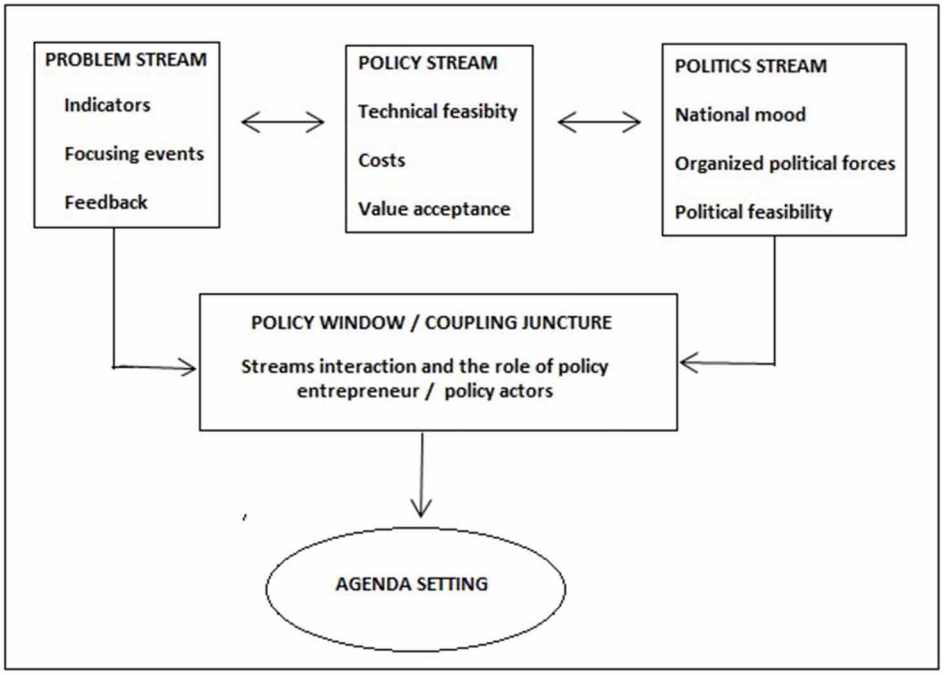
high positions or in bureaucratic functions; in Congress, whether they are parliamentarians or advisers), or outside it (in interest groups, in the academic community, in the media) are always ready to act in the moment when a political window opens. In general, they are specialists who have a reputation for competence, negotiation skills or have a certain political popularity.

The flow of solutions and alternatives includes the set of available solutions, not necessarily motivated by the perception of problems. Here the solutions or alternatives are discussed in specific communities of experts and defined based on their technical and financial viability.

Kingdon (2003) considers that the ideas generated in this flow appear in a disorganized and disorganized way, that is, they are not necessarily related to the perception of problems, there is often a clash with each other, generating new ideas and forming combinations and recombination.

The political flow arises from its own dynamics and coalitions are built in a process of bargaining and political negotiation. With the change of government, new agenda possibilities arise, as well as access to new interest groups for the new government.

Figure 1. Multiple flows models



In Capella's (2006, p. 29) conception, three elements must be considered in the political flow: the "climate" or "national mood moodïno", the organized political forces and the changes in the government.

The "national mood" represents something similar to the "fertile soil", for some ideas to germinate, helping to explain that some problems rise to the government's agenda.

Political forces relate to the pressures exerted by support or opposition groups leading to consensus or conflict in the political arena, signaling formulators whether the environment is favorable to proposals or not.

Finally, changes in government influence the agenda of both people in strategic positions and in the composition of the legislature. Special attention is drawn to the beginning of governments, considered the most propitious moment for the entry of demands that remained unanswered for a long time (Kingdon, 2003).

The three flows have a relative independence that develop according to their own dynamics. The convergence of the three flows at a given moment opens a "window of political opportunity" in the agenda definition process and allows the introduction of a new item in public policy (figure 1).

For Kingdon (2003), the window of opportunity is the combination of problems and solutions inserted in a favorable political environment, thus modifying the agenda. In this way, the problem is recognized, the solution is available, and the political conditions provide a moment of change that causes the convergence between the three flows and, consequently, the agenda appears.

THE INTRODUCTION OF THE HEALTH SECTOR IN THE EXAMINATION OF PHARMACEUTICAL PATENTS

The pharmaceutical industry is a sector that presents high technological dynamism, considering the introduction of new products on the market and investments in research and development (Tachinard, 1993). According to the sector itself, the process of inventing and developing new drugs is long and requires high investments. The pharmaceutical industry has a great propensity to protect its inventions by means of patents when compared to other industries. The patent protection of these inventions results in a strong oligopolizing tendency, as can be seen in any context in which medicines are subject to patenting.

The estimated expenditure on research and development of a new drug can reach up to US $ 800 million dollars (Dimasi; Hansen; Grabowski, 2003). On the other hand, Angell (2007) points out that the values of investments in research and development of drugs by large companies are extremely lower when compared to expenses with marketing and administration. The author also points out that a large part of the new drugs launched in the United States are variations of drugs that are already available on the market. This reality is associated with the great support of the government and the collaboration of academic institutions with American companies (Nelson, 2006).

An interesting issue that deserves to be highlighted is that, given the high prices charged by the pharmaceutical industries, it has been stated that the patent system would prevent the population from accessing essential medicines to a dignified life.

Such statement does not find justification, as Tachinard (1993, p. 59) points out that, according to the author, in the pharmaceutical industry, competition takes place via innovation, it is a sector with intense technological dynamism, in which investments in research and development are essential for the control of the markets. In this type of industry, competition is not based on price because medicines, essential health goods, have an inelastic demand. Competition in this sector is due to product differentiation and innovation.

From this perspective, repudiating drug patents in the name of access to medicines is not in line with the economic, scientific, and technological development of a country. in view of the provision of art. 27.1 of TRIPs - which establishes patent protection to all fields of knowledge if it is new, involves an inventive step and is capable of industrial application. It is inherent to the patent system, especially pharmaceuticals, its contributory role, particularly in the generation of such innovative new drugs.

For Silva, Britto and Antunes (2010, p. 1822), some critics attribute the high drug prices to the patent system. According to the authors, the patent monopoly causes great economic distortions, which in the case of medicines cause price increases, on average, of 300 to 400% over those practiced in the competitive market.

The industry's counterargument is that patents cover less than 2% of medicines on the WHO essential list and cover only 30 to 40% of ethical medicines (need a prescription to be sold), while each patented product faces competition from 2 to 10 nearby substitute molecules destined for the same treatment.

The industry also argues that the effective term of exploitation of the patent is shorter than its legal validity period, due to the long period of time between the patenting of the product and its launching on the market, depending on the testing deadlines. required by regulation. The term of effective benefit of the patent would thus be only 6.5 years.

Guise points out (2011, p. 12) that the patent gives the company the right to fix the price of the product created by it in the way that best suits it, since for a limited period, it will be the only one to exploit it .

In theory, profits enable the return on investments made and guarantee the incentive to continue innovating. It is the private interest (company) with a "pinch" of public interest (the society that now has an innovative product at its disposal). At first glance, it seems simple and even intuitive to accept the patent as an ideal incentive to produce new knowledge. The analysis of the tension that is established between the public and private interests, however, is nothing ordinary. Especially when it comes to a good that has no commodity, the medicine (Idem).

In view of this scenario, as advocated by Carvalho (2008, p. 55), the challenge of redefining the right to intellectual property in the light of the prevalence of human rights, especially the right to medicines, in a global society, whose fate and future are increasingly conditioned to the production, distribution and equitable use of knowledge.

The debates on intellectual property, especially in the context of access to medicines, gained considerable national and international notoriety when the AIDS epidemic emerged. At this juncture, Kingdon's multiple flow model is appropriate for analyzing the problems, solutions, and policies of examining pharmaceutical patents in Brazil.

The need of the Ministry of Health to negotiate the prices of antiretroviral drugs protected by patents with transnational companies to ensure national supply, demonstrated the fragility of Law 9.279 / 96 in relation to the protection of public health and highlighted the need for amendments to it.

According to Luis Carlos Wanderley, after the advent of the LPI, which allowed patents on pharmaceutical products and processes, the legislator, after some time in force of the new rule, chooses to establish an innovative mechanism in which the health agency starts to act as a member of the patent granting process. Therefore, the objective of Anvisa's prior consent is to implement an effective public health policy, considering that the improper granting of patents has a negative impact on the population's access to pharmaceutical assistance.

In this perspective, the provisional measure MP 2006 of 12/15/1999 was published, which after reissues was converted into law 10.196 / 01, of 14 February 2001, which provides in article 229-C for the institute of prior consent. It is worth mentioning that the "legislator", in this case, was the Executive Power itself that edited the MP 2006/99, later transformed into law 10.196 / 01.

The participation of the health sector in the process of analyzing pharmaceutical patent applications in Brazil has become exemplary due to the direct participation of this sector in the examination and patenting process, carried out at the institute of prior consent. Legitimized by Law 10,296 / 2001, the creation of this device within the health field (ANVISA, Ministry of Health) represented a measure to

protect public health and promote the public interest, in accordance with the provisions of article 8 of the TRIPS (REIS, 2005). However, the insertion of the health sector in the examination of pharmaceutical patents ended up further intensifying the debates about the scope of protection in the granting of pharmaceutical patents and access to medicines. The basis of this device lies in the fact that patents, when improperly granted, they bring an unjustifiable risk to public health, especially about access to medicines, by attributing an exclusivity in the commercial exploitation of a product or process to those who have not met the legal requirements (Guimarães, 2008).

In the view of Basso (2006), the main objective of this instrument is to "protect the social interest from possible risks to public health and technological development in the country". For this reason, Anvisa has the role of facilitating the process of analyzing patent applications, through a technical body specialized around medicine

It is undeniable that, since the creation of Coopi-Anvisa, discussions about the tension between the ownership of inventions, on the one hand, and the population's right to health, on the other, have become more "heated". This statement is because the "patentability" of medicines started to be debated within the scope of access to health policies and, consequently, it was a milestone in the regulation of industrial property in Brazil.

Issues regarding a) in- and Anvisa's constitutionality in examining drug patents; b) the legality of a double examination of patents in Brazil and, therefore, more delay in granting patents; c) the absence of pharmacists at the INPI to examine patent applications, among others, contributed positively to raising the importance of directing industrial property in the country, to meet the country's social, political, economic, and scientific interests.

In the opinion of Professor Denis Barbosa (2004, p. 2), if on the one hand Anvisa was given a discretionary power to grant or not patent applications based on the judgment of convenience and opportunity of the Administration, such a task is incompatible with the content of art. 5, XXIX of the 1988 Charter, in which it creates a subjective constitutional right to the examination of legal assumptions of patentability, in a linked procedure. However, on the other hand, prior consent is compatible with the 1988 Constitution, given that it gives prestige to the provisions relating to the protection of life and health. That is, when pronouncing on the granting of patents for pharmaceutical products and processes, mainly regarding the relevant conditions of unpredictability, in particular the offense to public health.

For lawyers and intellectual property agents, the creation of Coopi-Anvisa was widely criticized, since the "double examination" of drug patents in Brazil would cause more delay in granting these patents, in addition to discriminating against other areas of knowledge and be out of harmony with other world patent laws.

Critics at the international level were also pronounced regarding the institute of prior consent, such as the Pharmaceutical Research and Manufacturers of America (PhRMA) which pointed out the Brazilian government's concern in guaranteeing the intellectual property rights of the pharmaceutical sector industries (Guimarães, Correa, 2012, p. 35).

For Chaves, Vieira, and Reis (2008), due to the importance of the topic and the essentiality of pharmaceutical products, the Brazilian legislator understood that such an important subject would deserve the most careful and technically competent examination possible that the Brazilian State could have. Therefore, ANVISA's role in prior consent is not, therefore, that of simple interference in the process of granting patents, but on the contrary, it is a measure for the protection of patients, avoiding the granting of an undeserved patent. In addition, as provided for in Trips / WHO, each country has the right to regulate the patent granting system locally. This TRIPS forecast indicates that choices can be made in this area;

that is, that the adoption of a given intellectual property policy is the prerogative of the countries. In the Brazilian case, in 2001, the creation of prior consent represents the implementation of an IP policy in the pharmaceutical area, which emphasizes the relative autonomy that the country can exercise and the neo developmental perspective that prevailed in different governments since then, until the year 2014.

Thus, although prior consent is still a very recent mechanism in terms of implementation, the analysis guidelines adopted by Anvisa justify the inclusion of the health sector in the process of granting pharmaceutical patents, since they have been shown to insert issues related to public health in its examination. merit.

According to the theory of multiple flows, the process of creating the prior consent of Anvisa took place thanks to the combination of elements linked to the concern of the role of the health sector in the analysis of pharmaceutical patent applications arising from three flows: problems, solutions and political, which will be exposed below

THE FLOW OF PROBLEM

In the analysis of the flow of problems related to the granting of pharmaceutical patents, the high economic cost for the acquisition of drugs for the treatment of AIDS stands out, which started to threaten the viability of the National STD-AIDS Program. This led the Brazilian Government to adopt strategies to control the AIDS epidemic, which associated, in the late 1990s, prevention programs with industrial anti-retroviral copy engineering programs as a way of guaranteeing access to treatment; be it for the local production of medicines, or for the negotiation of prices, supported by the demonstrated ability to reproduce the molecules against HIV / AIDS (Cassier; Correa, 2010).

Before that, since the 1980s, the proposition of a system of tax and financial incentives has favored the reverse engineering by Brazilian public and private laboratories, of several essential medicines, among them the 1st generation drugs against HIV / AIDS. The copying of drugs invented until 1996 and, therefore, not patentable, generated a learning process that allowed the development and improvement of the research capacity of national laboratories. This is because the process of reproducing molecules by reverse engineering does not constitute a simple "copy", precisely because the patent documents do not describe the critical points of the synthetic routes. (Cassier; Correa, 2003, 2007, 2008, 2010).

Undoubtedly, with the proliferation of AIDS, the discussion on the granting of pharmaceutical patents became more evident, in view of the high cost of antiretroviral drugs and, consequently, the threat of limiting access. Law 9.313, of November 13, 1996, provides in Art. 1 that "People with HIV (human immunodeficiency virus) and AIDS patients (Acquired Immunodeficiency Syndrome) will receive, free of charge, from the Unified Health System, all the medication needed for your treatment ". The National STD / AIDS Program (PN-STD / AIDS) of the Ministry of Health of Brazil has come to be considered a reference model in the distribution of ARV drugs, a priority of the government health policy is the reduction of prices of ARVs protected by patents, with the pharmaceutical industries (Bermudez; Oliveira; Esher, 2004).

According to Miranda (2007, p. 123), the National AIDS Program has acquired several outlines, changing its action strategies and priority areas over the years. With the increase in the number of AIDS-related deaths, civil society intensified its actions to demand public policies that included the most diverse actions: street mobilization, legislative lobbying, lawsuits, among others.

During the year of implementation of LPI, in Brazil, the average cost of ARV therapy jumped from US $ 3810 to US $ 4860 (Teixeira; Vitória; Barcarolo, 2003). As a result, civil society entities, especially non-governmental organizations (NGOs), started campaigns to defend access to antiretroviral treatment as a measure of social justice and protection of human rights (Loyola, 2008). In this context, the largest international humanitarian aid organization in the health field in the world stands out, the organization Médecins Sans Frontières (MSF), which has been operating in Brazil since 1993 (Villela, 2010).

It should be noted that simultaneously with the development of a public policy for the control of AIDS in Brazil, we introduced generic drugs with the promulgation of the Generics Law, Law No. 9,787 of 1999 (Brazil, 1999), which can be attributed to a complex of factors, with emphasis on this work: the actions of health workers; the reaction to a neoliberal policy on the part of the state; the new Brazilian patent law; the national capacity for the production of essential medicines, observed since the 1980s and which continues in the case of AIDS (Cassier; Corrêa, 2003, 2007); and the participation of civil society in the fight against AIDS (Villela, 2010).

According to Loyola (2010), the policy of implanting generic drugs resulted, in large part, from the political will of government officials and strategically placed social actors who knew how to lead, mobilize, and combine several factors favorable to the enactment of the generics law. The author defines political will as the government's commitment to the success (or not) of a policy.

This situation shows the weakness of the dependence on international markets, justifying the elaboration of public policies aimed at greater protection of industrial property rights.

It is never too much to remember that in Brazil, in the period prior to the current Brazilian industrial property law, Brazilian public and private laboratories produced a copy, by reverse engineering, of antiretroviral drugs for the National STD-AIDS Program. With the adoption of patenting of medicines, since 1997, the copying of patented molecules is no longer carried out by public and private sector laboratories, further aggravating the local manufacture of ARV in promoting access to medicines (Cassier & Corrêa, 2003, 2007, 2008).

As an example, there is the national production of zidovudine (AZT) produced by the chemical and pharmaceutical company Microbiológica, which, in 1992, contracted a loan with FINEP for the purchase of equipment and scale transposition and developed the pharmaceutical forms of AZT in capsules. and syrup, the so-called "Brazilian AZT" (RABI, 2007).

Another point worth mentioning is the introduction of the pipeline device in Brazilian industrial property legislation.

According to Bermudez et al (2000), the total number of patent applications for drug pipelines deposited in Brazil corresponds to 1182 documents, of which the United States is responsible for 45%; followed by the United Kingdom (13%). Brazil was the holder of only 17 requests (1.4%), which explains, in part, why the incorporation of this device into the new industrial property law was widely criticized by civil society, educational institutions and capital companies national.

Thus, the problems that led to the insertion of the health sector in the examination of pharmaceutical patent applications were essentially based on the Brazilian government's effort to protect public health, particularly in ensuring access to medicines.

FLOW OF SOLUTIONS AND ALTERNATIVES

In the flow of solutions, Capella (2006) draws attention that alternatives are generated in policy communities, or communities that generate alternatives that are composed of specialists, researchers, parliamentary advisers, academics, civil servants, analysts belonging to interest groups, among others. others, who share a concern about a policy area.

In the present study, the flow of solutions and alternatives was characterized by the need for an approach to granting pharmaceutical patents more focused on aspects of public health, given that they are now recognized as an important mechanism to expand the population's access. medications.

Based on this understanding, some actors became involved in the defense of industrial property rights for the benefit of public health. Among them, it is possible to highlight the role of civil society that, after the military dictatorship period, reorganized and with the promulgation of the 1988 Constitution, through the National Movement to Fight AIDS, the right to health as a fundamental and universal right of every Brazilian citizen gained new contours and visibility (Miranda, 2006: 98).

Social movements, in the context of AIDS, started to demand access to treatment offered free of charge and universally, especially since 1996, by the public health system and by the private system, given the importance of maintaining public access policies and the challenges and obstacles imposed by the new rules for the protection of intellectual property (Villardi; Vieira; Carvalho, 2005).

The issue of industrial property, especially the entry into force of the patent law, was not an issue for organizations in the social movement to fight AIDS immediately. In fact, this debate was restricted to unions, class organizations and the private sector (Reis, 2015).

In the conception of Villela (2015), initially, the issue of intellectual property only appeared in the debates when it came to cases of shortages. It was from the granting of patents for medicines that the social movement gained strength, given the threat to the sustainability of the National STD / AIDS Program (Chaves et al., 2008; Villela, 2015).

In this context, it is worth highlighting the work of the international organization, Médecins sans Frontières (MSF), which sparked the debate that the technical aspects of public health should be the responsibility of the State and that civil society organizations should dedicate themselves to pressure the public power to formulate policies, to fulfill its constitutional duty (Villela, 2015).

At the Brazilian level, the interface between patents and public health took shape when the creation, still in 2001, of the Working Group on Intellectual Property (GTPI), within the scope of the Brazilian Network for the Integration of Peoples (Rebrip), which has participated in a quiet way positive in defending access to antiretroviral treatment as a measure of social justice and protection of human rights (Villela, 2010, p.114).

According to Villard (2018), the GTPI's position on the tension between patents and universal access, therefore, articulated in a complex way the incorporation of new drugs. On the one hand, it was important to incorporate the new drugs, since they would bring benefits to people living with HIV / AIDS, such as better quality of life and less adverse effects, and the strengthening of SUS. On the other hand, it was necessary to deal with the budgetary pressure that these medicines would exert, as they were medicines under a monopoly.

In the academic field, it is worth noting the work developed by the research group of the National School of Public Health (ENSP) of Fiocruz led by Jorge Bermudez (Bermudez et al., 2004, 143-145), who pointed out that the implementation of universal and free of charge to treatment for people living with HIV / AIDS in Brazil, imposed a series of challenges on the Ministry of Health, among them the

creation of a logistical system that would allow the purchase at affordable prices and the distribution of medicines at the national level.

The approach of alternative-generating communities can be expanded from the perspective of single health (One Health), which 11 years ago was defined as the integration between human health, animal health and the environment (OIE, 2019). However, nowadays this concept goes beyond this integration and encompasses the means to ensure the current needs of humanity and future generations. And, in the context of the defense of intellectual property rights in favor of the population's access to medicines, unique health includes a movement to promote professional collaborative communication with a global transdisciplinary dynamic, under the character "one planet, one health", managing the approaches of the actors mentioned above, integrating them, to obtain successful and sustainable strategies (Waltner-Toews, 2017). Therefore, in view of this perspective, the flow of solutions and alternatives proposed by Kingdon is inserted in the field of unique health, given that it is based on the establishment of strong interaction between managers, technicians, social scientists, among others, with the objective of to establish interdisciplinary and integrative health promotion strategies, regarding the population's access to medicines.

POLITICAL FLOW

The national climate to which Kingdon refers, in the political flow, in the present case, is characterized by the sharing of relevant issues in society, regarding the AIDS epidemic and the high prices practiced by the pharmaceutical industries, setting up a favorable environment for the formation of political agenda, that is, Anvisa's prior consent.

The recognition of the subject of patents and the impact on public health also benefited from the work of "political entrepreneurs", particularly, the Minister of Health José Serra, certainly the second most important man in the Republic, in the late 90's, during the government of Fernando Henrique Cardoso, who had successfully implemented the generic drug policy, which reached the market with quality and at affordable prices (Almeida, 2008).

Using Kingdon's approach, which highlights the importance of political entrepreneurs, it should be noted that the granting of patents came to be considered by Serra as such a strategic step in this market that he did not want Anvisa out of the process.

Undoubtedly, Minister Serra had enough political weight to carry out the reforms in the health sector that had been attempted recently.

In short, the performance of public policy entrepreneurs to include the health sector in the examination of pharmaceutical patent applications in the government's priorities is inserted in the vocabulary of Kingdon (2003), of the contemporary "national mood" about industrial property rights and access to medicines.

The analysis of these three flows allows the application of the creation of Coopi-anvisa to the continuous flow model, as shown in Figure 2, which summarizes the decision-making process that led to the insertion of the health sector in the examination of pharmaceutical patents.

FINAL CONSIDERATIONS

The debates on pharmaceutical patents and public policies on access to medicines in developing countries intensified in the 1990s, with the emergence of the most effective antiretroviral therapies against the AIDS virus, in view of the high price of these medicines. Also noteworthy is the role of non-governmental organizations in defense of access to antiretroviral treatment as a measure of social justice and protection of human rights.

The main contribution of the work lies in the unveiling of the arena and the actors involved in the creation of Anvisa's prior approval.

It was possible to verify that a series of events in the late 1990s contributed to the weakening of the national production of medicines in Brazil. Among them we can mention: the immediate signing of the TRIPS agreement, the impossibility of copying medicines and the insertion of the pipeline device in the LPI. Allied to these factors, we had the enactment of the generics law and the SUS distribution program for antiretrovirals that further aggravated the debate on the negative impacts of the granting of pharmaceutical patents and public health.

According to Kingdon's multiple streams model, it can be said that all conditions were present so that public policy, in this case understood as the creation of Anvisa's prior consent, entered the agenda and was quickly implemented.

This analysis does not exhaust the debate on understanding the political process of creating Anvisa's prior consent. However, it can bring a contribution: the events behind the creation of Coopi-Anvisa, which is of fundamental importance to understand how the country started to analyze patent applications with a public health bias.

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Chapter 11
Big Data at the Service of the Public Health Systems: Success Cases in Brazilian Public Management

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ABSTRACT

The great differential of organizations has been the strategic innovation through the best way to manage existing knowledge. The management of information and knowledge generated in the health area is no different, as is the case with the pharmaceutical sector. The major challenge of public health research is to promote the use of scientific and technological knowledge produced in more effective health policy and action strategies in order to provide effective health gains. New technologies are promising tools to support public health management. The current scenario, in which the world has been affected by the COVID-19 pandemic, has reinforced this understanding. This chapter aims to highlight the importance of using big data tools to make public health policies more effective. Examples of successful cases in different areas of Brazilian public management will be presented, aiming to reinforce the relevance of these tools for public health systems.

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INTRODUCTION

Knowledge management is a particular field under the management science theory, although the notion links an epistemological concept (knowledge), a concept that is at the center of many philosophical debates and that is linked to the perspective of efficient action in the company. The hybridization which results from the simultaneous use of the two terms induces the idea of an action situated in relation to teleological knowledge or, in other words, beliefs and certainties of a very particular nature. This hybridization is also described as one of the signs of the institutionalization of the company which is today supposed to create and manage knowledge (Cowan, 2001; Pirró et al., 2010).

Knowledge management presents itself as a major investment in the functioning of organizations and societies. It is also under this common denominator that the connection is established between the company that is based on knowledge and the society that is based on knowledge. The difference is that being the development of knowledge-based companies, they lead to building a knowledge-based society; as is usual in the conservative vulgate, where business prosperity was associated with society, and, finally, global employment as the sum of corporate jobs. This analysis allows us to affirm that the understanding of the knowledge company is the only valid one, without really having to face the problem of the transition from the company to the knowledge society(Pesqueux, 2005).

In this context, the pharmaceutical sector presents itself as one of the most capital-intensive areas of the economy. It presents relevant investments in Research, Development & Innovation (R, D & I) activities. In this aspect, it is only surpassed by the war industry (Gadelha, 2003; Magalhaes, JL et al., 2008). Their contribution to global health is unmatched. By the year 2021, drug spending by the world's population is expected to reach US $ 1.5 trillion and the sector's revenues will be around US $ 370 billion higher than in 2016 IQVIA, 20120).

According to the IQVIA (2020), there is a prospect of growth in drug spending of around 6% by 2023, most of which will occur in developed markets driven by the areas of oncology, autoimmune diseases, and diabetes. In these areas, are expected the most significant innovations (IQVIA, 2020).

In this sense, Knowledge Management requires the involvement and support of all the company's stakeholders to preserve, transmit and develop knowledge. Indeed, it is the individuals who are at the center of the creation of value and who hold the keys to the success of such a project. The management of the knowledge and know-how of the company is therefore not universal, it depends strongly on the culture of the country in which it is practiced (Balmisse, 2006).

Management analysis to integrate actions and to provide the effectiveness actions to generate technological innovation and consequently wealth of the country. Thus, a better management for information architecture, also known as business architecture, encourage a new understanding (Ross et al., 2006).

Certo & Peter (2005), regard analysis of the environment, which indicates that this context (business architecture requires information architecture) is monitoring by entire organizational environment to identify opportunities, challenges and threats, regarding assessing current and future risks (CERTO; PETER, 2010)

Information is a data or set of data articulated to construct a meaningful message. The way to organize the data is an intention. It is therefore partially subjective. The information implies a transmitter and a receiver but also a media whose nature is far from neutral (Kira TARAPANOFF (org.), 2015).

These poles suppose the existence of an aptitude, in the form of selective understanding, to extract the meaning of the information from the surrounding noise. Information is therefore a set of data placed in a context, mainly organizational for what interests us here, and bearing a particular meaning. Again, the

concept has given rise to considerable developments in the information system and the development of protocols to make information systems as efficient as possible. Three notions are generally associated: that of information system (with the question of its economic performance), that of quantity of information (with the tension that appears between the amount of information made available and the super information) and ambiguity (which opens the question of relevance, a question linked to the imprecise notion of "quality" of information) (Pesqueux, 2005).]

The 21st century is marked by the exponential era of data available daily on the web. This era of knowledge is characterized by the pressing need for new technologies to manage the brutal amount of data. This huge amount of data on the Web, characterized as Data Science, requires new approaches and perspectives for knowledge management.

Data Science drives a new generation of methodologies developed to extract economic and strategic value from a large and varied volume of data (structured and unstructured), allowing high speed of capture and analysis ("Gray, J. and Chambers, L. and Bounegru, L., The Data Journalism Handbook, O'Reilly Media, 2012; O'Reilly, 2007).

In this sense, thinking the spectrum of the health area in the light of data science tools to assist in the management of information and knowledge is fundamental. It carries challenges and opportunities in the globalization process, which is the catalyst for the evolution of the term "Global Health". Global health can be understood, at the same time, as a condition, an activity, a profession, a philosophy, a discipline, or a movement. However, it must be considered that there is no consensus on what Global Health is, nor a single definition. Its field of action has imprecise limits (Fortes & Ribeiro, 2014), however it is indisputable that we live health in times of globalization (Koplan et al., 2009).

Thus, this chapter will demonstrate cases of success in Brazilian public management with the use of data science in health in the services of the public health system.

Reflections about Analytical Solutions for Data Science

Data Science is conceptualized in various ways by researchers on the subject, but objectively one can conclude that it is a term referring to tools that aim to perform analysis of the large volumes of data currently generated in the world for the purpose of generating knowledge. These tools, unlike the systems used before, have the capacity to create large volume databases and process them. It is important to point out that mankind has been using databases to store information for a long time. A notebook or a computerized spreadsheet can be considered a database (Sousa & Carvalho, 2018).

In Brazil, in 1871 (imperial period), e.g., there was already a public body responsible for statistical activities that was the General Directorate of Statistics (Diretoria Geral de Estatística – Brazilian term). This body gave rise to the current Brazilian Institute of Geography and Statistics - IBGE. However, with the advancement of technology and population growth in the world, incalculable numbers of data and information are generated daily, which many current information storage systems do not support or do not have the capacity to generate knowledge through the collected data (IBGE FUNÇÃO, 2021).

In Brazil, it is estimated that the population has grown from approximately 119,000,000 (one hundred and nineteen million) people in 1980 to approximately 213,093,000 two hundred thirteen million and ninety-three million) people in 2021, according to a survey released by the Brazilian Institute of Geography and Statistics (IBGE) (IBGE, 2021).

Thus, for a public health agency to have knowledge, for example, of the profile of a particular citizen or even group of people for the purpose of establishing public politics aimed at solving social problems,

it is necessary to have tools that can store large volumes of data and filter them, creating the so-called "profiling", which is nothing more than the process of generating the profile of a particular citizen or group of people (Serpro, 2019). And, when generate a profile of a person or a group, consequently, if achieve knowledge about them.

. Therefore, a creating group profiles of people can be an important mechanism for public administrators can identify, for example, the cause of diseases that may affect a given group and thus be able to adopt public prevention policies.

In this way, the knowledge generated from the group profiles will allow the public administrator to adopt preventive measures that enable a better quality of life for citizens and also reduce the costs of public health systems with treatments and hospitalizations. Thus, it is concluded that the analytical solutions, created from the science called "Data Science" that studies how to treat, analyze and obtain information from large data sets, can be important tools to help optimize the services provided by the Public Health Systems of the world.

These tools, in truth, can not only collaborate directly with the health services, but also, and way no less importantly, help improve the Public Administration's contracting processes, as well as combat possible deviations of purpose in these procedures.

Another example, in Brazil they were created by the Court Union Accounts (TCU – Brazilian term) together with the General Controllership of the Union (CGU – Brazilian term) 3 (three) tools that aim at helping in the identification of possible fraud attempts in biddings as well as collaborating with the auditors at the time of writing, pointing out possible errors and even suggesting information related to the parties involved or to the subject matter.

The Court is responsible for the accounting, financial, budgetary, operational, and patrimonial control of the organs and public entities of the country regarding legality, legitimacy, and economy, by force of imposition of the Constitution of the Federative Republic of Brazil of 1988 (CRFB/1988).

The Comptroller General the Union (CGU) is the internal control body of the Federal Government responsible for carrying out activities related to defending public assets and increasing management transparency, by means of public auditing, corrective actions, preventing and fighting corruption, and ombudsman's office. The CGU also exercises, as Central Body, the technical supervision of the bodies that make up the Internal Control System and the Correction System and the ombudsman units of the Federal Executive Branch, providing the necessary normative guidance (*Controladoria-Geral da União*, 2021).

As the Central Organ, the CGU also exercises technical supervision over the bodies making up the Internal Control System and the Correction System and the ombudsman's office units in the Federal Executive Branch, providing the necessary normative guidance. The mentioned innovative tools used by the TCU and CGU are the ones called "Alice", "Sofia" and "Monica" (TCU, 2021).

"Alice" is a system of "Bidding and Edicts Analysis". According to the news published on the Internal Audit website of the Federal University of Amazonas, "Alice", which is the abbreviation for Bid Analysis and Edicts, reads daily bidding notices and price registration minutes published by the federal administration, in addition to some state and state public agencies. For this purpose, it collects information from the Official Gazette the Union and from "Comprasnet", the system that registers government purchases. From then on, the system prepares a preview of the document and points out to the auditors if there are indications of deviations (UFAM, 2021).

"Alice" checks, for example: if a bidding notice requires from the participants documents that the TCU does not consider pre-requisites; if the bidding is about to deliver a contract to some company prevented from hiring with the public administration or if the competing companies have partners in common.

The "Sofia" system – Guidance System on Facts and Evidence for the Auditor – (Sistema de Orientação sobre Fatos e Indícios para o Auditor – Brazilian term), according to the Legal Consultant Magazine portal, is a tool that helps the auditor when writing a text, pointing out possible errors or non-compliance and even suggesting information related to the parties involved or to the subject matter.

According to the portal of the Legal Consultant Magazine, the Integrated Monitoring for Acquisition Control (Monica system – Brazilian term) provides information on public procurement in the Federal sphere, including the Executive, Legislative and Judiciary powers, in addition to the Ministry Public. The "Monica" system even monitors the hiring for dispensation and unfeasibility of bids that are not monitored by the "Alice" system. In addition, the technology allows quick searches for keywords in the object of the acquisitions.

According to information released by the Court Union Accounts, in only one specific case, in which the "Alice" system identified inconsistencies in market research to establish the estimated value for the acquisition of drugs by a given public agency, it is estimated that R$ 8,3 (eight million three hundred thousand reais) was avoided, thus generating savings to the public coffers.

Thus, it can be concluded that in a country with geographical dimensions such as Brazil, which has 27 (twenty-seven) federal units, being 26 (twenty-six) states besides the Federal District and 5,570 (five thousand five hundred and seventy) municipalities, innovative tools are essential not only to identify and prevent the practice of possible corruption in bids, but also and in no less important way to enable states, municipalities and the Federal Government itself to optimize their bidding processes while reducing costs (IBGE, 2021).

Another success case with the use of Data Science tools in Brazil is the use of the tool by the State of Ceará in the management of Public Security. According to an article published on the website of the Ministry of Justice and Public Safety of Brazil, the use of Data Science technology in the State of Ceará collaborated to reduce the number of thefts and vehicle robbery and to increase the recovery rates of cars and motorcycles (Ministério da Justiça e Segurança Pública, 2021).

In addition, a reduction in the criminal indices was registered. At the time of publication of the news article, the city of Fortaleza, which is the Capital of the state of Ceará, was in its 14th month of reduction in lethal and intentional violent crimes - with 866 lives saved in 2019, and also registered a drop in the rates of violent crimes against heritage.

The same publication also highlights that due to the success case in the State of Ceará, the Brazilian Ministry of Justice and Public Safety decided to expand the use of Data Science tools to other regions of the country in order to promote the integration of large-scale data and assist in the development of public politics against crime, criminal organizations, and corruption (Silveira, 2019).

Considering the example of the aforesaid economy generated in the acquisition of medicines, it becomes evident that the creation of technological tools in the field of health can be salutary not only for the economy but especially for the patients.

According to an article published on the CIO website, the misuse of public resources generates millions of dollars in losses every year to certain countries in the world. This is a difficult practice to combat, being a real challenge for the public sector and for society. Therefore, the use of Big Data tools, such as machine learning solutions, are potential instruments to prevent misuse in the application of public resources directed to health. Currently some deviations are not prevented by the control methods used, preventing the best application of resources from the taxes collected from citizens (*Analytics e Big Data são poderosas armas contra a corrupção*, 2019; Cavalcanti, n.d.).

The Use of Data Science Tools in the Management of Public Health Politics

To relate the importance of Data Science tools to the development and better application of public health politics, it is important to emphasize that data is different from information, and the latter is also different from knowledge. It can be explained in a simple and direct manner that data are nothing more than the base material of information, and information is equally related to knowledge.

Therefore, to achieve good results in the management of public resources, it is not enough just to have data and information, it is necessary to process them to generate values, in this case knowledge, that can be applied to a certain area or subject.

It is worth highlighting, that no news related to the use of Data Science tools for control and analysis of data corresponding to the criteria taken into consideration for the definition of the list of strategic products for the Unified Health System (SUS), provided in Annex XCV of the GM/MS Ordinance of Consolidation nº 05/2017.

In Brazil, there are Productive Development Partnerships (PDP – Brazilian term). They are a public politic to strengthen the Brazilian public health system and that aims to leverage the Brazilian technological development, with a view to the productive, scientific, economic, and technological sustainability of SUS, having as guidelines the objectives described in Article 3 of the Consolidation Ordinance GM/MS no. 05/2017, which are:

1. To increase the population's access to strategic products and reduce the vulnerability of Unified Health System (SUS – Brazilian term);
2. Reduce the productive and technological dependence to meet the health needs of the Brazilian population in the short, medium and long term, following the constitutional principles of universal and equal access to health actions and services;
3. Rationalize the State's purchasing power, through selective centralization of expenditures in the health area, aiming at the sustainability of the SUS and the expansion of the production of strategic products in the country;
4. Protecting the interests of the Public Administration and of society by seeking economy and advantage, considering prices, quality, technology, and social benefits;
5. To foster technological development and the exchange of knowledge for innovation within public institutions and private entities, contributing to the development of Industrial Health Complex and making them competitive and capable;
6. Promote the development and manufacturing in national territory of strategic products for SUS;
7. To seek technological and economic sustainability of the SUS in the short, medium and long terms, with the promotion of structural conditions to increase the country's productive and innovation capacity, contribute to the reduction of the Industrial Health Complex trade deficit and ensure access to health; and
8. Stimulate the development of the public production network in the country and its strategic role for the SUS.

In addition, it is a mechanism that aims to generate savings for public coffers. According to a publication dated 09/05/2017 and found on the website of the Ministry of Health of Brazil, it is estimated to save approximately R$ 5 (five billion reais) at the end of the projects in phase III of the Partnerships for Productive Development.

According to Article 2, item I, of the referred Ordinance, which redefines the guidelines and criteria for defining the list of strategic products for the Unified Health System (SUS) and the establishment of Partnerships for Productive Development (PDP) and disciplines the respective processes of submission, instruction, decision, transfer and absorption of technology, the PDP are *"partnerships that involve cooperation through agreements between public institutions and private entities for the development, transfer, and absorption of technology, production, productive and technological capacity of the country in strategic products to meet SUS demands"*.

Thus, it is observed that the PDP represent an important state policy that aims to leverage the national technological development, with a view to productive, scientific, economic, and technological sustainability of the Unified Health System - SUS of Brazil, meeting the provision of Article 196 of the CRFB/1988. This article states that health is a

Right of all and duty of the State, guaranteed by social and economic policies that aim to reduce the risk of disease and other illnesses and the universal and equal access to actions and services for its promotion, protection, and recovery.

In this way and given the examples successful of the technologies used in other in the areas of optimization of public procurement processes and in combating deviations in purpose in bidding processes, it is possible to conclude that Data Science analytical solutions could make an important contribution to defining strategic products for the public health system. After all, with a population of approximately 213,093,000 (two hundred thirteen million, ninety-three million) people in 2021, certainly the amount of information, related to the health of the Brazilian population, produced daily is exceptionally large.

Therefore, tools that can concentrate and manage a large volume of information can help, for example, in better identifying the needs of the population as unidentified diseases or only partially identified by the current means, as well as signaling the possibilities, unidentified, of shortages of health posts and thus contribute to improving existing public policies or even create others to add to the current ones.

The last list of strategic products for SUS was released by the Ministry of Health in the year 2017, for presentation of PDP Proposal. Therefore, the amount of information corresponding to the criteria defined in Article 5 of Annex XCV of the GM/MS Ordinance of Consolidation No. 05/2017 should be currently extensive and complex.

Thus, a management system of large volume of information could contribute a lot to define the next list of strategic SUS products to be disclosed. In addition, it is possible to conclude that such tools could also be extremely valuable for other challenges related to public health policies, such as, for example, in identifying the reasons Brazil currently imports, according to an article published on the Institute of Science, Technology and Quality - ICTQ, 95% of the pharmaceutical inputs of the drugs produced in the country and, consequently, in helping to identify alternatives and make the best decision.

The Brazilian dependence on imports, about Active Pharmaceutical Ingredients - APIs, became very evident in the current year 2021. Several were the news published by the Brazilian press about the concerns of the Brazilian government regarding the impacts on the deadlines initially foreseen for vaccination of the population, due to possible obstacles in the processes of API acquisition from foreign countries such as China and India.

The Agency Brazil, which is the federal public news agency, published a story in March 2021 reporting that the Brazilian Ministry of Health, in response to questioning from the Brazilian National Congress about the vaccination schedule, said that the main problem in the initially planned deadlines could be

bottlenecks in the deliveries of imported APIs. Although it is a difficulty that has gained greater notoriety due to the implications caused in the fight against the Pandemic by Covid-19, it is an issue that has long affected the Brazilian economy.

According to DIAS (2016), in the year 2013 the trade balance deficit of the Health Industrial Complex - CIS the Brazil was US$ 11 billion dollars, with the import of APIs contributing relevantly to these numbers (Dias et al., 2016).

These values demonstrate without a doubt Brazil's extreme dependence on imported pharmaceutical inputs, generated by the lack of investment in technological development, and is therefore a problem to be faced by the country's authorities.

From 2013 to the present day there is no news of an increase in the Brazilian production capacity of API production that has the power to change the scenario of foreign dependence, thus, it is essential that Brazil review its public policies for investments in research and development and, consequently, the production of APIs in Brazilian territory to change the current scenario of extreme foreign dependence and trade balance deficit. Thus, it is reiterated that Data Science tools can be important mechanisms for establishing public politics that aim to change the current scenario in Brazil in the field of public health.

The tools can collaborate in the management of information about the facilities of companies capable of producing API in Brazilian territory; the necessary investments; the active pharmaceutical ingredients most needed in the country as well as the feasibilities and impediments arising from intellectual property rights, all in a quick and safe way.

It is also worth noting that management systems of large volumes of data and information can be fundamental for evaluations and decisions related to the improvement of legislation that establish guidelines and rules related to Brazilian public health, such as, for example, the rule that regulates the Partnerships for Productive Development, which is currently the Consolidation Ordinance GM/MS no. 05/2017.

Such tools if used could collect data and information that allow changing the current scenario of Brazil's extreme dependence on active pharmaceutical ingredients to produce medicines and vaccines. So, it would be possible to collect data and information regarding the number of national private companies as well as public institutions capable of producing pharmaceutical inputs; what investments are needed to better serve the public interest; the feasibility of public investments as well as the possibility of attracting private investments for the creation of public facilities for the production of inputs in order to allow the public manager to have the proper knowledge of the scenario and thus be able to plan the best strategies to mitigate the current scenario of total external dependence on the production of active pharmaceutical ingredients and thus reduce the trade balance deficit (Dias et al., 2016).

Considering that in Brazil there are, besides private companies, public institutions that have the purpose of producing medicines and vaccines, such as, for example, the Institute of Drugs Technology (Farmanguinhos) and the Institute of Technology in Immunobiological (Biomanguinhos), both linked to the Oswaldo Cruz Foundation and the Butantan Institute, it is possible to understand that only through the due knowledge of all the particularities of the Brazilian pharmaceutical and pharmochemical market the public manager will be able to decide, taking into consideration the particularities of the concrete case, about the budgetary and legal possibilities and viability of concentrating efforts in investments in public institutions and possible incentives for private companies.

The Consolidation Ordinance GM/MS No. 05/2017 establishes in its article 14, that the PDP proposals must present 3 (three) participating subjects:) the public institution responsible for absorbing the technology and manufacturing the product at the end of the technology internalization phase of the PDP; b) the private entity holder or developer of the product technology, which will be responsible for transferring

the technology to the public institution and, c) the public institution or private entity national developer and local producer of the active pharmaceutical ingredient (API) or critical technology component.

Thus, one can see that the norm establishes, in the form of item "c" above, the possibility of a public institution to figure as developer and producer in Brazilian territory of the active pharmaceutical ingredient (API).

However, currently, as can be identified on the Brazilian Ministry of Health's website, there are no public institutions on the current PDP lists, identified on the Brazilian Ministry of Health's portal, with this responsibility, but only private institutions. Therefore, Data Science tools can help the Brazilian public manager, after collecting relevant data and information, to decide on the opportunity and convenience of changing or not this current scenario in which there are no public institutions responsible for API production in Brazil (MACEDO, 2014; *Medicamento-Vacina-e-Hemoderivados---Parcerias-Vigentes---Parcerias-Vigentes.Pdf*, n.d.; Ministério da Saúde, 2021).

It is important to highlight that Data Science tools can also be used, by public institutions participating in PDPs as well as by the Brazilian Ministry of Health, as important allies in the monitoring and management of PDP information and the partners involved. Just as an example, it is worth mentioning the possibility of monitoring the shareholding changes of the companies that are members of a PDP as developers and producers of active pharmaceutical ingredients (API) in Brazilian territory.

As one of the objectives of the PDP is to strengthen the Brazilian market; reduce foreign dependence and contribute to reducing the trade deficit of the Industrial Complex of Health in Brazil and ensure access to health care, it could be harmful to the Partnerships if the companies that develop and produce active pharmaceutical ingredients (API) in Brazilian territory are acquired by foreign companies. After all, the decision on whether or not to maintain the activities foreseen in the PDP would again depend on foreign interests, going in the opposite direction of all efforts undertaken in the PDP to reduce foreign dependence.

This monitoring may also allow the Brazilian Ministry of Health to study the feasibility of changing the current laws to protect the interest of the Brazilian public health from the risks mentioned above and, no less important, to subsidize the Brazilian public manager regarding the decision related to investments in the restructuring of public institutions so that they can also be part of PDPs as developers and producers of active pharmaceutical ingredients (API) in Brazilian territory.

SUCCESS CASES IN HEALTH AREA

The use of Data Science tools can be fundamental in saving lives in times like the present, when the world population is facing the Covid-19 Pandemic, as well as in better managing urban planning in cities.

According to GOMES, the speed in data collection is a differential in competitiveness and veracity, which is a security method to verify and filter if the collected data and information are true or not, are intrinsic characteristics of the Data Science tools. Therefore, these are elements that raise the importance of the use of these systems by public management, since data collection, data filtering and the creation of knowledge about such data are indispensable mechanisms for the proper planning of the urban development policy of cities.

In Brazil, i.e., urban development politics are the responsibility of municipal administrators, and their objective is to order the full development of the social functions of the city and ensure the welfare of its inhabitants, according to article 182 of the CRFB/1988. Thereby, the use of a system that manages a

large volume of information can allow managers to previously collect information about the local public such as age, pre-existing diseases, place of residence, among others. In this sense, such information can collaborate in urban planning, allowing better results to be achieved in times of crisis or not, and to reduce possible harm to the collectivity.

In moments like the current one of facing the Pandemic by Covid-19, the existence of previously collected information about age and pre-existing diseases among others and the management and filtering of this information to allow planning based on the acquired knowledge can avoid possible formation of queues to receive the vaccine and, consequently, avoid crowds and thus better organize the immunization with the least possible risk for everyone.

An example of the use of Big Data analytics solutions in public management is the case of the Mesquita the Prefecture, in the State of Rio de Janeiro. According to an article published in the electronic portal of the Prefecture, the implementation of the "Colab" tool to support the municipal management aimed to create a direct channel with the population. The idea was to make it possible for the local population to claim for improvements in the city and alert problems that needed to be solved.

As informed in the referred matter, by July 8, 2020, close to the completion of two years of operation of the analytical solution in Mesquita, Colab received 40,358 demands, and of this total, 35,281, or 87.4% of the demands, were met. In the terms of the mentioned journalistic matter, the beginning of the use of the "Colab" system represented for the city of Mesquita what was defined as a "water divisor", once it was possible to considerably increase the attendance to the demands of the local population (Prefeitura de Mesquita, 2021).

According to another article published on the Mesquita City Hall website, the Colab tool was also used to obtain information and generate knowledge directed at fighting the Covid-19 Pandemic. The Mesquita Prefecture consulted the citizens through Colab and collected information about people who wanted to undergo the test. After registering in the system, the person received a contact from the health team and, if necessary, a time was scheduled for the city professionals to go to the citizen's home and collect material for the test, or the collection of material could be scheduled at family clinics in the municipality, not generating like that crowds that should be avoided at times like the present. This was a strategy for the Prefecture to this create epidemiological data in the municipality and, with the results of the studies, that is, after obtaining the knowledge, be able to evaluate, for example, which regions had the highest contagion. Therefore, based on the information collected, the system generated for the public manager and knowledge to act more precisely and appropriately to the case (Prefeitura de Mesquita, 2020).

Another successful example of the use of data science tools during the mass vaccination against the Covid-19 Pandemic occurred in the municipality of Serrana City in the state of São Paulo.

According to a news article published by the Butantan Institute (Butantan, 2021), which is responsible for the production and distribution of the Coronavac vaccine in Brazil, the use of the data science tool, called Tainá, allowed clinical studies to be conducted to obtain answers about the effectiveness of the vaccination.

The Institute needed to perform epidemiological data analysis in real time to understand the relationship between the vaccine, the transmission of the virus, and how they could impact the development of health frameworks of the population of the municipality of Serrana (LabNetworK, 2021).

Still according to the Butantan Institute, the Tainá technological tool allowed us to identify that immunizing the entire adult population of the municipality of Serrana caused symptomatic cases of Covid-19 to plummet by 80%, hospitalizations by 86%, and deaths by 95% after the second vaccination of

the local population. The results also showed that the vaccination protects both adults who received the two doses of the immunizer and children and adolescents under the age of 18, who were not vaccinated.

According to the director of clinical trials at the Butantan Institute, Ricardo Palacios "The reduction of cases in people who did not receive the vaccine indicates a drop in the circulation of the virus. This reinforces vaccination as a public health measure, not only individual" (Butantan, 2021).

Another important conclusion was the evaluation of the incidence of the disease in Serrana in comparison with neighboring cities. Serrana has about 10,000 residents who work in neighboring cities. However, while other nearby cities, where residents of Serrana work, showed an increase in the cases of Covid-19, Serrana maintained low incidence rates. Thus, it was possible to conclude that besides the drop in infections, the residents who work daily in other cities did not bring a relevant increase in cases in the city of Serrana.

Therefore, according to the aforementioned news article, the technological tool, which includes four tools: census system, volunteer monitoring system in the stages of the study, process control panels, and a chatbot to guide the population about the vaccination site and how to proceed in case of symptoms, besides facilitating the daily lives of all involved in the project through instant monitoring, it also allowed the Butantan Institute to have access to the centralization of all results, whether of tests performed, rapid tests, PCR and other tests, and this helped to organize the information of the studies and notify the health surveillance about positive cases.

ABOUT PERSONAL DATA PROTECTION

Notwithstanding all the advances and advantages that can be provided using analytical solutions, it is essential to emphasize that the public manager must keep in mind the precautions that need to be adopted in face of the personal data collected.

In Brazil, although the CRFB/1988 establishes in the list of fundamental rights and guarantees the inviolability of intimacy, private life, honor and image of people, in the form of subsection X of its Article 5, until the advent of Law 12,965/2014 called "Marco Civil da Internet", there was no specific rule regulating the collection, use, storage, processing and protection of personal data in activities performed on the Internet.

The law establishes in its article 7 the rights and guarantees of citizens regarding the collection, use, storage, treatment and protection of their personal data. However, only with the advent of Law No. 13.709/2018 called the General Law of Data Protection (LGPD), a specific rule was established to regulate the protection and privacy of personal data processed by Data Science tools.

The Law 13.709/2018 aims to regulate "*the processing of personal data, including in digital media, by natural person or by legal entity of public or private law, in order to protect the fundamental rights of freedom and privacy and the free development of the personality of the natural person*," according to its article 1.

Having said this, it is important to highlight that Data Science tools are currently indispensable instruments for societies due to the possibilities and facilities they create through information management, but it is necessary that companies and public institutions that manage data and personal information of citizens adapt to the laws of protection and privacy of personal data.

After all, the analytical solutions in question have shown themselves to be great allies in solving society's problems and advances in general, and it would be very harmful to everyone if this progress were to be discredited by the lack of security over personal information collected by the systems.

FROM THE INTERNET OF THINGS

The term Internet of Things (IoT) was coined by Kevin Ashton in 1999 and first appeared at the Massachusetts Institute of Technology (MIT). The research group of the RFID (Radio Frequency Identification) Research Laboratory and emerging technologies in sensing at MIT defined IoT as the worldwide network of interconnected objects, uniquely addressable, based on standard communication protocols (MOURA, F. R. E. et al, 2020).

With the advancement of technology IoT came to be conceptualized as a way to connect everyday objects such as smartphones and smart TVs to the Internet where devices are intelligently connected, allowing new forms of communication between things and people, and between things themselves (Kulkarne & Sathe, 2014).

According to work released by the company CISCO (2019) it is estimated that there will be 48.9 billion devices connected to the Internet and in use worldwide by 2023 while, the world population is approximately 7.6 billion people (UN, 2017), that is, the number of connected devices will be much higher than the number of the world population.

In this sense, it is worth mentioning that Forbes Magazine (FORBES, 2021), published an article reporting that smart bracelets were very useful in controlling the Pandemic by Covid-19 in conjunction with the health measures recommended by the World Health Organization.

According to the article, one of the applications of the smart bracelet occurred in the NBA, a basketball league in the United States. After the suspension of activities due to the Pandemic, players, coaches, and reporters covering the teams began to wear the bracelet, which, equipped with a tiny chip, emitted a warning by light and sound when users were too close to each other for long time. In addition, the wristbands stored information about the circle of people the user had contact with in the previous days and weeks.

This helped provide visibility on possible people to be warned in case of future Covid contagion, recommending isolation, for example.

Therefore, considering that technology is becoming more and more present in people's daily lives, the Internet of Things is a model that differs from trivial communication and information management formats and has the potential to be very useful for public health worldwide, and therefore needs to be further explored.

FINAL CONSIDERATIONS

Global Health is broad in its aspects. Therefore, promoting better health conditions for the population, is not restricted only to the production or access to medicines. Data Science solutions for health, can optimize costs and promote better access and speedily the populations of a society. In this sense, health systems have increasingly benefited from the area of Information and Knowledge Science in order that Data Science in the health area be processed more quickly to improve health services.

The pharmaceutical industry is an extremely important sector for the health sector. Its research, development and innovation provide mankind with medicines and treatments aiming at a better quality of life and health promotion. On the other hand, the government policies of each country, combine the promotion, attention, diagnosis, data security and access to all its population to improve their quality of life.

Considering the political, industrial, and academic context surrounding the field of public health and the challenges for knowledge management of Big Data in Health, the use of Data Science tools for better information management for decision makers becomes urgent.

Product Development Partnerships are success stories to help access new technologies more quickly and effectively for developing countries, such as Brazil.

In the same way, the use cases of Data Science tools, including IoT adopted during the vaccination to fight Covid-19, as highlighted in this chapter, should be copied considering the positive results obtained.

After all, as DRUCKER (2002) said, in the future "There will be no poor countries - only ignorant countries. And the same will be true for individuals, companies, industries, and all kinds of organizations."

In this sense, it is worth noting that a work called "The real-world use of big data", released by IBM in collaboration with Oxford University, revealed that organizations that perform information analysis take a competitive advantage over market competitors that do not analyze.

Consequently, although we do not intend to exhaust all the possibilities and alternatives that Data Science tools can bring for innovation and improvements in the Brazilian public health service, we can conclude that, in the face of all the above, for sure, these tools can collaborate in a relevant way to the optimization of health services and, consequently, to the quality of life of the Brazilian population, enabling not only savings to public coffers but essentially helping to save lives.

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Chapter 12
An Approach to Information Management as a Subsidy of Global Health Actions:
A Case Study of Big Data in Health for Dengue, Zika, and Chikungunya

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ABSTRACT

In the information age, it is urgent to work in a collaborative network, as well as the identification of researchers in specific areas in the globalized world. In this time, half of the world's population does not have access to essential health services, and more than one billion are threatened by neglected diseases. Information management helps in the identifying, extracting, and treating. In Brazil, the Lattes platform is the main curriculum repository for scientists and professionals in the different areas of scientific knowledge. After processing, 105 specialists were identified. Scientific articles published on Dengue, Zika virus, and Chikungunya are 11,743. The computational tool ScriptLattes proved to be efficient to extract, identify, and recover data from the curricula present in the Lattes database, contributing to the management of scientific knowledge in public health. Thus, Dengue, Zika, and Chikungunya infection data extracted from the platform generate information to assist in the knowledge management and decision makers for public health.

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INTRODUCTION

The Information Age places the web atmosphere as an environment to access, obtain, organize, and use data and information to understand, share, produce and disseminate knowledge. The internet makes the dissemination of information possible. This thought leads to the reflection that the internet is a means by which a great amount of social, cultural, political, and economic practices is formed and produced. This space is interactive, creates and generates information. The evolution of the web has created increasingly interactive spaces in which users can modify content, download, and make that data public. These interactions generate data, and these are produced by the exchange of information between servers and users. This phenomenon became known as "Big Data" (Jamil et al., 2016; Minelli, M. et al., 2013a).

The term "big data" is related to a new generation of technologies and information designed to extract value from large volumes of a wide variety of data, making high-speed capture and analysis of large volumes of data feasible. This new world of data generation requires a change in computing architecture to understand it. Both the storage, processing and distribution of data, in a secure way, is facilitated. Most of the data is unstructured information and thus makes it difficult to safely analyze it by traditional means. However, with contemporary identification and data mining strategies it is possible to generate essential information to help managers, as in research in the field of public health (Trelles et al., 2011; Wang & Hajli, 2017). However, it is noteworthy that the exponential growth of data not only requires new technologies to access and visualize them, but also the development of new methods for analysis that are efficient and effective in data processing (Quoniam, L, Lucien, A, 2010a).

Big Data refers to the third generation of the information age (Magalhaes, JL & Quoniam, L, 2015; Raghupathi & Raghupathi, 2014). Initially, this exponential data volume met the criteria of 3Vs: Volume, Variety and Velocity (Laney, 2001); later, 2 Vs were added: the Veracity and Value attributes. Some authors even attribute the last 3 Vs, such as Veracity, Versatility and Variety, where the combination of all "Vs" generates the "V" for Value (ALEIXO & DUARTE, 2015). According to Minelli et al (2013), Big Data is divided into perfect data storm, perfect convergence storm and perfect computing storm, and the latter is the result of 4 phenomena: Moore's law, mobile computing, social networks and computing in cloud (cloud computing). This collection of data must be treated to present information researched in a selective and objective way to increase business intelligence, in addition to allowing for an improvement in the decision-making process (Minelli, M. et al., 2013b).

At the institutional level, taking decisions without access to adequate information leads to imprecise and sometimes disastrous decisions. Decisions based on facts and reliable information are more likely to generate good results, giving decision makers subsidies to face daily challenges. Adequate information in a timely manner, develops effective strategies and proactively. This action can be called competitive strategy because it involves the business approach, such as the technological development found in patents. Therefore, data information management provides better knowledge management, as it maximizes the value of the organization's capabilities to distinguish the company from its competitors (J. Magalhães et al., 2017).

The 21st century presents itself as an era with 40% of the population connected to the Internet (McKinsey Global Institute, 2011). In this sense, O'Reilly (2007) suggested the term Big Data as a gigantic database updated in real time, which easily reaches thousands of terabytes of storage in different formats (O'Reilly, 2007a). Traditional relational database management systems cannot handle these large masses of data (J. L. Magalhães & Quoniam, 2013; Quoniam, L, Lucien, A, 2010b). Big Data drives a new generation of methodologies developed to extract economic and strategic value from a large and varied

volume of data (structured and unstructured), enabling high-speed capture and analysis (*Gray, J. and Chambers, L. and Bounegru, L., The Data Journalism Handbook, O'Reilly Media, 2012 - InfoVis:Wiki*, n.d.; O'Reilly, 2007b).

In recent years, the Internet has become an integral part of health surveillance. The collection and analysis of health data has considerable potential for health surveillance, to precede the diagnosis and indicate the probability of an outbreak or a case and thus anticipate decision-making in public health. The concept of surveillance has changed over the years, from a sector that aided patients to the systematic monitoring of adverse health events in the community with the purpose of improving control measures. It is in this sense, moving from the individual to the collective, that information and communication technologies have a considerable impact on surveillance, which is now described as the monitoring of health information (Klein et al., 2017).

Regarding health, it is considered a global public good, that is, health is not exclusive, as no one or no community should be excluded from its possession or consumption. Its benefits must be available to everyone. There is also the apparent consensus that health is not competitive and there should be no rivalry. In short, one person's health cannot come at the expense of other people's exclusion (Buse & Waxman, 2001; Haines et al., 2009; Hartz, 2012; Vance et al., 2009).

Therefore, on the health spectrum, it carries challenges and opportunities in the globalization process. It is noteworthy that this was the catalyst for the evolution of the term "Global Health". Global health can be understood at the same time as a condition, an activity, a profession, a philosophy, a discipline, or a movement. However, it should be considered that there is no consensus on what Global Health is, nor a single definition, and its field of action has imprecise limits (Fortes & Ribeiro, 2014), however it is indisputable that we live Health in times of globalization (Koplan et al., 2009).

Thus, it is essential to better manage Big Data information in health. In this sense, public health professionals seek to identify, for example, the most fashionable subjects researched by the population. In this way, they monitor the "fear epidemic" and provide the public with adequate information with scientific clarification. Another example is the early detection of disease outbreaks, either by official indices of health agencies or through social networks. These methods are used to analyze search behaviors and internet browsing patterns, including how people communicate and share health and surveillance information. The evolution of data and their respective treatments to identify trends, support decision-making in new discoveries and scientific and technological advances, are increasingly rapid (Klein et al., 2017).

The speed of information generated with the advent of Big Data for healthcare is unprecedented in history. Magalhaes et al (2020) demonstrates that in about 06 (six) months of the COVID-19 pandemic decreed by the World Health Organization (WHO), the scientific backing reached about 37 thousand publications in the PubMed database alone, another 03 were deposited (three) patent families and 2,871 coronavirus-related patent families. This represents a contribution to the management of knowledge acquired in record time from the COVID-19 pandemic (J. Magalhães, Hartz, et al., 2020).

Therefore, essential information obtained from Big Data mining in health is urgent for the Government, academia, organizations etc. Studies in any scientific or technological area are of great relevance for the decision-making of its managers. According to Wikipediaminer – Wikipedia's data analysis software – 47% of the daily volume of data added to the web is related to Health, and 43% of these are related to public health. Therefore, it is essential to think of new tools for identifying, extracting and analyzing Big Data related to health at the global level (J. Magalhães et al., 2016).

Thus, this chapter demonstrates an applied information science approach to data management for public health, and uses dengue, zika, and chikungunya diseases as a case study. In this sense, it presents

a scenario of essential competences in Brazil in the area in question as a contribution to decision-making in global health. For this purpose, the Lattes database – Brazilian repository of scientific and professional curricula – and the ScriptLattes tool for identification, extraction, and data mining, are used.

NEGLECTED DISEASES AND THE TRIPLE THREAT

The World Health Organization (WHO) declares that 80% of the world population does not have access to essential medicines. They live in low- or middle-income countries and are therefore neglected. In this context, new approaches are essential to carry out research for the non-traditional area of health. This reality is enhanced by the possibility of the emergence of endemic diseases and those that perpetuate poverty conditions, such as neglected diseases (ND), which do not attract Big Pharma investments because they do not generate profit; as an example dengue, zika and chikungunya (J. L. de Magalhães et al., 2016; Moon et al., 2012).

The G-Finder 2019 report, a platform organized by the Policy Cures Research study center that monitors global investment in research and product development for neglected diseases, the Brazilian government made a 42% cut in funding for research on neglected diseases between 2016 and 2017 (Mori, 2019). In addition to public investment in these areas continuing to decline, there is no interest of large pharmaceutical companies in funding studies for these NDs, since these diseases are closely linked to poverty and, therefore, would not generate the expected profit for the development of drugs for these diseases. Among the ND, one can list dengue, zika and chikungunya - considered here as the triple threat. As for dengue, it is rapidly emerging from a viral disease prone to pandemics in many parts of the world. It is a mosquito-borne viral infection that causes severe flu-like illness and sometimes brings a potentially lethal complication called severe dengue. The incidence of dengue has increased 30-fold in the last 50 years. It is estimated that 50 to 100 million infections occur annually in more than 100 endemic countries, putting almost half of the world's population at risk. There are about 2.5 billion people or 40% of the world's population living in risk areas favorable to transmission. Dengue is endemic in at least 100 countries in Asia, the Pacific, the Americas, Africa and the Caribbean (Bezerra et al., 2016; Guzman et al., 2010; WHO, TDR, 2006).

Chikungunya is a mosquito-borne viral disease first described during an outbreak in southern Tanzania in 1952. It is an RNA virus that belongs to the *alphavirus* genus of the *Togaviridae* family. The name "chikungunya" derives from a word in the Kimakonde language, which means "to become contorted" and describes the stooped appearance of patients with joint pain (arthralgia) (WHO, Control of Neglected Tropical Diseases, 2013). In recent years this disease has proliferated and in the region of the Americas from 2013, specifically reaching Brazil. It is transmitted by the *Aedes aegypti* and *Aedes albopictus* mosquitoes, common in many parts of the Americas. Infection with the chikungunya virus is rarely fatal but causes fever and severe joint pain in most people. Therefore, it is urgent to study new subsidies for this disease (CDC, 2016; Napoli et al., 2012; Remme et al., 2002).

Zika is a virus transmitted by *Aedes aegypti* and *Aedes albopictus*. It was first identified in Brazil in 2015. The virus received the same name as the place of origin of its identification in 1947, after detection in sentinel monkeys for monitoring yellow fever, in the Zika forest, in Uganda (Zanluca et al., 2015). It is considered an acute viral disease, characterized by pruritic maculopapular rash, intermittent fever, non-purulent conjunctival hyperemia without pruritus, arthralgia, myalgia, and headache. Most cases have a benign course and symptoms usually resolve spontaneously after 3-7 days. However, there

is the occurrence of deaths from the disease, an increase in cases of microcephaly and neurological manifestations associated with the occurrence of the disease (de Araújo et al., 2016; Sikka et al., 2016; Zanluca et al., 2015).

Faced with the problem in health and the need to improve information management in the area, it is necessary to plan and find ways to combat these evils that affect humanity through the management of knowledge generated every day to support more effective actions in combating these diseases (J. L. de Magalhães et al., 2016). Therefore, it is necessary to think that health should be understood from its social dimension and as a source of wealth, configuring a Health Economic-Industrial Complex (CEIS) that links highly dynamic industrial segments and the provision of care services. This complex incorporates new technological paradigms that determine the dynamism and long-term competitiveness of national economies, such as fine chemicals, biotechnology, microelectronics and new materials, nanotechnology, the sustainable use of biodiversity, among others. Virtually all segments included in the third technological revolution, fundamental to the Brazil of the future, have a critical space for their development in health (Gadelha et al., 2012).

INFORMATIONAL KNOWLEDGE MANAGEMENT

In the current society we live in, knowledge and innovation are closely linked to competitiveness and development. Management models based on competitive intelligence and knowledge management are considered necessary driving forces for economic growth and scientific innovation (Canongia, 2004).

In modern organizations, which aim to remain active in the market, it becomes a challenge for their managers to manage and disseminate the knowledge of employees within the institution itself, so that decision-making is more assertive.

To avoid inappropriate decision-making, managers should back them up with reliable information. To this end, managers must collect, filter and process this information so that it can be used to obtain a competitive advantage over its competitors. This data can come from all over, as there are currently many devices that capture data from different sources. In this way, for this professional to be able to make a rational decision, all the alternatives available should be listed so that all possible consequences can be analyzed (Choo, 2003).A large amount and variety of information is generated daily. This process is so intense that it is difficult to appropriate it in a conventional way. Thus, the latent promise is that Big Data will improve the vision of decision makers, facilitating and speeding up decision-making processes. Combined with computational tools consolidated in the market, it becomes possible to perform an analysis very quickly, without having to understand billions of data to make a decision. In this way, exploring data originated on the Web from different sources, the modern manager will not only rely on his intuition in the decision-making process, but will be able to make complex decisions faster and more assertively based on this data.

Institutions that use big data gain a competitive advantage over those that do not, as they are able to gain new insights into trends and behaviors that would otherwise not be possible, speeding up the decision-making process. The strategic use of Big Data makes it possible to discover new opportunities, fill gaps and even generate insights for the managers of modern institutions.

Knowledge Management has a universal character and can be applied both in public and private organizations, as well as in the business and academic world. It connects to several areas, especially with regard to information and people management, in which information and analysis flows are supported by

technologies and people (Rosenberg et al., 2008). Innovation has been a permanent mission in different types of organizations, also reflecting in the area of public health, which is one of the means that most accumulate capital and invest in innovation (Fonseca & Fonseca, 2013).

In this way, organizations have considered knowledge management as one of their most important tools, as they make the actions, in the organizational and individual plans, more assertive, thus allowing the continuous innovation of their products and services with excellence (Rocha et al., 2012).

Regarding public health, the management of large volumes of data generated daily in databases, electronic prescriptions and medical records and clinical repositories are of fundamental importance for decision-making, whether administrative or operational. Thus, it is up to managers to disseminate and share this knowledge not only with their employees, but also with other health professionals.

The data shared by the scientific community favors the advancement of science, as they facilitate development and innovation in the reuse and dissemination of these data by the community itself. This fact contributes to the so-called FAIR concept (Findable, Accessible, Interoperable, Reusable). According to this principle, health data must be locatable, accessible, shared and reusable in order to facilitate interoperability between systems and also solve problems related to lack of communication between these data (Almada et al., 2020; Henning et al., 2011). The FAIRification process intends to standardize the availability of these data, aiming to integrate the numerous databases currently available through the adoption of standards, metadata, ontologies and identifiers, so that it is then possible to reuse these biometric and clinical data (Henning et al., 2019). Thus, this digital transformation of healthcare allows for improvements in its services, through personalized and preventive medicine.

The reliability of data for analysis and, consequently, stratification of scientific and/or technological trends, help not only in decision-making by managers, but also in the formation of skills to innovate. In this scope, it is worth reflecting on Collaborative Intelligence (CI)[1] in informational knowledge management with peers. This action presupposes collaborative development processes capable of producing high-quality information on scientific and technological knowledge, whose governance is based more on scientific authority than on sanctions and integrated levels of individual involvement and responsibilities that characterize the final collective (Ambrosi, A et al., 2005).

Whatever the application area of CI, it must comprise a highly structured and networked activity. Research, in general, must be structured in networks, since the processes involved in R,D&I (Research, Development and Innovation) of medicines for health are increasingly complex. Thus, there is a need to form a multidisciplinary team aiming to establish a systemic view (Le Moigne, Jean-Louis, 1994; Pierret, 2006)[2].

An example of "Big Data" used in Brazil is the Lattes Platform, maintained by the National Council for Scientific and Technological Development (CNPq). This database integrates the academic curricula of researchers or research groups from public and private institutions. Academic, institutional and bibliographic information of researchers registered in it are found in this database, thus enabling reflection on the scientific and technological evolution of knowledge in the areas of Science, Technology and Innovation (S,T & I) (Brito et al., 2016).

Due to the large amount of information found in the Lattes database, to facilitate the management, extraction and recovery of this data, the computational tool ScriptLattes can be used (Brito et al., 2016; J. Magalhães, Hir, et al., 2020b; Mena-Chalco & Junior, 2009a). This is a GNU-GPL script in Python language with a free and open-source license, where it is possible to perform the automatic extraction and compilation of data, generating metrics, collaboration graph and geolocation map (Mena-Chalco & Junior, 2009b).

Therefore, identifying the essential information existing in the Big Data on neglected diseases (dengue, Zika and Chikungunya) for better knowledge management is configured as a contribution to global health, as it can support technological innovation - incremental, radical innovations or even frugal (J. Magalhães, Hir, et al., 2020a; Nigro et al., 2018).

SEARCH STRATEGY ON THE LATTES PLATFORM AND THE USE OF SCRIPTLATTES

For identification, extraction, and processing of data from senior competences in Brazil, regarding bibliographic productions, technical productions, artistic productions, guidelines, research projects, awards, and titles, the ScriptLattes software was used to identify and extract data in the Lattes' Platform.

The search was carried out on the Lattes Platform (BRASIL, MCTI., 2013) to get the greatest senior experts in the country. Thus, the search was centered on the terms in English and Portuguese: "dengue", "zica", "zika", "chicungunha" and "Chikungunya". For this purpose, Boolean expressions were used in the advanced search of the Lattes Platform (as shown in figure 1) such as "AND", "OR", "NOT" and "NEAR". For example: dengue OR zika OR zica OR chikungunya OR chicungunha.

Figure 1 shows the search engine and when elaborating, the Boolean was inserted in the field "this Boolean expression", to carry out the search.

Figure 1. Page dedicated to advanced search on the Lattes platform
Fonte: Lattes Platform (http://buscatextual.cnpq.br/buscatextual/busca.do?metodo=apresentar)

In this phase, the greatest national researchers who mentioned any of these terms in their scientific curricula were obtained and, thus, it was possible to create new search strategies for an overview of the senior competences of these diseases in Brazil.

Then, it was possible to define the criteria for the search to obtain senior researchers registered on the Lattes platform. The following options were available:

- All (doctors and other researchers, Brazilians, and foreigners);
- Brazilian and foreign doctors;
- Brazilian Doctors;
- Brazilian Doctors with any level of productivity scholarship;
- Brazilian and foreign doctors with any level of productivity scholarship and presence in the Research Groups directory;
- Brazilian PhDs with any level of productivity scholarship and presence in the Research Groups directory.

RESULTS

In each available criterion, the number of existing specialists was identified (see table 1). The total available in the database was 5,305 resumes. To extract data from senior specialists with active presence in Research Groups, the option "Brazilian doctors with any level of productivity scholarship and presence in the GP directory" was selected, representing 105 specialists.

Table 1. Lattes curricula related to triple threat

Item	Selected criteria for searching the Lattes base	Number of identified Lattes resumes
1	All (doctors and other researchers, Brazilians, and foreigners)	2943
2	Brazilian and foreign doctors	1024
3	Brazilian doctors	997
4	Brazilian and foreign doctors with any level of productivity scholarship	119
5	Brazilian doctors with any level of productivity scholarship	112
6	Brazilian and foreign doctors with any level of productivity scholarship and presence in the GP directory	110
7	Brazilian doctors with any level of productivity scholarship and presence in the GP directory	105

Source: Created by the authors.

Given the above, the 105 researchers (item 7 in table 1) were considered the main researchers in dengue, Zika and Chikungunya, with curriculums registered on the Latte's Platform. They have active research and presence in research groups, as they stand out from other researchers. It should be noted that these specialists represent 0.001% of the total registered resumes registered on the Lattes' platform.

With the identification of the Lattes ID (specific code of each curriculum assigned on the Lattes platform) of each of the 105 specialists, they were inserted in the ScriptLattes software to identify each curriculum on the platform, data extraction and, therefore, treatment for information visualization managerial such as: area of expertise in Research, Development and Innovation, ranking of the largest collaborators and their networks, scientific and technical production, university affiliation, guidelines and conclusion works, geolocation map, among others

It is worth highlighting the total number of articles published in journals, published books, book chapters published, texts in newspapers and/or magazines, papers presented at conferences, abstracts published at conferences, articles accepted in publications, work presentations, and other types of bibliographic production. All these productions are related to dengue, Zika and Chikungunya by the 105 senior researchers working in the Brazilian territory.

Table 2 shows the five largest contributors to research on the topic in question. The degree of collaboration on the left side of the table (Collaboration Rack) is a numerical value that indicates the impact of a member on the collaboration graph. This can measure the largest contributors in dengue, Zika and Chikungunya to global health.

Table 2. The top five bibliographic producers related to triple threat

Collaboration Degree	
Collaboration Rank	**Researchers**
4.3	Erna Geesien Kroon
3.5	Pedro Fernando da Costa Vasconcelos
3.5	Patricia Torres Bozza Viola
3.3	Rita Maria Ribeiro Nogueira
2.9	Mitermayer Galvão dos Reis

Source: Created by the authors.

It is noteworthy that the information refers to the study period when ScriptLattes was executed. As curriculum updates are constant, the results will be different with each new execution of the survey.

Other points that are worth mentioning is the geolocation map shown in Figure 2. In geolocation, you show the point on the map (generated by Google Maps and attached to the Script) of the performance of each researcher and in relation to their professional address that each specialist informed on your resume.

Figure 2. Geolocalization map
Source: Captura de Tela elaboração própria. ScriptLattes: (MENA-CHALCO e CESAR-JR, 2009) . Map: Google Maps®

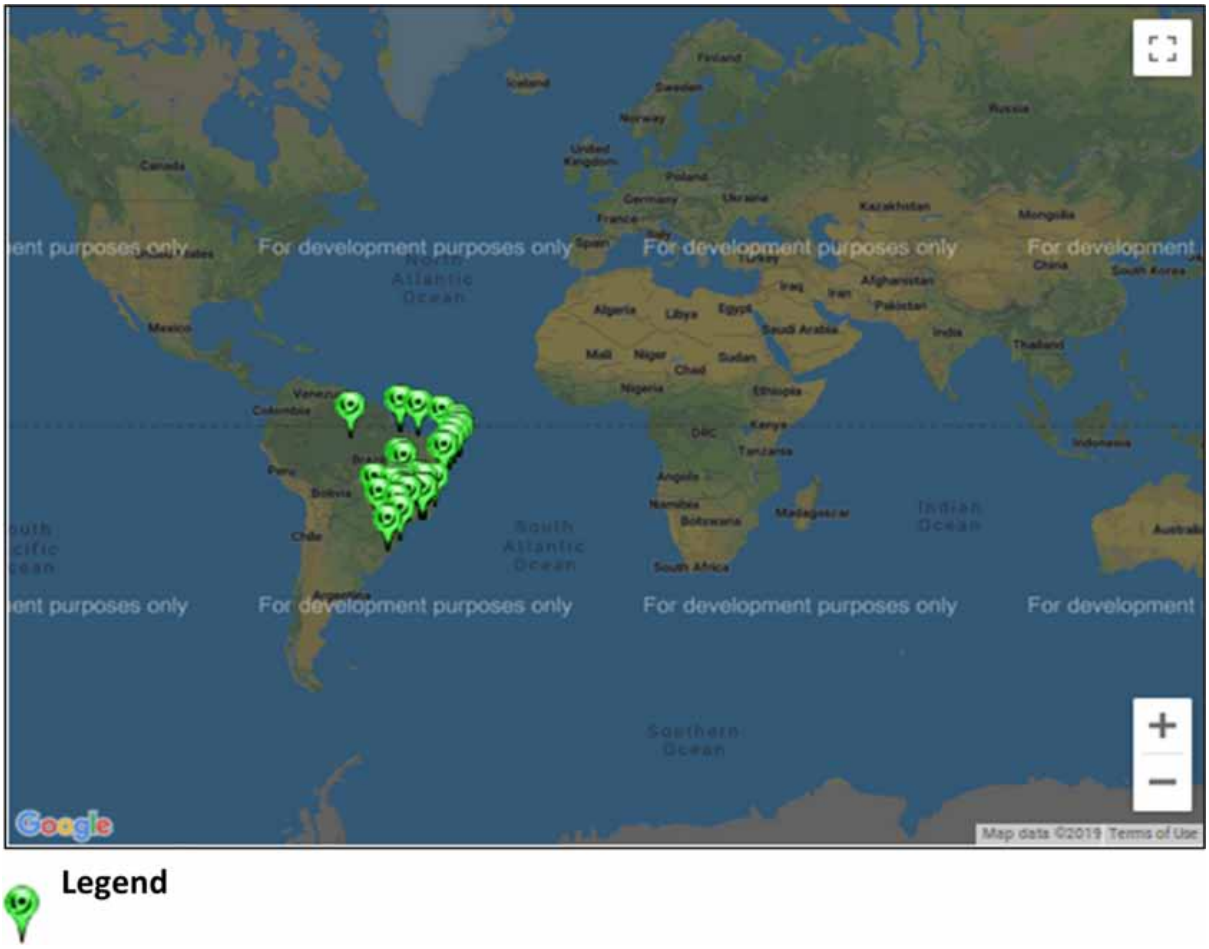

Figure 3. Senior expert example
Source: Created by the authors from ScriptLattes print: (Mena-Chalco & Junior, 2009b). Map: Google Maps®

By clicking on the symbol "  " shown in Figure 3, you can see the name of the senior expert on the triple threat – Vania Margaret Flosi Paschoalin, the Institute she works for, and her link to the Lattes curriculum. According to this map, it's possible to observe a greater concentration of specialists in the south and south-east regions of Brazil.

FINAL CONSIDERATIONS

The contribution of information science in the 21st century has radically changed the way scientific and technological knowledge is addressed. Combined with the avalanche of data that is generated daily on the web, there is an urgent need for better knowledge management to help decision makers in companies, governments, and academia. Nevertheless, the area of health is fundamental and, therefore, essential information for Global Health. Knowledge management, using information technology tools, could become a great ally in helping decision-makers in the private and public sectors alike

The importance of Big Data correlations linked to Health, combined with collaborative tools are fundamental to search for and identify essential information. This fact occurs, precisely in the fact that in the globalized world everything is constantly changing. Therefore, seeking and investing in knowledge management for technological innovation is essential. About public health, this search becomes even more essential, to provide decision makers in the field of public health with reliable and essential information.

In the country, 105 senior skills were identified in a triple threat: dengue, zika and chikungunya. With this identified cut, you can point horizons for better future management and decision making in the area in question. The complete paper published by these specialists were 11,743.

According to the applied methodology (doctors and other researchers, Brazilians, and foreign doctors - item 1 of table 1), the total of senior competence in triple threat represents only 0.01% of the total of doctors specialized in the Lattes platform. Considering the global issue of the triple threat and the need in times of the information age for data, it is concluded that information science tools, such as ScriptLattes, can help generate essential information for better knowledge management. In this way, it is healthy to support decision makers in Global Health on Dengue, Zika virus and Chikungunya. Nevertheless, the present study can be replicated for other diseases and/or expertise demanded by public health managers.

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ENDNOTES

1 Collective intelligence is a concept that describes a type of shared intelligence that arises from the collaboration of many individuals in their diversity. It is an intelligence distributed everywhere, in which all knowledge is in humanity, since no one knows everything, but everyone knows something (Bembem & Santos, 2013). On the other hand, it adds the concept of Competitive Intelligence by Martinet and Marti (1995), which began to be adopted in the 70s-80s, intensifying in the 90s and should reach its maturity in the beginning of the 21st century, whose main function is to supply information organizations to prepare them to challenge the competition and support the globalization of markets.

2 In the context of Systems Science and Philosophy, the term refers to the study of systems from a holistic point of view, to develop the logical, engineering, mathematics, and philosophical structures and paradigms for physical systems, technological, chemical-biological, social, cognitive, and metaphysical systems can be studied and modeled. https://en.wikipedia.org/wiki/Systemics.

Chapter 13
Productive Development Partnership as a Strengthening of the South–South Relationship

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ABSTRACT

Productive Development Partnership (PDP) established by the Ministry of Health comprehends cooperation, by agreements, between public and private institutions for development, transfer, and absorption of technology regarding strategic products in accordance with the demands of the Unified Health System. The PDP program represents one of the most important initiatives for building an industrial policy and systemic innovation in the health area. It also could promote the strengthening of the national production, public-private integration, favoring the incorporation of new technologies, which were dominated only by big multinational corporations in the private pharmaceutical sector. Additionally, the establishment of a PDP with a pharmaceutical company from a South American country, which is also part of Mercosur, expands the range of interaction beyond those already existing with American, European, and Asian companies, strengthening technical development-scientific of the region that will be able to catalyze the interaction with other companies also from the region.

INTRODUCTION

The Productive Development Partnership (PDP), instituted by Regulation nº 2.531 of November 12th, 2014 by the Ministry of Health (MS), consolidates the guidelines and criteria for the definition of the strategic products list of purchases by the Unified Health System (SUS).

PDP are partnerships that involve cooperation by an agreement, between public institutions and private entities for the development, transfer and absorption of technology, production, productivity and

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technological training in the country, regarding strategic products in accordance with the demands of SUS (Brasil, 2014).

In 2020, there were 76 PDP processes in place, of which the following product categories are observed: synthetic medicines (39), biological medicines (26), blood products (1), vaccines (4) and medical devices (6) (MS, 2020).

The analysis of already-established PDP shows that there are still no partnerships with pharmaceutical industries in South America. The possibility of establishing a PDP involving pharmaceutical industries in the region, and in addition to meet all the objectives set forth in Regulation nº 2.531/2014, may strengthen regionally the pharmaceutical sector, corroborating the guidelines of the Southern Common Market (MERCOSUR).

In this context, this chapter aims to contextualize the importance of the regional integration process of MERCOSUR countries, specifically regarding the health sector. This approach is justified by the impact that this integration is capable of having on: the well-being of the region's population; promoting local development; economic and political strengthening of the bloc in question; and, consequently, sustainable development of the region.

To achieve the previously established objectives, a bibliographic research was carried out with the purpose of understanding the universe of which, the theme is inserted, evaluating the public-private interactions potential, as well as the benefits that can be generated through these partnerships.

In order to carry out this work, bibliographical, documentary and applied research were carried out, searching for specific legislation, in addition to corporate consultations. We also sought to identify the history of policies instituted by the Brazilian government with a view to encourage and promote public production of medicines, in addition to identify strategic medicines for SUS that do not have yet this kind of partnership, as well as Official Pharmaceutical Laboratories (LFO) certified by Anvisa and the importance of Mercosur in strengthening the members.

In this way, this chapter delimits itself in presenting the process of formalizing the PDP of medicines, aiming at strengthening the South-South relationship.

BACKGROUND

The Need for a Public-Private Interaction

Institutional interactions for innovation are also a key factor when it comes to technology transfer, which is, the absorption of new technologies and production processes, by official laboratories, to produce medicines and other health technologies.

For engaging public and the private sectors to carry out the actions for the common interest, we should highlight the discussion on the need to establish new forms of partnerships that may guarantee the effectiveness of processes.

In this theme, the PDP stands out, as a tool launched by the MS in order to promote the expansion for accessing medicines and other health products, considered strategic for SUS, through the strengthening of the national industrial complex (Official Pharmaceutical Laboratories Association of Brazil) [ALFOB], 2019).

To increase the production of public institutions, one of the actions of the policy of the Industrial Economic of Health Complex (CEIS) was the consolidation of agreements between official laboratories

and private companies. In this scenario, private companies would transfer technology from the production of medicines to official laboratories (Sundfeld & Souza, 2013).

These are partnerships that seek not only the country's technological autonomy and the reduction of SUS's vulnerability to fluctuations in the international market, but also seeks a significant reduction in prices of these medicines (Sundfeld & Souza, 2013).

Sundfeld and Souza (2013), point out that with these agreements, the Ministry of Health will guarantee the production of medicines that were previously purchased from private companies, many of them, foreign. With this initiative, an average savings per year of R$ 100 million in expenses in purchases of these products can be estimated.

The public-private relationship should take on a new aspect, which the public uses private management instruments and the private increasingly assumes a responsible role related to the community and the common interest. Thus, the dichotomy between public and private, as if they only had opposing or antagonistic interests, should be set aside in the search for the efficiency and effectiveness of the actions of the State and the common good (ALFOB, 2019).

With this alignment, official laboratories will be able to seek and share solutions of common interest, optimizing the use of resources, taking advantage of synergies and strengthening unified positions in interinstitutional negotiation processes, which should become increasingly decisive in the present times (ALFOB, 2019).

In this sense, the evaluation of the possibility of establishing a PDP with private South American companies of Mercosur in the pharmaceutical sector, that have representatives in Brazil, would expands the range of interaction beyond those agreements are already in place with american, european and asian companies. In addition, this action may contribute to the strengthening of technical and scientific development in the region and may catalyze interactions with other Mercosur companies as well.

This way, it is believed that such partnerships would contribute to the development of the public sector, regarding the absorption of technology and the expansion of private companies in Brazil, strengthening productive partnerships within the MERCOSUR.

The Mercosur

The formation of regional blocs from closed states for common economic interests is one of the consequences of the globalization process. In South America, in the recent decades, there have been movements and varied dynamics of agreements with the objective of advancing regional integration. Examples of this process are the Latin American Integration Association (Aladi), the Bolivarian Alternative for America (Alba), the Andean Community of Nations (CAN), the South American Community of Nations (Casa) and the South Nations-Americanas Union (Unasur), in addition to the Common Market of the South (Mercosur) (Aikes & Rizzotto, 2020).

Mercosur, made up of countries of South America, is today a fundamental instrument for the promotion of cooperation, development, peace and stability in the countries that belong to the bloc (Common Market of the South [MERCOSUR], 2020).

Due to the worldwide recognition of the relevance and impact of the health sector on the human and nation development potential, in a sustainable way, it is understood the social and political importance of the integration of health actions in Argentina, Paraguay, Uruguay and Brazil (Gallo & Costa, 2004).

For contributing to the development of these countries, not only can production be directed to regional demand, but it is also possible to exploit the comparative advantage between the countries' production,

allowing the specialization of production, besides the multiple benefits, due to the increase of the potential market scale (Gallo & Costa, 2004).

Mercosur, aiming at the region consolidation, has been favoring the development of most diverse sectors, among them, health, education, justice, culture, transport, energy, environment and agriculture (Gallo & Costa, 2004).

Health earns its place in the Mercosur Strategic Social Action Plan (PEAS), in which the intersectoral articulation strengthening and joint work into institutional instances of Mercosur - in aspects linked to the Social Determinants of Health (DSS) - and the implementation of the research network in Public Health and DSS, are now considered priority objectives, among others, in Axis III, which treats the Universalization of Public Health (Braga, 2015).

In this context, planned and integrated regional intra-bloc development actions can represent a very useful tool to reduce the gap that separates the most developed countries from the less developed ones in such visible way (Gallo & Costa, 2004).

In 2018, the share of industrialized goods of Brazil reached a proportion of 86.6% in the Mercosur, ahead of the United States with 79.2%, the European Union with 55.3% and China with 11.5%. The bloc is also responsible for the second largest trade balance registered in the year, behind only China. This demonstrates a strong contribution by Mercosur to the Brazilian trade balance surplus (Magalhães, 2020).

An emphasis is placed on the impact that Mercosur is capable of exerting on the industry development in the member states, since it offers 'protection' to industries that are still in competitive disadvantage compared to more developed countries (Gallo & Costa, 2004).

Some principles should guide the integration in Mercosur for its self-sustainability, namely: political will, full democracy, voluntary association of countries, agreement with the economic/social development model, existence of a rule of law; and respect for the Human Rights (Gallo & Costa, 2004).

The Treaty of Asunción, a founding instrument of Mercosur, established a model of deep integration, with the central objectives of shaping a common market - with free internal circulation of goods, services and productive factors - the establishment of an External Common Tariff (TEC) in trade with third countries and the adoption of a common trade policy (MERCOSUR, 2020).

The Ouro Preto Protocol, signed in 1994, established the basic institutional structure of the Mercosur and gave the bloc a legal personality under the international law (MERCOSUR, 2020).

Mercosur is the main recipient of Foreign Direct Investment (FDI) in the region. The bloc received 47.4% of the entire flow of FDI directed to South America, Central America, Mexico and the Caribbean in 2016 (MERCOSUR, 2020).

The bloc constitutes a privileged space for investments, through purchase, share control and association of companies from the States Parties. The expansion of the economic integration agenda contributed to a significant increase in direct investments destined by the States Parties to the other members of the bloc (MERCOSUR, 2020).

Mercosur is going through an accelerated process of economic, commercial and institutional strengthening. The States Parties have consolidated a pragmatic integration model, focused on concrete results in the short term. The current meaning of the integration of Mercosur is the search for economic prosperity with democracy, political stability and respect for human rights and fundamental freedoms (MERCOSUR, 2020).

Given the importance of Mercosur for trade and for the economies involved, the internationalization of technical standards as a strategy for regulatory harmonization among Mercosur partners needs to be thoroughly evaluated and conducted at a pace that meets the possibilities and interests of the bloc's

members. The expectations of the partners in the agreement regarding their international insertion are in question (Tironi, 2020).

There is still much progress needed in order to consolidate the Common Market foreseen in the Treaty of Asunción, in all its aspects: the free circulation of goods, services and other productive factors, including the free circulation of people; the full application of the TEC and a common commercial policy; the coordination of macroeconomic and sectoral policies; and the convergence of national laws of the States Parties (MERCOSUR, 2020).

On the other hand, taking into account the great challenges for Integration in Mercosur, the construction of a Common Market with social justice, with a reduction of inequalities, should be taken into account the 6 (six) basic principles of our Federal Constitution and our Law: equality, universality of care, participation, efficiency, integration and decentralization (Gallo & Costa, 2004).

In the year 2020, international trade went through a time of great uncertainty: the clash between the United States and China, the presence of several global competitors, whether countries or companies, a global health crisis caused by COVID-19 and the constant demand for innovation and competitiveness are examples. Themes such as product and service diversification, global value chains, lowering barriers to trade and reforms to international institutions are increasingly frequent (Magalhães, 2020).

In this context, international agreements are emerging more and more as tools for maneuvering the interests of nations, as well as allowing a greater international insertion. A country's level of international participation can be measured precisely by its number of free trade agreements (Magalhães, 2020).

Magalhães (2020) considers that given the possibility of boosting integration into global trade, making Mercosur's rules more flexible regarding the signing of international agreements, may lead to a very effective strategy for greater competitiveness, not only for Brazil, but also for others member countries, since it is a viable solution to the current situation of political obstacle. However, the maintenance of the bloc and the search for greater integration is fundamental, since, although problems are found, Mercosur has achieved several successes and remains an important tool for Brazil and the region development.

Partnership Possibilities other than PDP

It is important to mention the existence of other strategic instruments of National Policy for Technological Innovation in Health (PNITS), regulated by Decree nº 9.245/2017 - which aims to promote the technological and economic sustainability of SUS, defining the structural conditions to increase the country's productive and innovative capacity, with a view to contribute in expanding access to health. In this sense, in addition to the PDP, we should consider the Technological Orders in the Health Area (ETECS), the Compensation Measures in the Health Area (MECS) (MS, 2018) and the Public-Private Partnerships - PPP (Brasil, 2004).

In general, ETECS is a special instrument of direct public purchase, addressed to very specific situations of which there are technological risks. It is regulated by Article 24th, item XXXI of Law 8.666/1993; by Article 20th of Law nº 10.973/2004; and section V of Decree nº 9.283/2018 (Rauen & Barbosa, 2019).

In Brazil, the first ETECS efforts were carried out decades ago, with the incorporation of the first vaccine production technologies to meet the National Immunization Program (PNI) and through this, the offer of large volumes of immunobiologicals allowed to contract projects for the transfer of technology to produce vaccines to the LFO. Two of the LFO's stood out in this technological incorporation activity, Fiocruz and the Butantan Institute, appearing, especially due to the revenues resulting from these projects, among the 20 largest groups that produce medicines in Brazil in 2017 (Ministério da Saúde [MS], 2018).

In September 2020, Fiocruz signed the ETECS contract with AstraZeneca, which holds the production, distribution and marketing rights for the Covid-19 vaccine for prevention, developed by the University of Oxford. ETECS will guarantee Bio-Manguinhos, Fiocruz's technical-scientific unit, access to the Active Pharmaceutical Ingredient (API) for final processing (formulation, filling, labeling and packaging) and quality control, aiming the production of 100.4 million doses of the vaccine against Covid-19, while guaranteeing the complete transfer of technology to Fiocruz, as established in the Memorandum of Understanding, signed in July 31 between the parties. The production of the vaccine was made possible by Provisional Measure 994/2020, later transformed into Law 14.107/2020, which opened an extraordinary credit of R$ 1.9 billion to the Ministry of Health (Brasil, 2020a and Brasil, 2020b).

The MECS, on the other hand, provide "trade, industrial, technological compensation measures or access to advantageous financing conditions" (as stated in § 11 of article 3 of Law 8.666/1993). This instrument takes advantage of the strong bargaining power of large government purchases, to allow different kinds of compensations, that may be decisive for choosing a particular supplier. Compensation agreements are particularly relevant for associating the commercial advantages of buying on a large scale with the compensation resulting from the size of the purchase, that is, the purchase of dozens of technologies gives the buyer a much higher negotiation capacity. This is particularly important in business environments that are often subjected to monopolies and oligopolies with asymmetric market power (MS, 2018).

The PPP is noteworthy as a medium and long-term service contract (from 5 to 35 years) signed by the Public Administration and regulated by Law nº 11.079/2004, whose value is not less than twenty million reals, but it is forbidden to sign contracts that have as their sole object labor the supply, equipment or execution of public works. In PPP, the implementation of the necessary infrastructure for providing the contracted service by the Administration will depend on financing initiatives by the private sector and the individual's remuneration will be fixed based on performance standards and will be due only when the service is available to the State or of users (Brasil, 2004).

PDP as a Strengthening of National Productive Base

The PDP instrument, instituted by the Ministry of Health in 2009, as a way of internalizing technologies which are considered strategic for the country and to meet the demands of SUS, has been promoting the strengthening of national production base.

As a result of the PDP, the Health Economic Industrial Complex (CEIS) was considered one of the six strategic areas for the future, due to its high intensity innovation and its potential to disseminate knowledge and innovation to the productive matrix (Gadelha, 2012).

The goal of strengthening the national production base is to favor access to therapies not yet made available by SUS to the Brazilian population, reducing the monopoly of few companies and the high cost of purchasing products from the private sector.

The need for such strengthening became very important with the advent of the pandemic, a period that the reflection on the capacity to meet Brazil's health demands and the dependence on imports of pharmaceutical supplies and medicines was emphasized.

PDP were created as part of a policy to strengthen, in particular, LFO. However, the history of more than ten years of validity of this type of partnership has shown the interest of private pharmaceutical laboratories, with national and foreign capital, in establishing partnerships with LFO.

If, on one hand, PDP promote the internalization of technology by LFO, on the other hand, private laboratories guarantee their participation in the public market for medicines and API, in a synergistic movement that may result in the future generation of new medicines.

Considering these premises, the hypothesis of this chapter is that, through the establishment of PDP between an LFO and pharmaceutical private groups of South American, it will be possible to transfer technology to produce medicines of interest to SUS, strengthening the production base in the region of Mercosur.

The Context of the PDP and its Objectives

The PDP program was created in 2009 as part of a broader strategy by the Federal Government to support the development of CEIS, to expand access to strategic products for SUS. The program is strongly based on the use of government's purchasing power as an instrument of Industrial and Innovation Policy and represents a central element in the strategy of building systemic innovation policies in health area (Vargas, Almeida & Guimarães, 2016).

The PDP program is a convergence supported by the Federal Constitution of 1988, reaffirmed by the SUS Law of 1990, encouraged by the National Medicines Policy of 1998, marked by the Law of Generics in 1999 and punctuated by the creation of the Regulation Chamber of the Medicines Market (CMED) in 2003, structured on a firmer basis with the Innovation Law of 2004, detailed with the National Policy on Science, Technology and Innovation in Health in 2004, and leveraged with the National Program to Promote Public Production and Innovation at CEIS and with the definition of the list of strategic products within the scope of SUS in 2008 (Sundfeld & Souza, 2013).

The main objective attributed to the PDP program in the view of the Ministry of Health, originally refers to the process of building productive capacities and innovation in the national health products industry, with the focus on strategic products for public health (Vargas, Almeida & Guimarães, 2016).

Based on Resolution nº 2.531/2014, the objectives associated with the establishment of the PDP were expanded and detailed, as shown in its third article (Vargas, Almeida & Guimarães, 2016).

I – to expand the population's access to strategic products and to reduce the vulnerability of SUS;

II - to reduce the productive and technological dependencies to meet health needs of brazilian population in short, medium and long terms, following the constitutional principles of universal and equal access to health actions and services;

III - rationalize the purchasing power of the State, through the selective centralization of expenditures in health area, with the view of SUS sustainability and the expansion of production of strategic products in the country;

IV - to protect the interests of Public Administration and society when looking for economy and advantage, considering prices, quality, technology and social benefits;

V - foreign technological development and the exchange of knowledge for innovation within the scope of public institutions and private entities, contributing to the development of CEIS and making them competitive and capable;

VI - to promote the development and manufacture in Brazil of strategic products for SUS;

VII – to seek SUS' technological and economic sustainability in short, medium and long terms, with the promotion of structural conditions to increase the country's productive and innovation capacity, to contribute for the reduction of CEIS's trade deficit and to guarantee access to health; and

VIII - stimulate the development of the public production network in the country and its strategic role for SUS (Brasil, 2014).

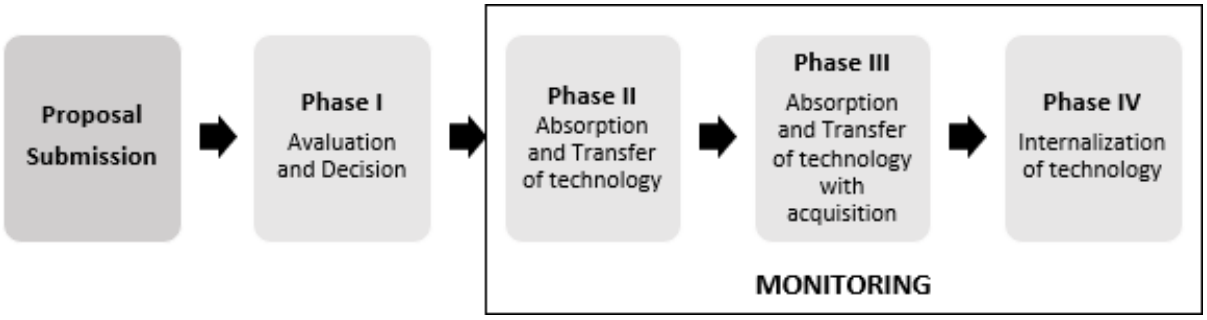
Subjects Participating in the PDP and the Stages of its Process

Silva and Resende (2017), consider that from this instrument of integration of public policies, sociotechnical networks were created within the scope of CEIS.

Sociotechnical networks are composed of the triangular relationship between the subjects participating in the PDP: the API manufacturer, which can be synthetic or biological; the private company and the public institution, with the supervision of the Technical Evaluation Committee (CTA), the Deliberative Committee (CD) and the Regulatory Technical Committee (CTR), responsible for the evaluation and monitoring of the projects. It also includes the relationship between the public institution and Anvisa, aiming at obtaining the product registration, as well as the coordination that the Agency performs with the CTR.

Based on Resolution nº 2.531/2014 and on the MS website, the process of establishing and achieving a PDP is organized into four distinct phases, as briefly shown in figure 1.

Figure 1. Steps of a PDP
Source: Adapted from https://www.saude.gov.br/saude-de-a-z/parcerias-para-o-desenvolvimento-produtivo-pdp. Accessed on 04/13/2020



A proposal submission must be made by the Public Institution, within the period that is determined by the MS, according to guidelines and requirements established in Resolution nº 5, of September 28, 2017, Annex XCV (MS, 2020).

The PDP term will be proposed according to the technological complexity, for the internalization of the technology, respecting the maximum limit of 10 (ten) years (Brasil, 2014).

Health Impacts of PDP

PDP are considered to be the course of action that has shown the most results so far, configuring technological and industrial policies as one of the attributions of public health policy (Silva & Resende, 2017).

As highlighted by Gadelha (2012), CEIS accounts for about 9% of the Gross Domestic Product (PIB) and for more than nine million direct and indirect jobs. In the view of the significant participation of the

pharmaceutical and pharmochemical segment in the production and incomes generated in this complex, it is plausible to estimate a high impact associated with the investments made in this subsystem.

According to Gadelha and Temporão (2018), in terms of product delivery, there was an evolution in the period 2011/2014, rising 134% in a period of 4 years, representing 35% of the centralized purchases of medicines from the MS.

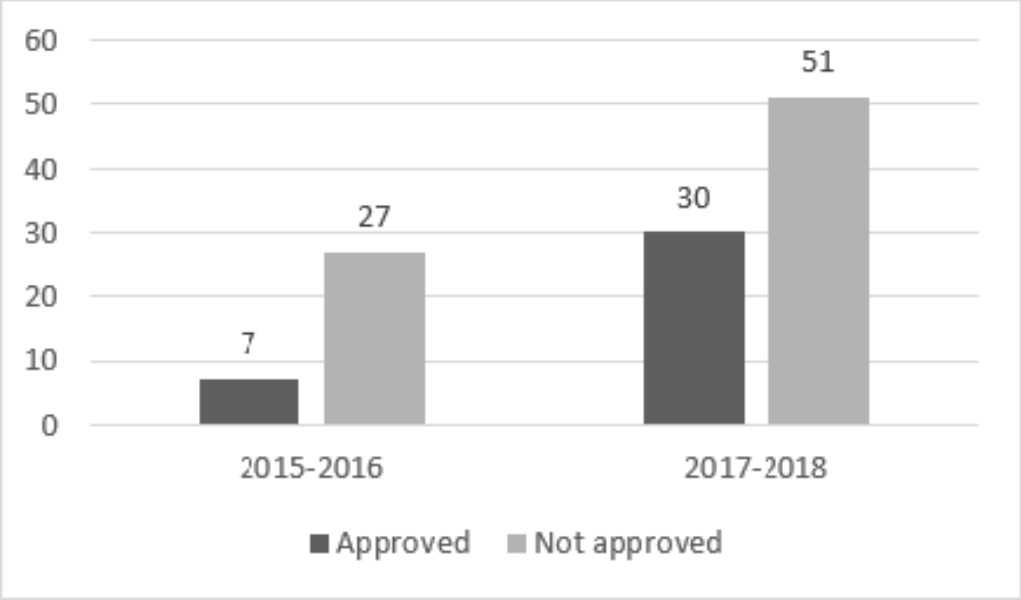
Gadelha and Temporão (2018) also reported that, according to a field survey, carried out in the period 2012/2013, the PDP projects, involved forecasting investments of R$ 13 billion, adding budget resources with credits provided by public funding agencies, with immediate effect on economic activity.

Estimates made by the Secretariat of Science, Technology, Innovation and Strategic Supplies in Health (SCTIE), indicated that in the period from 2011 to May 2017, when the PDP gained scale, the accumulated savings of MS was R$ 4.68 billion, when comparing the prices of the previous year to the PDP with those practiced after the beginning of its implementation (Gadelha & Temporão, 2018).

Analysis of the PDP Scenario

Figure 2 shows all PDP proposals submitted after the new regulatory framework came into effect in 2014 and may be an indicator of the difficulty in complying with the new rules, since the number of failed projects far exceeds the number of approved projects.

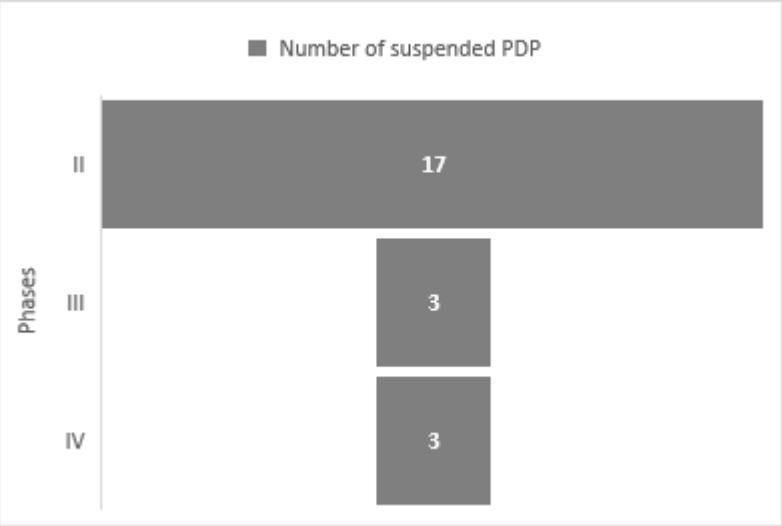
Figure 2. PDP project proposals (phase I)
Source: Elaborated by the author (2020), based on data from SCTIE/MS.



If the PDP has to undergo any adjustment at the recommendation of the committees, it shall be considered suspended. If the requirement is not met by the proponents, the next step is the extinction of the PDP (Varrichio, 2017).

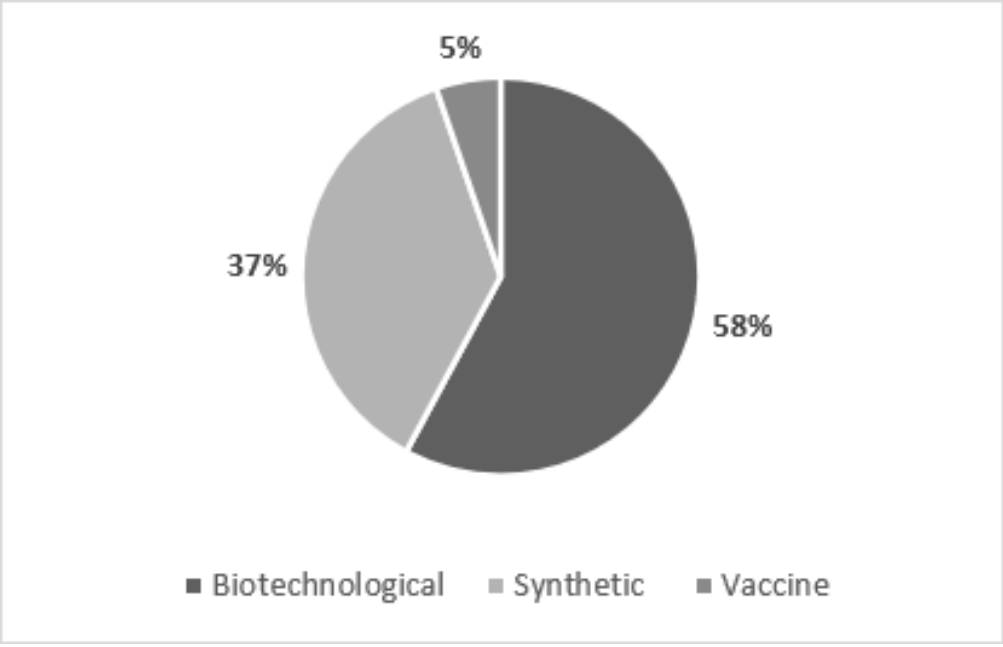
In this sense, Figure 3 shows that over these years, the phase that represented the largest number of suspended projects was phase II, of which technology absorption and transfer takes place.

Figure 3. Number of suspended projects per phase
Source: Prepared by the author (2021), based on information from SCTIE / MS



According to information from SCTIE/MS, the platform that obtained the highest number of suspended projects was biotechnology, representing 58% of suspensions, as can be seen in Figure 4 (MS, 2020).

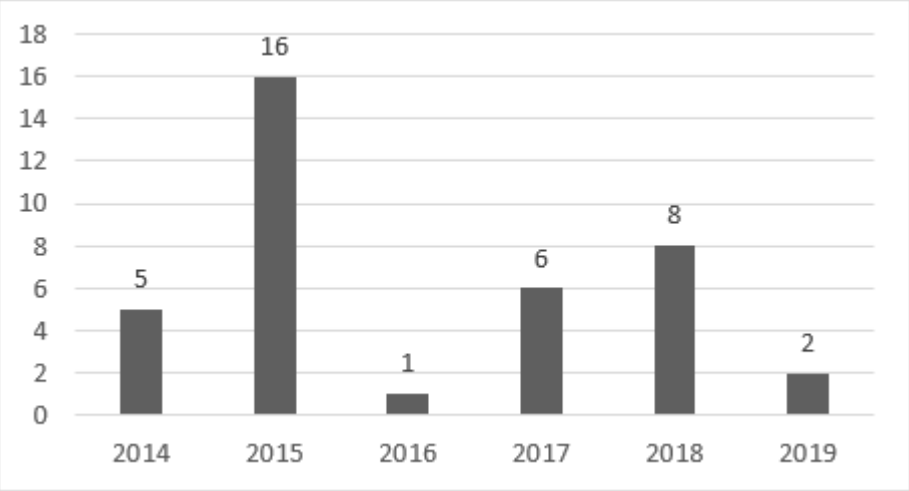
Figure 4. PDP suspended (medicines and vaccines)
Source: Prepared by the author (2021), based on information from SCTIE/MS



Taking in consideration the data presented in Graph 3, it must be considered the high degree of complexity for the development of a biotechnological product compared to a synthetic product.

As mentioned by Varicho (2017), with the change of the PDP regulatory framework in 2014, all current PDP had to adapt to this new legislation, with public institutions and private entities having a 180-day deadline for this adaptation. This fact resulted in the suspension and exclusion of several PDP throughout 2015, due to the non-conformities regarding the details of the legislation, as shown in Figure 5.

Figure 5. PDP extinct
Source: Prepared by the author (2020), based on data from SCTIE/MS.



Taking into account that adjustments may have occurred due to the publication of the new regulatory framework; and that the first legislation that instituted the PDP predicted a limited time of 5 years for the completion of all stages; that the new regulation proposes a maximum limit of 10 years for the completion of all stages for more complex projects, it is evident that despite all the efforts required to improve the process, there is still need to study the occurrences that are generating such delays, in the sense of proposing corrective actions that may even generate a new regulatory framework.

Even though it is not the chapter's focus to assess the reasons that cause delays during PDP projects, nor to offer solutions to the problems of this instrument, Silva and Elias (2019) mention that despites the MS having indicators in several programs and with an information and communication technology platform for monitoring, these do not include the PDP initiative. The strategic monitoring of the initiative is also not institutionalized by governance, lacking a business intelligence infrastructure that allows the transformation of data and information into useful knowledge for further action.

Fernandes, Lima and Chagnon (2020), consider that there are organizational and governmental challenges to be overcome for the conclusion of PDP. In relation to internal management, the biggest identified challenges are related to the planning of partnerships, the administrative bureaucracy of the public sector and monitoring of stages. In the governmental sphere, political interference and underfunding stand out.

Additionally, Fernandes, Lima and Chagnon (2020), verified the need to use appropriate management software or tools, which would allow for better information tracking, monitoring of deadlines and report-

ing. Thus, it would enable a holistic and transparent vision of the projects and would bring improvements in the communication of the project team with the involved areas, such as the organization and control.

Felipe *et. al* (2019) emphasize that if there is no strategic thought in the future of the Industrial Health Complex (CIS) and proper instruments for the use of research that brings together the creation of innovative products and practical solutions for the citizen, the country will not overcome the dependence and vulnerability of SUS, breaking the productive base on which, the translation would take place to enable universal access.

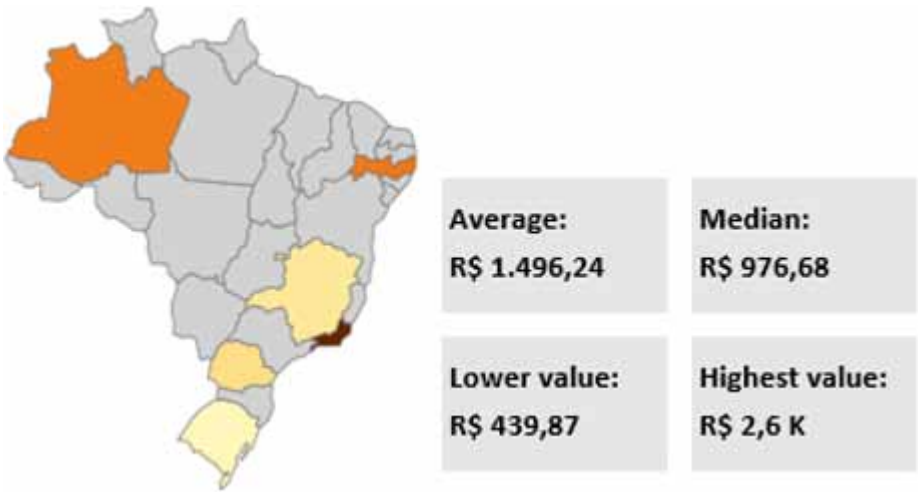
The State's Dilemma Involving Price of Medicines

The costs of biological medicines have strong impact on health systems, especially in countries in development, given the changing epidemiological profile, which consists mainly of chronic-degenerative diseases, due to the aging of the population, not to mention the huge deficit in the balance of payments due the importation of medicines, API and adjuvants (Gomes, Hasenclever & Paranhos, 2015).

As an example, the information presented in the Recommendation Report of National Commission for Technologies Incorporation (CONITEC) of 2018, regarding the incorporation of adalimumab in SUS for the treatment of moderate to severe active suppurative hidradenitis - considering the percentage of the adult population and the prevalence of this disease - show that the budgetary impact for SUS in the acquisition of adalimumab from 2018 to 2022 will be 188 million reais.

Corroborating to the aforementioned information, figure 6 shows the maximum and minimum unit values referring to the acquisition of adalimumab in 2020 and the purchasing states. When evaluating these amounts, there is a 491% variation between the amounts paid by the States, with an average value of R$ 1,496.24.

Figure 6. Public procurement by state for adalimumab
Source: Adapted from Painel de Preços. (n.d.). Accessed on 12/21/2020



The high range variations between States in purchasing of medicines, evidenced by the aforementioned information, may be an indicator of the absence of centralized purchasing by the Ministry of Health, missing the opportunity to use the State's purchasing power to obtain more adequate prices. In this sense, the need to strengthen the PDP instrument and the inclusion of new actors is emphasized, increasing the availability of medicines and reducing prices.

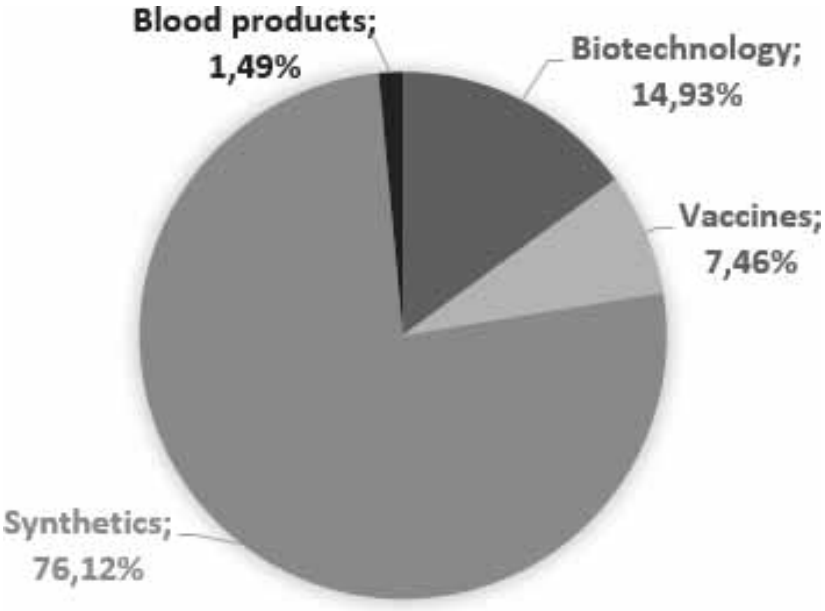
Considering the data which refers to the acquisition of PDP products, it is possible to verify that biological medicines - due to the complexity of production already explored previously - present a unit value 65.59% higher in relation to synthetic medicines, which correspond to 76.12% of the acquisitions, as stated on Table 1 and Figure 7, respectively.

Table 1. Acquisition of PDP products (medicines, vaccines and blood products)

Products	Quantity of Products	Average Unit Value (R$)
Biotechnology	10	384,065
Vaccines	5	27,999
Synthetics	51	5,855
Blood products	1	1,554

Source: Prepared by the author (2020), based on data from SCTIE / MS, 2020

Figure 7. Percentage of products purchased by MS
Source: Own elaboration (2020), based on data from SCTIE / MS, 2020.



A strategic action to speed up the internalization of this more complex technology and favor competition and consequently the reduction of prices, would be the formalization of PDP projects with more than one company involving the same API. In this sense, Resolution nº 2.531/2014 states that the PDP that first meets the established criteria and has the capacity to supply, may be responsible for covering the total demand of the Ministry of Health, until the other PDP meets the same criteria and the approved division of responsibilities begins for each PDP project (Brasil, 2014).

Thus, when analyzing the data in table 2, it appears that there is an attempt to foster competition, since 33.33% of the projects in phase II correspond to the possibility of executing more than one PDP per product.

Table 2. Products with more than one PDP project

Phases	Product with project in process	Product with more one project
Phase I	7	2
Phase II	33	11
Phase III	26	0
Phase IV	11	2

Source: Prepared by the author (2021), based on data from SCTIE / MS

It is important to point out that, in accordance with Resolution nº 2.531/2014, it is recommended the establishment of prices related to the acquisition of products subject to PDP, the technological contribution associated with the internalization of production will be considered and presented in a decreasing scale of values, in real basis, which will be considered according to the variation of the Brazilian Inflation Index (IPCA) or sectorial price index and, when applicable, the exchange rate, respecting the CMED regulation (Brasil, 2014).

Considering a long-term perspective, PDP also generates greater stability in acquisition prices in the face of fluctuations in the world market (Gadelha & Temporão, 2018).

In the context of health demand, Brazil presents great market opportunities, as the outlook points to both a substantial (non-reversible and long-term) growth in demand for CEIS and opening of new market segments that have not yet been explored to their full potential in the national context (Gadelha *et al*., 2013).

The identification of strategic medicines is extremely important in determining the context of policies applications that act on the demand side in the Brazilian health sector. A gigantic consumer market is created and can be used even in favor of national technological development. In fact, SUS is the main existing instrument to ensure the right guaranteed by the Federal Constitution of 1988 and is the largest buyer of API, medicines and equipment in Brazil (Varrichio, 2017).

The List of Strategic Products for SUS

The first legal framework referring to the list of strategic products for SUS, published in 2008, established that the revision and updating of the list would occur in every 2 (two) years and, exceptionally, and at the discretion of the MS, revisions and updates could be carried out at anytime.

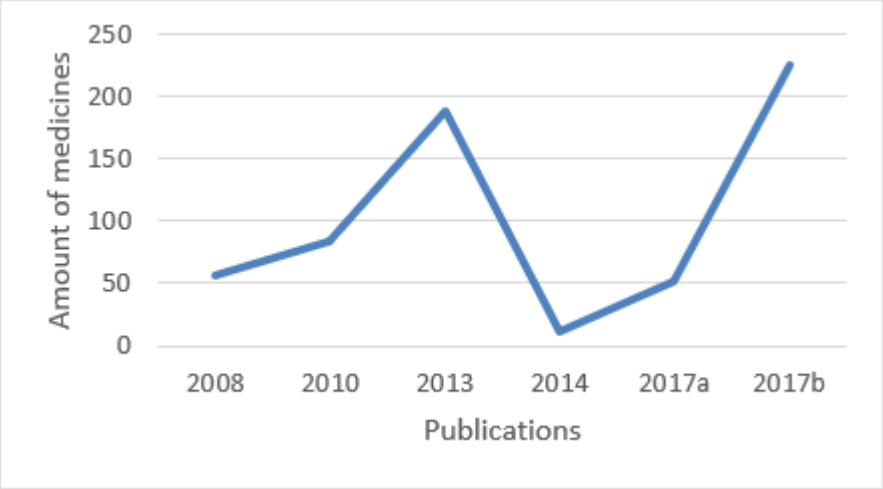
According to the new regulatory framework, Resolution nº 704/2017, the MS will define annually, the list of strategic products for SUS, in accordance with the recommendations issued by the Executive Group of the Industrial Health Complex (GECIS), considering the following criteria: importance of the product for SUS, according to health promotion, prevention and recovery policies and programs; centralized acquisition of the product by the MS or subject to centralization and the interest in national production of the product and its active pharmaceutical ingredients or critical technological components, relevant to CEIS (Brasil, 2014).

The list of strategic products for SUS consists of products that belong to the following groups: API, medicines, adjuvants, blood products and blood components, vaccines, serums, biological or biotechnological products of human, animal or recombinant origin; health products, such as equipment and materials for use in health; diagnostic products for in vitro use; and software embedded in the medical device or used in the transmission of health data, in the recovery, reconstruction and processing of signals and images or in the communication between devices (Brasil, 2014).

Regarding the frequency of updating the list of strategic products for SUS, it is possible to observe a gap in relation to the publication of that list, since there was only a review 5 (five) years after the publication of Resolution nº 978 / 2008 and, only in 2017, a new list was published with 56 products available for the submission of a PDP project, of which 21 of these are biological products.

The first list of strategic products for SUS, published in 2008, included 56 medicines and, when analyzing Figure 8, there is a considerable increase in the amount of strategic products for SUS in 2013, with an abrupt drop in 2014 and a new rise in 2017.

Figure 8. Amount of medicines considered strategic for SUS
Note: Resolution nº 252 (2017a) and Resolution nº 704 (2017b)
Source: Elaborated by the author (2020).



For the elaboration of graph 6, only the medicines listed in the mentioned resolutions were considered, excluding therapeutic classes that did not have specific medicines associated with them. Regarding Resolution 704/2017, strategic products for SUS were included, regardless the partnership to be carried out.

It is noteworthy that, from the 56 (fifty-six) medicines considered as strategic for public health, 36 (thirty-six) medicines do not yet have a PDP project. Thus, only 64.28% of the SUS goal was reached since the last publication of the list in 2017.

The Law 8080/1990 establishes that the incorporation, exclusion or alteration of new drugs, products and procedures, as well as the constitution or alteration of a clinical protocol or therapeutic guideline are all attributions of the MS (Brasil, 1990).

In 2011, the Law 12401 was published states about therapeutic assistance and the incorporation of health technologies within the scope of the SUS. This law defines the criteria and deadlines for incorporation of technologies in the public health system, as well as it defines that the MS, assisted by CONITEC, requires prior registration of the product in Anvisa. To regulate composition, powers and operation of CONITEC, the Decree 7646/2011 was published. CONITEC's operating structure is composed of two forums: Plenary and Executive Secretariat (Brasil, 2011a 2011b)

In this sense, from 2017 to 2020, CONITEC evaluated the incorporation of 149 drugs, of which 84 (56.37%) were recommended for incorporation in SUS and 64 (43.63%) did not have their incorporation recommended by CONITEC (CONITEC, 2021).

Thus, despite the fact that SUS annually incorporates new drugs, always after the formal recommendation by CONITEC, the list of strategic drugs for the SUS, which is the basis for idealizing PDPs, unfortunately has not been updated at the same speed.

The Official Pharmaceutical Laboratories

According to Gadelha (2012), Brazil had a network of 21 public laboratories, linked to the Ministry of Health, producers of medicines, serums and vaccines to meet the needs of SUS programs.

Figueiredo, Gonçalves and Magalhães (2020) highlight that the official sources on the LFO present different data. The MS website has two areas that present the public production of medicines: Pharmaceutical Assistance and Health Industrial Economic Complex. The Pharmaceutical Assistance area has 21 LFO and the Health Industrial Economic Complex area has 31. In contrast, the Official Pharmaceutical Laboratories Association of Brazil (ALFOB) has 21 LFO.

There is a centralization of LFO in the Southeast and Northeast, corresponding to 47.6% and 33.33% respectively. In contrast, the North region does not have public production of medicines and API.

The human resources of official laboratories associated with ALFOB correspond to 8,352 people, of whom 1,012 are masters or doctors, which corresponds to 12.72% of the total human resources. These employees are hired mainly according to the Brazilian Labor Laws, corresponding to 69% of all professionals. It is a contingent of 5,744 people, including those who entered through public tender or not. Public servants, in the general regime of public servants, are 1.961 people or 23% of the total (ALFOB, 2019).

Together, the LFO produce about 30% of the medicines used in SUS. In addition, with the agreements, the MS starts to guarantee the production of medicines that were previously purchased from private companies, many of them foreign, estimating big savings in the expenses with the purchase of medicines (MS, 2020).

According to the Alfob 2019 report, the volume of resources for the cost and investment of official laboratories is related to the ability of possible returns to be given to society.

In this context, the Alfob 2019 report states that the total investments of these entities were R$ 816.245.629,84 in the last three years, an amount that represents 5% of the total revenue of the official laboratories in the period: the investments were 6% of the revenue in 2016, 7% in 2017 and 4% in 2018.

The aforementioned report also highlights that the declared service sales were R$ 9.497.698,19 in 2016, R$ 7.444.127,91 in 2017 and R$ 9.975.510,97 in 2018, therefore proportionally small in relation to the volume of budget allocations and supply of products. Thus, it became evident that the supply of medicines and other health products is the main form of commercial activity for the LFO (ALFOB, 2019).

The need to maintain surplus results and increase the return given to society is fundamental to obtain more resources for funding and investment. Thus, it is important to evaluate the opportunities that can guarantee the expansion of access and the use of the public industrial park.

In this sense, it is necessary to understand the shortages of supply at all levels of health care and to act in a purposeful manner; strengthen the relationship of the LFO with the State and Municipal Health Secretariats and overcome barriers related to the bidding waiver process. Additionally, it is necessary that the LFO actively participate in the operationalization of the pharmaceutical assistance components; increase integration with the Central Public Health Laboratories (LACEN) network and with the hospital network.

We can understand the strategic role of the LFO for the provision of medicines oriented by the Ministry of Health, in addition to the sustainability of SUS. Therefore, the PDP instrument must continue to be part of the Ministry of Health's policy for the sector. In this sense, the incorporation of new actors, with proven technological qualification and with manufacturing facilities in Brazil and South America, may contribute greatly to the technological consolidation in the region and thereby, to increase the competitiveness of medicines from PDP.

The LFO Production Lines, Certified by Anvisa

In 2008, the CEIS policy and its financing program, added to the establishment of the PDP, supported by Resolution nº 2531/2014 and by Decree nº 9.245/2017, which instituted the National Policy for Technological Innovation in Health, allowed the official laboratories to incorporate technologies, expand sales and develop a policy of manufacturing investments, adapting to Anvisa regulations (ALFOB, 2019).

For the assessment of the possibility of carrying out technology transfer, the production lines of medicines certified by Anvisa from all LFO were observed, excluding the certificates issued on behalf of the LFO for pharmaceutical plants of international and national partners.

In this sense, it was observed that although there are 21 LFO, according to information from ALFOB, it was observed that only 13 LFO participate in any PDP project (MS, 2020) and only 8 have certification to produce bulk medicines (ANVISA, 2020). Therefore, it is considered necessary to carry out a technical evaluation in the LFO, with the objective of understanding the feasibility of adapting the respective facilities and, through investments in the plant by the government, making them potential partners of private companies.

The Vulnerability of the National Production Base in the Context of Covid-19

On January 30, 2020, the World Health Organization (WHO) declared that the outbreak of the new Coronavirus, COVID-19, constituted a Public Health Emergency of International Importance (ESPII). Subsequently, in Brazil, some regulatory frameworks were published to deal with the outbreak.

Faced with a risk of shortages, Anvisa published Public Notice in order to call on companies to provide information on inventories of products subject to health surveillance that could be used as essential inputs to fight the new Coronavirus and targeted the companies that own authorization or registration

in Brazil of medicines, health products, sanitizing products, cosmetics, food and API that could be used for the diagnosis, prophylaxis, control or potential treatment of COVID-19.

Considering Decree nº 6/2020 by which the National Congress recognized the occurrence of a state of public calamity; the risk of shortages of anesthetics, sedatives, neuromuscular blockers and adjuvant agents, among other medicines, in the brazilian market as a result of the increased consumption of these products used to fight the pandemic.

In addition to the aforementioned worrying scenario, the fragility of the national pharmochemical sector was evidenced, when on 07/14/2020 Anvisa published the Annual Review of Inspections in National Pharmochemical Industries, referring to 2019. In figure 9, it is possible to see the distribution of pharmochemicals in Brazil.

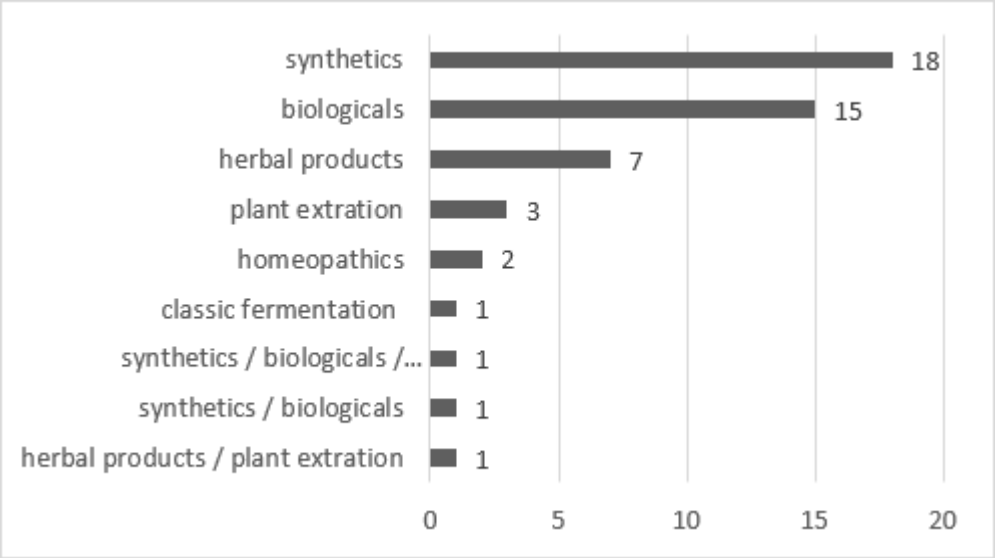
Figure 9. Location of pharmachemicals in Brazil
Source: Adapted from Brazilian Health Regulatory Agency, 2020. Accessed on 12/06/2020.

In the aforementioned review, Anvisa declares that the pharmachemical industrial park in Brazil is composed of 49 active companies, concentrated in the South and Southeast of the country, with 45% of the manufacturers located in São Paulo.

It is important to mention that, of these 49 companies, none of them is public, since there is no LFO with a manufacturing structure to produce synthetic API, configuring the dependence of LFO's on the acquisition of synthetic inputs from the private sector, which is often subject to exchange variation.

As for the type of input produced, Anvisa reported that the segment of companies is distributed as follows (Figure 10).

Figure 10. Type of API produced
Source: Adapted from Brazilian Health Regulatory Agency, 2020.Accessed on 12/06/2020



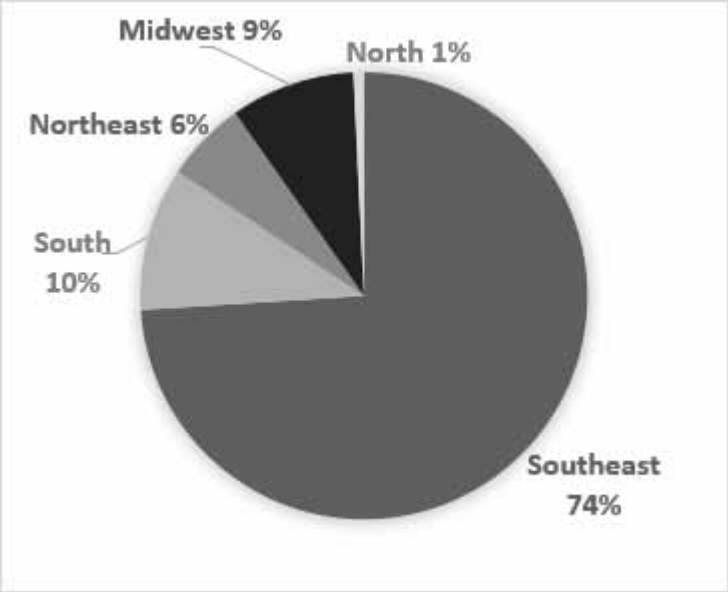
According to Costa et. al (2014), the production of pharmachemicals is a key factor to reduce technological dependence, being strategic for the Economic and Industrial Health Complex. Thus, it was considered essential to develop public policies that include specific incentives for this industrial segment of the pharmaceutical chain.

It is important to note that the instrument that has been most used to induce the strengthening of the brazilian pharmachemical industry is the formation of PDP. For this reason, equity in financial conditions for the entire pharmaceutical chain must be maintained through the National Economic Development and Social Bank (BNDES, Profarma). For the development of new API, in which the development of non-existent technological competences and an important social impact for public health are present, the BNDES must use instruments that reduce financial risk, including non-reimbursable resources (Mitidieri et. Al, 2015).

A study by Costa *et.al* (2014), evidenced that the production of API represented only 0.8% of the imported quantity in 2014, however there were clear indications that the PDP constituted a strong stimulus to the sector.

In relation to the pharmaceutical sector, when evaluating the current certifications granted by Anvisa to the producers of medicines (public and private), there is a concentration in the Southeast region, corresponding to 74% of the current certifications in Brazil (Figure 11), with emphasis to São Paulo with 69% of the certifications granted by Anvisa. Thus, such data show the inequality in investment in each region of the country regarding the industrialization of the pharmaceutical sector in Brazil, reflecting on the development of each state.

Figure 11. Factories with GMP medicines certifications
Source: Elaborated by the author (2020), based on Brazilian Health Regulatory Agency, n.d.. Accessed on 12/18/2020



Thus, the pandemic caused by the SARS-COV-2 virus showed the fragility of the national productive base of medicines and API, causing a reflection in society regarding the need to encourage the strengthening of national production, through economic incentives and public policies.

There is, therefore, the possibility for the Ministry of Health to increase the number of medicines made available by SUS, using the PDP instrument to strengthen the public industrial park.

Corroborating the expectation of an increase in imports of medicines and API, as a result of COVID-19, the Ministry of Industry, Foreign Trade and Services evidenced an 8.1% increase in the quantity (in tons) of imported medicines, in the period of January to November 2020 compared to 2019.

The map shown in figure 12 indicates the origin of the medicines with the highest added value (in US $, USA) and the highest technological density, imported during the period from January to November 2020.

Through Figure 13, it is possible to verify the countries with a participation above 4% in imports, showing a strong participation of the European bloc (43.7%). China (15%) and the United States (13%) also stand out as the largest exporters to Brazil.

The Covid-19 pandemic may represent the moment for us to restart a discussion on the role of productive, technological and innovation development policies for the security of the Brazilian State. The current case is notorious: the fragility of the national productive and technological base puts at risk the effectiveness of our health system (Leão & Giesteira, 2020).

Thus, Leão and Giesteira (2020) consider it important to understand that there are at least a handful of major public policies for which it is necessary to guarantee the technological and productive autonomy necessary to serve them. To depend almost entirely on global supply chains can compromise the ability to offer minimum conditions to the population, as shown during the pandemic.

Negri (2020) considers that to grow more robustly and to become a competitive economy, Brazil needs to invest at least 2% of its PIB in R&D to pair with the most competitive economies. The USA has a stable position in the percentage share of global R&D, from approximately 38%, in 2019. The

participation of Europeans has been reduced and dropped from 30%, in 2014, to 25%, in 2019. The participation of Brazilian companies was of only 0.12% in 2019, and has shown a downward trend, since in 2016 this participation was 0.22%. China's participation in global R&D jumped from 7%, from 2014 to 2016 and to 12%, in 2019.

Figure 12. Countries that export medicines and pharmaceutical products, except veterinarians.
Source: Adapted Ministry of Development, Industry and Foreign Trade, n.d. Accessed on 12/08/2020

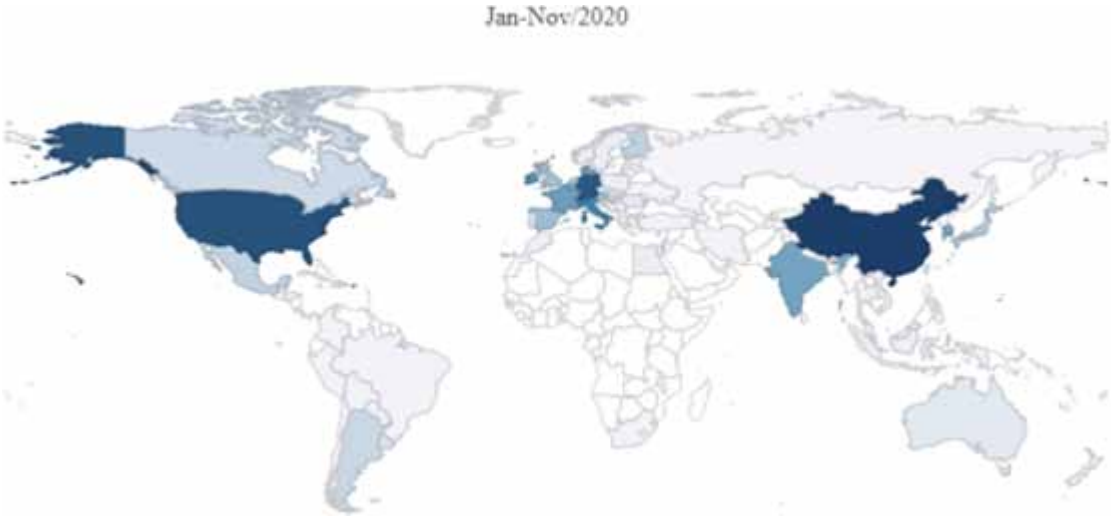
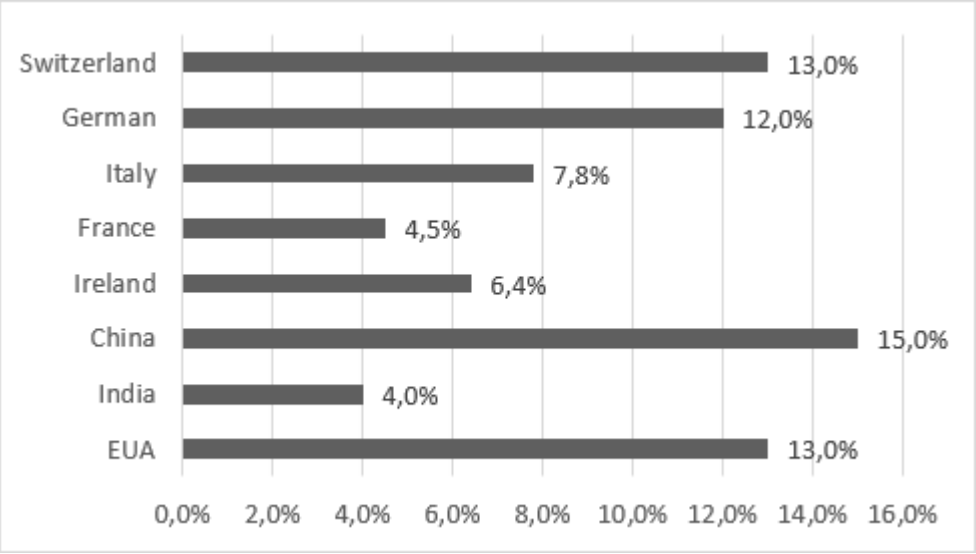


Figure 13. Countries that export medicines and pharmaceutical products (except veterinarians), in 2020.
Source: Adapted Ministry of Development, Industry and Foreign Trade, n.d. Accessed 12/08/2020



CONCLUSION

The present study showed that the PDP instrument represents one of the most important initiatives for building an industrial policy and systemic innovation in the health area, mainly based on the use of government purchasing power. However, in order to properly understand the scope of this instrument, it is necessary to insert it in a broader context of analysis, which refers to the construction of a set of policies and instruments to support CEIS.

Considering that CEIS includes everything from the production of medicines, equipment, API, diagnostic kits, among other products for prevention and treatment to prevention and health service provision activities, involving public and private institutions, the importance of the CEIS for the country's economic growth and social development.

It was possible to understand that the health area and its intersectoral relations in the areas of services and industry, constitutes one of the pillars of economic growth and scientific and technological development in the country. It is also one of the essential policies for social development, due to its contributions to job creation and social well-being.

Regarding the objectives of the PDP, it was observed that this instrument has been used as a mechanism for the development of national industry, by stimulating the consolidation and creation of new productive and technological capacities, as well as by the technological internalization with consequent reduction of fragility SUS, solving technological bottlenecks that generated high expenses with the purchase of products from private companies.

In view of the whole approach, carried out in the present study, it can be concluded that the establishment of the PDP instrument represented a milestone for the strengthening of the national productive base and in the public-private integration, favoring the incorporation of technologies that were previously dominated only by more developed countries or major powers in the private pharmaceutical sector.

Considering the regulatory gap that encompasses the list of strategic medicines for SUS, it is expected that, with the advent of the pandemic, the MS will be able to update this list to include the SARSCOV-2 vaccine, being able to evaluate the need to also include some constant medicine in the Public Notice, published by Anvisa.

In this way, in addition to having demonstrated the possibility of public-private interaction through the PDP instrument, there are also other types of partnerships that provide for the internalization of technologies by the public sector, also strengthening the interaction between the States parties to Mercosur by promoting the approximation of well-consolidated South American companies in the pharmaceutical market.

It is considered that the interaction between the Mercosur countries may increase the capacity to solve common problems through political articulations in the search for a common and solidary development, oriented to the strengthening of the industrial sector of the region, which can solve technological issues that separate countries which are most of the least competitive in the world market.

In this sense, the present study highlighted the need to deepen integration in the health area within the scope of Mercosur, aiming at strengthening the South-South relationship.

Regarding the need to strengthen the national industry, it is considered that the success of the PDP instrument can be an effective tool in the construction of a manufacturing structure that provides returns for the society and, consequently, public investments and more partnerships with private companies in order to reduce the technological deficit that separates the two institutions.

Throughout this chapter, it was commented that the biotechnology platform is the one that presents the greatest need for internalization of technology by the public sector, since in addition to setting a therapeutic trend, such medicines and API are expensive to purchase from private companies, many are imported and subject to exchange rate variation.

It was also commented on the fragility and inequality in the distribution of the national pharmochemical sector, since no LFO has technical operational capacity for the manufacture of synthetic pharmaceutical inputs, which is in line with the provisions of Ordinance 2531/2014 on the verticalization of production as one of the objectives of the PDP.

Considering these premises, the present study showed that the PDP instrument, created by the Ministry of Health in 2009, as a way to internalize technologies considered strategic for the country and to meet the demands of SUS and has been promoting the strengthening of the national productive base. Undoubtedly, it favors access to therapies not yet made available by SUS to the Brazilian population, reducing the monopoly of some companies and the high cost of purchasing products from private companies.

Certainly, the establishment of a PDP with a pharmaceutical company from a South American country, which is also part of Mercosur, expands the range of interaction beyond those already existing with American, European and Asian companies, strengthening technical development-scientific of the region that will be able to catalyze the interaction with other companies, also from the region.

Thus, the proposal in this chapter may be a starting point for the strengthening of a fruitful relationship within the scope of Mercosur, between an LFO and a south american pharmaceutical group, contributing to the development of the public sector, regarding the absorption of technology, for the expansion of a private company in Brazil and for the strengthening of productive partnerships within the scope of Mercosur.

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Chapter 14
Productive Development Partnership in Brazil:
A Case Study of the Antiretroviral Atazanavir

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ABSTRACT

Brazil was one of the first countries to adopt significant health policies to better attend people with HIV. The integrated analysis of the high cost of medicines, public health, and access to medicines comprises an extremely complex task, and Productive Development Partnerships (PDP) was the mechanism used by the Brazilian government, with a view to technological development and training of national production complex. The PDP of atazanavir was formalized in late 2011, and the agreement includes the transfer of technology, manufacturing, and distribution of the drug. The PDP emerges as a solution found by the government to minimize the Ministry of Health drug spending and encourage the local production. However, one should not ignore that there are risks associated with regulatory barriers and problems in negotiations with the holders of technology. Thus, this chapter presents a case study of the successes the management information of the productive development partnerships in Brazil as a collaborative tool for global health.

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INTRODUCTION

One of the challenges for public health in Brazil comprises the introduction of new policies and strategies that encourage innovation and development of the pharmaceutical sector in the country. Brazil was a pioneer in adopting policies to guarantee universal and free access to medicines against AIDS, important instrument for strengthening the national policy on access to medicines.

Acquired Immunodeficiency Syndrome (AIDS) is a pandemic disease and according to the global statistical panorama presented by UNAIDS, in 2020, 37.6 million people in the world were living with HIV and of these 27.4 million had access to antiretroviral therapy. Worldwide, there were 1.5 million new HIV infections diagnosed in 2020, a reduced number when compared to the 2.8 million registered in 1998 (UNAIDS, 2021).

In Brazil, from the beginning of the epidemic in 1980 until June 2020, 1,011,617 cases of AIDS were detected. Over the past five years, annual records show an average of 39,000 new cases. Since 2012, there has been a decrease in the AIDS detection rate in Brazil, with an average of 17.8 cases per 100,000 inhabitants in 2019, representing a decrease of 18.7%. Although there has been a reduction in AIDS cases throughout the country, especially in recent years, it is worth noting that part of this reduction may be related to the identification of data transfer problems between SUS management spheres, which can lead to a difference in the total number of cases among the municipal, state, and federal HIV/AIDS databases (Brasil, 2020).

In 2014, the publication of the Clinical Protocols and Therapeutic Guidelines (PCDT – Brazilian term) in the format of a protocol for HIV/AIDS and for other opportunistic or related diseases granted Brazil another vanguard step in the response to the epidemic, by becoming the first country in development and the third in the world to recommend immediate initiation of antiretroviral therapy (ART) for all people living with HIV/AIDS (PLHIV), regardless of CD4 count (Silveira, Corrêa, Barroso & Figueiredo, 2016). According to the Department of Chronic Diseases and Sexually Transmitted Infections (DCCI), the total percentage of individuals eligible for ART who started treatment within one month after taking the first CD4, reached the value of 64% in 2020 (Ministry of Health, 2020a).

In 2020, the federal government's investment was close to 1 billion and 840 thousand reais in serving the population with medicines for the treatment of people with HIV/AIDS and other sexually transmitted diseases, which represented 0.06% of all expenditures of the year (Portal da Transparência, 2020). An extremely attractive market for the pharmaceutical industry, and, therefore, one of the fields of greatest investment in research and development (R&D) and protection through patents on antiretroviral drugs (ARVs).

The integrated analysis of the high cost of medicines, public health and accessibility to medicines is an extremely complex task and, from the perspective of health policies, it appears that, despite the progress achieved in Brazil in recent decades, the commitment to ensure accessibility universal access to medicines and the right to health does not reflect our reality. Brazilian autonomy in the production of inputs, medicines and vaccines is still far away. Even so, national production, including public production, remains essential for the health system and for the Brazilian population (Chaves, GC, Moraes, EL & Castro, CGSO de, 2021; Possas, C., Scapini, R. & Simão, M., 2013).

In Brazil, the Department of Surveillance, Prevention and Control of Sexually Transmitted Infections, HIV/AIDS and Viral Hepatitis (DIAHV) of the Ministry of Health (MS), has been striving to improve its programmatic actions, seeking acceleration and qualification of the Brazilian response to HIV/AIDS, with a view to achieving the goals established in the Department's strategic planning and the 90-90-90

goals of the Joint United Nations Program on HIV/AIDS (UNAIDS), as well as the global consensus for the elimination of the AIDS epidemic in 2030 (Ministry of Health, 2018).

Despite producing some active ingredients and ARV drugs, Brazil does not have enough production volume to meet the country's demand, requiring complementary imports, in addition to the acquisition of drugs and medicines that do not have national production (Antunes et al., 2013).

The Official Pharmaceutical Laboratories (LFOs) have an important role in meeting the demand for antiretrovirals within the scope of the STD/AIDS program, both as producers and as price regulators and negotiators with pharmaceutical multinationals, which denoted their political relevance in an oligopolistic market with great political and economic influence of foreign firms (Almeida, 2018). However, the dependence on imports of pharmaceutical intermediates and active ingredients, mainly from China and India for the local production of ARVs, as well as the increase in the budgetary burden of patented drugs, associated with the external vulnerability in relation to the production of ARVs to meet the needs of demand from the national population stimulated and contributed to the search for strategies to enable a sustainable policy for the STD/AIDS program.

To reverse this situation, a new strategy involving official pharmaceutical laboratories and national companies was adopted by the Brazilian government, which was consolidated with the institution, within the scope of the SUS, of the National Program to Promote Public Production and Innovation in the Economic-Industrial Health Complex (CEIS – Brazilian term) (Ministry of Health, 2008) and Presidential Decree DNN 11.578 of May 12, 2008, which created, within the scope of the MS, the Executive Group of the Industrial Complex of Health (GECIS), with a view to consolidating the CEIS (Brazil, 2008a).

In this sense, a public policy was instituted that simultaneously encompassed health, industry, science, and technology, and which presented as one of the pillars the strengthening of public laboratories, with a view to promoting a competitive level, reducing the country's technological gap, and promoting the country's economic, scientific, and technological development (Cassier & Corrêa, 2013a; 2013b).

The Brazilian policy, called, Partnerships for Productive Development (PDP – Brazilian term) contracts between public institutions and private entities for the development, transfer and absorption of technology, production, productive and technological training of the country in strategic products for the SUS, was one of the mechanisms used, with a view to technological development and training of the national productive complex (Ministério da Saúde, 2012).

The emergence of PDPs represents a strategic action of the MS to assist the development of the Economic-Industrial Health Complex (CEIS – Brazilian term) combined with the policy of access to quality medicines, contributing to the development and innovation of the national manufacturing park of medicines, pharmaceutical and chemical inputs, and biologicals, as well as favoring the country's trade balance through the availability of nationally produced medicines. First PDPs were established, as of 2009, a policy that remained continuous in subsequent years. The nationalization of the production of APIs (pharmaceutical inputs) is one of the primary objectives of the PDP and takes place through: selection of technology by the public entity and contract between the technology owner and the national pharmacochemical industry, selected together with the public entity (Gadelha & Costa, 2012, Rezende, 2013, Silva & Elias, 2018).

Despite dating back to 2009, PDPs were regulated in 2012 and redefined in 2014, when the criteria for drawing up the list of strategic SUS inputs were established, in addition to disciplining PDPs. This regulatory framework presents the eight objectives of PDPs, which seek the economic and technological sustainability of the country, fostering industrial development to reduce the vulnerability of the SUS

and expand the population's access to medicines, vaccines, etc. (Ministry of Health, 2014, Ministry of Health, 2019, Albareda & Torres, 2021).

OBJECTIVE

The study consists of analyzing the implementation of the PDP of the antiretroviral drug atazanavir and verifying how the results obtained through this device can enable the objectives of the PDP, which include supplying the Brazilian MS, nationalizing the production of the drug, reducing dependence on imports, guarantee the regulation of sales prices to MS and facilitate access to medication, from the perspective of economic and industrial development combined with sanitary logic, for the social well-being of the Brazilian population.

METHODOLOGY

An exploratory study was carried out to identify the PDP that was under development in Farmanguinhos/Fiocruz until 2020.

We decided to do a detailed study about the partnership of the medicine atazanavir that was signed between Farmanguinhos/Fiocruz and Bristol-Myers Squibb (BMS) because we have had studied some years before.

Then, we analyze the gains from the partnership in order to guarantee patients access to antiretroviral drugs and the main contributions to the maintenance of the productive development policy.

We carried out bibliographic research of publications in several sources, disposable by the National STD and AIDS Program of Brazil, Institute of Applied Economic Research (IPEA – Brazilian term), Ministry of Health, National Health Surveillance Agency (ANVISA) and US Food and Drug Administration (FDA), as well as, laws and rules related to the strategic products of the SUS and technology transfer projects, using the keywords PDP, atazanavir and productive development partnerships.

In addition to the information obtained from the cited sources of information, we analyzed the internal documents of the PDP under development of in Farmanguinhos/Fiocruz including in the copy of the PDP Agreement signed to the atazanavir production, obtained from the website of the Working Group on Intellectual Property (GTPI) (http://www.deolhonaspatentes.org.br) (GTPI, 2015).

In order to identify the patents granted for atazanavir, a search was carried out in the FDA's Orange book, to identify the USA patents. After we searched the USA patents at the patent database of the European Patent Office (espacenet) to identify the number of the Brazilian patent. In the following, we searched the status of the Brazilian patent at the database of the National Institute of Industrial Property (INPI – Brazilian term).

RESULTS AND DISCUSSIONS

History and Overview of PDP in Brazil

PDPs are configured as a modality of technological order carried out by the State in the presence of technological risk, pursuant to article 20 of the Law on Technological Innovation, Law No. 10,973/2004 (Brazil, 2004a), amended in 2016, by Law No. 13.243/ 2016 (Brasil, 2016) and considering Ministerial Ordinance No. 128 of May 29, 2008 (Brasil, 2008b). They should not be confused with classic Public-Private Partnerships (PPPs), since they are established in accordance with Law No. 11.079/2004 (Brasil, 2004b) which defines them as administrative concession contracts, in the sponsored or administrative modality, hence the nomenclature of Productive Development Partnerships (PDP) for partnerships encouraged by the MS, as a new type of partnership or public-private collaboration.

PDPs are carried out between two or more public institutions or between public institutions and private companies, for the development, transfer and absorption of technology, production, productive and technological training in the country in strategic products to meet the demands of the SUS. The development of new technologies is also included in the scope of the partnerships (Ministry of Health, 2020).

Once the partnership is established, the LFOs start to receive the technology transferred from the pharmaceutical companies, drug producers and APIs, while the government guarantees the exclusive purchase of the internalized input, during the period of development of the PDP, in prices and quantities negotiated between the parties.

According to the Ministry of Health, the objectives of PDPs include the population's access to strategic products; the reduction of the vulnerability of the SUS with the pursuit of technological and economic sustainability in the short, medium and long term, with the promotion of structural conditions to increase the country's productive and innovation capacity and contribute to reducing the trade deficit of the CEIS and guaranteeing access to health; the rationalization of the State's purchasing power, through the selective centralization of expenditures in the area of health and economy; the reduction of productive and technological dependencies and promotion of the development and manufacture in national territory of strategic products for the SUS (Ministry of Health, 2020b).

The regulatory framework of PDPs, with the encouragement of the internalization of the production of pharmochemicals and medicines from the list of strategic products for the SUS begins with MS Ordinance No. 978/2008 (Ministry of Health, 2008b), which was followed by changes in the regulatory framework, with emphasis on MS Ordinance No. 2.531/2014, later revoked by Consolidation Ordinance GM/MS No. 5, of September 28, 2017 - ANNEX XCV (Ministry of Health, 2010; 2013; 2014, 2017a). The latest lists of strategic products for the SUS were defined throughout 2017, in Ordinances 252 (Ministry of Health, 2017b) and 704 (Ministry of Health, 2017c).

The new regulatory framework provided greater clarity and definition for the process of establishing PDPs, which includes four phases: I - submission and analysis of the proposal and, in case of approval, execution of the term of commitment (TC) between the MS and the public producer; II - execution of the project with the beginning of the TC implementation; III - product development, technology transfer and absorption and product acquisition by MS; and IV - internalization of technology by the public producer. The partnership proposals must comply with the guidelines, requirements and schedules provided for in Consolidation Ordinance MS/GM No. 05, Annex XCV, and will be submitted to the Evaluation Instances, Technical Evaluation Committee (CTA) and Deliberative Committee (CD) (Ministry of Health, 2017a).

The list of products considered strategic for the SUS will be defined annually by the MS and will guide the proposals for PDP projects for the following year. Strategic products for the SUS, which are the object of PDPs, will be acquired through the centralized purchasing system (Ministry of Health, 2014). Thus, it is expected that the new regulatory framework will be able to ensure greater transparency in the choice of partners, minimum content for the PDP projects presented and greater control over the partnerships entered, with a view to reaching the greater public interest, based on the realization of access health actions, and fostering national technological development, the foundation of public policy.

The PDP contracts provide for the nationalization of the API and are signed through a negotiation, which involves a downward trajectory for prices, in real terms, to reduce MS spending and expand access to health care by the population. The choice of products to establish partnerships is guided by the SUS Strategic Product List, providing policy direction and, therefore, giving it objectivity. Contracts involving products protected by patents will be signed if the patent belongs to the laboratory that will be a partner in the transfer of technology. As well as the institutions that supply and receive the contracted technologies, the MS and Anvisa play an intensive role in the contracting and monitoring of contracts (Almeida, A. C S., 2018).

Data from the Ministry of Health, updated until August 2021, show 85 existing partnerships with submission of partnerships made until 2018, involving 14 public laboratories and 28 private laboratories. The products expected from these partnerships are 53 synthetic drugs, 28 biotechnological drugs, 4 vaccines and 1 blood product. These products comprise several therapeutic classes, with a higher incidence of oncologic and antiretroviral drugs (Ministry of Health, 2021a).

Throughout the entire process, the monitoring of PDP projects resulted in the suspension of 21 projects and the extinction of 38 projects, most of which were related to PDPs entered in 2012 and 2013, with 12 and 16, respectively, terminated partnerships (Ministry of Health, 2021c, 2021d). The decision for extinction occurs due to the use of PDP projects in disagreement with the objectives set forth in Ordinance No. 2531/2014, withdrawal of the Public Institution in the project, impossibility of centralizing the purchase of the drug, non-incorporation of the product by CONITEC or due to non-compliance in a material manner and with the risk of schedule irreversibility.

According to the Department of the Health Innovation Industrial Complex (DECIIS), considering the advances and results achieved throughout the technology transfer processes carried out through PDPs, the savings generated between 2011 and 2017 were around R$ 4.68 billion. (DECIIS/SCTIE/MS, 2017). To establish the prices of products acquired during the process of absorption of the technology object of the PDP, the technological contribution associated with the internalization of production must be considered. The patent status will also be evaluated, with estimates of market values for products that are close to the patent expiration period and the relevant reduction in market prices resulting from companies' competition strategies. Prices must be presented in descending scale of values on a real basis and may vary because of the variation in the Broad National Consumer Price Index (IPCA), inflation and the exchange rate.

The term of validity of the PDP will be proposed according to the technological complexity for the internalization of the technology in the country, respecting the maximum limit of 10 (ten) years. The records of the product object of the PDP by the public institution and private entity at ANVISA must be included in the PDP schedule. Each PDP will be continuously monitored from the PDP project to the internalization of the technology for the purpose for verifying the expected advances in the production process, development, transfer, and absorption of technology (Ministry of Health, 2014).

PDP in Development at the Official Pharmaceutical Laboratory Farmanguinhos

By the year 2021, among the PDP Project Proposals approved by the MS, 13 have Farmanguinhos as a public partner (Figure 1) (Ministry of Health, 2021b), which participates in this public policy and seeks to be self-sustainable in the pharmaceutical sector with absorption of technology for the supply of drugs considered strategic for the SUS.

*Figure 1. Farmanguinhos PDP projects **
** Elaboration from the list of Partnership Projects for Productive Development (PDP), D&I - Extinct - Medicines, Vaccines and Blood Derivatives (Ministry of Health, 2021b).*
Source: Created by the authors, 2016.

Public Institution	Submission Year / Term of Commitment (TC – Brazilian term)	Product/ Phase	Private Partner	Private Entity / API (Active Pharmaceutical Ingredient)
Farmanguinhos	**TC nº 02/2011**	**Atazanavir III**	**Nortec/Bristol**	**Nortec**
	TC nº 07/2018	Daclatasvir II (Suspended)	Blanver	Microbiológica
	TC nº 08/2018	**Emtricitabine + Tenofovir** III	Blanver	**CYG Biotech Química / Nortec**
	TC nº 09/2018	Everolimus II (Suspended)	——	——
	TC nº 01/2012	**Imatinib (Mesylate)** IV	Cristália	Cristália
	TC nº 05/2011	Pramipexole III	Nortec/ **Boehringer**	**Nortec**
	TC nº 09/2009	**Rifampicin + Isoniazid + Pyrazinamide + Ethambutol (4 in 1 Tuberculosis)** III	Lupin	——
	TC nº 11/2018	Sofosbuvir II (Suspended)	Blanver	Microbiológica
	TC nº 07/2009	Tacrolimus IV	Libbs	Libbs
	TC nº 05/2012	**Tenofovir + Lamivudine (2 in 1)** IV	Blanver	**Globe /Nortec /CYG Biotech**
	TC nº 05/2012	**Tenofovir + Lamivudine +**	Blanver	**Globe /Nortec/CYG Biotech Química**

The year of 2009 marked the beginning of the PDP formalized at the Institution. There were 03 partnerships for anti-asthmatic, tuberculostatic and immunosuppressive drugs. In the following year, 2010, only one partnership would signed for an immunosuppressive drug. In 2011 and 2012, the number of

PDP grew again, with 05 and 06 partnerships, respectively, encompassing the class of antiretrovirals, prolactin inhibitor, antiparkinsonian, hyperphosphatemia, antiasthmatic and oncology. In 2013, in addition to another antiretroviral PDP, 02 partnerships were signed in biotechnology for application in diabetes. In 2015, 01 partnership for oncology was signed. The last partnerships were submitted in 2018, totaling 05 partnerships for antiretrovirals, hepatitis, immunosuppressants and antiretrovirals (Ministry of Health, 2021b).

All proposals for the Farmanguinhos PDP project received by MS were evaluated and approved by the CTA and the CD; formalized through terms of commitment between Farmanguinhos and MS, with the consent of the private partners involved, and went on to phase II, called the PDP Project.

After 13 years since the beginning of the initial milestone of the PDP in Farmanguinhos, the institution has 04 PDP Projects in Phase II, in which the implementation phase of the approved PDP project proposal and the term of commitment takes place until the partnership progress to Phase III. Six PDP Projects are in Phase III, with the start of acquisition of the product with the effective transfer of technology from the private partner to the public and public purchases in progress. Three PDP projects are in phase IV, which comprises the internalization of technology (Ministry of Health, 2021b).

The private laboratories involved in the development of current partnerships with Farmanguinhos are Lupin, Libbs, Bristol, Nortec, Cristália, Blanver/Globe, CYG, Boehringer, Microbiológica and ITF Chemical.

Farmanguinhos seeks to diversify its portfolio and in partnerships it has established new fronts in medicines and technologies reinforcing its presence in the fight against existing diseases. It was able to strengthen itself with new drugs for the treatment of HIV/AIDS, such as: Atazanavir, the combination of Tenofovir plus Lamivudine (one of the main drugs in use by the HIV/AIDS Program in Brazil), the combination of Emtricitabine plus Tenofovir, in addition to preparing for establish an immunosuppressant production platform, starting with the drug Tacrolimus. In addition to being able to internalize other important drugs such as Pramipexole, Cabergoline, Sevelamer, among others (Brasil, 2020).

Farmanguinhos, as a public laboratory, participates in this public policy and one of its challenges comprises the change in the scenario that restricts access to medicines by the population, due to the high costs and technological dependence of the national health system on multinational laboratories. The instrumentalization of PDPs is based on the absorption of technology that is transferred by private entities, with a view to acquiring expertise that will ensure knowledge and capacity to, in the future, manufacture and supply the medicine to the Ministry of Health.

During the PDP monitoring process, 10 Farmanguinhos projects were extinguished (Figure 2) (Ministry of Health, 2021d).

The Institution's deliberative board is the Deliberative Committee (CD – Brazilian term). The CD deliberated for the extinction of the Formoterol + Budesonide PDP due to the absence of a perspective of centralization, and the fact that the partnership did not show evolution.

The extinction of the Simeprevir partnership occurred due to the Health Surveillance Secretariat (SVS) informing that there is no expectation that Simeprevir will be presented as a therapeutic option in the next PCDT.

Sirolimus's PDP was extinguished due to Farmanguinhos having informed, through Official Letter, that it had withdrawn from the partnership and made available the market percentage for future PDPs.

The DC deliberated for the extinction of the Lopinavir + Ritonavir PDP due to the drug not meeting the definition of "strategic" for the SUS, since the national production is no longer relevant for the CEIS due to the reduction in demand for the final area (Secretary of Health Surveillance).

The Docetaxel partnership was terminated due to the impossibility of centralizing the purchase of this medicine.

*Figure 2. Extinct farmanguinhos PDP projects **
** Elaboration from the list of Partnership Projects for Productive Development (PDP), D&I - Extinct - Medicines, Vaccines and Blood Derivatives (Ministry of Health, 2021d).*
Source: Created by the authors, 2016.

Year of Extinction	Product	Public Institution	Private Partner
2014	Mycophenolate mofetil	Farmanguinhos	Roche/Nortec
	Docetaxel		Libbs/Quiral
	Budesonide + Formoterol, Salbutamol, Budesonide		Chron Epigen/Nortec
2015	Recombinant Human Insulin		Indar
	Darunavir		Apotex/ NT Pharm/ Globe
2016	Docetaxel		Cristália/Quiral
2017	Lopinavir + Ritonavir		Cristália
2018	Formoterol + Budesonide		Chemo Iberica/ Nortec
	Simepreve		Blanver/Microbiológica
	Sirolimus		Libbs

At the same time, the DC deliberated for the extinction of the Darunavir PDP and the Recombinant Human Insulin, as there was no full compliance with the provisions of art. 14 and sole paragraph of art.50 of Ordinance GM/MS No. 2.531/14 (effective at the time).

The partnerships of L-Asparaginase and Budesonide + Formoterol, Salbutamol, Budesonide were dissolved due to non-compliance with the requirements and conditions established in the Term of Commitment signed and in the regulations in force during the period of extinction.

The CD Committee deliberated for the extinction of the PDP for Mycophenolate mofetil, as Farmanguinhos informed, through an Official Letter, that it would not be possible to reach the minimum values defined for the acquisition of the drug.

The technical monitoring of training, technological and productive activities, the executive project and its schedule, the technical process of technology transfer and the development of capacities of Farmanguinhos to the new technological level, within the scope of the PDP, is carried out by the MS with participation of ANVISA, through the performance of specific committees, Technical Regulatory Committees (CTRs), based on monitoring reports, sent every four months by the institution and joint annual technical visits in manufacturing units, both public and private (Ministry of Health, 2014).

ANVISA instituted the CTRs for each Official Laboratory with the objective of monitoring activities related to the development, production, registration, and post-registration CTRs, developing activities under its attribution until the conclusion of the productive development partnership.

The technology transfer stages that involve the productive aspects demand the acquisition of equipment and instruments, and adaptation of the manufacturing area, considering characteristics of the technology and the regulatory obligations. If the completion of such steps exceeds the original forecast provided for

in the schedule due to the complexity of the scope of the services that will be contracted and, above all, due to budgetary constraints, it may compromise the development of the PDP phases.

The long period of time between the term of commitment and the start of drug production, regulatory barriers, and problems in negotiations with technology holders potentially interfere with the achievement of the PDPs and the strengthening of the national production chain.

The partnerships bring together participants from different sectors, with a view to maximizing their resources and skills to meet the end of drug development and distribution and improve access to treatment in the country.

Case Study: Atazanavir PDP

The first PDP of antiretroviral formalized approved by the MS with Farmanguinhos was of the drug atazanavir. It is a 2nd generation protease inhibitor azapeptide. The transfer of technology and the gradual integration of the drug's production process and its API are the basis for the signing of a purchase commitment by the Ministry of Health (Ministry of Health, 2021b).

The drug Reyataz, has as active ingredient the compound atazanavir, an azapeptide inhibitor of protease (IP), used for the treatment of HIV infection. It had its registration approved on June 20, 2003, by the FDA registration agency to market it in capsules of 100, 150, 200 and 300mg and powder of 50mg/pack (FDA, 2014). In the same year, it was already available in the US and several other countries through access programs for HIV (+) carriers who did not respond to their previous antiretroviral regimens, or those with high levels of triglycerides or cholesterol, insensitive to hypolipidemic (Silveira, Corrêa, Barroso & Figueiredo, 2016).

The Technical Cooperation Agreement for the sublicensing of patent exploration, technology transfer and supply were signed on 11/11/2011, between the Oswaldo Cruz Foundation - FIOCRUZ, represented by the Pharmaceutical Technology Institute - Farmanguinhos, and Bristol-Myers Squibb (BMS) aiming the transfer of technology of the drug atazanavir, in 200mg and 300mg dosages, as well as the production of the respective API, in national territory. The technology transfer of the active ingredient was carried out by BMS to the national private laboratory, Nortec Química AS (GTPI, 2015).

Atazanavir sulfate is protected by US patent, US5849911, owned by Novartis, filed on 04/09/1997, granted on 12/15/1998 and with expiration date 06/20/2017. Patent US5849911 has as a Brazilian corresponding patent BR9701877-5, granted on 09/28/2004, valid until 04/22/2017, whose protection includes derivatives, process for the preparation of these compounds and their salts, pharmaceutical compositions and use in diagnostic or therapeutic treatment for a retroviral disease (Silveira, Corrêa & Barroso, 2016). Although Novartis own the patent US5849911, the development of atazanavir has been licensed to BMS (Witherell, 2001).

Atazanavir Bisulfate is protected by US patent, US6087383, owned by BMS, filed on 12/21/1998, granted on 07/11/2000 and expiration date 12/21/2018. Its corresponding application filed in Brazil was rejected on March 31, 2009, and, therefore, is in the public domain in Brazil.

The PDP predicts that Farmanguinhos commits to purchase from BMS the entirety of MS's demand for the drug during the first 03 years after the granting of the sanitary registration. During the fourth and fifth year after obtaining the sanitary registration, Farmanguinhos will produce up to the equivalent of 50% of the total MS demand for the drug in the production facilities, using the national API, or if necessary, using the BMS API, whose price will be agreed with BMS; the remaining 50% will be produced by BMS (GTPI, 2015).

Farmanguinhos will pay BMS royalties, quarterly, in the amount corresponding to 4.5%, for the sublicense of the patent, as compensation for all investments in obtaining and maintaining the license to operate the patent, as well as for the acquisition, research and development of the technology related to the production of atazanavir sulfate and intellectual property rights. The amount should be calculated on the net sales value of the drug manufactured and sold by Farmanguinhos to MS, from the date of the first sale of the drug manufactured by Farmaguinhos until the patent expires (GTPI, 2015).

It is important to note that the payment of royalties by the Brazilian pharmacochemical company, Nortec, related to the production of the national API in Brazil, will not exempt Farmanguinhos from its obligation to pay royalties on the drug manufactured by Farmanguinhos, as described above (GTPI, 2015).

According to Farmanguinhos, the partnership should reduce 41% of MS spending on the drug. In 2011 alone, the government allocated R$ 128.2 million for the purchase of 25.38 million atazanavir capsules, to serve the 43,000 patients who, use the drug in Brazil (Agência Fiocruz de Notícias, 2011).

Evolution of the Atazanavir PDP Process

The development of the PDP for atazanavir followed the flow approved by the MS: i) presentation of the PDP proposal to the public institution, ii) analysis of the proposal, iii) approval of the PDP, iv) follow-up and monitoring. In 2010, within the established deadline, the submission of the PDP project proposal was carried out. In 2011, in view of the feasibility of carrying out the PDP, Farmanguinhos sent a document entitled "Executive project of the agreement for the development of the health industrial complex for the supply of products listed in MS Ordinance No. 978/2008" which contained the basic information about the project. In response, the MS, through DECIIS, issued Technical Note No. 47/2011/DECIIS/SCTIE/MS, informing that the Executive Project fully complied with the adjustments requested by the MS. Thus, the Term of Commitment No. 02/2011 was signed, which established parameters and conditions for the production and acquisition of the medicine object of the technology transfer (GTPI, 2015).

The contractual formalization took place at the end of 2011. The agreement includes the transfer of technology, manufacture, and distribution of the drug for a period of 05 years. During this time, BMS will transfer the technology from the API to the Nortec private laboratory and the drug to Farmanguinhos, which will start manufacturing it. In return, the government will guarantee exclusivity to the laboratory in the purchase of antiretroviral drugs during the transfer process. In the first two years of the partnership, BMS is committed to supplying the drug with the Farmanguinhos packaging, which has been happening since 2014 (Portal da Fiocruz, 2014a).

Due to technical-regulatory delays causing delays in complying with the technology transfer schedule, on 12/13/2019, a Technical Cooperation Agreement Reestablished and Amended for Technology Transfer and Supply was signed, effective 06/06/ 2019 to 12/31/2020, whose purpose includes providing technical support to Fiocruz for the completion of remaining technical activities within the scope of the Work Plan, providing the IFA, among other agreements, referring to the antiretroviral drug atazanavir, in the 200mg and 300mg dosages (DOU 113, 2019).

On 12/14/2020, the 1st Amendment to the Agreement was signed, which aimed to change the Remaining Technical Activities Plan contained in Annex I of the Addendum and extend the term of validity of the Agreement from 12/31/2020 to 31 /07/2021, or until obtaining the sanitary registration of the product atazanavir 300mg by Farmanguinhos with the inclusion of the national API, whichever came first (DOU 241, 2020).

On 07/30/2021, the 2nd Amendment to the Agreement was signed, which had as its object to extend the term of the reinstated agreement for 12 months, from 07/31/2021 to 07/31/2022, or until approval of the dissolution profile comparison of the product with national API by the purchaser, whichever occurs first (DOU 144, 2021).

The Executive Project and other documents related to the PDP are classified as secret in the secret degree[1] (Brasil, 2012b), and cannot be disclosed despite the publicity rule for the process. The MS's arguments for this are since the PDPs are carried out between public institutions and private entities, to reduce the vulnerability of the SUS, as well as to rationalize and reduce the prices of strategic products. Thus, according to the MS, they consolidate a process of internalization and development of new technologies considered strategic and with high added value (Albuquerque, 2015). In this context, the documents involved in the PDP process, discriminate the method, procedure, and implementation of the scientific and technological project and, for this reason, are part of a process, which, if made public, may harm or cause risk to scientific development and technological, of national strategic interest, as provided for in the Access to Information Law (Brasil, 2011).

However, the classification of information about the PDPs as a degree of secret secrecy is questionable since it is information that will be justly transferred to the government, in this case, Farmanguinhos, as provided for in the PDP principle. And as the contracting process in PDPs is not included in the list of bidding processes, it is important to manage accountability, to clarify why the choice of the public institution that will produce the drug and the national company that will produce the API, is important like any calculation of the costs involved.

The crucial question is: How can information from a public process, from a partnership whose objective is precisely to transfer technology to public authorities, not be accessible by society? What is available to the public is the disclosure of partial information about the benefits of the PDP, without the complete information justifying the expenses, investments and choices of partners being revealed.

There is no way to consider the process 100% confidential, there is certainly information that does not represent threats and the public interest in health-related issues would justify the availability of information and greater transparency in the process.

The confidentiality period is counted from the date of production of the information, and not from its classification; and for information in the reserved degree, the period recorded comprises 15 years, with no possibility of extension. The atazanavir process, comprising the Term of Commitment and Attachments, despite having been classified on 05/16/2014, has a production date on 05/06/2011. Therefore, it will remain confidential until 06/05/2026 (Albuquerque, 2015).

It is noteworthy that the content and discussion regarding the information on the evolution of the PDP phases of atazanavir were possible due to access to information prior to the date of classification of confidentiality.

Figures 3 and 4 show a general schedule of the evolution of the phases of the atazanavir PDP based on the 1st Contract (GTPI, 2015) and the amendments published in the Official Gazette (DOU). Phases I, II and III have already been completed. Phase IV is currently underway.

In 2012, the stage of development, industrial and technological training began. The production flow and the need for equipment acquisition or renovation, and for the construction or renovation of the physical production area were defined. BMS delivered the product dossier to Farmanguinhos and began developing the art of primary and secondary packaging for the product.

During the months of July and August 2012, the training of professionals from Farmaguinhos directly involved in the absorption of the technology began. A technical visit was made by the Farmanguinhos

team, with representatives from the production, quality control and pharmaceutical technology laboratory sectors, to the BMS production unit to monitor the entire production process and train.

The years 2012 and 2013 were marked by the registration pendency with ANVISA, which was approved only on January 13, 2014. Therefore, only from that year onwards the term of 10 (ten) years of the PDP begins to run.

Farmanguinhos obtained the registration of the drug atazanavir granted by ANVISA, through Resolution - RE No. 84, of January 10, 2014, published in the DOU of 01/13/2014, and made the first delivery of the drug to the MS on 07/25 2014, thus generating savings for public coffers.

It is worth mentioning that in the 1st delivery of the drug to the Ministry of Health, in 2014, the Bristol-Myers Squibb packaging was used, due to the lack of time to prepare the Farmanguinhos packaging. In the 2nd and 3rd deliveries throughout 2014, the Farmanguinhos packaging, provided for in the PDP Agreement, has already been used.

Figure 3. Evolution of Atazanavir PDP phases I and II
Source: Created by the authors, 2018.

PROCESS STEPS	ACTIVITIES		DATE STATUS
Phase I - PDP Project Proposal	Submission of PDP project proposal		2010 Conclude
	Signing of Term of Commitment and Technical Note		2010 Concluída
	Approval of the executive project		2011 Conclude
Phase II – PDP Project (Start of the implementation phase of the approved PDP project proposal and the term of commitment)	Signing of the Technical Cooperation Agreement between Farmanguinhos and BMS		2011 Conclude
	Development, manufacturing adaptation, industrial and technological training of the drug atazanavir and the API	Development, adaptation, and training of Farmanguinhos	2012 Conclude
		Technology transfer of analytical and production methodology from API to Nortec	2014 Conclude
	Presentation of documentation regarding the authorization/license/certificate of Farmanguinhos and BMS	Forwarding relevant documentation to ANVISA	2012 Conclude
	Forwarding relevant documentation to ANVISA		2012 Conclude
	Request and publication of the health record of the drug atazanavir subject to PDP by Farmanguinhos		2012 a 20 Conclude

The beginning of the drug supply to MS occurred in June 2014. As mentioned above, the drug was distributed with the Farmanguinhos package, but its production with national technology only took place in 2020.

Figure 4. Evolution of Atazanavir PDP phases III and IV
Source: Created by the authors, 2021.

PROCESS STEPS	ACTIVITIES		FORECA SITUATI
Phase III - PDP (Execution phase of product development, transfer, and absorption of technology effectively and signing of the strategic product acquisition contract between MS and Farmanguinhos)	Technology transfer and absorption, development, industrial and technological training	Signature of the Quality Agreement	2015 Conclude
		Technical visit to BMS for monitoring and training in production and Quality Control	2012 Conclude
		Transfer of the analytical methodology of the drug and the API	2013 a 20 Conclude
		Acquisition of materials for Quality Control and production equipment	2012 a 20 Conclude
		Execution of the refurbishment of the manufacturing area	2012 a 20 Conclude
		Production of the pilot batch with IFA from BMS and with the IFA from Nortec; drug studies obtained from the respective IFA	2016 a 20 Conclude
	Production and stability studies of IFA pilot batches (Nortec)		2016 Conclude
	Supply of the PDP drug atazanavir	Supply of the drug atazanavir by Farmanguinhos with production by BMS with IFA from BMS	2014 a 20 Conclude
		Supply of the drug atazanavir by Farmanguinhos with production by Farmanguinhos with API from BMS	2018 a 20 Conclude
		Supply and production of the drug atazanavir by Farmanguinhos with API produced by Nortec	2020 Conclude
	Post-registration publication of Farmanguinhos published by ANVISA	Petition to include a new manufacturing site (Farmanguinhos)	2020 Conclude
		Petition for inclusion of a new API supplier (Nortec)	2020 Conclude
Phase IV - Internalization of Technology	Completion of the process of development, transfer, and absorption of the drug atazanavir technology by Farmanguinhos, making it the holder of all the information to ensure technological mastery and capable of technological portability to meet the demands of the SUS.		2022 In executi

The acquisition of equipment by Farmanguinhos and the works to adapt the manufacturing area were carried out from 2012 to 2018. The production of a pilot batch in Farmanguinhos with the IFA from BMS and with the IFA from Nortec took place over the years 2018 and 2020. The request for inclusion of a new manufacturing site and new API manufacturer with ANVISA was made in 2020. It was in June 2020 that Farmanguinhos completed the manufacture of pilot batches of Atazanavir, a step that aimed to include of Farmanguinhos as a manufacturing site by Anvisa (Matos, 2020).

In compliance with the schedule, after carrying out all the steps provided for in the terms of the contract, the internalization of the technology will end in 2022, with the completion of the process of development, transfer, and absorption of technology object of the PDP by Farmanguinhos, making it the holder of all the information that guarantees technological field and capable of technological portability to meet the demands of the SUS.

When analyzing the development of the PDP stages, it is important to highlight that BMS indirectly managed to extend the marketing exclusivity with the signature of the PDP, since the patent for atazanavir sulfate expired in 2017. In addition, the completion of the development process, the transfer and absorption of the drug atazanavir technology by Farmanguinhos was not completed within the period initially foreseen for the PDP.

Factors Evaluation of Social Order, Technical and Economic

Social Order Factors

The social perspective of the PDP from ARV atazanavir is understood and supported by the well-known fact that AIDS is a disease of epidemic proportions, one of the priorities of the MS pharmaceutical assistance policy, and that it is part of an internationally recognized program.

Data extracted from the 2020 Epidemiological Bulletin reveal that in Brazil, in 2019, 41,909 new cases of HIV and 37,308 cases of AIDS were diagnosed, with a detection rate of 17.8/100 thousand inhabitants, totaling, in the period from 1980 to June of 2020, 1,011,617 AIDS cases were detected in the country. Since 2012, there has been a decrease in the AIDS detection rate in Brazil, which went from 21.9/100 thousand inhabitants (2012) to 17.8/100 thousand inhabitants in 2019, representing a decrease of 18, 7%. The data reveal that the highest concentration of AIDS cases in Brazil was observed in individuals aged between 25 and 39 years, in both sexes. Thus, despite the gradual reduction, Brazil still has a significant rate of individuals diagnosed with HIV (Boletim Epidemiológico, 2020).

Treatments carried out with ARVs seek to maintain control of HIV. The multiplication of HIV in the body is reduced with therapy, which recovers the body's defenses and, consequently, increases the quality of life of the seropositive. The long period of treatment or its discontinuation can lead to resistance to the virus and, therefore, the drug options tend to decrease. Through its public policies, the Ministry of Health seeks drugs capable of opening a new range of options for the treatment of AIDS, with efficiency in people who have acquired resistance to other combinations.

Atazanavir has been shown to be very effective in rescue situations, especially when combined with other ARVs. It is included in the list of ARV drugs present in the list of strategic products within the SUS, as one of the options for choosing PI and indication in combination with other ARV agents for the treatment of HIV-1 infection. Thus, its technological domain and production are essential to the development of the CEIS, which is why it comprises one of PDPs ARVs approved by the MS.

The obligation to nationalize the manufacturing of the API necessary to produce the drug is also a social factor to be considered regarding the convenience of the partnership, as it will contribute not only to encourage the development of the pharmochemical industry, but mainly, to ensure the independence of the SUS regarding this drug. It is, therefore, important to guarantee the continuity of the treatment of patients, safeguarding the supply of strategic medication in the face of commercial, economic, or political variations at the international level.

The social axis of the PDP of atazanavir or any other medicine becomes expressive when the partnership configures as a public policy for medicines and incentives to innovation and is materialized with the strong commitment of the Brazilian State to foster the national industry and the technological autonomy of the country. The use of inputs developed and produced by the country itself, by public institutions and companies with national capital, and by incentives to nationalization projects of production stages that are currently carried out abroad, and obtained by import, can give the PDP an important instrument in the expansion of access to medicines. However, it will be effective if it manages to make use of strategic instruments to reduce the vulnerability of the SUS to high prices, arising to some extent from fluctuations in the international market.

Technical Order Factors

The technical factors that can justify the PDP include the advantages of the selected technology compared to its similar ones, feasibility of transferring the intended technology, and gains in terms of technological training for Farmanguinhos and for Nortec, from the transfer of technology.

The patent and registration issue are technical factors to be considered. The company BMS holds the rights to exploit patent BR9701877-5, in the Brazilian territory, essential to produce the API and the drug, as well as being the only holder of the drug registration with ANVISA, criteria that place it as the only capable company to meet the necessary requirements for the formalization of the PDP with Farmanguinhos.

About patent protection on the drug and its API, the formalization of the partnership with BMS must ensure the transfer of technology so that all the know-how of manufacturing the drug, which includes tacit knowledge that is not available in patent documents is reached. For the PDP process to become effective and efficient, it is essential that the domain of atazanavir technology held by BMS is effectively transferred and that its transfer can bring learning gains, against potential competitors that may enter the market after the expiration of the patent, which occured in 2017, the date before the conclusion of the PDP's internalization phase.

It is estimated that the complete technology transfer process, starting from the granting of registration in 2014, will last up to 8 years; and that Farmanguinhos is able to produce the demand for the drug by the MS within its facilities, with the technical assistance of BMS. Once the technology transfer is completed, it is expected that Farmanguinhos will acquire manufacturing capacity to fully meet the demand of the MS for the drug. If any change in production technology occurs during the term of the agreement, Farmanguinhos will be assured access to and use of such improvements.

The implementation of this PDP may provide the training of human resources throughout the entire production chain and project development, and consolidation of a new industrial park in the national territory, which will result in the development of skills to generate more advanced technologies in the medium and long term.

For Nortec company, which will receive the transfer of technology from the API, the significant technical factor is the expansion of infrastructure and the improvement of existing production processes, which enable the creation of a renewal cycle for the company's assets, increasing competitiveness in the pharmaceutical segment.

The initiative of the PDPs is valid, mainly in its aspect of promoting the technological development of the pharmaceutical sector, considering that Brazil does not have sufficient production capacity for pharmochemicals and biologicals and needs to supply the demand with imports. While the SUS has a

chronic budget deficit, and the fulfillment of pharmaceutical care as determined by the Law requires substantial financial resources, the option of the PDP as an instrument of purchasing power for the Brazilian State to do so can be presented as a useful mechanism and effective if technical factors are duly considered and possible price reductions offset the expense of investments in the technical sphere.

Economic Order Factors

The economic point of the PDP concerns its strong production base, in addition to its significant participation in the generation, diffusion and use of innovation. Figure 5 shows the consumption and expenditure to meet the demand for atazanavir in Brazil, in the years 2011, 2012 and 2013, according to data presented by the MS on the Transparency Portal. It is observed that approximately 337 million reais were spent to purchase this drug (Ministério da Saúde, 2016).

There was no significant variation in the values practiced between signing the PDP (2011) and its establishment (2012 and 2013). The prices paid over the three years for the 200mg capsule were R$3.60, R$3.33 and R$3.40, respectively; and for the 300mg capsule were R$5.46, R$5.46 and R$5.58, respectively. The volume purchased in 2013 for the 200mg capsule was 50% more than in 2012 and for the 300mg capsule it was around 116% (Figure 5).

Figure 5. Quantity x cost per year of Atazanavir
Source: Created by the authors from data by MS - Portal da Transparência (Ministry of Health, 2016).

Apresentação	Ano	2011	2012	2013
Atazanavir 200mg	Quantidade (Un.)	5.580.000	4.000.080	6.000.000
	Preço (R$)	3,6075	3,3345	3,402
	Total (R$)	20.129.850,00	13.338.266,76	20.412.000,00
	Período	28/02/2011 a 31/12/2011	05/04/2012 a 31/12/2012	26/03/2013 a 31/12/2013
Atazanavir 300mg	Quantidade (Un.)	19.800.000	10.000.020	21.630.000
	Preço (R$)	5,46	5,46	5,586
	Total (R$)	108.108.000,00	54.600.109,20	120.825.180,00
	Período	28/02/2011 a 31/12/2011	05/04/2012 a 31/12/2012	26/03/2013 a 31/12/2013

According to the Health Price Bank (BPS – Brazilian term) - a system developed by the MS for the registration and consultation of information on purchases of medicines and health products made by public and private institutions, the values of the purchases were acquired of the drug atazanavir in the period from 2016 to 2021 (Figure 6).

Acquisitions for atazanavir 200mg in 2019 and 2020 and acquisitions for atazanavir 300mg in 2016 were not identified in the BPS.

In the period from 2016 to 2020 there was also no significant variation in the values practiced.

Figure 6. Quantity x cost per year of Atazanavir
Source: Created by the authors from data by BPS (BPS, 2021).

Presentation	Year	2016	2017	2018	2019
Atazanavir 200mg	Quantity (UF.)	5.324.880	5.110.560	1.320.000	____
	Price (R$)	3,32	2,96	3,18	____
	Total (R$)	17.678.601,60	15.127.257,60	4.197.600,00	____
Atazanavir 300mg	Quantity (UF.)	____	51.856.680	56.002.500	21.000.000
	Price (R$)	____	4,32	4,24	4,16
	Total (R$)	____	224.020.857,60	237.450.600,00	87.360.000,0

The cost of acquiring the technology is included in the amount agreed for the supply of the drug by BMS, throughout the transfer process, the amounts of which are provided for in the Executive Project. After completing the transfer of technology, Farmanguinhos intends to serve the entire public market in the national territory.

Given the low value of the reduction in values throughout the partnership, the agreement is not expected to lead to significant price reductions on the drug, as it defines a price reduction of only 5%, in addition to the payment of royalties of 4, 5% for BMS on sales of all generic versions.

As foreseen in the Agreement, the PDP foresees the purchase of 100% of the MS demand of the atazanavir produced by BMS in the first three years after the concession of the sanitary registration and in the fourth and fifth years, 50.0% of the MS demand. With the delay in sanitary registration and in the technology transfer process, BMS will be assured of the drug market even after patent expiration (GTPI, 2015).

A relevant factor that was not considered in the treatment of atazanavir PDP is the prediction of its use in combination. Although studies show that the use of atazanavir in combination with ritonavir is efficient, with inclusion in the WHO therapeutic protocol in 2013, there is no permission in the PDP agreement to produce medicines in combined form. The Agreement prevents the production of different presentations of 200mg and 300mg capsules.

As it is an ARV included in the STD/AIDS program, it is estimated that the incorporated technology will increase the degree of national sovereignty, save foreign exchange for the Union, increase the capacity of knowledge about the technology absorbed with the PDP, in addition to also providing the possibility of innovations and strengthening of CEIS.

In the governmental sphere, it is also estimated that the PDP will generate a decrease in the MS's expenses, in relation to the offer of this medicine, and therefore, expansion of access to the medicine, since the country will start to produce the medicine that will be offered by the Ministry of Health. For the Ministry, the PDP in question may also generate direct savings in government procurement, increase public investment in R&D by stimulating innovation, consolidating the national innovation system through the expansion of scientific and technological competences and its insertion in the public institution, productive densification of the Brazilian industrial park, aiming at sustained gains in labor productivity, in addition to promoting and sustaining inclusive economic growth.

CONCLUSION

The impact of the partnerships on the trade balance of the CEIS is still uncertain since the degree of nationalization of production that will be achieved with the signed PDPs is unknown; since depending on the technological complexity involved in the process, the government can relax the requirements regarding the depth of technology transfer.

Farmanguinhos stands out for having a significant number of PDPs signed, 18 projects over the years 2009 and 2013, which represents more than 20% of the total PDPs carried out by the MS, and seeks through this instrument to diversify its portfolio, with the inclusion of about 10 new high value-added products; in addition to increasing your billing. Among the drugs that will be produced are antiretrovirals, antiasthmatics, immunosuppressants, antiparkison drugs, tuberculostatics and antineoplastics.

For pharmochemicals, the greatest opportunity for PDPs comprises the acquisition of new capacities such as the strengthening of the national production chain with the entry of national players in government purchases (products with greater added value); the qualification of the national industrial park, in the medium term, with the internalization of transferred technology and generation of resources for investment in its basic skills.

The PDPs appear as a solution found by the government to minimize the MS's expenses with medicines and promote local production of medicines. However, it should not be overlooked that there is also a high risk of them, at the end of the process not reaching the expected success.

Among the risks, we highlight the lack of sufficient transparency to determine the productive capacity installed in public laboratories, given the need to obtain the necessary licenses from ANVISA; the time interval between validation of the PDP by the MS and obtaining registration from the public laboratory at ANVISA, which in the case of atazanavir lasted for more than 24 months; and the long period of time between the term of commitment and the start of drug production, associated with regulatory barriers and problems in negotiations with technology holders.

The most accurate assessment of the real gains obtained with the PDP of atazanavir, if not disclosed by the Ministry of Health, can only be achieved from May 2026, when the process, comprising the Term of Commitment and Attachments, is no longer classified as secret secrecy. To date, all studies were based on data obtained before the referred process was classified and from publications provided by the MS and its departments. With the end of confidentiality, we will have greater transparency in the results related to the PDPs and, as a consequence, a more accurate analysis of the purchasing power of the Brazilian State, carried out through the induction of this specific policy, as an important initiative for the supply of developed and produced inputs by the country itself, by companies with national or foreign capital and by incentives to projects for the nationalization of production stages that are currently carried out abroad, and obtained by import.

The new Ordinance No. 2.531/2014, which regulates PDPs, establishes some changes that were not considered when the PDP for atazanavir was established. A change refers to the start of purchase of the product by MS. With the new milestone, the beginning of the PDP is considered the first acquisition of the product, so that companies assume the commitment to technology transfer. Another is related to the maximum deadline for completing the project, which is now ten years. A technical committee will carry out the constant evaluation of the proposal and may even suspend projects that are stopped or that are not meeting the PDP criteria. Such measures provide greater security for companies and improve government monitoring.

So that no loss occurs, the rules for setting product prices and for the health registration of the drug must be well defined. The unit value, which should decrease over the duration of the partnership, should be subject to renegotiation in the face of changes in the market, such as the end of a patent, ensuring savings to public coffers.

The atazanavir PDP is expected to reduce the price for the government, reducing the budget bottleneck and expanding access to medicine, as well as strengthening the national production chain and the qualification of the national industrial park, in the medium term, with the internalization of transferred technology, helping to reduce dependence on international variations.

The PDPs, despite promoting production capacity, do not directly imply technological capacity as the technologies incorporated via technology transfer agreements did not favor the emergence of new product development projects. There is a contribution to the improvement of production processes, not to the development of new products. The impact of PDPs on LFOs' ability to innovate can be variable and is directly related to their structure and R&D performance.

The incorporation of technology, that is, technological development and the exchange of knowledge, should not take place in isolation, as the bargaining power desired by the Government will only be achieved if there is a forecast of investments in technological qualification and training of the team involved.

For the PDP to achieve an effective gain and meet all its objectives, partnership proposals must include technologies with long life cycles and avoid entering partnerships exclusively with holders of exclusive rights that are about to expire or have recently expired, seeking to more than one provider, with a view to maintaining market competitiveness.

The choice of drugs included in the PDP processes must consider how much they represent for public accounts, the prices practiced by current suppliers, the impact of these purchases on the country's trade balance, as well as the volume of public investments needed to nationalize production and all variables involved in the chain.

It is important to emphasize that there is no way to verify the fulfillment of the proposed objectives without constant monitoring and evaluation of the policy. In this sense, the normative framework lacks instruments that enable a clear analysis, since the emergence of the PDP policy, there are no documents proving the assessments that should be carried out by the Technical Assessment Committees (CTA) of the Ministry of Health.

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ENDNOTE

[1] The Partnerships for Productive Development (PDP), according to Ordinance GM/MS No. 2.531/2014, have, among other objectives, to foster joint technological development and strengthen the competitive capacity of public and private national producers in line with the reduction in prices of products considered strategic for the Unified Health System. Pursuant to article 23, item VI, of Law nº 12.527/11, article 25, item VII, Decree nº 7724/12 and article ninth, item VII, of the GM Ordinance /MS No. 1.583/12, the Ministry of Health classifies as secret, the Terms of Commitment, as well as the reports of the Technical Evaluation Committees and the decisions of the Deliberative Committee, as well as the other documents that make up the processes administrative bodies whose objects are partnerships for productive development involving technology transfer. It should be noted, as established in article 2, item XIV, of Ordinance GM/MS No. 2531/2014, that the Term of Commitment is the instrument signed between the public institution and the Ministry of Health (and not "partnership agreement"), and this document is also classified in the degree of secret secrecy and composes the administrative processes of the PDP.

Chapter 15
Knowledge Integration and Its Role in the Training of Health Professionals:
The Cabo Verde Experience

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ABSTRACT

Relevance is the basic value of any training project, in the cutting-cross of knowledge, attitudes, and competencies to be transmitted through the pedagogical process. Trends in science and the new directions of global health research requires personnel with vision, maturity, and skills for strategic planning. We are looking at a deepening gap between the professional status quo and the aspirations of society. This chapter aims to reflect on the role of the university focusing on the pillars that support it, in the context of training health professionals, and the central role of communication in the exercise of the profession and in health promotion. The approach is based on a theoretical review and the case study of Cabo Verde, as a SIDS. The role played by these professionals would have a direct impact on the definition of public health policies. These would be based on knowledge; the interface of innovation in health, management, and social organization; and on dialogue to improve systems from the perspectives of One Health and Global Health.

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INTRODUCTION

Relevance is the core value of any training project. And this is equivalent to saying that the selection of knowledge, attitudes, and skills to be transmitted to apprentices in the health areas, through the pedagogical process, should not be done only according to the self-referenced criteria of the professions. To these must also be added the needs and demands of society. It is important, however, to underline that the demand to adapt training to the social context is all the greater, the deeper the ongoing process of change. In such a context, training becomes an object of questioning. We would say of interpellation by governments, intergovernmental organizations, professional associations, the press, users, and others. In addition, social demands give rise to academic institutions and the actors involved in an enormous creative effort, encouraging them to introduce reforms in the curriculum and in pedagogical practices that guarantee the sought-after external relevance to the training provided. A consequence of this type of process is the reduction of the space for autarky and inertia of academic institutions, which then assume a greater interdependence with their contextual environment and the need for pedagogical innovations.

The objectives of this chapter are to reflect on what models of training health professionals are necessary, considering the breaks and challenges currently posed by the references of "one health", "health for all" and "global health" and on the central role of communication in the exercise of the profession and in health promotion. By indelibly marking our time, such references encourage higher education institutions to conceive and implement a training process capable of empowering their students, future professionals, with new skills and attitudes. We refer to those who enable them to think and act by integrating knowledge from different disciplines, to learn continuously in the work process and throughout life (developing action-research skills), to communicate fluidly with their peers and users, to exercise leadership and to interact with the community. The role played by these professionals would have a direct impact on the definition of public health policies. These would be based on knowledge, the interface of innovation, health, management, and social organisation on dialogue with a view to improving health systems from the point of view of Global Health.

Without prejudice to a comprehensive reach, the reflections that we are going to develop here are empirically based on the Cabo Verde an experience of training professionals.

This reflection will be based on a conceptual review of health, applied to a case study - Cabo Verde, through the discussion of the pedagogical model in health training (Health Training: What Pedagogical Model) from the perspective of transdisciplinarity (Viewing health education in a transdisciplinary perspective).

NEW TRENDS IN HEALTH CONCEPTUALIZATION

In recent times, the gap between the professional status quo and society's aspirations has deepened. And it is through this gap that the traditional concept of health began to be called into question. This has occurred at least since the famous definition of the World Health Organization (WHO) inserted in its Constitution of 1946, which tells us that health is a state of complete physical, mental and social well-being, and not just the simple absence of illnesses. The positive or salutogenesis concept proposed by Aaron Antonovsky (Antonovsky, 1996) was then enshrined. This concept had the advantage of being more comprehensive, as it included in its focus social and personal resources, as well as physical capabilities (Becker CM, 2010). The trigger for this change was and has been the growing need to go beyond the

limits of a health approach centered on combating disease and on clinical and hospital medicine with a focus on the individual. Since then, the objective has become that of overcoming a type of health action resulting from the mere application of the concept of pathogenesis, based on the study and fight against the development of the disease. A vision now seen as restrictive, minimalist, and reactive. This way of thinking and acting started to be affronted and contested, in the name of a new approach, characterized by comprehensiveness. We would say that the traditional concept is today impelled and challenged to include new topics, such as the interdependence between human, animal and environmental health, as well as the imperative of "health for all", seen not only as a demand for political and ethical forum, but equally as the only way to ensure effectiveness and sustainability of health policies.

It is in this line of evolution, marked by the imperatives of conceptual scope and social and environmental inclusion in the health approach, that the Sustainable Development Goals (SDGs) - proposed by the United Nations to guide government action until 2030 - emerge as the right frame of reference for health planning for all. Implementing the SDGs implies, however, establishing a broad way of articulating the contribution of the various sectors and public policies, with a view to achieving increasing levels of well-being for the population. It must be recognized that this is a major challenge for countries with "sectoralized" approaches to health, centered on the hospital and pharmaceutical sector (Delgado & Lima Fortes, 2020).

Another dimension of this new conceptualization stems from the need to change the traditional patterns of interaction between the user, the health professional and the institutions providing care. This guidance aims to ensure a greater degree of transparency and accountability for the actions of those involved in the health process. As a result, the position of "doctor-king" and the non-dialogue health professional and issuer of sentences, which relegates the user to a passive and subordinate role, ends up being called into question. An unsustainable subordination, as we are increasingly in a society in which health literacy increases rapidly under the action of science diffusers (health dissemination programs) and the expansion of the rights of users and consumers. We move towards the idea of health citizenship, which is based on sharing responsibility among all participants, ending, or at least attenuating, the fracture of assistants/assisted persons in the traditional relationship between health professionals and users. If the latter can demand access to information and explanation, but in return they become co-responsible for their own and the community to which they belong. This empowerment of users is undoubtedly one of the causes of the emergence of another ideal of relationship between health professionals and society.

Finally, it is worth highlighting the appreciation of the global health dimension, which sees health as a human right, a key component of equity, sustainability and human security, and a global public good, particularly considering the weight of cross-border dynamics in determining the health security of each country, especially small island states such as Cabo Verde.

In our view, the reconceptualization of health through the One Health concept translates well the proposed break with the old paradigm, as it can deal with the complex interdependencies between human, animal, and environmental health, but also between the spheres local, national and global, as well as between the user, the professional and the organizational context and, finally, between the biological, psychological and sociocultural dimensions. Anyway, the One Health concept is a requirement of complex thinking, that is why it is tributary of multi and transdisciplinarity. Therefore, the One Health approach extends the very concept of "health professional", extending the range to veterinarians, environmental engineers, phytosanitary agents, sociologists, social workers, as well as actors and disseminators of medical knowledge from a salutogenic perspective. It is perhaps important to say that the challenge to professional practices originates both in local society and in the international arena. Despite being dif-

ferent, these two contexts, the local and the international, end up interweaving complex relationships with each other.

At this point, it is imperative that we ask how the evolution of society has led to the formation of new expectations regarding the skills of health professionals. What groups and types of professionals should you consider in this analysis? To answer this question, it is necessary to analyze the changes that have been taking place in Cabo Verde society, taken here as a study case, and their impact on the health sector, namely through the emergence of new demands and expectations regarding the roles played by professionals in the field, *strictu sensu*, namely physicians, nurses, managers, and political authorities. Our hypothesis is that some changes in society, whether driven by external dynamics or internal influences, have eroded the effectiveness and even the legitimacy of certain ways of thinking and practicing health, ways that were previously unquestioned or, at least, widely accepted. What are these changes?

CHARACTERIZATION OF CABO VERDE

The Country

As one of the approximately 50 Small Island Developing Countries (SIDS) in the world, Cabo Verde has its own characteristics that require specific measures in the equation of whatever type of activities, from where the need felt by the authors to highlight it here as a conditioning factor.

This geo-demographic "smallness" constitutes its first contextual mark, but certainly not the only one. The archipelago is front a long strip of semi-desert climate stretching from the Arabian Peninsula to the east to the Atlantic to the west. Belonging to this region of the Sahel imposes on Cabo Verde a heavy servitude in terms of agricultural feed capacity, by submission to a sparse and random rainfall regime or to prolonged drought cycles.

The archipelago's vulnerability is further aggravated by the fact that its territory does not have natural resources that can serve as a basis for economic and social development. The few exportable raw materials do not carry enough weight to leverage lasting economic growth. But the constraints do not stop there.

Territorial dispersion is another obstacle to development. Apart from two islands where there is some urban concentration, Cabo Verde has a highly fragmented territory over which the population is very asymmetrically part. Composed of ten islands, nine of which are inhabited, endorsed unequally with potential, and just over half a million inhabitants, insularity determines a very unequal distribution of the population within Cabo Verdean space. generates "economies of scale", which the costs of

This structural feature generates unsavings, which increase the costs of economic, social and health investments across the archipelago, but more profoundly on the small islands. Attempts to compensate for smallness and dispersion with greater integration are hampered by transport and communication costs, which are relatively high. Any organizational activity, whether public or private, that wants to be developed in any field at national level deals with the non-small costs of archipelagic dispersion, compromising its viability and sustainability.

As a result of the articulation between dispersion and low connectivity, a structural inequality between the islands is established, which translates into the distorted distribution of opportunities for access to goods and services between the various communities. For example, access to specialized health care and the more advanced levels of education has much greater difficulties for those residing on small islands – the size of which does not offer "critical mass" that stimulates economic, educational, medium-sized,

public or private health investments – than for the inhabitants of the most densely populated islands, such as Santiago, S. Vicente, Sal or Boa Vista.

Another example is the migratory currents from the interior to the cities, and from the peripheral islands to the most endorsed with infrastructure and opportunities, or the most recent migration of rural populations to the emerging mass tourism hubs, according to the Cancun model. One consequence, due to the living conditions they manage to have, is to contribute to the emergence of peripheral neighborhoods where housing precarities prevail, the absence of basic sanitation infrastructure, forming ecological and social environments conducive to the emergence of health problems, some of which have epidemic potential.

Let us continue in this effort to characterize Cabo Verde's insularity. Although they have a global impact, climate change is a particular threat to small island states, either because of their smallness and insularity, or because of their status as sovereign entities. In the case of Cabo Verde, the gains arising from the regional integration process in the ECOWAS (Economic Community of West African States) space are far from being able to offset the costs that global challenges impose on national sovereignty. One of them, which is gaining increasing importance in determining collective destinies, is security. We are referring, for example, to the capacity of an island microstate such as Cabo Verde to face illegal fishing, the depredation of biogenetic resources, the discharge of polluting material by international shipping, the illegal trafficking of narcotics.

Despite what was said above, the insular condition, if well perceived and treated, also offers opportunities. It is necessary to adopt adequate measures and solutions and produce competent responses adjusted to the specificities of the country, as has happened in some other states/archipelagos. The studies prove that despite the constraints, island microstates have advantages, namely in terms of the quality of governance. In Africa, they have presented a government performance superior to that of continental states. Countries such as Mauritius, Seychelles, Cabo Verde and S. Tomé and Príncipe have stood out for their indicators. This difference is notorious in sectors such as education and health. The islands have hosted successful experiences in terms of graduate and postgraduate education in health, despite their joviality.

Health Training

Cabo Verde started the local training of health professionals in the late nineteenth century, as determined by Provincial Ordinance No. 80 of April 23, 1900 (BO No. 16) which provided the basis for the implementation of the practical nursing course program, carried out under the tutelage of the Health Services. Later, after independence in 1975, under the coordination of the Ministry of Health, the course was resumed. It was, however, only basic and medium training. (Martins, 2015). Higher education, even with independence, continued to be carried out outside the country and only very gradually began to be provided locally. Also, because the installation of higher education in the archipelago was a slow and relatively late process, when compared to many other African states. Firstly, because unlike them, namely the Francophones and Anglophones, the colonial experience did not provide Cabo Verde with higher-level academic institutions. Not even in its last phase, as happened with the General Studies in Mozambique and Angola. Furthermore, with independence, instead of creating the national university for reasons of prestige, the archipelago bet on the continuation of the expansion of basic education, on adult literacy, and on the preparation for the expansion of secondary education, concentrated, until then, only on Mindelo and Praia. It was precisely with the aim of training teachers for the secondary schools that were to be founded that the first experience of higher education in the country emerged. In other

words, in 1979, the Secondary Education Teacher Training Course was founded, later transformed into the Teacher Training School. At about the same time, given the urgency to create a merchant marine fleet that would guarantee the supply of essential goods to the internal market, which was then largely dependent on imports, the Government established the Training Course for Marine Personnel, on the island of S. Vicente. Apart from these two cases, which represented the urgency in terms of teachers to respond to the strong demand for secondary education and for seafaring personnel to meet the needs of the national fleet, higher education was not a priority for Cabo Verde's governments in the 1970s, 80's and 90's of the 20th centuries. Hence, it was only in 2001 that the first university in the country was set up. And even so, it was a private initiative and foreign capital. We are referring to the Jean Piaget University of Cabo Verde. In the meantime, higher institutes were created based on the experiences of training teachers (Higher Institute of Education), seafaring personnel (Higher Institute of Engineering and Marine Sciences) and civil servants (National Institute of Administration and Management). The University of Cabo Verde (Uni-CV), a public university, was created in 2006, and its genesis resulted from the merger of the three public institutions. In addition to the University of Cabo Verde, more universities were opened, and the archipelago now has ten higher education institutions.

It should be noted that the importance given to health training for the social and economic development of the country, the existing demand from individuals, government and private institutions, and the scarce national supply determined the incorporation of health - as an area of knowledge, training, research and service provision – by various universities. As far as Uni-CV is concerned, the range of training has been diversified with professional courses (Bio-diagnosis, Maintenance of Hospital and Hotel Equipment, Radiology), undergraduate (Nursing, Psychology and Biological Sciences) and postgraduate (Medicine and Public health). In addition, scientific research projects in health were launched, as well as extension activities, aimed at the participation of professors in congresses and other international scientific events. If the need felt by the labor market for specialized professionals was evident, it was no less clear that the universities themselves had a shortage of qualified teachers to train them. Especially in graduate school (Martins, 2015; MSSS, 2005). For this reason, most of these trainings were and have been carried out in close partnership between the University of Cabo Verde and institutes from Portugal and Brazil. At first, the gain compared to the past consisted in bringing teachers instead of sending students. In addition to being cheaper, this solution had several advantages. From the outset, that of generating inter-university links, leading the Cabo Verdean university to join collaborative networks that, starting with teaching, continued to research and extension. The incorporation of foreign professors provided opportunities for knowledge transfer, gradually leading to the maturing of Uni-CV staff. This rewarding and empowering experience, it can be said, was only possible thanks to the financial and diplomatic support of organizations such as CAPES, in Brazil, the Science and Technology Foundation and the Calouste Gulbenkian Foundation, in Portugal, the Spanish Cooperation Agency and Cabildo de Tenerife, Spain. It is fair to acknowledge that if, gradually, the higher-level formative supply was emerging and growing in Cabo Verde, this is due in large part to international cooperation.

TRANSITIONS WITH REFLECTIONS ON PEOPLE'S HEALTH/WELL-BEING

Cabo Verdean society is currently undergoing a process of change. It features the simultaneity of transitions. Let us call up some of them, namely those that have more evident repercussions on the provision of health care, considering the One Health perspective. The data allow us to sustain that the country is

in the middle of the following transitions: political, demographic, epidemiological, nutritional, rural/urban way of life, just to mention these. Before characterizing them, even if summarily, we believe it is best to start by trying to make the concept of transition more complex. We do this because the word transition is used too often in a generic and evolutionary way, as if a certain epidemiological state, for example, followed another, but without conflicts, hesitations, reversals, and shocks, when the transition it is usually characterized by the overlap and coexistence of traits from different periods. In our view, this is a phase of History in which the "dialectic of the times" occurs, within which the persistence of old situations or diseases (infectious and parasitic) coincides with the appearance of new illnesses, in general chronic and non-transferable. The same can be said of the political or demographic transition.

The Political Transition

The political transition has a great weight in the management of social transformations and in the patterns of interaction between people and between them and the physical and social environment. It is marked by the overlapping of inherited habits and customs with emerging practices and ways of understanding brought about by new ideologies. With the proclamation of independence in 1975, Cabo Verde began the transition from a colonial regime, with specific features typical of that phase – such as widespread illiteracy, worrying health rates, poorly developed living conditions, poor physical environment, cyclical droughts with famines and deaths, remnants of relations based on slavery – for a nationalist regime, 'ideally' of freedom, committed to launching social, cultural and economic bases to fight hunger, overcome uncertainty and social exclusion. Later, in 1991, the implementation of multiparty democracy gave way to a new process of accelerated change, marked by pluralism and competition. Press, union, party, and business pluralism starts to coexist with attitudes and postures of the previous period, characterized by greater directism and central planning. The liberal culture based on the idea of the "health market" coexists, albeit in an inadequate way, with the expectations of a provider and protector State, more in line with the previous political model. At each electoral cycle the layer overlaps are highlighted. A clear example is how the approaches to issues linked to the health-disease binomial balance, in their interpretation, in the equation of fundamentals and in the choice of solutions.

It is important to emphasize the importance of characterizing the terms and rhythms of the demographic transition in Cabo Verde and trying to scrutinize how this has changed the health profile of society and, consequently, created new challenges for organizations and health professionals. The demographic regime of the former Cabo Verdean society was characterized by a high birth rate, driving significant population growth rates, despite the general mortality level, with special emphasis on an important infant and general mortality and the weight of emigration. However, famines, caused by the frequent droughts typical of the Sahel region, canceled out the accumulated population balances. This has been the case since 1583. See the works of António Carreira, Eduíno Brito and Ilídio do Amaral in this regard (Amaral, 1991; Carreira, 1984).

This demographic regime closed its life cycle in 1950, since from that date onwards, droughts stopped generating massive mortality, with a significant impact on the causes of death, and population growth became uninterrupted from then on. Then came the first phase of the demographic transition, marked by the persistence of high birth rates and the trend decline in general mortality and particularly in infant mortality. Vaccination campaigns carried out in the last phase of the colonial period and then, more intensely, after national independence – when maternal and child protection actions gained intensity – led to an acceleration of the population growth rate in subsequent decades (Delgado, 2009; Varela, 2014). We

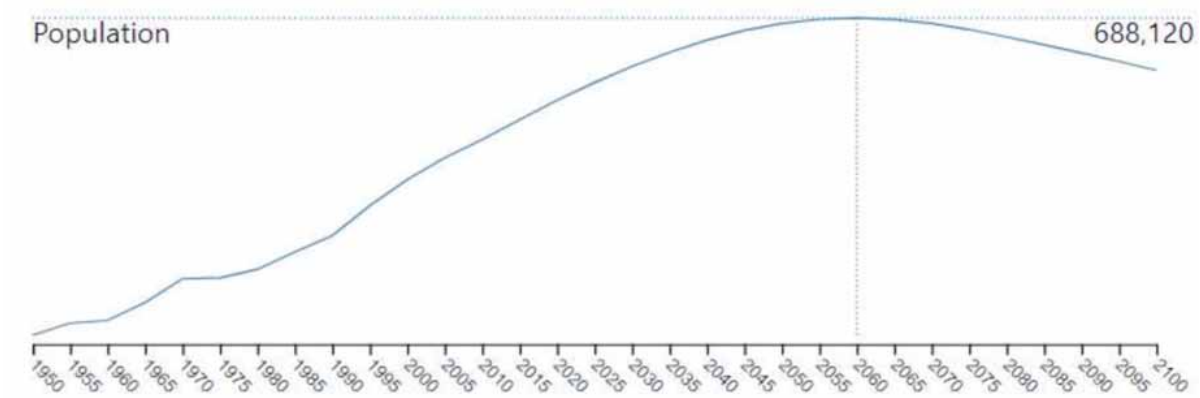
then entered the demographic bonus period, in which fertility per woman began to show signs of slowing down, the number of young people increased significantly – because of the high birth rate and low infant mortality of the previous period –, being that of people elderly women still little expressive, although with a tendency to grow in later times. In recent years, already in this century, the historical trend started in 1950 has deepened, along with the emergence of new phenomena. Overall mortality dropped from 5.6 deaths per 1,000 inhabitants in 2000 to 4.8 in 2010, and infant mortality went from 26.2 per 1,000 live births to 20.1 on the same dates. The maternal mortality rate from causes related to pregnancy and childbirth also showed a downward trend, which allowed the country to be among the nine countries that managed to achieve, in 2015, the goal of the Millennium Development Goals/ MDG regarding under-five mortality and maternal mortality (Alkema et al., 2016). In addition, fertility per woman showed a significant reduction trend and life expectancy experienced a strong increase. This phase is usually seen as a window of opportunity for economic policies and health systems. Called a demographic bonus, it is characterized by an increase in the weight of potentially active age groups in terms of employment and an expansion of the stock of those who will reach older ages. This is evidenced by the study of the configuration of the age pyramid, highlighting the evolution of various parameters on the situation and dynamics of the population, how it grows, how it is distributed, the rate of aging, fertility, and mortality rates, allows us to know the composition of groups, important information to anticipate needs, plan future solutions and plan interventions with the population. Looking together at the age pyramids for the decades between 2010 and 2060, taken from the world site www.populationpyramide.net, it is important to note the changes that have occurred or predicted in the structure by age groups of the Cabo Verdean population in the half-century under study (2010-2060) (Delgado & Fortes, 2020).

Demographic Transition

The variations in the structure of the population of Cabo Verde are accentuated, highlighting three important aspects: (i) the gradual and constant narrowing of the base of the pyramids resulting from the decrease in births, year by year. This finding is explained to the gradual improvement of the living and health conditions of households by the application of public policies, which have influenced the health of children and women. Furthermore, they began to have better access to family planning and other primary health care and consequent decrease in deaths among children; ii) the expansion of the apex of the pyramid, by increasing longevity and improving health care for people who reach older ages and iii) the moderate robustness of the working population in the age groups between 20 and 64 years, which tends to grow, bringing the percentage differences between the bands (INE, 1983, 2011).

Overall, projections of Population Pyramids of the World from 1950 to 2100 (PopulationPyramid.net, 2020) indicate that Cabo Verde's population grew just over 11% between 2010 and 2020, will grow by around 9% between 2020 and 2030 and close to 24% from 2030 to 2060, when it reaches the expected peak of the population, close to 690 thousand people (Figure 1), with the current pattern of population development. In this circumstance, a new transition is expected, a reversal of the growth rate, with the population decreasing, as is expected in other parts of the world.

Figure 1. Cabo Verde - population evolution between 1950 and 2100
Source: www.populationpyramide.net, accessed on 28/06/2021



Fonte: Population Pyramids of the World from 1950 to 2100
www.populationPyramid.net

As shown in Table 1, between 2010 and 2060, it is expected to accentuate the pattern of reduction of younger age groups, by half in the 0–4-year group, and about one third in under 20 years of age; and for adults of active age, from 20 to 64 years of age, this reduction is less pronounced

Table 1. Population (%) by age groups between 2010 and 2060

Age groups	2010	2020	2030	2060
Children (0-4 Years)	10,6%	9,3%	7,5%	5,3%
Young Adolescents <20 Years Old	33,7%	36,7%	32,0%	22,4%
Adults Between 20 and 64 Years Old	50,3%	58,5%	60,8%	56,9%
Adults [3] 65 years old	5,4%	4,8%	7,2%	20,7%

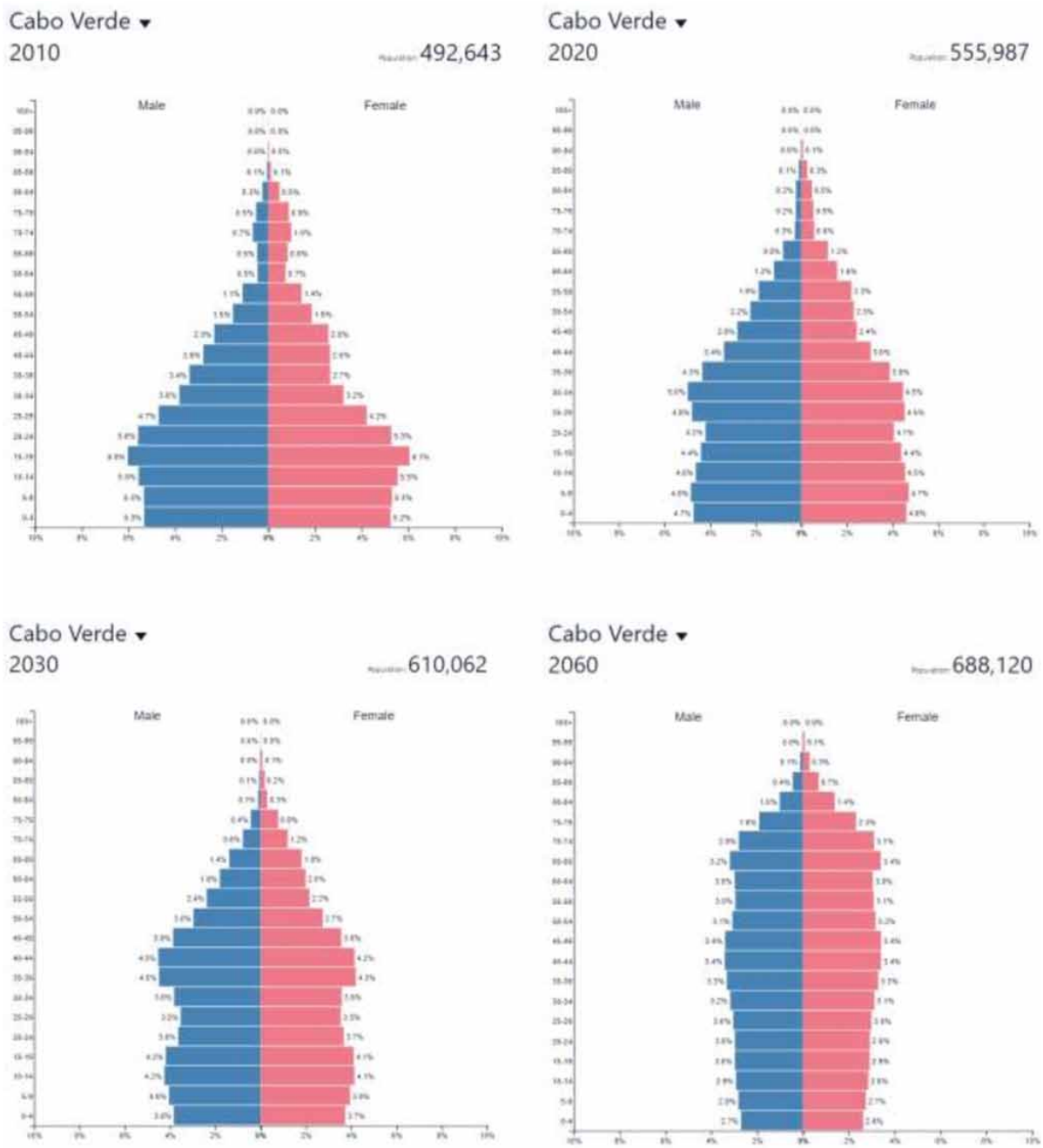
Source: www.populationpyramide.net, access on 05/19/2021.

The big change in the age structure will be in the universe of the older people, aged 65 or over, whose percentage will increase one and a half times between 2020 and 2030 and will be close to being four times more, in 2060 (Figure 2).

Therefore, there is a clear trend towards an aging population and a retraction in the number of young people. These demographic changes must demand close attention from planners, managers, and health professionals, because they will translate into problems that require specialized and innovative solutions. The increase in the average age of the population will make new needs appear and will change the type of care to be provided. Changes in the demographic profile, combined with the tendency to make the country a residential tourism destination, creating a permanent floating population (health tourism) in

it, will be relevant factors in the reconfiguration of the National Health System (NHS) in the medium and long term.

Figure 2. Cabo Verde - comparison of the population pyramid of 2010, 2020, 2030 and 2060
Source: Population Pyramids of the World from 1950 to 2100 PopulationPyramid.net



Source: Population Pyramids of the World from 1950 to 2100 www.populationPyramid.net

In this context, an incident and well-structured health promotion policy is important, capable of mobilizing people to create healthy lifestyles, avoiding chronic diseases that derive from behaviors and ways of life. Alcoholism, unbalanced diet, smoking, risky sexual behavior, sedentary lifestyle, among other behavioral deviations, will tend to be increasingly erected as combat targets by the authorities in their efforts to reach new levels of health (Gonçalves et al., 2015). The issue of healthy and active aging then becomes a topic of growing importance in public health. The initial gain from increased life expectancy will henceforth be seen as a necessary, but not sufficient, condition for collective well-being. Long life is not enough. Also, because we could be facing a dilemma in which lifestyle changes - such as an unbalanced diet, lack of physical activity/sedentary lifestyle, smoking, obesity and harmful alcohol consumption, and the increase in non-communicable diseases (NCDs) - would compromise gains achieved with the reduction of infectious diseases, and, consequently, with the increase in life expectancy and the aging of the population. Ultimately, the elderly (mainly, but not only) would be deprived of well-being (health), work capacity and wealth generation, and, on the other hand, with the increase in health care costs. The physical, psychological, and social quality of aging becomes the goal to be pursued. Achieving this goal will require greater investment in "education and communication for health", with a view to creating "health citizenship", in which the user, who owns his/her own health, should at least be a partner of health professionals. The relationship between the two will be based on co-responsibility. Likewise, it will be necessary to resort to the One Health approach, since ensuring healthy eating, for example, will involve integrating quality food production practices into the concept of health. The question of the use of pesticides in agriculture, as well as the control of phytosanitary threats resulting from the importation of plants, will become relevant for the Cabo Verdean health authorities.

Epidemiological Transition

Cabo Verde is supposed to be in an epidemiological transition. That is, moving from a period in which infectious, contagious and parasitic diseases were dominant, to another period in which the main causes of death and morbidity became chronic non-communicable or degenerative diseases, resulting from ways of life unhealthy, requiring a different set of public interventions, particularly in the rethinking of human resources.

In fact, the epidemiological transition may represent for countries with the profile of Cabo Verde the "double or multiple burden", that is the coexistence of two profiles of diseases, namely: chronic, degenerative and non-communicable aggravated by inadequate environmental, climatic and social development conditions, which deepen the state of well-being, with the persistence and reemergence of diseases previously eradicated or almost, such as malaria, for example, or else, with the emerging diseases, such as recent viral infections, constituting an increased challenge for fragile health systems.

Meanwhile, the socio-economic transition revolves around the unbalanced development of people's living conditions and the consequent mobility of the population towards economic development poles, in search of better opportunities on the islands with a greater tourist inclination (Sal, Boa Vista, S. Vicente) and in the country's capital. Such mobility causes, on the one hand, the depopulation of some municipalities, especially their population of working age, and, on the other, it generates improvised neighborhoods, peripheral to the cities, with social and physical environments without the minimum conditions of quality of life and which are recognized as important determinants of poor health, a reality that fits the pattern of 'rapid urbanization' on the African continent. (Abrahams et al., 2011; Craveiro et al., 2016). Cabo Verde follows the trend. Urban characteristics vary widely between cities

and within the same city the formal part (organised, planned, with infrastructure) coexists with that of informal settlements (unauthorised, unplanned, without infrastructure). All of this creates and reflects socioeconomic and cultural inequality, which affects its residents' health and disease patterns (Vlahov et al., 2007). These conditions, in turn, are normally associated with dietary change, energy-dense diets and nutritional imbalance, accompanied by changes in physical activity patterns (Craveiro et al., 2016).

These changes usually happen quickly, sometimes silently, and cause new problems or exacerbation of existing ones in the social context, resulting in the need for new balances with approaches adapted to new patterns (Delgado, 2018).

The expansion of the urbanization process, the massification of basic and secondary education, the rapid increase in demands, whether for health for all, permanent care, quality of life, access to water, or the emergence of the need for the one health approach, such as saline intrusion in agricultural soils, the use of pesticides in agriculture, ocean acidification. they constitute challenges and pressures on health systems and lead to the reconfiguration of the profile of professionals, the most important resource for people's well-being.

The shift from the focus of providing care to individuals and the disease to that of "people-centered care" - considered as the individual with their own needs, in interaction with the family and the community in their environment - requires additional training, with implications in the educational process. "People-centered care" may well be the disruptive force that transforms our thinking about the education of newly graduated health professionals and the training or ongoing professional development of those already in work. The disruptive effect arises because people-centered care, supported by technology, increases the complexity of service delivery – yet another challenge for health systems that already face low productivity growth and high levels of inefficiency (OECD, 2017).

The adoption of automation has been relatively slow due to difficulties in meeting technology compliance standards and human resources capabilities. Furthermore, with the transfer of tasks to machines, human workers will need to be reconverted to focus on "reflective practice" – empathic and creative approaches – and on harnessing the benefits of automation while mitigating its negative effects. Thus, the transformation of education and training systems will be a complex and continuous process, framed in four themes: (1) taking advantage of digital technology and automation in education and training; (2) Integrate human-centered design into education and training; (3) facilitate interprofessional collaboration and multidisciplinary education and (4) sustain lifelong learning and flexible progression in care (Fronteira et al., 2020).

When discussing these issues, it is assumed that there will be a complex interaction of responsibility between regulators, accreditation bodies, training institutions, government ministries and professional organizations, requiring an explicit commitment to the harmonization of objectives, coordination of plans, special consideration for practices innovative solutions and agreed accountability roles. It is expected to reach the profile of health professionals with the following skills and abilities: transdisciplinarity; leadership; communication skills; ability to problematize, competence to deal with unpredictability. To acquire these skills, it is imperative to demand and prepare: i) an appropriate teaching class, ii) teaching/learning methods that encourage attitudes of autonomy, leadership, communication, inquiry and investigation; iii) curriculum adjusted to new challenge.

HEALTH TRAINING: WHAT PEDAGOGICAL MODEL?

The profound changes underway in local and global society call for a new skill profile for health professionals.

Even though it is not easy to determine quantitatively and qualitatively the scale of the gap between society's demands in relation to the competences of health professionals and the competences currently held by them, the fact is that this deficit is clearly noticeable by the various sectors involved in the process. That is, both for those who are on the side of the provision of care, as for those who are provided. In fact, the need for a new profile has become consensual. However, the gap can only be overcome, with a clear benefit for everyone, if, in the first place, it is seen as a problem to be resolved. A critical moment in its resolution is, therefore, when dissatisfactions generate awareness and drive diagnoses. Secondly, awareness of the deficit of knowledge and attitudes needs to be converted and inspire plans and processes to respond and overcome the status quo.

However, there is no more efficient way to provide health professionals with new skills, adapting them to the challenges of the present, than through training, because in this place, it is possible to identify the existing deficit and prepare the overcoming process. It is also desirable to complement the process of change at the training level with the establishment of new rules that regulate professional activity within the various organizations that provide healthcare to society, because there is little point in training professionals with new values and attitudes if then, in the world of work, will not be able to put them into practice. In these cases, at least in part, the training investment may be lost. Without prejudice to this necessary complementarity, our focus is on acquiring new skills in the training process.

Changes lead training institutions to ask themselves what the critical skills are professional needs to perform well and how to pass them on to their trainees. In other words, they ask the following question: what knowledge, attitudes and values allow students, as future professionals, to understand and act in a world with the demands of "One Health", Global Health and Health for All? And then, they ask what didactic and pedagogical strategies and resources they should use so that, at the end of the training process, students incorporate such skills and competences. These issues only become operational if approached analytically and by dimensions. In search of answers, educational institutions find themselves in the need to critically assess their training offers.

Current trends in science and new directions in global health research require staff with improved vision, maturity and capacity for strategic planning. Aware of this need to strengthen and improve knowledge, it is essential to rethink the pedagogical model in force in the training of health professionals and envisage new training approaches that respond to the demands and needs of the new social, economic, cultural, and global structure. New health professionals are required to commit to current changes and transitions and be able to recognize and adapt without losing awareness of the unity of life and nature.

The University is a privileged space for the development of a more integral, fair and sustainable society. Its essential functions are: to train professionals; offer advanced level education; carry out studies, researches and scientific investigation aimed at development and function as a social institution (Guimarães & Silva, 2010). The three pillars that underpin the university are Teaching, Extension and Research. However, the predominant institutionalized sectorization and disciplinarization has halted transdisciplinarity in its training process, and consequently a real integration of knowledge, that is, a universality in the University

Just as Public Health integrates the environment, biology and society, we understand that health education should be guided by equal integration, allowing health education (biology) to communicate

with the environment and the social sciences. The integration of knowledge and communication skills are essential not only to guarantee a solid scientific training, but also to improve interpersonal relationships in the work environment, to encourage teamwork and consequently to improve quality, reduce costs and customer experience.

The University as a training institution has a crucial role in the training of these new professionals, and in the centrality of communication in the exercise of the profession and in health promotion. The training of health professionals with communication and leadership skills seems to be the path to greater autonomy, empowerment, trust and responsibility on both sides, concomitantly generating greater empathy, dialogue, participation and satisfaction. The capacity for negotiation and decision-making is reinforced, as well as the commitment to establish a society engaged in the management and leadership of positively transforming public health programs, based on the interface of innovation, health, management, and social organization, and on dialogue, with to improve health systems from a Global Health perspective.

Training and research, in the short, medium, and long term, can stimulate the development of critical and innovative thinking, necessary for the generation of professionals and leaders who support their practices in knowledge that result in improving the health of the population. It is necessary to rethink the training and assessment models, the concepts of quality and success, often based on individualistic models, which exacerbate the cult of individualism. We must think about the collective, teamwork and integrated and integrative responses. And communication between different types of knowledge seems to be the key to a more integrated and global society. This perspective of a holistic, integrative, and transdisciplinary training contributes to a greater awareness of the social, governmental and political responsibility of those involved, both at local, regional and global levels. Health service delivery institutions will be strengthened and more integrated, with the capacity to predict and manage situations of public calamity, focusing on the integrity of populations.

The COVID-19 pandemic introduced humanity to the "real globalization" and how countries and communities are interdependent despite economic, political, social, environmental, cultural differences, among others. The panic that hovered and still hovers over institutions and governments should make us reflect on the new challenges posed by the pandemic, especially regarding the training of health professionals and their ability to communicate and manage chaos.

To what extent have our academic institutions prepared professionals to face and manage unpredictable situations, catastrophes, epidemics, and pandemics? How to integrate social and knowledge mobilization mechanisms and institutions in these situations? What tools and skills in communication and crisis communication? What spaces for communication, sharing and practices exist during the initial training process?

The materials brought by the One Health concept reflect the understanding that human health is determined, whether in interaction with many factors related to the world of other animals, the environment and the planet, or the interdependence between the countries of world, which propose a planetary look at fundamental health issues, and join the challenges of small and island countries, particularly in the management of human resources in health, to give more emphasis to the relevance and scope of specific preparation solutions, organization and management of health professionals. The ambition, in these cases, will be to trigger, with priority and importance, deep and calm reflections on the world concepts that are accentuated as interdisciplinarity and/or transdisciplinarity and to study how the lessons learned can influence their practical application and facilitate the resolution complex issues in a small country, in a globalized world. A country like Cabo Verde with half a million inhabitants, in which in the public university, there is a context of training of several health professionals, and which advocates

health work teams as the best way to respond, with criterion, to the growing needs of its population and planetary experience, seems prudent, although bold, propose to study, together, the creation of a transversal and common process to the initial training of the various types of health professionals, ongoing, from conceptualization and consensus building, the study of its assembly, awareness and implementation. This process can be materialized through the creation and statement of an institution that analyses the cross-cutting foundations of health sciences, organized in a "School" of health sciences.

It is intended to build a vision and a practice similar and common to all types of professionals involved, enhancing the positive effects and gains from each of the branches of health sciences included and sustaining the spirit and practice of teamwork, increasingly fundamental in health actions.

This effort will go towards harmonizing basic human health education, towards epistemological sustainability, reaching and maintaining a high level of knowledge and skills. The aim is to train human resources with a broad view of health, from causes, risk factors, individual and collective behavior, to all determinants, but also knowledgeable about pathologies, diagnosis, follow-up and therapies, losses avoidable and non-avoidable, used to working in a team, interacting with peers and in a transdisciplinary way, knowledge and attitudes that are essential for the necessary leap in quality to raise the level of health development.

It seems clear to us that Cabo Verdean training institutions need to extend their training offers to new areas of knowledge, considering the One Health concept, the training of all types of professionals needs to be, fundamentally to enable them to interact and communicate with the "people's health" in a holistic way, in all aspects of promotion, prevention, treatment, rehabilitation and provision of palliative care and not just treating the disease. It is imperative that the organic units of universities focused on health explore the interfaces with agricultural and environmental sciences, with information and communication technologies (ICTs) and social sciences, enriching existing courses and proposing new ones. Topics such as phytosanitary protection, rural and urban sanitation, sanitary engineering, nutrition, biomedicine, human motor skills, bioinformatics, biosafety, molecular biology and others will enrich the offer, alongside more classical training such as physiotherapy, medicine, nursing and clinical analysis, among others. An immediate gain from this posture is to overcome the current state of narrowing of demand, which is excessively concentrated in a few courses, such as nursing, medicine, clinical analysis, and physiotherapy. In this sense, the offer of training in health that currently exists represents a bottleneck. The main objective of this expansion is to make the range of professionals necessary for an approach that is not only focused on the individual and the fight against the disease but understands health as a state of well-being and security, with human, animal and environmental, individual, community and collective, as well as local, regional and global. This also requires a profound transformation of the academic environment in which training takes place, a transformation that tends to include the very mission of health schools, departments, or faculties.

With these reflections, we can follow paths to consolidate an innovative education process, with a common basis for the health sciences and to influence the training of other professionals in related fields, linked to the social determinants of health, who are convinced of the relevance of this start together, to reinforce a salutogenic approach. The essential aspiration for this School will be to serve as a place for the development of basic subjects related to the human, animal and environmental person and organized in common, completing the first cycle, then following each course, independently of its technical branch, but preferably still under the coordination of the school.

The institutionalization of a School is materialized, above all, through the creation of a model with principles and values more in line with vision of the One Health, with precepts and rules, to perpetu-

ate an educational process, with a common trunk transversal to the professions of and contribute to the paradigm shift in integrated responses to the gaps in the health system, through the improvement of training and qualification of human resources in health (RHS), the interaction between professional groups, the development in health institutions, a humanized organization and practice to produce and provide health care to people, considering the balance of their relationship and interaction with the animal and environmental world.

Globally, it should be faced and framed in a broader process of investment in health (and in general development) that will translate into the increase, diversification, and qualification of human resources in health, with well-defined goals aimed at strengthening the National System Health (SNS) and the private sector, in favor of the health of the Cabo Verdean population, naturally seeking to safeguard the personal concerns of students and professionals.

With the evolution of human life and survival conditions, the epidemiological profile in rapid transition and the transformation of the surrounding conditions, the training of all types of professionals needs to be, fundamentally, to enable them to interact and communicate with the "people's health" in a holistic way, in all aspects of promotion, prevention, treatment, rehabilitation and provision of palliative care and not just treating the disease well, which occupies an important space in current training processes. Furthermore, the incorporation of education in aspects related to risk factors and health determinants is important for professionals to understand and pay attention to the influence of external conditions on health-disease processes.

A "School of Health Sciences" should also serve as a framework for relations with the various partner training institutions, national and international, taking advantage of the wealth of experiences that exist in each one, which will certainly help to overcome obstacles and find solutions adapted to the context of the country, namely the financial sustainability of health training in Cabo Verde and from a perspective of internationalization that should be a goal. This could also be a support for sustainability, due to the resulting economy of scale, but with an appreciable cost-benefit ratio. It will be necessary to prepare students, interns and professionals about awareness of the costs of health care and curbing the overuse or misuse of resources. Concomitantly, there should be a common action with the institutions providing health care to adapt to the innovations that are being introduced.

At the level of undergraduate courses, this call to diversify the offer, considering the small demand, implies a profound reorganization of courses. It is desirable that, given the existing affinities, that training at this level have common trunks, in which the objectives to be achieved are a solid knowledge of the basic sciences, the exercise of critical thinking and immersion experiences in extra-academic work contexts. The basic trunk creates the opportunity for the student to develop interdisciplinary thinking and for the university to share teaching and teaching resources. Intermediate and terminal cycles are for learning knowledge and attitudes in specific areas. It is important to overcome the opposition between theory and practice, being in several matters the adoption of the teaching method based on the problem, that is, the Problem Based Learning (PBL).

The training of health professionals must be carried out in an academic environment in which there is a link between teaching and research. In this case, it is essential to develop a robust graduate program, oriented towards the creation of knowledge in critical areas for increasing health security. In the absence of a graduate degree, there will not be the necessary specialization and qualification of skills. The advantages of investing in the development of this level of courses are wide and its structuring effects for Higher Education Institutions (HEIs). This level of education will force training institutions to seek greater international cooperation, as a means of transferring knowledge and translational research,

encourages them to equip themselves in terms of access to libraries and databases, and guides the training of students towards the questioning, reflection, problem solving, and the creation of new knowledge and its better application to contextual reality. It is possible that, because postgraduate studies have greater demands, small universities feel urged to organize themselves into consortia, putting infrastructure and teachers in common. Furthermore, through an internationalized postgraduate course, universities will have the opportunity to readjust their faculty and structure their lines of investigation.

For a long time, the traditional teaching model was imposed and accepted, based on the mere transmission of knowledge. However, due to multiple factors, such as the rapid increase in knowledge production, and the facility of access to a vast range of information, the teaching and learning process has come to represent an interaction between all actors. In this context, active methodologies have emerged as a proposal to direct the teaching and learning process in search of the active participation of all involved, focus on the reality in where they are inserted. For, the active teaching and learning methodologies, in which strong stimulus is given to the recognition of the problems of the current world, making students able to intervene and promote the necessary transformations.

The active methodology is an extensive process and has as its main characteristic the insertion of the student as the main agent responsible for their learning, committing to their learning (Morán, 2015). Therefore, the main characteristics of the teaching strategies guided by the active method are to have the student as the center of the process, the promotion of student autonomy, the position of the teacher as a mediator, activator and facilitator of the teaching and learning processes, and the encouragement of problematization of reality, as well as constant reflection and teamwork (Diesel et al., 2017).

One of the great advantages of this methodology is the placement of the student as the protagonist of his knowledge construction process, where he interacts with the subject under study instead of only receiving it passively from the teacher. Historically, professional training in health has been based on traditional teaching methods, based on a very technical training. However, in recent years there has been discussion about the effectiveness of this model in training professionals with a reflexive critical spirit, able to solve problems in their work context. Thus, several studies have discussed the use of active methodologies in the learning teaching process, in the context of professional health training (Cardarelli, 2017; Fini, 2018; Roman et al., 2017).

In higher education institutions, traditional teaching still prevails. In this context, their responsibility increases to promote the changes needed to form proactive professionals who can act in contemporary society and who are instruments of transformation in their reality. Thus, it is essential to incorporate innovative methodologies in Health Education to promote training directed to the needs of society and to emerge health professionals who mobilize intellectual, emotional, personal and communicational skills in their work.

Without a doubt, to form a health professional with a critical and reflective spirit, to be able to solve impasses in their professional environment and in society, there is a need for a training process that goes beyond the content and technical teaching. It is necessary to have a formative process that stimulates reflection, creativity, critical thinking, autonomy, and responsibility with continued learning, which is in line with the proposals of active methodologies. Although, the use of innovative methodologies does not exclude traditional methodology, both can even be successfully combined in the teaching learning process.

LOOKING AT HEALTH EDUCATION FROM A TRANSDISCIPLINARY PERSPECTIVE

Training is inherent to human existence, as, from a macro perspective, it contributes to the development of the profession and, at a micro level, to personal development. Therefore, when talking about health education, the first word that comes up is complexity. This word has been one of the most used to characterize the global landscape and the problems presented in it as: the demographic-epidemiological-socio-economic transitions combined with the marked difference between rich and poor, the phenomenon of globalization which, together with new communication technologies, shows the disparities between countries that make the global situation complex, insecure and fragmented.

The term transdisciplinarity is not easily characterized. Transdisciplinarity is about the innovation of working, in learning environments, two or more contents facing a single line of reasoning. It arises because of the advancement of knowledge and the challenge that globality poses for this century. Thus, going back a little in history, we realize that transdisciplinarity had its origin in the theorem of Gödel, author who, in 1931, proposed to distinguish several levels of reality, and not just one level, as understood by the dogma of classical logic. (Santos, 2008). To propose a definition of transdisciplinarity and its application to health, it was suggested that it be based on the possibility of communication between agents in each field and on the transit of the subjects of the discourses and not between disciplinary fields, and through the circulation of discourses. So, for a better understanding of this concept, we resorted to some references that deal with the subject.

In the early 1990s, the first World Congress on Transdisciplinarity took place, a space in which a kind of "protocol" was drawn up, with a set of fundamental principles, of transdisciplinary ideals, called the Charter of Transdisciplinarity. This document was systematized by Edgar Morin, Basarab Nicolescu and Lima de Freitas and states that transdisciplinarity does not seek the mastery of various disciplines, but the opening of all disciplines to what unites and surpasses them. The transdisciplinary vision is resolutely open insofar as it goes beyond the field of the exact sciences due to its dialogue and its reconciliation, not only with the human sciences, but also with art, literature, poetry and inner experience (Rodrigues, 2016).

If we are going to carry out the lexical decomposition that allows us to identify the meaning of words, in the transdisciplinary approach, the prefix "trans" defines what is at the same time "between" and "beyond" any discipline, bringing a deeper meaning of the same and global, so when it comes to health education focused on the person, this prefix "trans" helps us to understand the concept of global man, between and beyond any disciplinary categorization, a clearly more complex concept. To do so, it is necessary to transgress the limits of disciplinary approaches, to make possible the emergence of a new, broader and more general, integrative paradigm. Therefore, transdisciplinary education reassesses the role of intuition, imagination, sensitivity and the body in the transmission of knowledge.

In the context of health education, different concepts are usually used Transdisciplinary, Interdisciplinary and Multidisciplinary as if they were synonymous, which causes some confusion in their understanding and, therefore, Morin defines and differentiates these concepts as follows: interdisciplinarity, multidisciplinarity and transdisciplinarity, difficult to define because they are polysemic and imprecise (Morin, 2003). Interdisciplinarity can mean, quite simply, that different disciplines are placed around the same table, as different nations position themselves at the UN, without doing anything but asserting, each one of them, their own national rights and their own sovereignty in relation to the neighbor invasions. But interdisciplinarity can also mean exchange and cooperation, which makes interdisciplinarity something

organic. Multidisciplinarity, on the other hand, constitutes an association of disciplines, due to a project or an object that is common to them; the disciplines are now summoned as specialized technicians to solve this or that problem; on the contrary, they are in complete interaction to conceive this object and this project, as in the example of hominization. In the case of transdisciplinarity, it is often a question of cognitive schemes that can cross the disciplines, sometimes with such virulence, that they leave them in a trance (Rodrigues, 2016; Vaillant & Campos, 2017).

That said, we realize the complexity of all these concepts and the difficulty of understanding them, therefore, transdisciplinarity is the concept that best fits this perspective when addressing health education. However, it should not be perceived as an absolute that has an answer for everything. It offers us the possibility of elaborating a new mode of representation, better able to model the concept of global man and its challenges. Thus, we will employ the concept of transdisciplinarity that allows for an organized way of thinking that crosses different disciplines to become an integrated unit. That is, it allows us to consider a multidimensional reality, structured by multiple levels, rather than a single level, one-dimensional reality of classical thought. In this case, health would be like the central area, which transcends biology, which is interconnected with other knowledge such as communication, demography, management, sociology, politics and whatever else is needed.

In the scientific field, for Severo & Seminotti, complexity emphasizes interdisciplinarity and transdisciplinarity, understood as different possibilities of relationship between disciplines or beyond disciplines. While interdisciplinarity seeks to integrate different disciplines, understood as specific fields of scientific knowledge, transdisciplinarity seeks, in addition, to integrate scientific knowledge with other modes of knowledge production historically constructed by humanity, seeking a rigorous dialogue not only between exact and humanities, but also between science, art, culture, tradition, religion, inner experience and symbolic thinking (Severo & Seminotti, 2010).

Transdisciplinarity transforms our view of the individual, the cultural and the social, referring to a respectful and open reflection on the cultures of the present and the past, of the West and the East, seeking to contribute to the sustainability of human beings and society (Coll, et al., 2002). Therefore, transdisciplinarity can be perceived as something more than disciplines that talk to each other through common knowledge, it is a way of thinking about contents, giving them a complementary unity, an integrating element.

Currently in the scientific context we have been experiencing a flood of knowledge production, and with it brought many challenges related to fragmented thinking, mainly due to the proliferation of knowledge, which is rapidly changing and is divided into isolated areas, a phenomenon known as "disciplinarity" according to Vilela & Mendes (Vilela & Mendes, 2003). This complexity experienced nowadays has been a driving force for actors involved in this field to play an active role in this process of unification between the disciplines. However, the complexity of health education requires a more integrated approach and for this we will have to remove "disciplinarity" and use transdisciplinarity as a starting point.

The notion of multiprofessional education is not new, but the way it should be delivered is. Experience has taught educators that the mere act of sitting students side by side in a classroom does nothing to improve interprofessional relationships, cultivate understanding, or promote mutual respect between professions (Severo & Seminotti, 2010). And without a doubt it will be a great challenge in the educational environment, which will require different teaching approaches from the educator to overcome it.

The development of transdisciplinarity provides an understanding of the interrelationship between professional areas with all their complexity and plurality. Therefore, it is imperative that transdisciplinary

education begins in training, creating an environment in which trainees can develop appropriate attitudes to allow collaboration to flourish later in the professional world.

The higher education system exerts a great influence on society, in all its aspects, while it is influenced and determined by historical and social conditions. Its strategic position in the development of countries does not result only from technological innovation processes, production and dissemination of science and culture, but especially from its impacts on the training and qualification of the workforce (Leonello et al., 2011). Therefore, it is indisputable that one of the biggest current challenges in Higher Education is the commitment to training qualified professionals through innovative training proposals capable of responding to current demands, many of them caused by the complexity of the globalized world and the need for a new way of analyzing knowledge, in favor of changes in the quality of professional training.

In the search for these changes in the education system, a reformulation is required to adapt to the current needs imposed by society, both in the sense of meeting social demands and the need to rethink and adapt professional training to the new social context that presents itself. In this sense, the required innovations emerge from the need to go beyond the traditional boundaries of teaching disciplines (Mainzer, 2011). In this way, it seeks to promote new teaching methodologies in Higher Education, which help the integration of knowledge from the various professions through actions organized to promote qualified initial training, as well as its respective impact on society. And as the University, a privileged place for knowledge production, it will have the responsibility to respond to these changes by creating a more flexible and innovative workforce, through the implementation of planned and organized educational actions.

For the training of health professionals, this movement of renewal and change is essential, and the conception of transdisciplinary teaching and education for transdisciplinary professional practice in health constitutes a global movement (Lavin et al., 2001).

There are many realities when it comes to health training, because of global multiplicity and the investment that each nation has made in this area. However, it is important to recognize that health education has made incredibly significant qualitative leaps, especially in recent years and Cabo Verde is no exception. However, the concern with training is not only verified at the level of initial training, as can be seen by the plethora of training offers in health, which demonstrates the concern with having qualified professionals.

Therefore, an efficient educational system will be able to provide quality education in a transdisciplinary perspective, providing an understanding of the interrelationship of different professional areas with all their complexity and plurality. Since transdisciplinarity maximizes learning by working with images and concepts that jointly mobilize the mental, emotional, and bodily dimensions, weaving both horizontal and vertical relationships of knowledge.

FINAL CONSIDERATIONS

The evolution of education, worldwide, tends to move away from the directive perspective towards a more reflective education, moving from a biomedical paradigm to the holistic paradigm, stimulating the scientific spirit and reflective thinking and allowing to train subjects with competence to promote social development, in addition to promoting the development of autonomy.

The relevant peculiarities in small and island countries such as Cabo Verde, highlight the particularities and give extreme importance to the context in which the educational process takes place, with specific milestones conditioning the course of the evolution of education and other aspects essential to the lives

of people who, in a perspective of change, require wit, knowledge and ambition to carry forward the process of training health professionals.

It seems clear to us that Cabo Verdean institutions need to extend their formative offerings to new areas of knowledge, considering the "One Health" approach. It is imperative that the organic units of health-facing universities explore interfaces with agrarian and environmental sciences, with information and communication technologies (ICT's) and social sciences, enriching existing courses and proposing new ones. The complexity in this form of teaching consists of construction, which is impregnated by exchanges and articulations between the different professions (Mendes et al., 2008). From this perspective, transdisciplinarity goes beyond a juxtaposition or sum of different knowledge, in this sense, it must occur based on communication between subjects and interactions with each other.

In the scientific sphere, transdisciplinarity is a current and well-worked issue. It is conceptualized to structure and organize a greater amount of comprehensive knowledge, facilitating the understanding of multiple causes that affect a given reality (Fortes, 2009). In this perspective, it is observed the importance of this concept to be present in health teams, as a factor of unification of the way of seeing users in a holistic perspective, where knowledge complements and facilitates the performance of others. Thus, transdisciplinarity becomes the key to the decentralization of the biomedical model, and the strengthening of the holistic view.

It is inevitable, therefore, that academia does not question how to promote transdisciplinarity in health education. It is believed that there are several strategies and paths to do so, however, one of ways to instigate and develop transdisciplinary practice is to exercise it in the academy itself, with integration between several courses in the health area and not only, which in the future will form the class of health science workers. Only after academics, in particular Cabo Verdeans, to understand the importance of this integration for the user and the community, and adapt the communication channels to this importance, it will it be more likely to incorporate the technique of transdisciplinarity into professional life and become better able to provide themselves with the tools and mastery to think and practice health differently, focusing on training models of Cabo Verdean health professionals with an analytical perspective, incorporating the essential renewal movement and change of which Lavin speaks (Lavin et al., 2001)

However, there is no more efficient way to provide health professionals with new skills, to suit them to the challenges of the present, than through training, because in this place, one can identify the existing deficit and prepare the process of overcoming it. It is also desirable to complement the process of change at the level of training with the establishment of new rules governing professional activity within the various organizations that provide health to society, because it is not much use to train professionals with new values and attitudes if, later, in the world of work, they will not be able to put them into practice.

The health professional must adapt to reality and be prepared to lead and deal with the changes faced by the health sector, being essential the performance of universities in this context, providing students with collaborative work between sectors, seeking to replace a fragmentary conception of scientific knowledge through a unified conception. However, there are many weaknesses pointed out and the challenges to be overcome for transdisciplinary education in the health area, since traditional defragmented and disjointed teaching is still strongly present in current education.

Therefore, health training is expected to obtain competencies that come from a theoretical-practical training process that works as an instrument of personal and professional development. That is, a process of individual transformation that reaches the dimension of knowledge (knowledge), know-how (capacities) and know-how (attitudes). Globally, it should be faced and framed in a broader process of investment in health (and in general development) that will translate into the increase, diversification, and qualifica-

tion of human resources in health, with well-defined goals aimed at strengthening the National System Health (SNS) and the private sector.

This process, from a progressive perspective, must begin with the trainers themselves to be aware that teaching, rather than transferring knowledge, is to facilitate the trainee to create the possibilities for his own production or construction, in the assertion of Paulo Freire (Freire, 2006). It is perceived as essential that the teacher knows several methods, their functions, objectives and applicability, to combine strategies that promote active students (Colares & Oliveira, 2018). Therefore, the concept of transdisciplinarity helps professionals involved in the growth and development of their knowledge, and consequently improve the praxis existing practices in the teams.

Therefore, also in Cabo Verde, with a view to making an educational system more efficient, it will be necessary to reform the existing one to provide quality education in a transdisciplinary perspective, providing an understanding of the interrelation of the different professional areas with all its complexity and plurality. With these reflections, we can follow paths to consolidate an innovative education process, with a common basis for the health sciences and to influence the training of other professionals in related fields, to reinforce a salutogenic approach.

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Chapter 16
Happiness as an Expression of Health: A Dialogue Between Law and Psychoanalysis

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ABSTRACT

Health gained a global prominence and became a right declared by the World Health Organization in 1948. In the 21st century, it is understood as a complete well-being of the individual, far beyond the absence of disease. In this context, the right to happiness translates as an expression of the aspirations for the realization of the right to health. Thus, this chapter aims to understand, in the light of the Freudian perspective, the aspects of soul life that lead the individual to the exhausting task of seeking happiness and seeks to reflect the possible contributions that legal science can offer to the improvement of individual well-being as a right health in the context of global health. Freud's theories about the formation of the psychic apparatus, his conception of malaise caused by culture and legal interventions that can possibly contribute to the reduction of individual unhappiness are presented.

INTRODUCTION

When looking at history, it is possible to see that the theme of happiness or well-being[1] it occupies a notorious centrality in man's life since time immemorial. In this sense, by agreeing with Aristotle that the pursuit of happiness is the end of human actions (Aristóteles & Flores, 2021), it must also be agreed

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that the normative purpose does not find another predicate. The rights to freedom, self-determination and dignity expressed in the Universal Declaration of Human Rights (United Nations, 1948), they must aim at the subject's own happiness even if in the final analysis of the semantic-normative sense.

From another perspective, when thinking about happiness in the context of global health, it is observed that many authors have called the phenomenon inserted in the phenomenon of globalization. It is noticed in different forms, but which, recurrently, evoke the adjective global in their theories, such as: global system, global culture, global process, and global health. This semantics unfolds at the end of the 20th century and promises, as an inexorable destiny, to definitively establish itself in the 21st century. a new paradigm in the international health and political arena (Matta & Moreno, 2014). Thus, the globalization process is the engine of the evolution of the term "Global Health" and, in recent years, as "One Health". This fact brings challenges and opportunities in the field of health as well as the individual's well-being (Fortes & Ribeiro, 2014).

In this evolution of society, the human being intensifies the search for well-being or happiness, and this permeates the broader state of health. Health is now considered a sphere of life for men and women in all their diversity and uniqueness. The process of transforming society is also the process of transforming health and the psychological and health problems that exist in it (Allen et al., 2007; Jong & Jackson, 2001; Minayo et al., 2000). The concept of health in the 21st century is a health ecosystem that promotes the well-being (happiness) of the individual and society as a "unique health". One health is concerned with an entire ecosystem, including the sustainable development of human beings, animals, ecology, and the broader social dimensions, in a mutualism of health and well-being of the individual and the environment in which they live (Zinsstag et al., 2011). Therefore, the most important thing is to take care of life so that the individual is happy and that the vulnerability of falling ill and the chances that the subject is a producer of incapacity, chronic suffering and premature death of individuals and population are reduced (Minayo et al., 2000).

Scientific studies in the health area about happiness or subjective well-being gained momentum with the advent of Positive Psychology, notably from the 1990s, which proposed a significant change in focus: from the repair negative aspects and from diseases to health promotion from the positive aspects of the human being (Camalionte & Boccalandro, 2017a).

From this, when science and the State join efforts to transform the knowledge generated into public policies that favor the promotion of individual health, it is possible to glimpse a gain in the population's quality of life, translated as well-being, or in other terms: happiness itself (Camalionte & Boccalandro, 2017b).

Happiness could be defined as the predominance of the frequency of occurrence of positive emotional experiences over negative ones (Scorsolini-Comin, 2010) and be subdivided into two dimensions: objective well-being (welfare), which encompasses the objective circumstances of life (income, education, health, leisure, transportation, among other domains) and subjective well-being, explained by subjective life experiences (Pereira, 1997).

In this subjectivity, it is necessary to question what happiness is. Is it possible to reach it? Can Law, especially Human Rights, contribute to its reach? Is happiness, as a state legislative commitment, a path to success that can be achieved through public actions?

To answer these and other questions as well as identify possible factors that contribute to the failure of the goal of happiness with normative support, a dialogue between psychoanalysis and Law is proposed as a contribution to the individual's health status.

From this, the construction of arguments that defend the norm as a true instrument of mitigation of socially imposed sacrifices for the development of happiness are added to the objectives. It is intended to present possible solutions for reversing the process of legal-social repression.

Nevertheless, the chapter promotes an understanding of how important health assessment is in a broader context and how the management of this information is decisive for the planning, management, and implementation of the Global Health concept for One Health. This includes contributing to the discussion in academic circles, that the happiness as an expression of health, permeates in including non-discrimination, equality, security, and cooperation make up, etc.). This new way of thinking involves psychology, Law and One Health's Relationship.

Regarding the kind of methodological study carried out, it is characterized as exploratory, descriptive, and explanatory. Exploratory in the sense of becoming familiar with the phenomenon of happiness as an expression of health and, in turn, how the Law can mitigate the individual's discomfort in the point of Freud's psychoanalytical view. Descriptive in that it aims to describe the characteristics of the Freudian vision for a population's happiness and, finally, explanatory in that it deepens the knowledge of Freud's concept of happiness and dialogues with the Law to assist in achieving happiness as one of the expressions of health.

HEALTH AND WELL-BEING AS A RIGHT

The Pursuit of Happiness is not New

When observing the domestication of fire, the construction and development of tools, from the most archaic to the most modern, as well as the achievement of science and art can serve as examples of some initial efforts undertaken by man to improve his own earthly condition (Freud, 1930), besides contributing to the argument that the theme of happiness occupies a prominent place in man's life since time immemorial.

In this context of seeking happiness as a goal added to the imperatives of the modern world, it is noted that individuals have incorporated new and successive needs into their lifestyles. The effect of this behavior can be extracted from the capitalist system itself that dominates most of the world. In this context, two consequences can be seen: the first is that, always faced with a new consumer demand, happiness can be postponed until the conquest of the new good or service is satisfied. The second concerns the quantification of happiness as a parameter for success. Since the economic measurement of happiness is difficult to achieve, determining how happy one can be is susceptible to severe errors. Despite this, there are already institutional mechanisms that seek to define the development of a society based on the precepts by which its conception is understood (*World Happiness Report 2020*, 2021.; *Constitution of Bhutan*, 2008.)[2].

Although it is said that measuring happiness is difficult to assert, it is not intended to criticize or repress the use of mechanisms that contribute to its achievement, since any effort to guarantee or aim to ensure human well-being is welcome. But, given the difficulty of understanding its concept, the rhetoric is necessary: how much is needed to determine existing happiness? If the availability of resources can serve as an example as a factor for the expression of happiness, how much would the individual need to conclude that he is happy? Therefore, the amount of goods and wealth needed to feel happy is not

the same for all individuals, and it is possible to recognize that there is a difficulty in delineating the contours of happiness uniformly in all existing civilizations.

If happiness is subjective, some may say that it is in the comfort and comfort that material goods provide as a true translation of fortune. Others say that it is in health or education that it is represented. There will still be those who claim to be able to find it in the conquest of power or social status considered favorable and satisfactory. It should be noted that everyone will be equally right. Apparently, due to the subjectivity of its scope, its concept is far from a consensus.

Philosophy, religion, and science have dealt with this subject at different times. After all, to understand the meaning of happiness is to understand the purpose and concept of man himself.

From the pre-Socratics to modern philosophers, virtue and knowledge were preponderant attributes for the achievement of man's happiness. To happiness was added pleasure, despite the efforts to contain it. In Democritus it was seen that self-knowledge and interest in the world allow the balance of passions as a path to happiness. Socrates defended the practice of the good as an expression of virtue, to allow the subject to reach its fullness. In the Hellenistic period, Aristippus of Cyrene identified pleasure as the driving force of life. He defined as a sage the one who learned to enjoy it autonomously. Epicurus agreed that pleasure is the beginning and end of a happy life. He concluded that the goals of true happiness and the secure knowledge of desires will direct choices and renunciations to the best advantage of the health of the body and the serenity of the spirit. Even for Epicurus, there is only a need for pleasure when its absence is perceived. Man should be advised to distance himself from pleasure whenever unpleasant consequences come from it. Antisthenes argues that pleasure should be avoided at all costs. For him, happiness requires affective autonomy, since in the enjoyment of pleasures man becomes a true slave of passions (Paula, 2014).

Other thinkers admitted additions and corrections from their experiences and points of view. For Descartes, happiness is not, in itself, an object of knowledge, but the search and contemplation of the truth, while Diderot believed it to be the result of chance (Paula, 2014).

Individual well-being is also a contingency theme of religion. Especially with the contributions of St. Augustine, with Christianity the outside world and the body itself became a place of sin and suffering. Happiness became an expression of salvation and is observed as a virtue of the soul. From man will be required a life of surrender and dedication to God as a means of keeping him from corruption and ephemeral pleasures, although salvation is not an act conquered by free will, but dependent on faith and grace. Happiness from a Christian perspective is a post mortem promise (Paula, 2014).

Despite the delight in penetrating the intricacies listed by philosophers to lay bare the difficult task of finding the heart of happiness and the desire to insert vast references from Epicurus' letter to Meneceus (Epicuro & Jakobsmuschel, 2019), the proposal of the work is restricted to observing the individual's psychic behavior from the Freudian perspective. In this sense, it is possible to understand how Human Rights can become more effective for Health in this context of well-being and, thus, contribute to the achievement of individual happiness. With this approach, it is expected that the Law can help to mitigate the malaise of man in society, without losing sight of the fact that health is not only a subjective good, but a universal legal good available to human beings.

Therefore, it is imperative to understand the human being's impetus to seek happiness, justified as an expression of their organic aspirations. The formation of the psychic apparatus will be briefly presented.

Global Health and the Right to Health

In 1948, with the creation of the World Health Organization (WHO), the Right to Health gained a little more global prominence, since the very purpose of the international entity is to guarantee the highest level of health for all human beings, advocating that the state of physical and mental well-being does not only consist in the absence of diseases or illnesses, but mainly when a set of values and principles are established and available to all individuals, anywhere on the planet. (*WHO | The Right to Health*, 2012).

From the atrocious experiences of the Second World War, it became imperative for the international community to mature to recognize that every person, simply because he is a human being, has rights. In this context, by declaring the universalization of Human Rights, the international community undertook to assent a set of rock-solid values and principles that can confer freedom, equality, and well-being to the individual. Among the most diverse rights recognized internationally, health - in its multifocal aspect - appears as a guarantee of safeguarding human dignity (United Nations, 1948).

For health to be considered a global good, two aspects need to be considered. The first is that it is not exclusive, that is, no individual or community should be deprived of its access, and the second is the non-competitive and non-rival character, since a person's health cannot be at the expense of the exclusion of others (Fortes & Ribeiro, 2014).

Health in this new millennium must be seen as a global problem. The globalization of health is a good for which we must work in an explicit and programmed way, as it becomes a desirable social purpose, either for its intrinsic value or as a symbol of the predominance of human values over other interests (Oliveira & Cutolo, 2018). In a global context with rapid changes in the disease patterns, the best understanding of the Health context is to consider the broad spectrum of the ecosystem containing the social, economic determinants of health and the diversity of institutional agents, given the considerable change in the global health scenario in recent years (Kickbusch & Berger, 2010). Thus, it is necessary to think about health and its occupations in the expression of the well-being (happiness) of the individual.

Health and its Occupations

The conception that health should be seen from a comprehensive and plural perspective brings other aspects closer to its effectiveness. In this context, economic, political, and social factors will influence the dimension of concreteness that is intended to be achieved. Health is not only promoted through the health sector, in a strict sense, and must be extrapolated by a concept of integrality, interdisciplinarity and intersectionality. If all areas of science must contribute to the individual's well-being, the multifocal way of thinking about health must also consider a broad vision that is not excluded from education, agriculture, specific associations of patients with certain diseases, Law, or any other branch of knowledge. The interconnection of relationships is essential for a more comprehensive and comprehensive care for the human being. That is why the deconstruction of the understanding of health as the mere absence of disease is defended (Oliveira & Cutolo, 2018).

It is also important to emphasize that health, as a subjective good, should not be thought of as a state burden and will not represent the same thing for all people, but will depend on the time, place, context, and social class of a people. Thus, individual, scientific, religious, and philosophical values will be real challenges and opportunities for the complete effectiveness of a globalizing health (Scliar, 2007).

The discourse on the relationship between health and quality of life has existed since the birth of social medicine, in the 18th and 19th centuries. McKeown (1982), Breilh et al. (1990), Nuñez (1994) and

Paim (1994) demonstrate that this relationship crosses the entire history of Western and Latin American social medicine, since in most studies related to health the reference term is not only the quality of life, but the living conditions for such, since the lifestyle and the living situation are terms that make up part of the semantic field in which the theme is debated. An example of this is the statement by Olga Matos (1999) that the better a democracy is, the broader the notion of quality of life and the degree of well-being of this society will be.

Health and the Expression of Happiness

Machado et al (2015) shows, in modern times, that happiness is defined as a fundamental emotion characterized as a lasting state which is combined with the absence of negative emotions, the presence of positive emotions, life satisfaction, social engagement, and objectives in life. Another concept that has been largely used for defining happiness within the specialized literature is subjective well-being. The new paradigms of wellness of the individual are anchored in the fusion of the new concept of the field's health: health promotion, health education, preventive health, and health management are changing, and perspectives are merging. This new vision brings a new sense of energy to defining wellness (happiness). It is relevant to mention that the concept of quality of life is a broader terminology, also involving happiness itself (Allen et al., 2007; Machado et al., 2015; Tay & Kuykendall, 2013). Once the period of absence of these negative emotions is over, the state of unhappiness returns to the individual. Thus, achieving happiness is complex and permeates numerous factors in different cultures.

The culture that is established in a society is gradually built by the desires of its people, represented, including, by its rulers. Collective life is translated by the morality of its individuals and is expressed in the rules of conduct and culture of that civilization. It is constantly evolving. The regulatory framework created from this society represents their desires for better living conditions in harmony and healthy. As seen above, the characterization of health in the 21st century goes beyond the absence of disease, it is the complete well-being (happiness) of the individual, since it is understood as an expression of health. In this sense, the rights expressed in the laws of a society demonstrate the vision of the intrinsic relationship between quality of life conditions and health as an expression of happiness (Minayo et al., 2000).

By this line of thought, well-being is almost unattainable, since the individual may not express their own desires for happiness, in favor of the society in which they are inserted, since their real desires may meet the moral legislation of that civilization. This attitude causes insecurity in your social life because represses his hidden desires in order not to be punished by society itself. This resignation practiced by the individual in each social environment brings personal unhappiness and, therefore, difficult achieve the health advocated in the 21st century (Segre & Ferraz, 1997).

The search for a global health that promotes the individual's well-being in society, transits through the utopian and distressing search of the subject to happiness. With his own personal beliefs and values, man can become a distressing being when he diverges from opinions and expresses his feelings in the culture of the environment in which he lives. Therefore, observing the relationship of rights in the society in which he lives, the expression of the relationships of good coexistence and well-being configure the tension and affliction for the achievement of happiness. Nevertheless, the suffering that these situations bring to the individual goes against the Right to health defined by the WHO, that is, health is not just the absence of disease, but it is the situation of perfect physical and mental well-being and social. This is an advanced definition for seventy years ago, however, a utopia in the present century when we reflect the individual as a whole – health and disease, his body and psyche (Oliveira & Cutolo, 2018).

The full happiness of an individual within civilization seems to be something impossible, since man renounces his freedom and inner will for his own security of well-being (happiness environment) ensured by the condition of the right to live in that civilization. So, with this attitude, happiness has already been compromised (Segre & Ferraz, 1997).

It is noted that the reach of happiness becomes relative, since it involves several variables that can lead the individual to 'expression of happiness'. Machado et al (2015) demonstrates a literature review with influencing factors such as biological, psychological, sociodemographic, economic, age, interpersonal relationship, Religiosity and volunteering, educational level, sports and leisure, mental health etc. Thus, the study of happiness from a scientific perspective, together with a realization of its implications for health is promising and fascinating, especially if believed that medical indices of good health are not always in agreement with the perceptions of the patient or society (Allen et al., 2007; Machado et al., 2015; Mitchell et al., 2013; Tay & Kuykendall, 2013). For example, Machado et al (2015) present an interesting case that occurred in the city Matsigenka in the Peruvian Amazon:

… over the past 30 years health indicators have improved greatly, but during the same time this population reported itself as sicker and unhappier. Perhaps for similar reasons psychiatry has failed to increase subjective well-being in the general population, despite extensive pharmacological advances and new psychotherapeutic techniques. Probably, the focus has been almost exclusively pathological.

Nordenfelt (1993) presents the new concept of health characterized by the dimension of quality of life, in which the vital goals are conceptually linked to the notion of happiness. A person's vital goals are such states of affairs as are necessary and together sufficient for his minimal happiness. This new dimension of happiness attributed to the individual's quality of life presents itself as a conceptual requirement that happiness must have a duration. There is (normally) very little point in establishing or assessing such happiness as only has a moment's duration. This state of happiness is related to some kind of intervention (whether it be medical, social or self-administered) which leads one to enduring state of happiness of the members of the population (Nordenfelt, 1993).

Therefore, it is necessary to better understand the intricacies of the instinct and intrinsic will of the human being in search of complete well-being. Giacomoni (2004) states that well-being is an area of psychology that has been growing in recognition in recent times. This area covers studies that have used the most diverse names, such as happiness, satisfaction, state of mind and positive affect, in addition to being considered the subjective assessment of quality of life (Giacomoni, 2004; Scliar, 2007). This understanding will be better understood by the psychoanalytic dialogue and the right to health from the perspective of happiness, as Human Rights can contribute to the mitigation of health malaise in the individual's environment.

THE PSYCHIC LIFE OF THE INDIVIDUAL IN FREUD'S VIEW

The physician Sigmund Freud, engaged in the treatment of hysterical patients, became interested in interfering in studies of the individual's psychic constitution. It was through hypnosis that the neuropsychiatrist used the cathartic method to investigate the psychic constitution. Thus, replacing hypnosis with the method of free association of ideas (Carloni, 2011).

For Freud, there is an intense and powerful environment where drives develop. These go beyond the brain organ and conscious acts, as these contents are within the immediate reach of the individual who deals with experiences in a timeless and non-linear way. This instance was called the unconscious (Freud, 1938a).

With the outline of the unconscious, it was possible to understand that in the soul life nothing perishes. Despite its difficult representation, there is a conservation of what is primitive alongside what is undergoing visual transformation (Freud, 1930). The human mind was divided into three instances: Id, Ego and Superego.

The first psychic instance, the Id or Isso, is expressed in the unconscious and is characterized by the composition of hereditary influences that the individual brings with him (Freud, 1938a). The Id works as a faithful depository of libidinal drives and is governed by the pleasure principle (Freud, 1938b) seeks to fulfill your desires immediately and at any cost. In this deep place of the psyche, there is no fear or predisposition to self-preservation, unlike what happens in the Ego.

The Ego (or I) serves as a mediating instance between the Id and the world around it. Governed by the principle of reality, it contains absorbed values and ideals, equalizing the instinctual satisfactions of the Id. Due to its constant state of wakefulness and self-preservation, it avoids facing strong stimuli, through the escape of displeasure, adapts to stimuli it considers moderate and seeks modify the outside world to suit your own convenience (Freud, 1938a).

Finally, the Superego (or Superego) acts severely in the influence of the Ego, repressing the desires of the Id. The Superego restricts instinctual satisfactions while also imposing new needs on the human being, mainly due to the influences it introjects from the environment external. In this sense, parental teachings and reprimands, added to aspects of culture, are incorporated into the person through the superego, forming a third power in the psychic instance of the human being (Freud, 1938a). Race, people, religion, economy, and social norms are examples of these cultural aspects.

The psychoanalytic studies defended by Freud also observe that sexuality is a central theme in a person's life, not from puberty but from birth onwards and drives will have relevant influences on individual behavior (Freud, 1938c). Freud highlights two drives that will guide the soul life: Eros and Thanatos. The first represents the life drive and comprises the sexual energy (Freud, 1938c). Thanatos means the death drive that everyone intrinsically carries. Both drives act together in psychic life in combination or contradiction (Freud, 1938b).

In addition to the fact that sexuality is present in the individual's life, since birth, Freud sought to clarify that the concept of sexual and genital are different and that a person's sexual life is nothing more than obtaining pleasure itself[3]. Therefore, the search for satisfaction does not appear in the individual only through sexual acts, but through sublimations, adapting to socially accepted purposes. This is what is seen as the concept of displacement of the libido: if originally intended for reproduction and sexual satisfaction, its main objective is shifted to other activities that allow the production and maintenance of culture by sublimation or repression (Freud, 1908)[4].

In the experiment on cultural sexual morals and modern nervous disease (Freud, 1908), it is possible to observe that in addition to the natural sexual morality[5]. There is also another sexual morality called cultural. This, in turn, is the result of the work and production of the psyche and implies certain disturbances and sacrifices to the individual.

Like philosophy, psychoanalysis agrees that the purpose and intention of human beings is happiness. However, confident of the scientific truth that was constructed, it is not through virtue, knowledge, or

faith that it will be achieved, but through the satisfaction of one's own organic impulses, whose main intention is the search for pleasure and the diversion of everything what causes you displeasure.

CULTURE AS A SOURCE OF DISEASE

In the Freudian view, the conduct that leads the individual to the purpose of happiness is governed by the pleasure principle, even if it is dammed over time. However, this principle is transformed and adapted under the influence of another: the principle of reality, which employs certain moral constraints causing the renunciation or sublimation of desires (Freud, 1930).

As noted, natural sexual morality is subject to disruption and sacrifice. There is a permission for culture to act as a strong influencer of soul life (Freud, 1908). The common cultural heritage requires each subject to give up an expressive part of their aggressive inclinations and their libidinal drives. This also imposes deprivations that will cause internal suffering. For Freud, culture would have two subjects. The first would be all the knowledge and capacity of human beings to dominate the forces of nature to extract their needs from it. For the other subject, it would be that all the devices necessary to regulate human relations among themselves, especially the distribution of good (Freud & Sigmund Freud Collection (Library of Congress), 1927)

Culture uses impediments, prohibitions, and deprivations as mechanisms for its defense. This is because, generally, people only obey prohibitions under certain pressures from the external environment and those who are unable to renounce their impulses will be considered outlaw (Freud, 1908). In this sense, culture and everything contained in it would be the main impediments to the individual's full happiness and the Law would not be separated from the production of this discomfort. This semantics is called by Freud as discontent in civilization.

Although painful from an individual perspective, Freud recognizes that culture is also organized as a true source of protection against human beings and their power to self-destruct, consecrating gains to humanity. Without culture, man would be subject only to his natural state and would incur countless risks (Freud & Sigmund Freud Collection (Library of Congress), 1927).

Thus, although it is recognized that life in modernity implies certain fatigues that cause discomfort to human beings, they would not be the source of the greatest unhappiness for the subject. For Freud, man's unhappiness is in the intrusion that culture performs in the soul life and in the harmfulness caused by the restriction to sexuality (Freud & Sigmund Freud Collection Library of Congress, 1927).

The problem lies in the fact that for most people, there is a bearable limit to the load of instinctual sacrifice that the individual can make (Freud, 1908) in the name of maintaining the culture. When these limits are exceeded or expressed too much, space opens up for the manifestation of neuroses (Freud, 1908).

Therefore, when observing that this process is natural and cyclical, it is possible to recognize that the possibilities of happiness are already limited by the individual's constitution (Freud, 1930). Man would only be given the possibility of sudden satisfaction of needs that have already been repressed (Freud, 1930).

Law as an Expression of Culture

As order and justice are imperative social needs, it is known that group life imposes multiple demands. Although there are other normative instruments that influence and condition collective life, such as morality, religion, and social standards, it is the Law that holds the attribute of coercibility, causing individuals

connected to it to base their behavior on the logic of lawful versus unlawful. Therefore, it is accepted that the Law is a necessary imperative to protect the individual from the will of the stronger (Freud, 1930). In this way, primarily corresponding not to individual needs, but to a lack of the community.

While the Law is expected to be a source of protection and security, it is equally perceived that this cultural core is also a source of displeasure, as it imposes equal standards of conduct and distances itself from the idea that the collectivity is nothing more than the that the sum of individualities. Those who fail to appropriate the pre-established standards will suffer the effects of repression.

Thus, as it is the result of human elaboration, the Law ontologically is located as a cultural product (NADER, 2020). If psychoanalysis is right and culture is a notable source of displeasure, the Law will also follow the same path, imposing certain drive requirements on the individual's full development, limiting the reach of his happiness. The crucial point of the problematic of the instinctual demands arising from the legal instruments is to realize that freedom – so limited – is not in itself a cultural asset, but a subjective psychic aspiration, as Freud has already put it (NADER, 2020).

Despite the Freudian defense that sexuality (and consequently its instinctual satisfaction) is an expression of the goal of happiness, what is perceived is that the various cultural embargoes on sexual freedom compromise the full development of the individual, contributing to the increase of its malaise in society. These cultural embargoes have been accompanied by law over the centuries. Examples abound, including the prohibition of incest and child sexuality, the determination to choose a love object, the imposition of monogamy and the marginalization of pleasures whose ends do not find support in procreation. To corroborate the claim that the Law is a source of libidinal restriction, some highlighted examples deserve observations.

Incest is a universal sexual interdiction, even though it is common for individuals, in adulthood, to express affective interest between individuals in the same family. Disgust is justified when it comes to relationships between adults and children or when there is an unequal power dynamic as in the case between parents and children, in which consent is withdrawn. Cristine Metter emphasizes that incest is taboo because it is often associated with intrafamily sexual abuse, but emphasizes that censorship comes from a cultural development and does not find instinctive arguments (Metteer, 2000). In presenting the thesis *Some "Incest" Is Harmless Incest(...)*, METTER questions the political difficulty of regulating parental relationships between capable adults. Several countries around the world have already disqualified incest as a legal asset protected by criminal law. Despite this, there are still States in which the union between members of the same family finds obstacles or restrictions.

Another taboo that finds legal and social reluctance to face it is child sexuality. By ignoring its existence and importance, the Law contributes to the protection of children and adolescents from the perspective of innocence, out of balance with the promotion of public policies that expand sexual education among minors (Carvalho et al., 2012). The argument does not defend the encouragement of sexual practices among children and adolescents, but the recognition that sexuality is a characteristic present in all ages, with different manifestations and that, therefore, it deserves to be addressed properly. An example of this was the articulation of a campaign promoted by the Brazilian government in 2020 aimed at combating teenage pregnancy. To reach the goal, the campaign used the motto of sexual abstention as the main contraceptive method, causing great mobilizations in the scientific community. This case can support the argument that the sexuality of children and adolescents is predominantly seen from a pejorative angle associated with "problems" such as unwanted pregnancies, sexually transmitted infections, and violence. In contrast, facing sexuality as an element of individual affection and autonomy,

not limited to reproductive purposes, is a way to build a more educated society and, consequently, more autonomous, and less repressed.

On the other hand, interaction between people of the same sex is a more recurrent theme in legal forums, perhaps because of the pressure that organized society has used globally and the progress that several countries have made in promoting rights aimed at the population LGBTQIA+[6]. Data from the World Health Organization show that until the 1990s, homosexuality was considered a mental illness. Since then, a lot has changed. By 2020, 124 UN member states allow consensual same-sex sexual acts. However, several other countries continue to legally determine their citizens' choice of love object by criminalizing same-sex relationships. Twenty-seven states punish equal sexual intercourse with criminal penalties exceeding ten years in prison to life imprisonment and six states adopt the death penalty (ILGA WORLD, 2020).

The restriction to sexual freedom and individual autonomy with legal support does not end in the aforementioned cases. Another restriction that stands out is the monogamous consensus as a translation of normality. It is still established in Western society that union with multiple people is synonymous with fetishism and perversion. This is one reason why the law, especially family law, follows the trend of not recognizing extramarital relationships, imposing mononormativity as a standard of living.

Given the above, cultural restrictions find legal and normative support with justification for the representation of social values. However, the Law is intended to provide the security bases for collective life. State interference in individual life through the legal route must not take place in such a way as to create excessive impediments to human development.

For this reason, it is argued that the construction and adaptation of law, both in the international scope and in the domestic legal system, consider, in addition to the social and political factors already commonly observed, the aspects of the psychic constitution of the human person. The state equalization of the moral, ethical, and religious influences of a cultural society and the individual's psychic needs can be a way to mitigate the malaise of man in society and the Law has to offer important contributions to this success.

HUMAN RIGHTS UTOPICALLY AT THE SERVICE OF INDIVIDUAL WELFARE

If, on the one hand, Law has served to contribute to culture in the sense of limiting individual freedom, requiring libidinal sacrifices from its recipients that impede access to happiness, it is also certain that these aspirations are not at all absolute. This is because Human Rights are presented as a category of rights whose purpose is based precisely on the protection of the individual against the State and society itself. It should be noted that they were recognized as a global need to protect the subject from the excesses and disparities that history records (Comparato, 2018). The propaedeutic argument for the construction of Human Rights is the recognition of dignity, whose attribution places man in a position of certain superiority in relation to other species (Silva, 2000). In the light of Kantian philosophy, it is stated that due to the dignity attributed to man, the person is a center of legal imputation Silva (2000). Because dignity is a determinant character of the human being, the need to build universal and inalienable norms that protect the rights of people is established by the international community.

Thus, legally, and historically human rights have as a pillar the protection of the individual in society, guaranteeing their right to freedom, equality and, above all, their dignity. This applies wherever you are and under any jurisdiction to which you are subject. In this perspective, whether the rights established at

the international level or those provided for at the domestic level of States, called Fundamental Rights, the protective rights of people will primarily have the power to: a) safeguard dignity, b) safeguard minimally adequate living conditions of the human being and c) prohibit excesses that may be committed by the States or by individual (Guerra, 2020).

The question that arises is that, given the psychoanalytic view that man will only find his happiness when he enjoys the satisfaction of his organic drives, how can human rights be legitimate instruments to lead the individual towards this full happiness?

The answer is that no category of law will be able to guarantee man's happiness in its entirety, even if liberal and non-interventionist postures are encouraged by the planet. First because, despite the universality and the erga omnes character attributed to Human Rights, its effectiveness depends on a faithful commitment between the States of the international community. Second, even if ample freedoms are truly granted to the individual, other drives (such as aggressiveness) will still be subjective organic aspirations. However, they will need to be tightly controlled for the advancement of organized society, especially those that involve sublimated sadistic pleasures.

Thus, if the Law is not in itself capable of ensuring the achievement of full happiness on the part of the human being, what can compete with it is the contribution to alleviating the impacts of the malaise that culture produces in the soul life. The first step is the assumption of the state's commitment to guaranteeing the application of rights already universally recognized, assimilating that the achievement of happiness is intrinsically connected with the need for freedom. Important concessions to the sphere of individual freedom still need to be recognized and put into practice, which is why it is stated that the purpose of human rights is utopian.

The Lack of Effectiveness of Human Rights

Understanding the raison d'être of Human Rights involves the understanding that the international community collectively resolves to create a superior category of rights that protects all individuals without distinction and wherever they are on the planet.

To do so, it was necessary to embrace the softening of the idea of state sovereignty and the relativization of local culture. In the wake of this reasoning, this category of rights is now endowed with an erga omnes character and normative superiority[7], universality being an important feature in the attempt to confer global effectiveness on the conquered postulates.

When it is stated that the need for effectiveness of already recognized rights is a factor that hinders the achievement of happiness, the intention is to conclude that it is the low effectiveness that represents one of the factors that contribute to the maintenance of the individual's malaise in collectivity. This is mainly caused by the lack of commitment of the States.

As for universalism, it can be highlighted that: i) human rights are universal because they apply to everyone, regardless of race, gender, color, ethnicity, religion, nationality, sexual orientation, social class or political position, ii) they are universal because they must be observed at all times, regardless of the situation experienced and iii) must be respected by all cultures (RAMOS, 2018). However, one of the main impediments to its effectiveness lies precisely in the cultural embargoes sustained by different nations.

Among other justifications, failure to observe Human Rights is sometimes supported by cultural relativism (Piovesan, 2018). In addition to the cultural argument, other state objections to the universality of human rights can be observed: i) the philosophical argument, based on the existence of multiple evaluative perceptions of the world, ii) the argument of the lack of adhesion or engagement of States, iii)

the argument geopolitical, in which human rights are negotiated when faced with other state interests, iv) the developmental argument, which translates into the justification for the lack of economic resources (RAMOS, 2018).

A contemporary example is the practice of female genital mutilation practiced in several countries around the world, especially in Africa. Under the argument of cultural preservation, thousands of girls are genitally mutilated to be inhibited from sexual pleasure and to serve only for procreation. Despite being illegal internationally, the act is still adopted daily, causing risks to the physical and psychological health of women (OMS - Organização Mundial da Saúde, 2008).

Due to the jus cogens nature of human rights, its non-observance makes the violating State's responsibility to the international community emerge, with the advent of numerous duties of reparation, including the commitment of agreed international agreements. However, despite the entire legal framework built both to protect the individual and to hold the violating State responsible, the best way to guarantee effectiveness is not necessarily through international litigation, but through voluntary adherence and responsible action by States. The more States are engaged in creating public policies that guarantee the application of human rights, the faster the international community will approach its utopian objective of protecting human beings.

In view of this, it is understood that the path to the fulfillment of the protection of human rights can and should use litigious instruments that guarantee its observance. However, it is the state's commitment, through legislative, administrative, and judicial practices, that in fact (and in law) will enable the university of human rights. If the state's non-compliance with people's rights is true, it is certain that man's happiness will be even more distant.

The Need to Control Aggressive Impulses

It was mentioned that alongside the life drive, another drive acts with a strong influence on the soul life: the death drive. This drive also creates bodily demands that always seek to establish themselves, even if in a sublimated or displaced way. From the death drive comes the desire for aggressiveness and the so-called sadistic pleasures. By observing the savage institutes of the individual, Freud settles:

The feeling of happiness in the satisfaction of a wild instinctual drive not tamed by the Self is incomparably more intense than the satiation of a tamed drive. The irresistibility of perverse impulses, perhaps the attraction of what is prohibited in general, finds an economic explanation here. (Freud, 1930) – Translation by Maria Rita Salzano Moraes.

Freud claims that all humans are endowed with destructive tendencies. As a result, the organic inclination towards aggression disturbs the relationship with others and translates into behaviors considered antisocial and anticultural. For him,

(...) human beings do not have a quiet nature, eager for love, and at most can even defend themselves when attacked, but, on the contrary, they are given the right to also include among their instinctual abilities a powerful portion of inclination for aggression. As a result, the neighbor is, for him, not only a possible collaborator and a sexual object, but is also a temptation, with him to satisfy his tendency to aggression, to exploit his workforce without compensation, to use him sexually without his consent,

to appropriate his property, to humiliate him, to cause him pain, to martyr him and to kill him. (Freud, 1930) – Translation by Maria Rita Salzano Moraes.

Sadistic pleasures represent the logic of disgust and violence. Sade is an enemy of laws, hates restriction, hates society, only believes in the destructive power of the individual, does not agree with social optimism or with the political project aimed at collective happiness sadism represents all the enjoyment experienced in the suffering inflicted on others. Psychiatrist Krafft-Ebing bestowed medical status on this term in 1981, in Psychopathy sexualism: "dreadful aberration of debauchery; monstrous and antisocial system that revolts nature" (Leal, 2019). Therefore, sadism will care little for the pillar of Human Rights: dignity.

Culture will demand the sacrifice of these impulses, prohibiting, through the Law, the practice of acts that compromise the dignity of the human person. In addition to classic examples such as the prohibition of torture, cruel and degrading treatment, the imposition of due process of law, the maintenance of practices that were once maintained by cultural justification, but which in fact represent nothing more than manifestations, has been recognized as illegitimate. sublimated from sadistic pleasures. The prohibition of the practice of dwarf throwing and hate speeches that defend the extermination of a certain cultural society are examples of this.

Thus, Freud's assertion that full happiness is an unattainable state seems to have little opposition to the results achieved by Law. Even if Human Rights are the object of commitment and positive responsibility at the global level by all States, culture and consequently the Law, will need to contain the behaviors that lead men to discharge their aggressive impulses with the intention of protecting the development of their own species human. And if the sacrifice of drives is imperative for the maintenance of collective life, it will also suppress part of the subjective plenitude.

Human Rights as a Contribution to Happiness

So far it has been established that the Law is not capable of giving the individual access to full happiness, since in the name of maintaining culture, it has the function of coercing human beings to behave so that collective life is the most bearable and harmonious as possible. It is because of these demands that man finds himself increasingly displaced from his goal of happiness and spends libidinal sacrifices to insert himself in the cultural parameters determined as correct. Furthermore, it was seen that the simple recognition of rights that protect human beings does not guarantee their effectiveness, since a committed action by the States is imperative.

In contrast, Human Rights can also be translated as a true balance between individual needs and cultural demands. Two rights will be presented, with a view to illustrating people's rights as mechanisms for approaching the subjective and arduous goal of individual happiness.

The first is the right to happiness. The choice of narrative for this right is because it is based on other institutes that are already largely consolidated: freedom, equality, and security. The second example refers to a category that expresses, in a more specific way, the freedoms indispensable to individual well-being according to the aspirations of the Eros drives defended by Freud: sexual rights.

The Right to Pursue Happiness

Despite not being recognized as a right in the international sphere, the right to happiness is determined in several Constitutions around the world and is gradually gaining notoriety in international organizations. Therefore, it is necessary to recognize that happiness as a legal expression is not new. Admittedly, it is easier to identify justified administrative political actions on individual well-being than overt normative aspirations for the same purpose.

In 1776, happiness had its historic landmark as a value established in the Declaration of Independence of the United States of America, which sought to ensure, in a futuristic perspective, the freedom of Americans based on their search (Comparato, 2018). Since then, several American state constitutions began to provide for the law in question [8]. Still as a legacy, the French Revolution also used happiness to support its libertarian ideals.

Currently, in different legal systems it is possible to find the right to be happy. The Kingdom of Bhutan presents the immaterial legal good in its Constitution. In the political charter of the kingdom, happiness appears as an ideal to be achieved as an individual guarantee and political duty of the State. In Africa, countries such as Namibia, Ghana, and Nigeria – traumatized by the historical atrocities that befell them – have inserted the individual guarantee as a translation of well-being and security in their Political Charters. In Brazil, a Constitutional Amendment Project came to pass, without success, to link happiness to social rights.

However, it is inevitable to exhort oneself to the questions: should happiness be in the law? Would the difficulty of its conceptualization and its excessively subjective aspect not create greater legal insecurities? Defenders of the proposal of happiness as a normatively protected good prefer to attribute a principled nature to the institute. This is because as a principle, happiness could be fulfilled in different degrees, whose optimization mandates would produce abstract radiant effects and would demand greater care for application in the concrete case. Leal (2019) demonstrates that the aspirations for freedom, equality and security, translate into the right to happiness, which is an uncertain principle in the list of fundamental rights (Leal, 2019).

The right to pursue happiness can be conceptualized as the right to plan and give to a project to satisfy legitimate preferences, considering its chances of success (Leal, 2019). Relativity is one of the characteristics of the right to happiness [9]. This means that once recognized, its effectiveness must not be accepted at any cost. No rights are absolute. Therefore, rights of third parties must be preserved, imposing the fight, for example, of the manifestation of sublimated sadistic pleasures that place human dignity at risk. The right to happiness can still be presented from some dimensions, of which three deserve to be highlighted: i) the right to public happiness, ii) the right to seek happiness (freedom) and iii) objective well-being (social rights) (Leal, 2019).

The first dimension concerns the right of citizens to have access to the public sphere and to interfere in their community's political decision-making. From this angle, the concept of public happiness consists in the individual's right to participate in public life effectively in all decisions that affect the legitimate interests of the community (Leal, 2019). The perspective is in line with the Freudian view about the individual's position in the community. In The Discontents in Culture, Freud says:

(...) in the developmental process of the individual, the pleasure principle program, the fact of finding the satisfaction of happiness, is maintained as the main goal; insertion into or adaptation to a human

community seems to be a difficult condition to avoid, which must be fulfilled on the path that leads to the attainment of this goal of happiness". (Freud, 1930)– Translation by Maria Rita Salzano Moraes.

In another passage in the same text, Freud continues:

(...) in the cultural process the goal of establishing a unity out of human individuals is by far the main thing; the goal of becoming happy actually still exists, but it is pushed into the background; and it almost seems that the creation of a large human community would work better if we didn't have to worry about the individual's happiness". (Freud, 1930)– Translation by Maria Rita Salzano Moraes.

Therefore, from the public dimension, the Right to Happiness represents the insertion of the individual to the group that belongs not only passively, but also politically active.

The second dimension, which is the right to seek happiness, translates into the idea of freedom (negative) and represents the individual's right not to suffer illegitimate interference by the State or individuals in their private life (Leal, 2019). Without freedom there is no room for the pursuit of happiness, in whatever meaning, especially from the demands of the psyche as a true organic and subjective aspiration.

As for the third dimension, the right to happiness is aimed at the objective perspective and would be assured when social rights are effective. Through the State's supply of goods and access to education, health, housing, work and other decent conditions for survival, the minimum conditions necessary for the pursuit of individual happiness will be guaranteed.

Having presented the above ideas, the right to happiness is nothing more than the translation of the effectiveness of other rights already established internationally (such as freedom, equality, and security), with the increase of a subjective justification: the need for be happy. For this reason, it is concluded that affirming the right to happiness in the international sphere, as a direct legal good and translated as a potestative right, can represent an expansion of what has been called utopia and further broaden the debate about its unsatisfactory effectiveness.

As a counterpoint to the arguments previously listed, the theme of happiness as a norm is very interesting, in addition to being enriched by enthusiastic arguments. However, it is understood that the legal efforts to grant greater freedom to the individual can come from the realization of the rights already made available, namely individual freedoms, so dear to the full happiness of the human being. Human rights have driven States and world society to respect the individual in their subjectivity, especially when their lifestyle choices do not compromise or harm others.

Sexual Rights

In Freudian psychoanalysis, sexuality is a determining factor for individual development, as it is understood that, on the one hand, the release of sexual energies is a means of freedom from repressive social forces and, on the other hand, that culture is a source of repression of these libidinal drives. Thus, finding the seal and protection of the law to freely reverberate subjective sexuality proves to be essential to reduce the malaise of men in society.

For this reason, it is important to mention the legal movements that seek to verify the application of human rights aimed at the vital need for sexuality. The World Health Organization understands sexuality as an integral part of the individual, influencing the personality of every human being. The report on sexual health, human rights and law also defines the term as a central aspect of being human throughout

life, encompassing sex, gender identities and roles, sexual orientation, eroticism, pleasure, intimacy and reproduction (World Health Organization et al., 2015). However, despite the scientific knowledge that has already been formed on the subject, coming from both psychology and biology, the theme still encounters resistance in social circles and, therefore, the most varied legal restrictions have still prevented the individual from gaining his freedom sexual.

RIOS (2006) highlights three problems that impede the realization of sexual rights. For him, the majority, moralistic and biomedical arguments would be factors that hinder the national legislative advance. As the law is still predominantly built by heterosexual men, everything that is different has connotations of an affront to democratic desire. It is a fallacy that should be compelled by the very universality of human rights. Another aspect is that morality built within society often regulates the correct way of living together, containing value distortions.

In the search for recognition of sexual rights, some international conventions have shown themselves to be important for the topic to gain universal relevance and be debated in a multidisciplinary way, with the consequent and necessary legal expression. The International Conference on Population and Development, held in Cairo in 1994, and the World Conference on Women, held in Beijing in 1995, are considered important for the dissemination of the proposal of sexual rights, intimately connected to the universal right to freedom. In 1997, the XIII World Congress on Sexology, in Valencia, established a set of guidelines that, from the Universal Declaration of Human Rights, recognize the existence of rights because of the free experience of sexuality. The reasoning was that if health is a fundamental right, sexuality is equally so as an expression of health,

In short, sexual rights comprise the right to freedom, the right to autonomy, integrity and security of the sexual body, the right to sexual privacy, the right to pleasure, the right to sexual expression, the right to free association, the right to free and responsible reproductive choices, the right to information based on scientific knowledge, the right to comprehensive sexual education and the right to sexual health.

The specific purpose of these rights is to protect individuals against torture, ill-treatment, invasion of privacy, denial of opportunities and other forms of discrimination because of the free expression or experience of sexuality. In addition to reproductive freedom, it seeks to give the individual the rights to feel pleasure based on autonomy and privacy. However, it must be recognized that discussions on the subject go far beyond the normative recognition of free practice, and encounter various complexities that will require from the legislator a certain amount of courage and wisdom so that the morality reflected in the norm is nothing less than the moral rational (Kant, 2016).

Aspects ranging from the freedom of choice of the sexual object, freedom of expression about this chosen object to the limits of the practice of acts are subjects covered by the theme, namely: is it possible to be asexual without this having legal consequences? Do freedom and autonomy encompass the right to decide on reproduction? Is there a state duty to provide contraceptive supplies? Do people living under special care have their right to sexual intimacy violated? These are just some of the pressing issues that the Law needs to face for the effectiveness of human rights to gain fullness.

As an example, the rights of people with disabilities can be presented. Although the United Nations Convention on Persons with Disabilities asserts several commitments to be signed by States to safeguard the full and equitable exercise of these people's fundamental rights and freedoms, the sexuality taboo in this scenario is a little more latent, mainly due to a possible excessive paternalism.

While the issue is sometimes neglected among States, Australia and Denmark have already shown advances in addressing the issue with scientific responsibility. In Denmark, sexual expression is a right of people with disabilities and a facilitation policy has been included to help these people find sex work-

ers. Caregivers are trained for sexual counseling and to intervene with aids to reduce the difficulties of the act. They can even build an action plan for the placement of sexual accessories. In Australia, health agencies and organizations fund sex workers for people with disabilities and offer courses to service providers. Although the initiative is private, there is support from the government (Vehmas, 2019). It should be mentioned that, although commendable, the policy is criticized for the argument that a closer look at the concrete case cannot be lost sight of, since the degree of disability will greatly impact the ability to grant the sexual act (Jeffreys, 2008).

In this sense, by stating that the individual needs to have recognized the right to sexual freedom so that it is possible to express their potential and exclude the forces of coercion and exploitation mentioned earlier, the discussion about the need for commitment of the States to establish national laws that guarantee fundamental human rights and that establish bases for developmental public policies.

FINAL CONSIDERATIONS

The understanding of happiness is an old priority established in social studies precisely because its pursuit has always been a human being's goal. In this sense, values such as non-discrimination, equality, security, and cooperation make up the list of basic principles for the happiness of peoples and their harmonious relations. It is with the focus of a comprehensive and inclusive perspective that global health is in line with the imperatives of a happy life.

Happiness is a subjective phenomenon of the human being's will and attitude towards his own life and towards the society in which he is inserted, since he abdicates his sublimated desires in favor of acceptance within the society he lives. This view of understanding health in its broadest sense (beyond the mere absence of disease and symptom relief) places the importance of studying the individual in a broader sense, that is, considering the issue of well-being also within the fields of research of Psychiatry and Psychology. This plural understanding aims to achieve the concept of global health in society expressed in which the individual has the Right to Health listed in the hall of Human Rights

Psychoanalysis focused on the theme and Freud's contributions about the formation of the psychic apparatus allowed the construction of the argument that it is not through faith, virtue, or knowledge that the stage of full happiness is reached, but through satisfaction of the psychic drives organically incorporated in the human being.

It was observed that the possibilities of entire happiness would be compromised by the individual's own constitution, since a certain psychic instance (the Superego) acts as a strong influential restrictor of the Id. Culture and everything in it, makes use of impediments and prohibitions to contribute to the demands of instinctual sacrifices, causing significant discomfort in the individual.

Although it is recognized that life in modernity implies certain strains that cause discomfort to human beings, they would not be the source of the greatest unhappiness for the subject. Man's unhappiness would be in the interference that culture performs in the soul life and in the harmfulness caused by the restriction to sexuality.

Since the unconscious is timeless, non-linear, and imperishable, all existing drives in the psyche do not simply cease to exist because of the sacrifices made in the name of maintaining culture. Aggression, for example, is introjected and becomes capable of causing guilt and fear in the individual. It comes from both the external repressive authority and the severity of the Superego itself. This leads to the path of punishment.

On the other hand, when observing the impacts that the Law produces on the individual's development, it was noted that in certain aspects it can do little. In others, however, it was noticed that the excessive limitation arising from the Law or society in the pursuit of pleasure, contributes to the maintenance of high rates of unhappiness.

Legal science, with all its technique and development, cannot contribute to the total achievement of human happiness, even if utopically this is one of its greatest goals. Despite this, it is gradually possible to make contributions that at least alleviate the individual's discomfort in the social context. In this sense, two categories of rights were presented, the right to seek happiness and sexual rights.

It is defended that the conception that the Law is an adaptation process should be seen from a Sinalagmatic perspective. While man in society will need to adapt to the imperatives of the norm, sacrificing his organic tendencies, legal norms must be established and revised to adapt to social aspirations, without neglecting to observe the individual's psychic constitution.

Psychology has offered important contributions to Law, especially to Forensic Science. However, it still employs a timid influence in legislating practice. However, it is necessary to recognize that the human person (before being subject to rights) is subject to desires, destined for instinctual satisfactions. Therefore, the solution to alleviate the individual's discomfort may lie in the balance between just and innate individual demands and equally legitimate cultural demands.

Health can (and should) be seen as a corollary of the state of dynamic balance between the organism and its environment, whose reach of the individual's well-being in society is nothing more than the reach of the very concept of health.

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ENDNOTES

1 In this work happiness and well-being are used as synonymous expressions.

2 Gross Domestic Happiness (FIB) is the new UN indicator created to measure a nation's development. Since 1972, the Kingdom of Bhutan has used it to ascertain the progress of its goals as a society.

3 Freud classified the phases of satisfaction and pleasure into four: a) oral, in which the child identifies the pleasure through the mouth through the act of sucking, since the baby does not just look for food; b) sadistic anal, when there is the discovery of sensations in the excretory act and the awakening to aggressiveness; c) phallic and latency, phase in which the child goes through the most important fantasy complexes for the formation of his personality (Oedipus and Castration Complexes) and d) genital.

4 Repression is the act of repressing and defending against unbearable desires, feelings, and memories to eliminate them from consciousness.

5 Natural sexual morality comprises good health, aptitude for life and the constitution of the individual.

6 The term LGBTQIA+ represents the political and social movement that defends diversity and seeks representation of rights. The term refers to lesbians, gays, bisexuals, transsexuals, queer, intersex, asexual and other groups and variations in sexuality and gender.

7 *Jus cogens* imperative rule is one that contains essential values for the international community, and that, therefore, has superiority in the clash with other rules of International Law.

8 The Constitutions of Virginia, New York, Ohio, Pennsylvania, among other American states explicitly provide for the expression "happiness" in their texts.

9 Once happiness is recognized as a fundamental right, it would be endowed with the characteristics inherent to this category: historicity, imprescriptibly, non-renunciation, inalienability, relativity, universality, and immediate application.

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