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Digitalization of Medicine in Low- and Middle-Income Countries

Paradigm Changes in Healthcare and Biomedical Research

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Contents

Digitalization of Healthcare in Low-and Middle-Income Countries (LMICs): An Overview

Zisis Kozlakidis and Karine Sargsyan

Abstract

The digitalization of healthcare- considered as the collective outcome of individual digitization attempts- is an ongoing global trend, which has accelerated during the COVID-19 pandemic. It occurs at a different rate and follows different implementation pathways across the world. However, there is still little published information relating to this process in Low-and Middle-Income Countries (LMICs), a knowledge gap which this good addresses head on. In this first chapter we present an overview of the main themes of the current book, the rationale behind the choice of terminologies and also the aims of this book. The latter are to highlight the many yet disconnected success stories from LMICs, to identify challenges and opportunities, and to maintain the spotlight on the dynamic nature of the healthcare digitalization process.

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Keywords

Digital health · Digitization · Low-and middle-income countries · LMIC · Personalised medicine

1 What Is Digital Health

The term digital health has many definitions in the current scientific literature, like many other technologically-driven terms, e.g., Artificial Intelligence (AI). For the purposes of this book, the overall definition remains quite general, i.e., a collection of activities that includes digital care programs, technologies within healthcare and society, aimed at enhancing the efficiency of healthcare delivery and in making medicine more personalised and precise (Fadahunsi et al. 2021). The necessity for the adoption of such a broad definition, stems from the very topic of this book. Low- and middle-income countries (LMICs) do not constitute a uniform entity, even though they often get grouped together for the purposes of simplification. Instead, LMICs are a collection of individual cases that present many similarities and overlaps in healthcare, due to their underlying commonalities, e.g., resource-restricted settings, population pressures, healthcare burden, etc. As such, the implementation and potential adoption of digital health will be highly context-driven, thus, the definition of dig-

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ital health would need to remain broad so as to ensure inclusivity. Indeed, this book hosts chapters contributed by over 100 authors from over 25 countries, covering as many aspects and perspectives as that was possible to achieve within the publication confines imposed by the nature of a book publication.

2 Why Is It a Good Time to Talk About Healthcare Digitalization in LMICs—Coalescence of Forces

A number of distinct factors justify the creation of the current book at this point in time. The information explosion in healthcare is well-known (Wilson 2001; Beath et al. 2012), and is the result of a significant increase in computing power, coupled by a significant reduction in data storage costs, facilitating the production and storage of increasingly larger volumes of data (Shastri and Deshpande 2020). At the same time, the increasing penetration of hand-held and internet enabled devices had led to an explosion in data generation and data consumption within healthcare (Feroz et al. 2020; Wood et al. 2019). In turn, this increasing need on both sides of data, i.e., significant increase in production and consumption of healthcare data, lays the ground for further innovative approaches, utilizing the new technologies needed to cope with the digital pressures within healthcare. New methods of inquiry are emerging in thinking about innovations in the wider healthcare field, and that is inevitably also reflected in the approaches of understanding and interpreting those findings for the scientific literature (Kozlakidis and Catchpoole 2021a). This is particularly true within LMICs, where driven by the necessity of severe funding limitations for example, digital healthcare implementations may be very innovative.

Thus, as alluded above, one main factor is the *technological advance* (from '-omics'analytical technologies to digital surveillance programs used for public health), able to accommodate more functions than ever before, and as such generating more data than ever before. The second main factor is the market itself: there exists a more *mature environment for digital health* applications as part of routine practice. Indeed, the COVID-19 pandemic has functioned as an accelerator in terms of entrenching digital technologies within routine services (Kozlakidis and Catchpoole 2021b). For example, digital technologies have been used for remote post-operative monitoring more intensely than ever before (Beauharnais et al. 2022; Mousa et al. 2019), as well as an innovative platform for bringing healthcare professionals and patient groups together, e.g. breast cancer patients (Abusanad 2021). While it is anticipated that some of this activity may revert to pre-pandemic protocols, this is not going to be universally true, and as such a considerable portion of digital healthcare capacities will remain integrated within the overall healthcare systems (Jazieh and Kozlakidis 2020), strengthening the existing digital healthcare market, and its relative position as proportion of the annual healthcare budget. Thirdly, there is an accelerated penetration of mobile phones that has now been coupled with increased penetration of *internet-enabled services* (Kelly et al. 2020). Whereas mobile phone penetration in south-east Asia has been over 90% in most major countries for over a decade, the necessary internet-enabled infrastructure, i.e., ensuring sufficient connectivity and bandwidth, such as needed to operate healthcare applications, has only been available for only a few years in most locations, if at all (Hoe 2022). Finally, the COVID-19 pandemic has provided the required evidence that digital healthcare implementations can be *financially viable*, e.g., in the servicing and monitoring of repeat prescriptions (Macariola et al. 2021). However, such cases are still the exception within LMICs, and a wider adoption would require appropriate policy support (Bloom 2019).

3 Focusing on LMICs vs Resource Restricted Settings

Healthcare systems in many LMICs are complex and tend to operate under immense pressures in terms of healthcare delivery. However,

it is also appropriate to recognise that many LMIC healthcare systems have undoubtedly improved over the last few decades (Dinh et al. 2020). For example, the areas of maternal health and preventative medicine have benefited from a sustained drive to implement universal standards of care (Siseho et al. 2022). It is also appropriate to recognise that there exist pronounced healthcare access inequalities within high-income settings, and that certain regions of high-income countries (HICs) may indeed not be all that different for LMICs in terms of healthcare access (Doty et al. 2021). In the latter case it might be more appropriate to speak of resource-restricted settings, irrespective of the reported national average income, as a more representative picture. The opinion of the editors of this book is that indeed a resource-restricted setting perspective will be more appropriate in the longer-term, and as more data becomes available. Such a shift in terminology and research frameworks would become both inevitable and complementary to the current LMICs/HICs view. However, at present the LMICs focus of this book serves a dual purpose: (i) continuity and easier comparability with the published scientific literature, as well as (ii) the view of digital healthcare innovations and implementation within the framework of universal healthcare coverage, as has been supported and introduced in many LMIC settings in the last two decades. From a digital healthcare perspective, it remains paramount to still understand the systemic challenges and opportunities, prior to fragmenting investigations further within regional settings that can be stratified according to local income availability.

4 The Nature and Aim of this Book

Taking the above into account, the aim of the book is to provide a representative picture of healthcare digitalization in LMICs. Specifically, how digital healthcare applications have been implemented in particular countries and healthcare fields, e.g., paediatrics, dentistry, medical genetics, etc. In doing so, the book is highlighting specific examples, the plurality of context-driven solutions, and the many opportunities that still exist regarding digitalization of healthcare in LMICs. To this end, the example of the Kingdom of Saudi Arabia is utilised as the benchmark of high attainment in terms of integration of digital health, within a purpose-driven policy framework. The examples from Poland, Cyprus and China talk about the transition economies that have successfully integrated many digital health applications within routine operations, yet a fully integrated digital healthcare ecosystem has not been fully attained (but remains firmly within their grasp in the immediate future). The chapters with LMICs-specific examples, are supported by extensive work on the necessary preconditions for digital healthcare success, such as infrastructure, investment, systems design, social acceptance, etc. Over 80 authors from 15 different countries, most of which are LMICs) have contributed to the chapters presented in this book. It is a deeply collective work that provides a holistic and representative view of the current nature and status of individual digitization attempts of healthcare in LMICs, as well as the collective view of digitalization. From the editorial perspective, we anticipate that his book will spur many forward scientific discussions on the subject, and will form the basis of further such investigations on what is perhaps one of the most critical aspects of the future, global healthcare systems.

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Digital Health: Needs, Trends, Applications

Zisis Kozlakidis, Tracy Wootton, and Karine Sargsyan

Abstract

Digital health and the digitalization of healthcare are universal trends, supported by the increasing use of technology, increasing development of relevant infrastructure, reducing accessibility costs and technological advancements. The term digital health is a blanket term that covers a wide range of themes and applications. In this chapter, the term digital health is further reviewed, as different facets of it are accommodated within the different chapters of the book. Additionally, the main differences between digitization of healthcare between high-income and low-and medium-income countries (LMICs) are highlighted. Furthermore, there is particular attention given to the differences between digital application innovation versus diffusion. Taken together, this chapter provides a concise overview on the background and common understanding that should be used when reading this book, and the particular angles used to investigate the digitization of healthcare in LMICs.

Keywords

Digital health · Digitization · Low-and middle-income countries · LMIC · Trends · Healthcare applications

1 Introduction

As with many other blanket terms, digital health has many definitions. In its broadest sense it refers to the use of information and communications technologies in medicine and other health professions to manage illnesses and health risks and to promote wellness (Ronquillo et al. 2017). This is a very wide scope and thus it is inevitable that digital health will have many different facets, and consequently will be 're-defined' closer to the viewpoints of different authors or different disciplines within which it is used, such as health informatics. Digital health is not a new concept in healthcare and some of its earliest uses refer to the adoption of computerised methodologies for the systematic organisation of patient files (Krishnan and Neuss 2022). However, even in this limited context of electronic hospital records (EHRs), implementation was slow and highly

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fragmented, because the collection of data for public health records (and later on for surveillance) was affected by a historic lack of investment in digital technologies (Vandenberg et al. 2018). In the beginning of the twenty-first century the notion of digital health changed fundamentally as the advent of the internet and improved capabilities for international data transfer meant that digital health was viewed both as a local as well as an international need, with an increasing emphasis on the harmonisation and interoperability of extant systems. The more recent experiences from the outbreaks of infectious diseases (Ebola virus, Zika virus, and currently SARS-CoV-2 virus) have added yet another dimension to digital health: the responsiveness to public health emergencies inclusive of the end user and wider public (Knawy et al. 2020).

Indeed, as technology develops and its integration into routine clinical practice increases, it can be anticipated that consequently the plurality of digital health definitions will also increase, reflecting on the ever-widening user base. At the same time, it is important for a more consolidated taxonomy to be developed on digital health, consolidating digital health concepts/spheres of influence, for use in research, policy development, public health and clinical practice. To this end, there have been some recent, excellent attempts in shaping and understanding this existing ambiguity (Värri 2020; Iyawa et al. 2016), and these would need to be maintained in the future. At the very heart of this ambiguity in digital health definitions lie the many different needs, where it is anticipated that digitalization will improve health services across the board. The World Health Organization (WHO) shares this view, and considers digital health to be linked to the general support of introducing and emboldening universal healthcare systems globally. To this end, the key objectives of digital health for the WHO are: (i) the translation of existing and produced datasets into action, contributing to decision-making; (ii) the use of digital technologies to enhance connectivity and information transfer, including remote communication activities and (iii) the systematic assessment of national and regional needs in relation to emerging new technologies, including the support of technological co-development (World Health Organization 2021).

Therefore, reflecting on the many different needs and definitions, neither this chapter or this book, take a singular view on digital health. Instead, as the book includes over 80 authors from more than 20 different countries, each chapter contains a working definition for digital health so as to facilitate the authors in developing their arguments fully. While this entails the inherent danger of potentially conflicting views, the editors have considered that to be a desirable outcome. Indeed, the current lack of a *bona fide* definition for digital health indicates that there are, and will be, conflicting approaches to such a definition and as such it serves the wider scientific community and interest for those differences of opinion to remain visible.

The overall approach in constructing the current chapter is that of a narrative review, in which the most recent policies, guidelines, and publications from the last 5 years have been identified through a literature search, with further additional manuscripts being identified through 'snowballing', i.e., using reverse citation tracking to find articles that cited others already deemed relevant to the review (Callahan 2014). This narrative review approach was chosen because the aim of this chapter is to provide a broad perspective and explore the general debates and developments. A systematic review approach has been used in other chapters because they focus on unique and specific queries using explicit methodologies (Rother 2007).

2 Differences and Commonalities Between Needs in HICs and LMICs

One of the most pronounced differences in digital health viewpoints is the one that exists between High-Income Countries (HICs) and Low-and-Middle Income Countries (LMICs). This book provides a detailed example from both sides: a HIC implementation and success story is shared

by authors from the Kingdom of Saudi Arabia and by Poland, where the former provides an example of a nearly completely integrated healthcare system, while the latter describes the significant strides and achievements in getting to this stage. They should be viewed as akin to maturity models (Wendler 2012) highlighting a path of evolution for systematic development and improvement. What is common for these two mature examples is that they are using digital health as the engine for growth of the healthcare reach and efficiency and are achieving healthcare services as part of routine practice that would have been difficult to imagine only a decade ago. Thus, the view of digital health is both in terms of individual services as well as of the wider healthcare system. By contrast, while there is a good theoretical understanding of the wider digitalization benefits in healthcare as a whole in many LMICs, most of the examples represent individual institutional success stories, indicative of what can be further achieved, though not representing a healthcare system developed in its entirety.

At this point it should be noted that digitalization need not follow the exact same path of emergence in HICs and LMICs. The implementation of digital healthcare is highly context-driven (Gjestsen et al. 2017), needing to adapt to the user-base, available infrastructure, and political and regulatory frameworks. As such, LMICs should be expected to develop distinctly different approaches in the digitalization of their healthcare (Rossman et al. 2021; Surka et al. 2014). For example, in HICs, digitalization is dominated by the discussion on improving tertiary healthcare capacity (Al-Kahtani et al. 2022) and/or the consolidation of existing services (Vandenberg et al. 2020), while in most LMICs, tertiary healthcare is available to only a small section of the population. In most LMICs, healthcare is provided by primary healthcare centres, e.g., in Nigeria this proportion is as high as 85% of the population (Ugo et al. 2016), as such the path to digitalization would be predictably different. Furthermore, in HICs digitalization in healthcare is often linked with insurance providers (Posselt and Kuhlmann 2020), with the potential to add value in existing systems. However, in LMICs a large portion of employment is in the informal sector; for example, in some areas of Kenya this can amount to over 80% of the labour force (Were 2020). Thus, the market forces that will define the context for healthcare digitalization are distinctly different, and this would inevitably be reflected in the implementation pathways. The next section will investigate some of those trends in digital health and innovation with a focus on LMICs, thus setting the background for the subsequent chapters that will provide a deeper insight into specific contexts across the world.

3 Trends in Digital Health, Trends in Digital Innovations

Ubiquity of digital environments: Digitalization has been increasing across all fields of human activity and the introduction of many new technologies have led to the 'datafication' of many routine public health/governmental activities, including in healthcare, albeit with different intensities (Redden 2018). The increased presence of digital environments, as well as increasing experience in implementing digitization programs, are likely to ensure a continued growth for digitalization in healthcare in HICs and LMICs alike. At the same time, digitalization has resulted in an increasing overlap between the production and consumption of data, e.g., patients are increasingly both creators and consumers of healthcare data, highlighting the need for greater accountability on data use, as well as a greater oversight of the 'translation' process, i.e., how this data is feeding into ongoing routine activities and decision making (Agostino et al. 2022).

Fragmentation and lack of uniformity: The possibility of data users to add their own comments and perspectives in healthcare or even physiological measurements via wearable devices has been viewed as a way of improving existing services (Minniti et al. 2016) if implemented well. However, this opening up of interaction possibilities has not always been as successful as originally anticipated. For example, in many sub-Saharan African locations, such an

interaction was limited to existing vertical programs, e.g., HIV surveillance, and required substantial educational input for staff to be effectively implemented (Kwame and Petrucka 2020). Additionally, the increase of data production, means that a strict hierarchical data structure may not be adequate, as more horizontal platforms may be required, e.g., platforms where patients and doctors would interact directly. This inevitably can lead to the (limited) decentralization of information within healthcare systems, where local larger healthcare units would be intermediate holders of information/platform hosts, and then the data would be integrated at a higher level of structural hierarchy.

However, the multiple sources of data production, mean that there is a high heterogeneity inherent to the healthcare data, rendering the collected big data less informative using current conventional technologies (Dash et al. 2019). Thus, the anticipation is that eventually the data processing will be performed closer to the data producers, utilising distributed technologies, and that a greater data harmonization will be implemented by the necessity of data interoperability as well as the implementation of predictive machine learning technologies (Dash et al. 2019). The need for data harmonization is not new (Liu et al. 2010; Zisis 2016), however the ever-increasing digitalization maintains this need at the forefront. The implementation of Health Level 7 (HL7) Fast Healthcare Interoperability Resource (FHIR) standard (Braunstein 2019) has led to some uniformity allowing partial interoperability (Edoh 2020), although implementation in LMICs remains highly fragmented and requiring the adoption of LMIC-adapted implementation frameworks (Hussein et al. 2023; He et al. 2023).

Lack of regulations, lack of incentives: The complexity and heterogeneity of healthcare data, as described above, generates expected questions regarding the data regulation. In HICs, well-defined data regulatory frameworks have been adopted, e.g., the General Data Protection Regulation (GDPR) in the European Union (Voigt and Von dem Bussche 2017) that applies across the entire data processing workflow, from data generation, to storage, dissemination and use. Within LMICs, the development of data protection regulations remains an ongoing process (Akintola and Akinpelu 2021; Vodosin et al. 2021), with the COVID-19 pandemic having acted as an accelerator in terms of the need of enacting such regulations (Hussein et al. 2023).

While the lack of relevant regulations might be one of the barriers to digitalization of healthcare in LMICs, the lack of financial incentives presents a second, equally important, barrier. Digitalization in HICs was driven by a mix of private companies investing in the creation of digital health solutions, coupled by governmental incentives (Abernethy et al. 2022). For example, the driving force for the nation-wide adoption of EHRs in the US was the Health Information Technology for Economic and Clinical Health (HITECH) Act, enacted as part of the American Recovery and Reinvestment Act of 2009, incentivizing the adoption of EHRs (Institute of Medicine (IOM) 2004). This substantial public investment into the digitalization of healthcare was justified on the grounds of improved patient safety, operational efficiency and quality of care (Institute of Medicine (IOM) 2010). Indeed, by 2019, i.e., a decade after the enactment of the relevant legislation, approximately 86% of office-based physicians and 96% of non-federal acute care hospitals had adopted certified EHRs (Health IT Dashboard 2023). This represents the greatest adoption of digitalization in healthcare by data volume ever recorded. At the same time, multiple studies have documented improvements in care quality (Atasoy et al. 2019; Buntin et al. 2011), however, caution should be exercised in attributing the improvement of care quality to a singular parameter such as EHRs adoption, as it is likely due to the confluence of a number of factors.

In LMICs, the introduction of financial incentives across the board is unlikely due to the many competing financial pressures, however, incentivization programs have been successful within vertical sets of activities, e.g., physicians in Nigeria (Adedeji et al. 2022), CashAdvance schemes in Kenya for healthcare providers (de Wit et al. 2022), public health professionals during COVID-19 in Indonesia (Aisyah et al. 2022a)

and others. As a result of the increasing digitalization of healthcare in LMICs, new models have been proposed for financial incentivization that are more appropriate for resource-restricted settings (Dohmen et al. 2022), including perspectives akin to micro-finance initiatives, where individual patients/professionals can be rewarded minimally for each completed digital interaction (Faulkenberry et al. 2022).

Lack of infrastructure: The lack of infrastructure is a consistent parameter of operating within LMICs, and equally for supporting digital health advancements (Chen et al. 2022; Nit et al. 2021), although the digital infrastructures are growing in many regions such as India, Vietnam (Winkie and Nambudiri 2023), Indonesia (Aisyah et al. 2022b), Rwanda (Chen et al. 2022) and others. The creation of digital infrastructure is not sufficient by itself, as digital literacy remains at low levels in many countries (Nit et al. 2021; El Benny et al. 2021). Hence the lack of infrastructure should not be regarded in isolation simply as the need for capital investment on technologies, but as part of the digital health environment inclusive of digital literacy. Finally, it should be noted that even when infrastructure is in place in LMICs, it is often required to perform in different ways and/or environments to the one it was originally created for. This need for 'tropicalization' of infrastructure, i.e., the adaptation of its performance to LMIC context is critical for the long-term performance and impact of such investments (Tran 2016; Coto-Solano 2020; Ombelet et al. 2018).

4 Applications in Healthcare: Adoption Versus Diffusion

At this point it is important to make a point differentiating between adoption and diffusion of digitalization. While there is a partial overlap of the factors that affect both, they do also contain distinct elements. Specifically, common elements include the availability of adequate training, policies and procedures for end users, and financial incentives at a system level (O'Donnell et al. 2018; Betmouni 2021). Differentiating factors focus on the scale of operations, the need to utilise prototypes to empower adoption, to engage social networks to affect diffusion, the interoperability of operations and the longer-term view that diffusion affords the digitization process (Mason 2015; Plum et al. 2020). There are currently many more studies published in the scientific literature regarding point adoption of digital solutions than studies on diffusion, owing to the fact that the latter require more time for investigation, but also suggesting that diffusion occurs at a slower rate (Omotosho et al. 2019). Having said that, the diffusion studies from rural India (Haenssgen and Ariana 2017; Schierhout et al. 2021), Cambodia (Nit et al. 2021), Kenya (Dohmen et al. 2022), and Nigeria (Adedeji et al. 2022), are informative in highlighting the need for context-driven implementations of digitalization and provide examples of how such a nuanced approach can be achieved in the field.

5 Opportunities

Taking the examples mentioned above into account—and the fact that they represent only a fraction of ongoing activities globally—it is clear that digitization of healthcare in LMICs is only at the first stages of this process. There have been many excellent reviews and books about the future opportunities that digitalization is likely to confer on healthcare in general (Menvielle et al. 2017; McKee et al. 2019; Glauner et al. 2021), but few focus on LMICs specifically, as it is a much more new and fragmented area and more difficult to assess and predict (Tambo et al. 2016). Therein also lie the many opportunities for the creation of new digital innovations, defining new pathways for implementation and impacting the population healthcare in ways that have remained nascent. The recent COVID-19 pandemic served as a proof-of-principle that digitization of healthcare in LMICs, at least some aspects of it such as surveillance and diagnostics, is indeed possible and can provide system-wide advantages to individual countries. Being able to link such initiatives to the introduced universal health coverage services provides the added-value proposition of

a rich data resource that can be then used for data mining and inform decision-making of policy-makers and clinicians alike.

6 Conclusion

Digitalization of healthcare has gained momentum over the last two decades and the COVID-19 pandemic acted as an impromptu accelerator for the implementation of digital applications across the world. While this trend of increasing digitalization remains steadfast in the background, a number of differences exist in the digitalization trends and processes between HICs and LMICs. This chapter provided an overview of the main trends, i.e., ubiquity of digital environments, fragmentation and lack of uniformity, lack of regulations, lack of incentives and lack of infrastructure, inclusive of digital literacy. Specific examples have been highlighted from across LMICs, demonstrating that digitalization is indeed possible and can be successful, however it would need to follow a different pathway to that used in HICs and be adapted to the individual contexts in which it is being introduced.

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The Emergence and Growth of Digital Health in Saudi Arabia: A Success Story

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Abstract

The development of Digital Health in Saudi Arabia has been evolving at a rapid pace, in alignment with the health sector's 2030 Transformation Program. This chapter will cover the development of the digital health sector and outline some of the main technologies that serve it. As an introduction, the journey of digital health, specifically Electronic Health Records, among other technologies within the landscape of Saudi Arabia, have been outlined. Followed by an introduction of the digital health transformation, technologies and solutions that were introduced or enhanced in the existing digital market, including: Telemedicine, patient portals, mHealth, wearable health monitoring technologies, virtual reality and augmented reality, artificial intelligence, blockchains, and the Seha virtual hospital. The chapter will be explored through references to key players in the digital health ecosystem, such as the patients, providers, the Ministry of Health (MOH), other regulators and initiatives, including their contributions to digital health in the Kingdom. The chapter will conclude with implications and opportunities for investment in this field, specifically artificial intelligence (AI). Research, partnerships and changing healthcare reform are highlighted as driving improvements in Saudi Arabian digital health.

Keywords

Digital health · Saudi Arabia · Telemedicine · mHealth · Artificial Intelligence (AI) · Technologies in Saudi Arabia · Digital Solutions

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1 Introduction

1.1 Brief Explanation of Digital Health and Its Significance

Digital health can be defined as the use of technology, such as mobile devices, software, and sensors, to improve health outcomes and healthcare delivery (Ronquillo et al. 2022). These technologies can include a range of applications, from remote patient monitoring and Telemedicine to health information systems and electronic health records (EHR) (Ronquillo et al. 2022).The main goal of digital health is to improve access, advance and enhance the quality of healthcare services and lower any incurred costs. Electronic health records also aim to develop patients' personalized healthcare plans (Hermes et al. 2020). In this regard, the Kingdom of Saudi Arabia (KSA) offers a mature example that can be highlighted as a success story, both in terms of the outcomes to the patients as well as in terms of developing an integrated, digital healthcare ecosystem.

1.2 Historical Context of Digital Health Adoption in Saudi Arabia

Saudi Arabia has made vast advancements in digital health adoption (Fig. 1). Digital health implementations started as early as the mid-1990s, but these projects were mainly isolated initiatives by a few governmental hospitals (Ministry of National Guard Health Affairs 2022; KFSHRC 2023). During the early 2000s, a more structured and unified approach emerged, leading to numerous collaborations among health institutions in Saudi Arabia and the formation of the healthcare reform committee (Altuwaijri 2010). In 2002, the healthcare reform committee established an information technology (IT) strategic plan for healthcare, which aims to further enable the management of similar digital tools (Altuwaijri 2010). Concepts in Telemedicine were tested as early as 2008 (Al-Kadi 2012), and in 2009, implementations of Telemedicine solutions were offered to assist in diabetes management (Al-Kadi 2012; Dawood and AlKadi 2023).

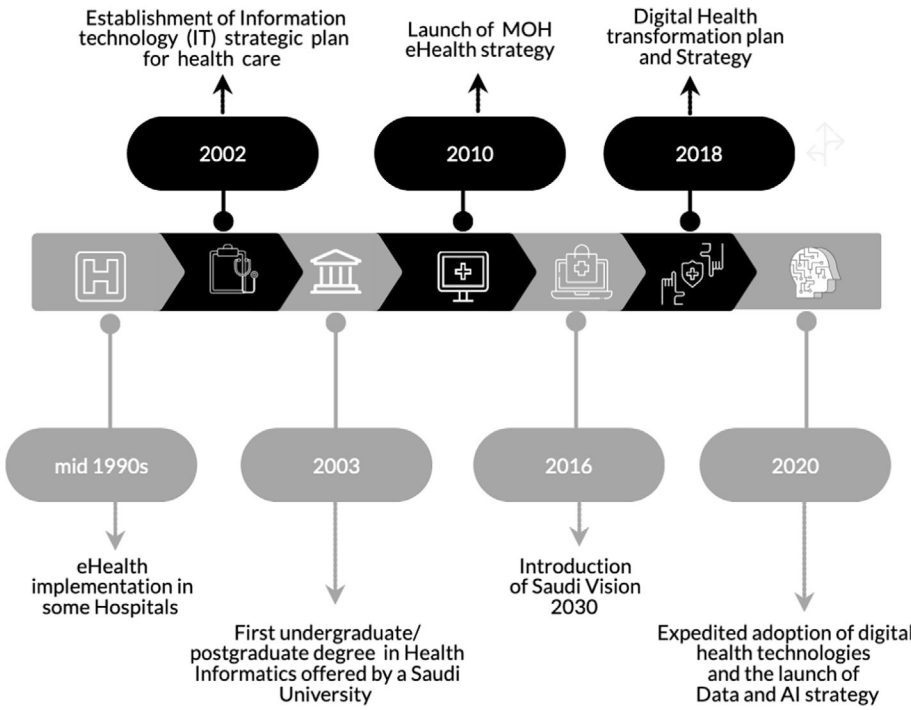

Fig. 1 Key milestones in Saudi Arabia's adoption of digital health

The Ministry of Health (MOH) first launched its eHealth strategy in 2010 (Ministry of Health Saudi Arabia 2018). Health in Saudi Arabia was revolutionized in 2016 with the introduction of the Saudi Vision 2030, a comprehensive plan for economic and social development, including the launch of the National Transformation Program (NTP) (Vision 2030 2016). In this plan, healthcare was classified as a top priority, and a commitment to adopt digital health technologies to improve healthcare delivery and outcomes was issued (Vision 2030 2016; Nation Transformation Program 2022). In 2018, the MOH launched its new Digital Health transformation plan, which outlined a roadmap for adopting digital health technologies across the country. The strategy aims to improve the overall healthcare quality. The goal of this plan is to create a modern, efficient, and integrated healthcare system that meets the population's needs. Furthermore, the plan seeks to improve access to healthcare, reduce costs, and improve patient outcomes (Ministry of Health Saudi Arabia 2018). Between 2019 and 2021, the COVID-19 pandemic caused the expedited adoption of digital health technologies in Saudi Arabia, leading to the expansion of digital health infrastructure and the introduction of many population-level applications by the government (Alharbi et al. 2022; Unified National Platform 2022; Butcher and Hussain 2022; Ministry of Health Saudi Arabia 2023a, b)

1.3 Overview of the Population Structure in Saudi Arabia

According to the General Authority for Statistics, the total population in Saudi Arabia was 34.1 million in 2021, with an expected increase of up to 39.4 million by 2030, in which males accounted for 56.8% of the total population (General Authority for Statistic 2021). The Saudi citizens accounted for 63.6% of the total population, with non-Saudis accounting for 36.4% (General Authority for Statistics 2021). The country is witnessing an accelerated level of population growth at an annual rate of 2.43%. A major demographic shift is predicted in the next decade, with an increase in the growth rate of the elderly population (over the age of 60) of 3.2% to reach 4.63 million by mid-2030 (Health Sector Transformation Program 2021). This shift in the structure of the population is accompanied by an increase in the burden of non-communicable disease that requires high sub-specialized medical and surgical care (Alasiri and Mohammed 2022). This will undoubtedly increase the demand for long-term healthcare services capable of serving an aging population. The Health Transformation Plan has considered the burden of non-communicable diseases among several factors as core challenges and has worked to set priority initiatives to address them (Health Sector Transformation Program 2021). As a response, the MOH announced a reconstruction of the healthcare system. The MOH's plans will not only focus on improving therapeutic and preventive healthcare services, but it will also attempt to reduce any created financial strains (Nation Transformation Program 2022; Alotaibi et al. 2022; Ministry of Health Saudi Arabia 2023a).

1.4 Overview of Saudi Arabia's Healthcare System

Healthcare services in Saudi Arabia are provided through both the government and private healthcare providers. The leading governmental provider is the MOH, which provides a network of hospitals and primary healthcare centers, distributed throughout the country, representing over 60% of healthcare services. The remaining 40% are provided by other governmental healthcare providers, as well as private healthcare providers (Young et al. 2021). The healthcare system in Saudi Arabia is mainly governed by the MOH, as they issue the strategies and policies that guide health services throughout the country (Sebai et al. 2001; Unified National Platform 2022). The MOH institutes healthcare as a right of the entire population, providing free healthcare for all Saudi citizens and non-Saudis working in the public sector (Mufti 2002). The MOH's health services liability for the holy Mosques'' pilgrims and visitors further distinguish the Saudi health-

care system (Walston et al. 2008). Historically, the expenses associated with healthcare were solely financed by the Saudi government, taking up 6–8% of the country's annual budget (Ministry of Health Saudi Arabia 2023c). Financial burdens combined with population growth, encouraged the Saudi Arabian government to move towards privatization (Rahman and Alsharqi 2019; Nation Transformation Program 2022). The first steps were taken in 2003 when the Cooperative Health Insurance recommended that mandatory employment-based health insurance should be implemented (Alkhamis et al. 2014).

1.5 Overview of the Digital Health Transformation Landscape

Saudi Arabia's digital health transformation plan is committed to creating an ambitious goal of an economically conscious and modernized healthcare system that meets the entire population's needs. The plan's fundamental goals are to improve access to care and patient outcomes, increase efficiency, improve care quality, and strengthen health information systems. To mobilize these goals, the plan has built initiatives that expand Telemedicine services, introduce EHRs and develop a National Health Information Exchange (HIE) platform (Ministry of Health Saudi Arabia 2018; Health Sector Transformation Program 2021). Additionally, the plan seeks to bridge the gap between public and private sector organizations to facilitate their communication and delivery coordination (Health Sector Transformation Program 2021).

2 Current State of Digital Health in Saudi Arabia

2.1 Digital Health Solutions and Technologies in Saudi Arabia

Saudi Arabia has made significant investments in digital health infrastructure, enabling Telemedicine, mobile health (mHealth) applications, remote monitoring, Artificial Intelligence (AI), and Blockchain technology (Health Sector Transformation Program 2021). In the first quarter of 2023, 26% of the country's annual budget, which accounts for $50,491 million, was dedicated to the health and social development sector. This amount is actually an increase of 31% from the previous year (Ministry of Finance Saudi Arabia 2023). By improving access to care, enhancing patient outcomes, and reducing the cost associated with traditional healthcare delivery models; these technologies work towards addressing goals set by the digital health transformation plan (Ministry of Health Saudi Arabia 2018, 2023a). Nevertheless, effective integration of these efforts into the healthcare system is still developing, as discussed in the proceeding sections.

One of the first digital health technologies to be adopted worldwide was EHR (Evans 2016; Graber et al. 2017). Saudi Arabia started implementing EHR in the early 2000s to provide a digitalized alternative that allows quick access, backup and recovery of patient data (Sebai et al. 2001; AlSadrah 2020).The MOH adopted an EHR system (the Unified Health File) to improve clinical performance, reduce errors in patient history records, and provide a national database of patient records (Ministry of Health Saudi Arabia 2023d). The use of EHRs improved patient care by equipping doctors to make more informed decisions based on accurate and real-time data (Yousef et al. 2020). Studies conducted in Saudi Arabia found healthcare providers to be knowledgeable of EHR systems (Hasanain et al. 2015; AlSadrah 2020; Otaybi et al. 2022; Alsahafi et al. 2022; Alharbi 2023). Electronic Health records' role in aiding and controlling noncommunicable diseases has also been assessed and found to be a valuable tool (Hazazi and Wilson 2021). The use of EHR can be seen not only within MOH institutions, but also in many of the medium-large private hospitals in Saudi Arabia (Aldosari 2014).

As indicated earlier, EHRs were developed to preserve patients' vital information, from basic demographic data to details of medical diagnosis and management plans. Accessing those data through online portals or mobile applications represents the potential impact of patient engagement and improvement in healthcare delivery

(Dendere et al. 2019; Lyles et al. 2020). A successful initiative within the Saudi digital health transformation plan is the implementation of patient portals. Patient portals are a service offered by many healthcare institutions, both private and government, to empower patients to become active stakeholders regarding their health. Patient Portals are secure platforms that provide the patient's access to health-related information. They also provide open channels that allow patients to communicate with their healthcare provider. The potential benefit of the patient portal relay on improving the quality of health services provided and facilitating the work of health practitioners and improving healthcare delivery (Lyles et al. 2020; Yousef 2021; KFSHRC 2023a; Ministry of National Guard Health Affairs 2023). Positive results reported from studies indicated enhancement of preventative behaviors and management of chronic conditions through those portals (Hazazi and Wilson 2021). In addition, evidence has shown that patient portal use in the primary care setting has enhanced patient engagement, improved communication, and cut costs (Amante et al. 2014; Hazazi and Wilson 2021). The next step is to progress to the Unified Health File system aimed at preserving all patient information and eliminating duplication of patient's data throughout various healthcare organizations (Young et al. 2021; Ministry of Health Saudi Arabia 2023d).

Telemedicine entails utilizing digital communication as well as technology in diagnosis, evaluation, and medical assessment by facilitating the interaction between patients and their healthcare providers (Ministry of Health Saudi Arabia 2022a). Telemedicine is a part of the countries' digital health strategy (Ministry of Health Saudi Arabia 2018). The COVID-19 pandemic required a contact-free solution, which drove the world towards Telehealth (Keesara et al. 2020; Omboni et al. 2022). Saudi Arabia embraced the use of Telemedicine through the adoption of the Sehhaty application to face the demands of the growing population (Alharbi et al. 2021). Sehhaty is an MOH developed unified platform that offers multiple health services. It encompasses the delivery of Telemedicine, health monitoring services, booking of appointments and vaccinations, in addition to health information and other health services offered to the public (Ministry of Health Saudi Arabia 2023e). Governmental and private hospitals, in addition to Telehealth startup Cura have also adopted Telemedicine platforms, including Telepharmacy services (Cura 2023; KFSHRC 2023b; Ministry of National Guard Health Affairs 2023; Dr.Sulaiman Alhabib Medical group 2023). Similarly, hospitals have implemented Telepharmacy services that provide remote prescription, medication management and home-delivery of prescriptions (Algarni et al. 2022). Furthermore, physicians are able to prescribe medication remotely using the Wasfaty or Anat applications. The Wasfaty application serves as a gateway between the patient and a network of pharmacies both governmental and private, enabling them to fill prescriptions or refill regular medications (Wasfaty 2021; Ministry of Health Saudi Arabia 2023f). While the Anat app is a platform designed for health practitioners, it offers services that make their job easier and improve the quality of care provided to patients such as e-prescriptions (Ministry of Health Saudi Arabia 2015, 2023f).

In several nations, mHealth applications are becoming an increasingly significant instrument for the delivery of healthcare (Consolvo et al. 2008). mHealth aims to improve healthcare practitioners' outreach by overcoming distance, time zones, and cost barriers to deliver accessible and low-cost therapeutic services (Vaghefi and Tulu 2019). The MOH introduced several mHealth applications, such as Mawid, to improve the patient experience. Mawid is a free smartphone application that allows users to book, cancel, and/or reschedule appointments at primary care clinics, as well as manage referral appointments to general and specialized hospitals (Alanzi et al. 2022; Ministry of Health. E-Services) eReferrals were shown to be effective in lowering wait times, enhancing access to secondary care, and improving referral patients' information accuracy (Tian 2011). During COVID-19 Mawid helped the users determine the risk of COVID-19 contamination by encouraging them to submit their symptoms and travel information into the application for the risk assessment test. It also assists users in raising awareness about

COVID-19 and provides preventative instructions to be followed (Alanzi et al. 2022).

As the Saudi Arabian government is keen on protecting the health and safety of its citizens and residents from the risk of the spread of novel coronaviruses, the Saudi Data and Artificial Intelligence Authority (SDAIA) developed the Tawakkalna application to aid government efforts to combat COVID-19 (Dawood and AlKadi 2023). The Tawakkalna application was developed in collaboration with the MOH and all relevant authorities during the curfew period to facilitate the electronic issuance of movement permits for government and private sector employees, as well as any individual, assisting in containing the spread of the pandemic in the Kingdom (Binkheder et al. 2021b; Dawood and AlKadi 2023). As we return to regular life, Tawakkalna continues to assist in' displaying users' health status and other services. In addition, as part of encouraging social responsibility, Tawakkalna allows individuals to report breaches to the MOH in the event of a suspected case (Saudi Data and AI Authority 2023).

Saudi Arabia has been a pioneer in the use of remote monitoring technology to enhance patient outcomes. For example, the remote monitoring of chronic diseases such as diabetes and hypertension allows for the promotion of daily treatment and lowers the risk of hospitalization (Alanzi 2018; Alessa et al. 2021). The use of smartphone applications to help with hypertension self-management is becoming increasingly common. However, few commercially available applications have the potential to be useful and have acceptable security and privacy measures in place. A recent study in Saudi showed that commercial application use for self-management of hypertension is effective, usable and acceptable by patients (Alessa et al. 2021). Diabetes mellitus is one of the chronic health conditions that can benefit from self-management education utilizing mHealth applications. A Little research has been undertaken in Saudi Arabia to explore the efficiency of mobile technologies in diabetes management. Nevertheless, studies on the use of mobile applications for disease management and healthcare delivery have shown positive results (Alanzi et al. 2014, 2016). To date, no clinical trial demonstrating the efficiency of these methods for diabetes treatment in the Kingdom has been published. An application referred to as "SAED" was evaluated in a pilot study by Alotaibi et al. (2016). The SAED application was found to positively influence the innervation group by significantly decreasing HbA1c levels and enhancing diabetes awareness (Alotaibi et al. 2016). This application is used for diabetes monitoring, a helpful tool in improving the diabetes care of Saudi patients. The SAED application can also give healthcare professionals vital medical information about each patient. Easing the process of decision-making in their diabetic treatment plan. Incorporating an instructional tool can give diabetic patients pertinent information for better diabetes control. This is especially crucial in distant areas of Saudi Arabia, where healthcare facilities are still poor and lack specialized diabetes care. Adopting such an application will ensure appropriate medical intervention and treatment can be provided (Alotaibi et al. 2016).

Like the rest of the world, wearable health monitoring technologies in Saudi Arabia are increasingly being used. Smart watches or wristbands can track a variety of physiological characteristics and wirelessly transmit data to smartphones (Torres-Huitzil and Alvarez-Landero 2015; Yeh 2016). Wearable devices are used to monitor and collect information on people's health issues, such as glucose levels, blood pressure and heart rate (Vijayashree and Sultana 2018). While wearable devices have become a world norm, Saudi Arabia has also joined in the development of wearable sensors due to the growing demand from health consumers. For example, a real-time pilgrim tracking and health monitoring system was utilized using Arduino. Each pilgrim is given a wearable sensor that detects their location and primary health information. This sensor is linked to the control room to take fast action in case an alarm is received from the device (Rajwade and Gawali 2016). Also, a wearable personalized medicinal platform has been developed, where a wearable device can dispense medication and vitamins at varying doses depending on the individual needs

(KAUST Innovation 2016). Another example is Qawam, a headwear addition capable of monitoring posture. The goal is to prevent neck and back pain that results from incorrect posture during computer and smartphone usage (Qawam 2021).

In various medical professions, Virtual Reality (VR) has been utilized to improve health outcomes (Alanazi 2022; Bayahya 2021; Bruno 2022). Further, VR in education and training allows medical students to virtually enter the human body to gain a comprehensive understanding while simulating real-life therapies (Eddy 2021; Dhar et al. 2023). Employing VR in medical education allows students to train in a simulated scenario for comprehensive surgical education at a significantly lower cost. In Saudi Arabia, the application of VR versus conventional methods in teaching has shown promising results in undergraduate medical education (Sultan et al. 2019). Augmented reality (AR) is also being used to give students hands-on learning experiences, such as simulating patient and surgical encounters, so that medical interns can practice emerging techniques (Bhugaonkar et al. 2022). A study evaluated the efficacy of AR among patients undergoing orthodontic treatments in Saudi Arabia. Patients who underwent education through AR displayed higher levels of knowledge retention of oral hygiene instructions than patients who received information from leaflets (Aljabry et al. 2023).

In Saudi Arabia, VR and AR have also been utilized in settings related to clinical psychology. A randomized control trial in Najran, a city southwestern of Saudi Arabia examined the effect of applying VR for patients undergoing cesarean sections. It found that use of VR glasses channeling 3D natural videos with sounds such as Quran (the holy book of Islam) or soft music during anesthesia resulted in a reduction of stress and anxiety levels among patients undergoing cesarean sections (Almedhesh et al. 2022). Others have proposed the use of AR as an alternative to Cognitive Behavioral Therapy (CBT) in patients with attention deficit hyperactivity disorder (ADHD) through the design of an AR-therapist (Alqithami et al. 2019). The AR-therapist incorporates gaming and utilization of AR to engage the patient and facilitate the treatment of ADHD patients. Although this model has been implemented and has shown efficacy in a single patient. The comparison of the AR-therapist to traditional CBT for the treatment of ADHD still needs to be evaluated with a cohort of human subjects (Alqithami et al. 2019).

Another important development in the field of digital health is the growing interest in Artificial Intelligence (AI). Although AI implementations in healthcare started as early as the 1950s, the full potential has only been witnessed in the past two decades, with the advancements in machine learning and language/image recognition algorithms (Kaul et al. 2020; Roser 2022).With the COVID-19 pandemic quickly straining healthcare services early in 2020, the Saudi Arabian government, led by SDAIA, utilized the use of AI to face the growing demands of the healthcare sector.

Artificial intelligence can also be used as a 'Phenotype tool' assisting in a preventive approach style of healthcare, commonly used in the field of public health. Using predictive analytics can help identify patients at a higher risk of developing chronic diseases such as diabetes (Alshammari et al. 2021a, b). By also examining patient long-term information, such as medical history, lifestyle habits, and genetic information, AI algorithms can analyze this and determine which patients may develop a particular disease (Alshammari et al. 2021a, b). These preventive approaches can assist healthcare decision-makers in identifying tools for early intervention, leading to a healthier population and reduced healthcare costs. However, AI implementations still have a long way to go, and Saudi Arabia recognizes the potential of AI and the role it will have in the healthcare sector (National Strategy for Data & AI 2020). In particular, the advancements in diagnosing various diseases, including cancer, diabetes and cardiovascular disease (Jiang et al. 2017). During the Riyadh Digital Health Summit (2022), a panel of 13 key experts identified 7 priorities recommended for adoption in order to face future pandemics. Artificial intelligence landed third on this list, indicating the potential it possesses (Al Knawy et al. 2020).

Blockchain is another technology being used worldwide in many industries, including Finance and Healthcare. It is used to securely transmit and store data. This is an important aspect when dealing with digital health due to the sensitive nature of patient data and the strict privacy rules (Shi et al. 2020). Hence, the incorporation of Blockchain technology into the Saudi healthcare sector, taps into its capabilities to ensure patient confidentiality. (Alsufyani et al. 2020), and to improve the healthcare system's efficiency, security, and transparency (Alharthi et al. 2020). The Saudi Food and Drug Authority (SFDA) is currently exploring the use of blockchain to trace products' journeys. That will allow the two parties, the supply chain entities and consumers to enhance their transparency and security, that will feed into establishing trust (Saudi Food and Drug Authority 2023).

Finally, the Seha Virtual Hospital is an innovative digital technology that has been introduced to the Saudi digital health market. It is considered a specialized healthcare virtual facility that can accommodate up to 400,000 patients annually. It employs advanced technologies that offer specialized services. It also has the capacity to assist around 152 hospitals throughout the Kingdom, in addition to 15 primary specialized health services and 34 sub-specialized services (Ministry of Health Saudi Arabia 2023g). The Seha Virtual Hospital has embraced a patient-centric approach to healthcare delivery, improving patient outcomes and experiences. The hospital utilizes all the advancements already well established in the Kingdom such as; EHRs, Telemedicine and AI, and remote monitoring technologies (Alsufyani et al. 2020; Ministry of Health Saudi Arabia 2022b). These technologies have helped bridge the gap between patients and providers. Overall, Saudi Seha Virtual Hospital's adoption of digital health solutions and technologies has had a significant role in offering digital health services in the governmental sector (Ministry of Health Saudi Arabia 2018, 2023g) . A list of available digital health solutions and technologies are summarized in table 1 (Table 1).

Table 1 Summary of digital health solutions and technologies in Saudi Arabia

Technology	Use/Application	Benefits	Examples
EHRs	Digitalized patient records	Improve clinical outcome, reduce patient history errors	Unified Health File
Telemedicine	Remote consultations, diagnoses, and prescription	Reduces travel time, improves access to care	Sehhaty, Cura
Telepharmacy	Remote prescription management and home delivery	Improved medication adherence, reduced errors	Wasfaty
mHealth	Health monitoring, appointment scheduling, reminders	Convenience, increased patient engagement	Mawid, Tawakkalna, Sehhaty
Wearables & Sensors	Health tracking, monitoring vital signs, and activity	Continuous data collection, early detection	Fitbit, Apple Watch,
Patient Portals	Patient's access to health information	Convenience, health management, patient engagement	MNG-HA Care, Altakhassusi Portal, HMG patient portal
VR/AR in Healthcare	Medical training, pain management, and rehabilitation	Enhanced learning experiences, reduced pain	Medical Realities, VR training programs
AI in Healthcare	Image analysis, drug discovery, predicting patient outcomes, decision support systems, critical thinking	Enhanced speed and accuracy of diagnoses	Saudi AI-powered radiology platforms
Blockchain	Ensuring data security, privacy, and interoperability	Increased trust, streamlined healthcare processes, ensuring patient confidentiality.	Saudi Blockchain healthcare pilot projects
Virtual Hospital	Virtual facility that integrates EHRs, telemedicine, remote monitoring, and AI	Convenience, improve access to care, reduce travel time. And many more	Seha Virtual Hospital

2.2 Assessment of the Level of Digital Health Adoption and Awareness

Early research indicated a low percentage (approximately 30%) of use of digital health among healthcare organizations and negative attitudes from the healthcare workers relating to health information security and lack of sufficient training in using digital health applications (El-Mahalli et al. 2012; Albarrak et al. 2021). However, recently the perception and belief about the benefit of digital health implementation in a practical setting have changed (Thapa et al. 2021). Many reports indicated that digital health in Saudi Arabia is evolving steadily due to many factors including, but not limited to good network infrastructure across the country, a high percentage of internet users among the population that reached 98% in 2021, the launch of health information system in numerous governmental hospitals since the early 2000s, (Shouli and Mechael 2019; World Bank 2021; Al-Kahtani et al. 2022a). This has been evident during the COVID-19 pandemic, emphasizing the importance of digital health as an indispensable resource for patient care (Alghamdi et al. 2021). For example, Telemedicine emerged in some of the healthcare settings prior to the pandemic, but the adoption of Telemedicine has been moved forward during the pandemic with improvement in healthcare providers and patients' awareness, and willingness to use such resources (Omboni et al. 2022). Similar observations have been reported in many health-related fields, including medical students, pharmacists, and the dental profession (Alsahali 2021; Chaudhary et al. 2022; Al-Kahtani et al. 2022a).

The available literature assessing the level of digital health adoption and awareness highlighted the importance of providing proper training to healthcare workers and education to the general population (Al-Kahtani et al. 2022b). Many qualitative studies highlighted the issue of understanding the cultural perspective in terms of application of and adoption of health technologies. Based on a qualitative study, cultural factors such as the language and communication of patients and the electronic literacy of healthcare providers are considered the main factors that potentially influence the adoption and awareness of digital health (Alodhayani et al. 2021). However, there is still insufficient data on the level of awareness of the implementation of digital health for both healthcare providers and patients. This can be attributed to the context and setting of those studies (Alodhayani et al. 2021; AlSalloum et al. 2023). A recent study examined patients' awareness and satisfaction with four main MOH e-services (Seha, Moed, 937 Services, and Wasfati.). The study reported that 77% of participants were aware of such services where the demographic characteristics and level of education played key roles in the awareness of e-health.

2.3 Measuring the Digital Health Implementation in Saudi Arabia

The advancements in digital health development and implementation necessitates a comprehensive evaluation for their effectiveness and long-term impact on population health outcomes (WHO 2021). Understanding the healthcare landscape and the population's needs is the first step in evaluating and implementing digital health technologies (Soobiah et al. 2020). Some studies indicated that the digital health efforts within the Saudi healthcare system have been efficient in reducing time, cost, and efforts of the healthcare providers to provide care (Otaibi 2019). However, the available literature that discussed a framework for monitoring and evaluating digital health implementation and progress is lacking. Some of those studies were formative evaluations, which assesses the readiness for digital health transformation at different hospitals. Other studies evaluated the effectiveness of specific eHealth applications (Alharbi et al. 2021; Al-Kahtani et al. 2022a). For example, one study examined the effectiveness of the Seha, an eHealth app, in improving healthcare delivery and efficiency and indicated that adopting digital or eHealth technologies would address some of

the problems in the health system related to low patients' satisfaction and limited resources (Alharbi et al. 2021).

In 2013, the World Health Organization (WHO) issued a global strategy on digital health that calls for developing and maintaining digital health infrastructure. And since 2015, the MOH has made remarkable progress in implementation of digital health; however, the status of the digital health implementation has not been unified by providers across the country (Alharbi 2018). In an effort to highlight the importance of digital technology for the global health and care system, the Riyadh Declaration on Digital Health in 2020 was formulated. This landmark forum emphasizes the role of digital and data technologies in promoting local and global resilient healthcare systems through the articulation of seven key priorities and nine recommendations for data and digital health (Al Knawy et al. 2020). The fact that Saudi Arabia hosted this forum is a showcase that the country is taking leading steps and a prominent position in the realm of digital health. Still, further research with appropriate measures and high-quality data on the evaluation of digital health efforts and outcomes and their impact is essential to support the implementation of further digital technologies. In addition, evaluations are expected to provide justification to further promote investment in the field (Al Knawy et al. 2020; WHO 2021).

3 Digital Health Ecosystem in Saudi Arabia

3.1 Overview of the Digital Health Ecosystem in Saudi Arabia

A digital health ecosystem is a health-centered environment that encompasses all individuals, governmental and private entities, innovations, technologies, data and resources, key players necessary to advance the digital health program (WHO 2021). The digital health ecosystem in Saudi Arabia is an evolving and developing sphere. The maturity of digital health in the Kingdom has been captured through Global Digital Health Index (GDHI). This measure assessed components of advancement in digital healthcare such as leadership and governance; strategy and investment; legislation policy and compliance; workforce, standards and interoperability, and infrastructure services and applications (Global Digital Health Monitor 2023). Currently, the GDHI in Saudi Arabia reached a maximum maturity (phase 5), an improvement from previous years where it was placed at the phase 4 level of maturity (Al Shouli and Mechael 2019; Global Digital Health Monitor 2023). These improvements are attributed to government and private sector collaborations to promote and embrace digital health technologies. The success and sustainability of digital health in Saudi are also reliant on an influx of investment, support, and continued cooperation (Ministry of Health Saudi Arabia 2018).

3.2 Overview of the Key Stakeholders in Saudi Arabia

To ensure that the goals of the digital health transformation plan are met, all stakeholders should be involved in its implementation process. Encouragement of innovation and intersectoral collaborations is a priority in the Kingdom (Ministry of Health Saudi Arabia 2018). This section will highlight some of the key stakeholders in digital health in the Kingdom. This includes; patients and providers, regulatory bodies, academic and research institutes and other governmental initiatives. This section will outline their roles and contributions to developing the digital health arena.

The experience of a patient with digital health in Saudi Arabia is now further enhanced by the changes in healthcare reform (Ministry of Health Saudi Arabia, Digital Health Strategy 2018). The patient's acceptance and proper utilization of these solutions are vital for better health outcomes (Lupton 2014). This is why user-centered designs have been adopted (Calvillo-Arbizu et al. 2019). The national strategy places the health consumer at the center of the health model. Focusing on patient-centered care, which

includes patient involvement in the decision-making process for improving their health outcome (Amin et al. 2020; Alotaibi et al. 2022).

The healthcare provider also plays a critical role in digital health adoption (Petersen et al. 2015). As the primary users of digital health technologies, healthcare providers are responsible for the successful implementation and adoption of these technologies (Petersen et al. 2015). Primary healthcare providers in Saudi Arabia comprehend the benefits of EHR, which include; the efficiency, the accuracy of documentation, and the availability of information when it is required (Hazazi and Wilson 2021). The government also supports their education and advocates to increase their knowledge in digital heath (Hassounah et al. 2020).

The MOH manages and regulates digital healthcare services in the Kingdom, it oversees the healthcare industry and formulates regulations governing both the public and the private health sector (Ministry of Health Saudi Arabia 2018; Al-Kahtani et al. 2022b; Alqahtani et al. 2022). The MOH's efforts are outlined as the National Standards for eHealth in the Kingdom, which is the roadmap for the digital health transformation plan (Ministry of Health Saudi Arabia 2018). In addition, the MOH sets the necessary guidelines for data sharing, privacy, and it overlooks all ongoing digital health initiatives in the country (Digital Government Authority 2023a). An example of the MOH's regulation of digital health services is its governance of the interoperability of e-prescriptions (Ministry of Health Saudi Arabia 2015). Another regulatory body involved in digital healthcare services is the Saudi Data & Artificial Intelligence Authority (SDAIA). The SDAIA was established in August 2019, by a Royal Decree aiming to facilitate the transition in achieving Vision 2030's goals. SDAIA's responsibilities lie in advancing the data and AI agenda (Memish et al. 2021). Global investment in the health sector is seeked out and regulated by the Ministry of Investment Saudi Arabia (MISA),formerly known as the Saudi Arabian General Investment Authority (SAGIA) (Ministry of Investment Saudi Arabia 2023). The MOH, SDAIA and MISA are all governmental entities that align their efforts to achieve national goals within the Kingdom towards Vision 2030 targets and initiatives.

Digital health care services are also regulated by the Saudi Health Council (SHC) (Saudi Health Council 2023).The SHC's role, among other things, is to ensure enhancement of healthcare services between different stakeholders. It acts as a liaison that properly bridges the different entities together allowing proper collaboration to take place without any duplication of efforts (Saudi Health Council 2023). Another regulator is the Council of Health Insurance (CHI) previously known as Cooperative Health Insurance. The CHI is concerned with insurance companies and service providers. Their mission is to advance the health outcome of beneficiaries by enabling the use of transparency and equity value-based care among stakeholders (Invest Saudi 2017; Council of Health Insurance 2023). In addition, the SFDA is responsible not only for drug and food regulation but also for regulations concerned with medical devices. For example, the SFDA ensures necessary guidelines are present for medical devices marketing authorization for AI and machine learning. A crucial step that will facilitate adoption of medical devices into the Saudi market (Invest Saudi 2017; Saudi Food and Drug Authority 2022).

The growth and development of the digital health profession in the country is also a priority. Although research and development in the field is fostered at multiple universities in the Kingdom, these efforts only started in the 2000s (Al-dossary et al. 2021). There are 16 identified Universities that offer degrees in a variety of programs in Health Information Management, spread out at different geographical locations in the Kingdom. The majority (10) are public programs, and the rest are private programs (Al-dossary et al. 2021). All 16 Universities offer bachelor's degrees in health informatics. However, only five provide a master's degree. The earliest program started around 2003, at the Imam Abdulrahman bin Faisal University (Al-dossary et al. 2021). Most of these Universities have a set pathway to pursue a Doctor of Philosophy (PhD) scholarship oppor-

tunities in Health Informatics supported by the Ministry of Education (MOE). This will ensure further research and development in the field (KSAU-HS 2023). Furthermore, the Saudi Commission for Health Specialties guarantee proper classification and registration of these scholars and provides opportunities for further professional development (Invest Saudi 2017).

The Saudi Association for Health Informatics (SAHI) aims to improve efforts for further development by promoting research and engaging professionals in conferences, exhibitions, and networking opportunities (Saudi Association for Health Informatics 2023). In 2018, The Misk digital health accelerator program was launched to support startups and entrepreneurs in the digital health sector, through mentorship, fundraising, and networking (Misk 2022). The NHIC also works to advance the field of health informatics through the introduction of initiatives (Public consultation Platform 2022) In addition, the Saudi Electronic University (SEU) has recently collaborated with the MOH. This collaboration offered professionals in the field access to blackboard licenses from SEU to be utilized for training purposes. Ultimately, this collaboration is expected to build capabilities and strengthen online health practices among professionals (Saudi Electronic University 2022).

3.3 Analysis of the Key Players in the Ecosystem

In Saudi Arabia, family ties and values are very important (Al-Khraif et al. 2020).The patients' caregivers or family members' role as a stakeholder cannot be overlooked, as family members are usually in charge of supporting elders (Al-Khraif et al. 2020; Petersen et al. 2015). Elders usually seek help from a family member when accessing information from the mobile internet (Xiong and Zuo 2019). Digital literacy, level of education, as well as necessity for technology access, are aspects that dictate if older adults actually adopt certain technologies (Neves and Amaro 2012). Usage of user-centric designs in the developmental process of digital health technologies or eGovernment services can help increase adoption within young and adult populations (Alanezi et al. 2012; Calvillo-Arbizu et al. 2019; Khan and Lutfi 2021). The eGovernment services can only be considered for adoption when the quality is up to the consumers 'standard (Choudrie and Alfalah 2016).

Health providers in Saudi Arabia have expressed digital literacy (Hasanain et al. 2015). In spite of all offered support, providers lack reliable infrastructure, resources, and training act as major challenges in digital health adoption (Alshahrani et al. 2019). Satisfaction and improvement in their experience with digital health technologies became evident after the COVID-19 pandemic (Alsaleh et al. 2021). The COVID-19 pandemic has provided a push to help accelerate this digital transformation (Alharbi et al. 2022; Alkhalifah et al. 2022). For this reason, the rush of digital health technologies into the Saudi Market was accompanied by numerous tactics to empower and educate the health consumer (Hassounah et al. 2020). The MOH scheduled live television broadcasts of the official spokesperson presenting up-to-date information daily. The MOH also utilized its social media platforms, Twitter in particular, to support this goal. In addition, it collaborated with a number of health entities to establish the Prevention Ambassador Initiative web-based course, to address health rumors on social media platforms (Saudi Press Agency 2020; Hassounah et al. 2020) . Other efforts included the provision of new laws by the Saudi Public Prosecution for sharing misleading or inaccurate electronic information (Riyadh Daily 2020).

The digital health market has witnessed rapid growth that requires the personal data protection law (PDPL) to oversee privacy policies and procedures. Accordingly, SDAIA and National Data Management Office (NDMO) released guidelines and rules for Personal Information Protection and Sharing of Data (National Data Management Office 2020; Digital Government Authority 2023b). The main objective of this law is to govern the process by which digital technol-

ogy is utilized in healthcare while maintaining the necessity of protecting the privacy and security of personal information. (Digital Government Authority 2023b).

The maturation in protection laws allowed MISA to open the doors for local and international investments (Unified National Platform 2023). To add to the appeal of investing in Saudi's HealthCare and Life Sciences (HCLS) sector, MISA has granted foreigners 100% ownership of their investments (Ministry of Investment Saudi Arabia 2021).This has lead to the direct investment of foreign companies such as Roche in Saudi's HCLS sector with the aim of unlocking investment opportunities including digital health solutions (Ministry of Investment Saudi Arabia 2021). Additionally, the MOH has signed Memorandums of Understanding (MoUs) with international as well as local companies to support the National Transformation Plan for the healthcare sector. An example of an international collaboration is the MoU with General Electric (GE) to provide digital health solutions to the Kingdom (GE 2018). Locally, an MoU with Inma to provide and implement Telesurgury services (Alturki Holding 2022). The advancement of the digital health strategy also includes partnership and MoUs between private companies such as cloud solution and Dell technologies to provide technology solutions for the health care sector (Cloud Solutions 2021).

4 Future Outlook and Opportunities

4.1 Discussion of the Challenges of Digital Health Solutions in Saudi Arabia

Digital health implementation in Saudi Arabia can provide sustainable solutions and improve access to healthcare with higher levels of consumer satisfaction. Moreover, it offers many other benefits in improving patient health outcomes. This is evident through streamlining the delivery of care, improving communication between patients and healthcare providers, providing personalized treatment plans based on individual needs and preferences, as well as increasing access to quality care for underserved populations (Kuwabara et al. 2019; Haleem et al. 2021), moving away from silos and towards a greater integration of the healthcare ecosystem.

The Health Sector Transformation Program (Ministry of Health Saudi Arabia 2018) identified a number of challenges that can be addressed through digital health implementations. Concerns such as premature death, an accelerated level of population growth, the burden of non-communicable disease (mainly diabetes) as well as the burden from road traffic injuries are all areas that need immediate interventions to improve the quality of health services currently provided.

Other challenges that face the healthcare sector include lack of awareness among stakeholders, privacy concerns, cultural factors, regulatory challenges, and cost considerations (Al-Jumaili et al. 2015; Alnemary et al. 2017; Ministry of Health Saudi Arabia 2018; Alkhateeb and Alhadidi 2018; Almubark et al. 2019; Alnaim 2019; Alakhali 2020; Alodhayani et al. 2021; Alsahafi et al. 2022; Alahmadi 2023). The somewhat overlapping roles of the regulatory bodies and the health or financial service providers may lead to a conflict of interests. Thus, inconsistencies in primary and specialized healthcare, rehabilitation, long-term, and home care services, and patient care may affect the quality of treatment plans monitoring of patient's outcomes (Vision 2030 2016; Khan and Iqbal 2020; Nation Transformation Program 2022). Furthermore, there is a lack of robust, consistent, and integrated digital information systems across all hospitals, which could enable better resource management, activity levels, product quality, and performance (Health Sector Transformation Program 2021).

With an increasing population, including a growing elderly population, and a considerable number of expatriates and international visitors, the healthcare system must modernize its approaches in order to meet growing demands

(Vision 2030 2016). It should be noted that this challenge has been identified and been taken into consideration within the health sector transformation program initiatives. Adding to this, many of the initiatives within this program set outcome evaluation to follow up the projects with defined performance indicators, especially those initiatives that related to improved performance of MoH hospitals and medical centers (Health Sector Transformation Program 2021). Furthermore, Saudi Arabia is the custodian to the two holy mosques attracting more than seven million Umrah visitors during 2022, including four million worshipers with Umrah visas (Alarabiya 2023). Ensuring their safety and disease control is an ongoing challenge facing the healthcare system.

Acknowledgement of these challenges requires collaboration between government agencies, healthcare providers, technology companies, and other stakeholders to ensure that the population benefit from these transformative technologies and that the right capabilities are being built (Al-Kahtani et al. 2022b). Challenges are prioritized according to national goals and population needs (Alshuwaikhat and Mohammed 2017).

Another trending issue is the health literacy level among the Saudi population, with 46% considered health illiterate (Alahmadi 2023). Although access to health information is available, the amount, accuracy, quality, and reliability of it might not be suitable (Alsahafi et al. 2022), resulting in a misinformed, confused and often overwhelmed health consumer. The wide access to social media networks among a generally tech-savvy younger population has led to another more trending concern facing health consumers which is the spread of misinformation (Infodemic) on the Internet. Misleading information on digital platforms can negatively impact population health, spreading anxiety and fear which leads to health consumers adopting unhealthy behaviors (Pian et al. 2021). Furthermore, the internet contains an immense amount of health information. However, the majority of it is in English, not Arabic, the main language in Saudi, thus compounding the potential for misinformation (Al-Jumaili et al. 2015; Alnemary et al. 2017; Alkhateeb and Alhadidi 2018; Almubark et al. 2019; Alnaim 2019; Alakhali 2020; Alahmadi 2023).

Overall, the implementation of digital health provides sustainable solutions (Thapa et al. 2021). It improves patient outcomes by streamlining the delivery of care, improves communication between patients and healthcare providers, provides personalized treatment plans based on individual needs and preferences, as well as increases access to quality care for underserved populations (Kuwabara et al. 2019; Haleem et al. 2021; Alodhayani et al. 2021; Alsahafi et al. 2022).

Adding to this, the duplication of health service provision and financing for the same beneficiary, which results in unjustified variance, overuse, and underuse, leading to efficiency shortfalls (Trinh et al. 2008). Another identified challenge is related to the presence of a gap between supply and demand in the health workforce that has led to an increased dependence on foreign labor. Furthermore, there is a lack of robust, consistent, and integrated digital information systems across all hospitals, which could enable better resource management, activity levels, product quality, and performance (Health Sector Transformation Program 2021). Finally, there is a need to strengthen governance systems that contribute to reducing challenges to the health of the population and the quality of health services provided (Ministry of Health Saudi Arabia 2018; Chowdhury et al. 2021).

4.2 Discussion of the Future Opportunities for Growth of Digital Health in Saudi Arabia

The Saudi government's commitment to digital transformation is evident. Through strategic programs such as the NTP, the government can act as a catalyst furthering the adoption of digital health strategies and initiatives (Vision 2030 2016; Health Sector Transformation Program 2021). The government is also committed to providing

the right infrastructure for a prosperous digital health environment (Health Sector Transformation Program 2021). In 2021, the internet penetration rate in Saudi Arabia increased to 98.1% compared to 95.7% in 2019 (Communication, Space & Technology Commission 2021). Residents in Saudi Arabia are now offered high speed coverage from mobile networks, which consists of 4G and 5G coverage capabilities with wireless and fiber optic connectivity (Aldiab et al. 2022). The trust in digital solutions amplified with the adoption of health applications, such as Sehhaty, Tawakkalna applications, during the COVID-19 pandemic. The growing interest of citizen adoption and usage of e-services can have a ripple effect towards the development and innovation in more digital health technologies. Future opportunities lie in Saudi Arabia, given how it is becoming a market that capitalizes on investing in digital health solutions. This is evident through the Vision 2030 Privatization Program (launched 2018) which aims to improve the quality of services in 16 sectors within the country, including the health sector (Vision 2030 2022).

Furthermore, future opportunities in Saudi Arabia are also associated with the growing population of digital natives. Based on the total population estimation in 2021, more than 30% are between the ages of 15–35 years (General Authority for Statistic 2021). This age group is comfortably utilizing and navigating digital technologies, further enabling transformation of digital health and its development (Communication, Space & Technology Commission 2021). Capitalizing on this age group by educating and building their capabilities will help close the digital divide among elders and help increase satisfaction among users of digital technologies. Furthermore, building capabilities in Saudi Arabia will also facilitate advancements towards the Sustainable Developmental Goals (SDGs) in achieving indicator 4.4.1: "proportion with youth and adults with information and communications technology (ICT) skills" (United Nations 2022). Saudi Arabia intends to fulfill this SDG through attaining fundamental data and AI literacy skills by training 40% of its workforce by 2030 (National Strategy for Data & AI 2020).

Opportunities persist given the current deficiency of published literature surrounding digital health. The government recognizes the need to connect research with national development, especially with fields that support national programs such as health informatics. In order to understand existing publications Binkheder, Aldekhyyel and Almulhem (2021a) assessed the health informatics publication trends in Saudi Arabia between 1995 and 2019. The authors found that most of the published literature discusses clinical informatics (73.1%), and the rest covered consumer health informatics (22.3%) and 4% only covered public health informatics (Binkheder et al. 2021a). This emphasizes the opportunities that lie within furthering research and development in these fields.

In a global survey, Saudi Arabia was ranked second when answering "whether artificial intelligence products and services will make the lives of respondents easier." Fully aware of the potential opportunities that lie within AI, SDAIA launched the National Strategy for Data and AI, a long-term plan aimed at implementing AI in five sectors in the country, including education, government, healthcare, energy, and mobility (National Strategy for Data & AI 2020). In order to facilitate the implementation of the strategy across the government entities four subsidiaries were created under SDAIA: the National Information Center (NIC), the National Data Management Office (NDMO), and the National Center for Artificial Intelligence (NCAI) (National Strategy for Data & AI 2020). According to the strategy, integration of Data and AI into healthcare will "increase access, enhance preventative care, and accommodate growing demand (National Strategy for Data & AI 2020). The opportunities in AI are endless and will continue to develop, attracting further growth and investments. The goal of the strategy is to reach $20 billion in local and foreign investments by 2030 (National Strategy for Data & AI 2020). A commitment to Saudi's future as a global hub for Data and AI has been established, and with it the advancement of healthcare through digital health will continue.

5 Conclusion

The government of Saudi Arabia has been exploring the potential impact digital health can have on the healthcare sector since the late 1990s. Initiatives by government health entities quickly developed into national collaborations under the umbrella of the Saudi MOH. The past two decades witnessed digital transformations in the healthcare sector which improved the quality of health services, reduced medical errors, utilized health resources, and reduced costs. Alongside this transformation came national strategies, regulatory bodies and law, and public health campaigns to address health literacy within the population.

One of the main factors for success is the advanced mobile connectivity and stable country-wide coverage incorporating high-speed 5G networks. In addition, the majority of the Saudi population already uses the internet with a growing number of digital health users. This reliable infrastructure was evident during the COVID-19 pandemic when most healthcare services converted to a virtual form relying heavily on mobile health applications. As of 2022, over 68 million doses of the COVID-19 vaccine have been administered in Saudi Arabia indicating that 80% of the population (approximately 27 million) have booked and received the COVID-19 vaccines through the MOH mobile application Sehhaty. This suggests widespread use and acceptance of the Saudi population.

Vision 2030 has set objectives for the healthcare sector, and digital health can no doubt assist in achieving them. In particular, much focus has been on trends using technologies such as AI, Data mining, Genomics, and Bioinformatics. As technologies evolve and new devices develop, it is imperative that we continue to address critical issues related to data security and confidentiality. We also need to focus on patient satisfaction through a patient-centric approach to healthcare. Additional research is required to examine the impact of such technologies and identify potential areas for growth. Digital health has already had a significant impact on the healthcare sector in the Kingdom, and we expect to see further incorporation of future innovations, putting Saudi Arabia at the forefront of digital health adoption and utilization.

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The Digital Divide Based on Development and Availability: The Polish Perspective

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Abstract

Contemporary Poland has achieved great strides in the process of digitization of healthcare with some impressive implementations in recent years. However, despite the marked process, the situation regarding broadly understood digitization, innovation in medicine, development of approaches and solutions based on Artificial Intelligence remains imperfect. Having said that, there are dynamic institutions that have registered both clinical and scientific achievements based on digitisation and whose mission, in part, is to influence decision-makers so that the development of modern technologies encounters as few obstacles as possible. Current challenges are the result of the Polish healthcare system structure, which was problematic even without the context of innovation and digitalization. Consequently, this is reflected in the approach to medical education as well as in the attitude of healthcare professionals towards solutions which are considered new and unknown. This chapter summarises the challenges specific to Poland and healthcare digitisation, and highlights the progress that has been achieved thus far.

Keywords

Artificial Intelligence (AI) · Poland · Medical implementation · Regulation · Data poverty · Medical imaging · Biobanks · Digital Medicine

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1 Introduction: An Overview on the Use of Artificial Intelligence in Healthcare

Artificial Intelligence (AI) has become one of the crucial tools for improving healthcare worldwide. Its disruptive nature is evident in almost every healthcare sector across the globe, and its exponential growth led to the use of the term "AI revolution" in healthcare. In the EU and US there were only 21 certified AI algorithms for health-

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care in 2015 and this number has increased to more than 450 algorithms after just 5 years.[1] AI growth is particularly visible in radiology, cardiology and oncology, among other fields.

Artificial intelligence has no strict definition, as it's challenging to define AI in a way that won't become outdated quickly. Typically, we use the term "AI" to describe algorithms that can perform tasks requiring human intelligence, such as visual perception, speech recognition, decision-making, and natural language processing. In other words, AI is a mathematical algorithm that learns from data we provide.

The benefits of AI in healthcare are numerous. One of the most significant advantages is enhanced accuracy, leading to more precise diagnoses and treatment plans. AI algorithms can improve efficiency by automating many routine tasks, relieving healthcare professionals to focus on more complex and personalised patient care. AI can, therefore, help healthcare providers save time and money.

2 Real Examples of AI Implementations in Medical Area in Poland

Poland has embraced the use of innovative technologies in healthcare. According to a report created in 2022 by the Polish e-Health Agency, 6.6% of hospitals, and 2.5% of all medical entities, use AI solutions. The vast majority of them use AI for CT and MRI analysis.[2] When it comes to telemedicine, it is used by 32.4% of hospitals and 25.5% of all medical entities.

Some new technologies in healthcare are reimbursed by the National Health Fund, however it's not a common standard. One of the examples is the system of continuous glucose monitoring by scanning and measuring the concentration of glucose in the intra-tissue fluid using a sensor placed on the arm and sending the result to a smartphone application (or a dedicated reader). It tracks the level and variability of glycemia and alerts about dangerous hypoglycemics by displaying trend arrows.

Few AI projects are funded directly by the Ministry of Health. During the COVID-19 pandemic pilot project on electronic stethoscopes that uses AI algorithms for sound interpretation was implemented in Polish healthcare. There are also public grants for hospitals and technological companies that create and validate AI algorithms, provided by the National Centre for Research and Development and Medical Research Agency.

AI is also implemented and successfully used in medical establishments throughout the country on their individual initiatives. For example, the Radom Oncology Center is one the first such institutions in Poland that has reached for AI in imaging diagnostics.[3] Next, the hospital in Ostróda is implementing a voicebot system which is supposed to facilitate the operation of the facility. "Odrodzenie" hospital in Zakopane uses AI solutions for histological specimen analysis and uses hospital budget as a funding source.[4] Some projects are also funded by European Funds, as with project implemented in National Cardiology Institute on AI solutions for non-invasive myocardial infarction diagnose or Copernicus Hospital project that was focused on finding kidney tumours in CT scans by AI algorithm.[4]

The Polish healthcare startup sector is experiencing rapid growth. According to the report entitled Top Disruptors in Healthcare 2022, third edition (a document prepared annually by the AI in Health Coalition), 47% of startups are developing AI solutions for medicine.[5] In following editions, more than 60% of startups were involved in AI for healthcare. Almost 30% of startups have solutions certified with a CE mark, and nearly

[1] Muehlematter UJ et al.; Lancet Digit Health; 2021; Mar 3(3): 195–203

[2] https://cez.gov.pl/sites/default/files/2022-09/Raport%20CeZ_2022.pdf

[3] https://www.linkedin.com/pulse/sztuczna-inteligencja-ai-w-obrazowaniu-metod%C4%85-%C5%82ukasz-pruszy%C5%84ski

[4] https://aiwzdrowiu.pl/wp-content/uploads/2022/03/Przegla%CC%A8d-AI-TO-NIE-SCI-FI-Przyklady-wdroz%CC%87en%CC%81-innowacyjnych-w-zdrowiu.pdf

[5] https://aiwzdrowiu.pl/wp-content/uploads/2022/06/Raport-Top-Disruptors-in-Healthcare.pdf

90% have their product at the stage of at least MVP (Minimum Viable Product—a product version that has enough functionality to meet the expectations of the first customers and provide feedback for further product development).[5] This demonstrates that Poland is an attractive location for the creation of new technologies.

3 Regulations and Data Poverty Trap

Thanks to the activity of the already mentioned AI in Health Coalition, Poland is also one of the first countries to introduce guidelines on AI implementation in medical entities. According to the declarations provided at the official website[6]: "AI in Health Coalition aims to shape policy for the development of artificial intelligence in the Polish health care system." Their goal is to create an environment that enables rapid and widespread use by the Polish health care system of the latest advances in AI, as they believe that AI solutions in health care should respect the central role of the medical professional in patient care and instil confidence in the patient. More details can be found in the AI in Health Coalition Manifesto. An important document, i.e. *White Paper on AI in clinical practice* was co-created by AI in Health Coalition and representatives of Ministry of Health, e-Health Agency, Medical Research Agency, Patients Ombudsman Office, Polish Hospital Federation, National Medical Chamber and other important healthcare organisations.[7] The White Paper answers common questions about AI implementation in medicine, such as: May AI diagnose by itself? Should patients be always informed about AI diagnosis? Should we ask patients for consent for using AI? May AI decide about the admission of a patient? And who is responsible for AI diagnosis?

However, despite resolving the aforementioned uncertainties, we still face many regulatory challenges. AI algorithms used for diagnosis and treatment are considered "high-risk" AI algorithms, so we have to be sure their sensitivity and specificity are comparable to currently used diagnostic and therapeutic methods—particularly in regard to the effectiveness of physician' decision. There is a wide range of literature that discusses issues related to AI bias, explainability, and other challenges, however one of them is directly related to transitional economies—that is access to medical data.

To create effective and safe AI algorithms in healthcare, we have to use vast amounts of good quality data. We should also train algorithms on data that comes from patients similar to those who will be treated and diagnosed by a particular algorithm. In other words, if we want to use AI algorithms for European patients, this algorithm should be trained mostly on European patients' data. An algorithm trained on data, e.g., Asian patients could have significantly lower sensitivity and specificity when used on patients from Europe or the US. This means that countries that cannot provide access to medical data for AI algorithms creation could fall into a "data poverty" trap[8] and therefore could not develop AI in medicine, even if they are able to buy existing solutions created in other parts of the world. It's crucial to understand that this may be a gap that we cannot overcome with money, therefore we have to act on preventing the emergence of this gap.

On the other hand, there is a strong need to protect personal data, especially such sensitive data as medical data. Decisions of using data by third parties must be based on data subject consent. We have to secure access to medical data that will be fair, democratic, decentralised, patient-centric—and scalable.

In Poland medical data sharing model is being developed based on Data Governance Act.[9] The same way patients donate their blood or marrow, they can consent for the usage of their data for research and development purposes. The Polish

[6] https://aiwzdrowiu.pl/en/

[7] https://aiwzdrowiu.pl/wp-content/uploads/2022/11/15.11_HIPERL_ANGIELSKA_BIALA-KSIEGA_AI-W-ZDROWIU_2022.pdf

[8] https://www.thelancet.com/journals/landig/article/PIIS2589-7500(20)30317-4/fulltext

[9] https://digital-strategy.ec.europa.eu/en/policies/data-governance-act

Donate Your Data Foundation is a legal controller of patients' data, and based on patients' consent it can collect, anonymize, and distribute data to the third parties.[10] Thanks to this model access to data is democratised without compromising patients' right to privacy.

In summary, several implementations of innovative solutions in healthcare were succeeded and already functioning within institutions that support the development of this area. Nevertheless, difficulties still arised. In the following paragraphs, some examples of difficulties because of digital divide remain a challenge for Poland is presented.

4 Basic Challenges in Data Generation

The Polish healthcare system generates an immense amount of data. For instance, in the in-hospital setting, from admission to discharge, the gathered data concerns all the necessary bureaucracy, i.e., patients' written consents, but more importantly, medical data. These data constitute priceless material for all socioeconomic and scientific analyses. However, several general barriers interrupt its wider analytical use.

The most crucial obstacle is still widespread keeping medical records in paper form, making its analysis more time-consuming. These should be gradually improving, as some legislation that pushes electronic medical documentation (EDM) has been passed in Poland.[11] Furthermore, even if the EDM is implemented, there are various software providers for specific recipients. In other words, each hospital or outpatient clinic may use individual single software. Systems usually do not communicate with each other—the medical data cannot be easily transferred between the systems; thus, the integration is also difficult.

There were attempts to unify the data gathering—since December 2019, all health-providing institutions in Poland have been obliged to upload the information about medical events to the government-administered platform—P1.[12] Physicians cannot prescribe the drugs, and sick leaves omitting the P1. The platform is a promising step, but it is insufficient. The analytically most valuable, precise medical data, including biochemical parameters or clinical descriptions of the patients, is not gathered in P1. This is a significant shortcoming of the platform, considerably reducing the value of the data for scientific or analytical purposes.

Moreover, the uploaded information is not free from bias, e.g., the uploaded ICD-10 codes, which should describe the patient's primary diagnosis, frequently do not reflect the actual medical condition. This is a common practice to slightly modify the ICD-10 code to increase the amount of received money from the public payer. Some ICD-10 diagnoses and ICD-9 procedures are being paid better than others, tempting the health institutions managers to upgrade the reported diagnosis.

Given all the problems mentioned above, telemedicine has not had a favourable environment for further development. All of the links in the healthcare chain function in isolation, with no access to the medical data generated by its different parts. The development of the structured, universal informatics system for medical data collection and analysis has merely been initiated.

The issue is highlighted when the available medical data is supposed to be prepared for artificial intelligence analyses. In our institution—Institute of Heart Disease, Wroclaw Medical University—we performed a series of experiments that included unsupervised machine learning techniques called clustering,[13] to analyse the heterogeneity of the acute heart failure (AHF)

[10] https://podarujdane.pl/

[11] https://isap.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=WDU20180000941

[12] https://www.euro.who.int/__data/assets/pdf_file/0018/163053/e96443.pdf

[13] Frades I et al.; Methods Mol Biol; 2010;593:81–107

population. Two AHF registries gathered in 2010–2012 and 2016–2017 had to be prepared to apply the algorithms. The collected data, although very similar content, was stored and described differently—the columns in the excel files had distinct names and formats. The first task which had to be performed was the unification of coding. Then the files were merged. Furthermore, the data included many outliers and missing data—it was manually put from patient documentation to the electronic records—therefore, it was prone to mistakes. These limitations were not sustainable for the machine learning analyses—the data had to be manually curated. Implementing more advanced database systems for medical data gathering, which, e.g., enable the validation of the input data, would make it more convenient in further stages of data analysis. Eventually, once the data was manually pre-processed and prepared for the ML algorithms, the calculations were relatively easy to perform, which resulted in 2 full-text scientific articles.[14]

5 Barriers in the Field of AI-Based Medical Images Analysis

As mentioned above, the use of AI -based systems in medical imaging is perhaps one of the most promising achievements in healthcare. Nowadays, several AI-based models show the ability to generate meaningful information from complex images such as angiograms, computed tomography scans or magnetic resonance images. It is also known that such solutions can be approved by institutions such as Food and Drug Administration (see: an example with diabetic retinopathy detection[15]). This approach creates great opportunities in healthcare. However, there are also numerous barriers, especially in countries that are not leaders in this area.

One of the major barriers is that most of the advanced software requires dedicated, high-performance hardware. These AI-models need a significant amount of computing power for processing complex datasets. Several programs are created and tested on specific components such as graphic cards. In consequence, to use these programs only recommended hardware should be installed. It concerns especially models in the early stage of development, with a limited number of compatible components. Another limitation is combining AI technologies with existing imaging systems in hospitals, which usually cause a lot of challenges. For instance, real-time analysis of angiograms during diagnostic procedures requires a connection between modern software and an angiographic system. Frequently it is associated with the necessity to redevelop the whole existing diagnostic laboratories. It underlines the necessity to design new IT infrastructure suitable for the expandability of advanced tools.

In the Polish healthcare system implementation of AI models analysing medical images is commonly limited to offline analysis. This is due to a couple of obstacles. In the majority of centres, all medical imaging data are not collected in a systematic, structured way. AI analysis of medical records need standardised and correctly labelled images. Frequently, a group of enthusiasts manually search databases to find the appropriate projection of images, formulate it and send it further to external professionals. In the end, the process is time-consuming and exposed to bias during gathering data. It also reduces the possibility to analyse a large amount of data. In a wider perspective, it limits the chances to train algorithms on the major datasets. It creates the need to develop transparent methods for data collection, for instance, compatible with commonly utilised software managing medical images. Furthermore, the developed methodology should be focused on research purposes, selecting data based on particular features. From a technological point of view, the lack of automated, prepared datasets and the possibility of data transfer, lead to discouragement in several centres to take the first steps in AI implementation.

[14] Urban Sz. et al.: Biomedicines; 2022 Jun 27;10(7):1514

[15] https://www.aao.org/education/headline/autonomous-diabetic-retinopathy-screening-system-g

6 Limitations Resulting from Educational Reasons

As mentioned in documents published by the WHO[16,17] in recent years Digital Health has turned out to be an extremely important trend in the development of medicine. Partially this resulted from the pandemic, when the WHO supported the international mobilisation aimed at strengthening collaboration related to digital health interventions, addressing such as challenges as pandemic management. The G20 Digital Health Taskforce highlighted the value of sharing resources, utilities at the national and international levels for contemporary society. Further initiatives of WHO resulted in publishing a Global Strategy on Digital Health 2020–2025,[41] which clearly refers to the fact that digital technologies constitute an integral element of daily life. Therefore, it is worth noting that with extensive exploitation of the potential of digitalization of medicine, we require readiness for the appropriate treatment of unimaginably large data sets. The challenges associated with it are not only related to safe and effective data sharing, but also developing new discoveries and drawing conclusions that could not be drawn before. Such opportunities are provided by modern data analysis technologies, such as artificial intelligence (AI).

Consequently, we can predict that modern analytical techniques, like AI will soon become an integral part of many diagnostic, treatment, research and scientific processes. The optimum use of the AI's potential in the medical and pharmaceutical sectors involves raising the awareness and engagement of health professionals. Hence, it should definitely appear as a part of education conducted at medical universities.

However, in Poland, as in other European countries, the content of medical studies is prepared and announced at the level of the government regulations[18,19] due to the fact that the profession of a medical doctor is associated with particular rules. For example, many invasive procedures (e.g. blood collection) must be performed by a person with officially confirmed qualifications (for the doctor, for the nurse). Consequently, these rules also affect the areas of education. In other words, the primary objective for any Medical University is to provide educational contents which will be in line with the contents of the official documents.

Importantly, the regulations referring to the Polish MD education, until the end of 2022 (when this publication is created)[42] did not contain any elements which were directly related to education within any innovative area of medicine (such as digital health, e-health or computational medicine, which may refer to AI). In other words, for example, when Wroclaw Medical University proposed an idea to educate young doctors in the field of artificial intelligence in medicine, it was necessary to propose an entirely new set of criteria, created "de novo" in order to propose the documents describing the course. Such a procedure is necessary while planning the content and characterise educational offer addressed to students of course (e.g., what such a course could give to a person, who attends this training as an element of his or her medical education) and to confirm that such a course can be officially included within the programme of medical education.

The draft of the amendments to official regulations[43] related to medical education in Poland, are currently being prepared and will probably be implemented in 2023. Characteristically, the new standards include issues related to broadly understood electronic services (e-services, e.g., e-prescription, e-documentation) including principles of operation of information and communication tools and services in health care (e-health), or issues related to health services using ICT systems. However, the regulations still lack topics

[16] https://www.who.int/news/item/07-12-2020-g20-first-time-released-report-on-digital-health-interventions-for-pandemic-management

[17] https://apps.who.int/iris/bitstream/handle/10665/344249/9789240020924-eng.pdf

[18] https://isap.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=WDU20220001742

[19] https://legislacja.rcl.gov.pl/projekt/12367852/katalog/12941600#12941600

related to computational medicine, algorithms or any issues related to, for example, supporting diagnostics or supporting medical decisions, by solutions based on artificial intelligence.

Paradoxically, the White Paper[7] mentioned above remains the only available document created to prepare the medical community for the changes resulting from the development of artificial intelligence in medicine.

7 Limitations Resulting from Lack of Awareness

Lack of education in the field of innovation in medicine, implemented at the systemic level at the earliest possible stages of medical studies, may be both the cause and the effect of the lack of awareness in the medical community regarding the principles or the possibilities of using AI.

In 2022 we conducted an anonymous survey to assess the beliefs and knowledge of AI in the medical community. The survey was designed to measure the broadly understood beliefs, knowledge and awareness among medical staff (i.e., employees of medical universities, clinics and hospitals, medicine students, etc.) in the field of artificial intelligence in health.

The questions related to beliefs, the person was asked to express his/her opinion about a given belief using a scale starting from: completely disagree and finished by: completely agree. Sample questions in this part of the survey were: "AI-based solutions can support medical staff by allowing them to focus more on the patient", "AI-based solutions will make patient treatment more effective" or "AI-based solutions will improve the quality of patient treatment".

Questions about the level of knowledge were structured in order to ask the subject to judge whether a given sentence was correct or not, using a similar scale ("this sentence is wrong" vs "this sentence is correct"). Examples sounded as follows: "Data from hundreds or thousands of patients (subjects) need to be obtained to develop an AI-based algorithm" or "Solutions based on certified AI algorithms are safe and dependable".

At the end of the questionnaire, there were questions about the surveyed person (age, sex, education, with only people practising a medical profession or studying at a medical university to choose from).

The survey was available online for approximately 8 months. The link to it was intensively promoted both on-line (the website of the project, the website of the Ai-in-Health Coalition and even at the and even on a subpage of the website of the Polish Chancellery of the Prime Minister, as part of the initiative of the health working group) and on leaflets.

The survey and its results will be the subject of an extensive scientific publication, therefore in this chapter we will only provide a general summary of the observations.

There were over 800 visits to the survey's website. However, the most surprising and disturbing finding from our research was that only few respondents actually solved the entire survey. Despite full anonymity and the relatively neutral nature of the questions, the respondents did not want to demonstrate their knowledge (or lack of knowledge) or beliefs. We had only 130 surveys which were completed and 691 which were solved only partially.

Beliefs were assessed positively, most of the responses oscillated around full agreement or slightly below full agreement. The respondents appreciate the benefits of AI, such as accelerating healing processes or improving the quality of medical services.

The answers regarding the lack of legal regulations regarding the use of AI in the diagnostic process were definitely diverse—the respondents either rather agreed with it or marked the answer from the middle of the scale, which suggested that they did not know whether such regulations exist.

The vast majority of respondents, who were medical doctors or students from the medical faculty, did not agree that "AI-based solutions can replace physicians" however there were single answers which allowed such possibility.

In a question where we asked the respondents to rate their own level of knowledge in the area of AI using a 10-point scale (with 1 for have no

knowledge and 10 for an expert) most people rated themselves at 5, i.e., half of the scale. However, further questions where it was verified whether the respondents knew basic terms in the field of AI, such as decision trees, neural networks clustering or supervised learning showed that these concepts are still not well identified, as the responses were very diverse.

To sum up, there is a need for intensive educational activities among doctors aimed at increasing the awareness and understanding of how AI can support medicine. Such education should start as early as possible, preferably during medical studies. Unfortunately, this task has not yet been fully implemented and it is difficult to assess how much time it will take to prepare for educating in this area at the system level. One thing is certain—without education, the use of AI in medicine will be definitely limited, which will be a big obstacle in keeping up with the dynamic development of these issues all around the modern world.

8 Challenges Related to Biobanking in the Era of Big Data and Digitalization

8.1 Types of Data Stored in Biobanks

Nowadays, biobanking has become an increasingly visible field, without which reliable research in the area of drug discovery and development or new medical treatment implementation would be impossible. That is why biobanks shall be recognized as professional tools for innovative research performance. Generally, biobanks are associated with places, where the responsibility for professional preparation of biological material for intended purpose is held. Nevertheless, it should be also emphasised that biobanks also act primarily on data, which are a critical element of all operations. Three categories of data can be identified in the biobanks: (1) data from pre-analytics, (2) data directly connected with participant/donor and (3) data resulting from the obligation to safeguard participant/donor/patent's rights fulfilment.

The first group of data is mainly generated by biobank. Their quality and the amount strictly depend on the biobank, specific requirements from implemented standard(s) or particular agreement conditions between biobank and partner (i.e., Pharma/Biotech co-operation, where the specification is precisely detailed). Following technological related processes documentation data can be included here:

- collection (date/hour, staff traceability, type of equipment and materials used in the process, adverse event/incidental findings)
- transport (start/finish time, temperature registries, deviations)
- qualification and biological material reception (volume, sample coding, deviations such as lipaemia, haemolysis, etc.)
- processing (time, materials and reagents used in the process, process parameters, aliquoting and the amounts of aliquots)
- storage (traceability, location, storage conditions).

For all indicated processes only some of the examples have been shown. Despite data from technological processes also information from auxiliary procedures shall be collected such as.: infrastructure supervision, including validation, calibration and internal checking, environmental conditions, personnel responsibility for dedicated processes, qualifications and competences requirements, internal/external audits, data from service/materials providers. Quality control (QC) data also provides a relevant number of records. Regarding to the international ISO standard 20387:2018 dedicated for biobanks, QC data shall be derived from biological material, associated data and processes (clause 7.8: Quality control of biological material and associated data).[20]

The second and third group of data which can be identified in biobanks is related to the participant/sample donor. Among all data related to par-

[20]EN ISO 20387:2018 Biotechnology—Biobanking - General requirements for biobanking

ticipants taken part in the study, it is possible to perform advanced research and development work that meet the assumptions for Evidence-Based Medicine.

Among the data related to the study participant, it is possible to distinguish such data, thanks to which it is possible to carry out advanced research and development work, and thus to meet the assumptions for Evidence-Based Medicine.

The following data can be included such as diagnostics data, treatment information, disease severity status, pathology data, demographics, case history, any questionnaire data, recurrence/follow ups data. Image data (CT, MRI, PET-CT, X-ray, ultrasonography, histopathological results) are a significant part of the data. All data in biobanks are usually stored in two formats: (1) paper (informed consent, reports on retrieval, transport, qualification, processing, sometimes surveys) and electronic (e. g. surveys, test results, medical data). As for data storage systems, the most common are excel files, databases (on-premises or in the cloud), sometimes allocating access to resources in another location. However, it should be noted that any paper document can be converted to an electronic version, which is then backed up. Some biobanks use dedicated systems, which consist of many interconnected and interdependent modules. As a result, the biobank is able not only to store data, but also to manage it in a complete way at every stage of biobanking and in every area supporting the biobanking process (e. g. storage, disposal, reporting).

Biobanks use data primarily from medical procedures or scientific research involving humans. Due to the generation of a broad data repository during standard patient treatment, clinical trials or population cohort study, it is possible to conduct and apply an innovative approach to standardisation of methods supported by evidence published in systematic reviews, randomised meta-analyses or observational studies. Critical data that should always be present in biobanks are informed consent forms with exclusions and consent to data processing resulting from the GDPR.

8.2 Data Collection, Storage and their Usage. Trust in Biobanking in Terms of National Solutions to Overcome Digital Divide Based on Development and Availability-Regulations and Standards

The vast majority of data collected and processed in biobanks will be sensitive, personal/identifying data and will therefore be subject to the requirements of the GDPR for EU countries. This is particularly important to ensure maximum protection for the subject. The functioning of biobanks in some countries has its own regulations in the form of statutory regulations (Estonia- *Human Genes Research Act,*[21] Hungary- *National legislative act on the protection of human genetic data, on the human genetic studies, on research and on the operation of the biobanks,*[22] Iceland- *Acts on Biobanks no.110*[23]). Unfortunately, Poland has not yet developed a biobanking law, despite the efforts of the BBMRI. pl Consortium, which was established to achieve the common objectives of the European BBMRI-ERIC infrastructure policy in the field of biobanking. Thus, biobanking is not regulated by law in Poland. Biobanks in the scope of their activities are guided by those prepared by the consortium BBMRI. pl as part of the project "Creating a Polish Biobanking Network based on BBMRI-ERIC infrastructure" or *Code of Conduct of Processing of Personal Data for Scientific Purposes by Biobanks in Poland*[24] and *Quality*

[21] https://www.riigiteataja.ee/en/eli/531102013003/consolide

[22] Hoxhaj I. et al.; European Journal of Medical Genetics, 2020, 63, 4, 103841

[23] The Biobanks and Health Databanks Act] 1), No. 110/2000, as amended by Act No. 27/2008, No. 48/2009 and No. 45/2014

[24] https://bbmri.pl/kodeks-postepowania-w-sprawie-przetwarzania-danych-osobowych-dla-celow-badan-naukowych-przez-biobanki-w-polsce/

Standards for Polish Biobanks (QSPB),[25] *Manual of Biobank Quality Management (MBQM).*[26] Nevertheless, it is important to underline that standards and codes are voluntary and there is no legal obligation to apply them outside the members of the Polish Biobanking Network. Furthermore, their usage allows them to function according to the guidelines adopted by the environment.[27]

*Standard*s refer to the safety and security procedures for biobank operations (Chap. 15 from QSBP[25,26]). The requirements for basic methods of securing IT infrastructure including biobank system sample management, where digital data are stored were also underlined. It directly influences the donations willingness and donor's trust, that his/her samples and associated data will be used properly and stored in a secured manner[20,21].

The QSPB *Standards*, which have been prepared and implemented within Polish biobanking activities, also pay special attention to ethical and legal aspects (Chap. 5 from QSBP[25,26]) where principal recommendations for impartiality, confidentiality, responsibility and respect for autonomy are raised. The detailed information regarding rules for informed consent preparation, communication with participants and bioethics committee role together with sharing of biological material and data for non-commercial and commercial usage of biological samples/data are presented. Moreover, ownership issues and privacy protection are described. Biobanking that complies with relevant ethical and legal standards may increase the quality and public trust in science and research [20,21].

According to the requirements which have been described in QSPB, in 2017–2020 an audit process has been carefully organised and performed in Polish Biobanking Network.[28,29] The results clearly showed that 85% from Polish Biobanking Network entities have fulfilled the requirements dedicated to ELSI aspects, while only 40% of requirements were achieved in the Safety/Security area. The excellent results (100%) have been accomplished by BBMRI.pl Consortium biobanks. It was also interesting that the QMS implementation was extremely significant if the comparison to the biobanks without any system was done, only in the ELSI area the impact has not been noticed.[24]

Trust is one of the factors influencing the willingness of donors to donate biological material to biobanks. Therefore, BBMRI.pl went ahead of expectations. And an information security audit program was launched. Each biobank associated in the Polish Biobanking Network (both members and observers) which went through the program (voluntary participation) received report, recommendation and was offered support. What is more important the summary of anonymized reports revealed most frequent shortcomings, and areas that need more attention. These conclusions were reflected in Chap. 15 from QSBP[25,26] of the second version of The *QSPB*[25,26] and covered physical security, backup, cloud services and review of basic security mechanisms. Also, in terms of ICT technology, the biobank environment is strongly differentiated from very mature entities that can afford proper IT support, either within their own resources or the institutions they are subordinated to. Mature biobanks have implemented LIMS/BIMS systems, established, not necessarily formalised, methodology for dealing with research data. Less advanced or newly established ones are working on implementing appropriate mechanisms both in the areas of security and data processing.

At the network level, there were also prepared dedicated tools to facilitate sample information management—a BIMS class system as well as solutions for samples or data discovery.

[25] Red. Matera-Witkiewicz A. et al.; Standardy Jakości dla Biobanków Polskich; v.2.00, Wrocław, Poland, Wydawnictwo Uniwersytetu Medycznego we Wrocławiu, s.210, 2021. ISBN 978-83-7055-661-7; e-ISBN 978-83-7055-662-4

[26] Matera-Witkiewicz A. et al.; Manual of Biobank Quality Management; Springer, 2023, ISBN: 978-3-031-12559-1

[27] D. Simeon-Dubach, Z. Kozlakidis; Biopreserv Biobank. 2018; 16: 1–2

[28] Ferdyn K. et al.; Biopreserv Biobanking, 2019, 17, no.5, 401–409

[29] Matera-Witkiewicz A. et al.; Front. Med., 2022, 8, 780294

It is important to note that all research regarding biological material and associated data are based on the same principles as any trial where human is engaged.[30,31] For biobanking trust and donor protection three step system in contemporary ethical assessment shall be kept, where independent ethical committee, international/national codes of ethics and finally regulations are present.[32] Polish Bioethics Committees are dedicated to giving opinions for medical experiments and every project, where biological material and associated data are planned to be used. Presented regulations are contained in updated law act on doctor and dentist. It is required that each project of any experiment involving humans or biological material/data to be submitted to an independent bioethical committee for approval. It is also forbidden to perform any medical experiment before the positive opinion. The law is far too narrow and excludes all experts in the field of research where biological material/data are used. From 2021 in Poland only doctors and dentists can be accepted as head/manager of specific projects. This discriminates all researchers from other fields and disciplines (i.e., biologists, biotechnologists, bioinformaticians, data scientists) who are qualified to lead projects involving biological material/data. Such investigators often have a much higher level of competence in the laboratory techniques, IT and biostatistical methods used in scientific analysis and advanced research. This law unfortunately effectively has closed the way for excellent researchers to lead such projects.

Data sharing in national biobanking is essentially based on the patient's informed consent, in which he/she determines what may be made available and on what terms. Provisions that do not explicitly refer to biobanks themselves, but may support them in terms of their activities are, for example, the Act on Patients' Rights and the Patient's Ombudsman (Dz.U.2022.1876). In Chapter 7 art. 26 p. 4 the legislator indicates the method of making medical records available: Medical records may also be made available to a university or research institute for use for scientific purposes, without disclosing the name and other data allowing identification of the person to whom the records relate.[33] This record makes it possible to conduct scientific activities based on anonymized medical data. The Act also specifies the method of making electronic medical records available for control purposes (legal act from 27 Aug. 2004 on publicly financed health care services Dz.U.2022.2561[34]), referring to the data format records specified in separate regulations. These, in turn, refer to another law and Art. 18. Legal act from 17 Feb. 2005: Computerisation of the activities of entities performing public tasks Dz.U.2023.57.[35] The Act points out that at the request of the Minister responsible for computerisation, minimum requirements for ICT systems and public registers will be defined by means of a regulation. These actions shall ensure the consistency of the operation of ICT systems used for the performance of public tasks by specifying at least the specifications of the data formats, communication and encryption protocols to be used in the interface software, while maintaining the possibility of using those specifications free of charge; the efficient and secure exchange of information in electronic form between public bodies and also between public bodies and authorities of other States or international organisations. In addition, it is intended to ensure that the National Interoperability Framework meets the requirements regarding semantic, organisational and technological

[30] International Ethical Guidelines for Health-related Research involving Humans; Council for International Organizations of Medical Sciences (CIOMS), 2016, ISBN 978-929036088-9

[31] Deklaracja Helsińska Światowego Stowarzyszenia Lekarzy (WMA) Etyczne zasady prowadzenia badań medycznych z udziałem ludzi; 2013

[32] Czarkowski M.; Role of bioethics committees in the biobanking activities and research on human biological material; 2021; https://bbmri.pl/raport-elsi-dotyczacy-roli-komisji-bioetycznych-w-dzialalnosci-biobankow-i-badaniach-na-ludzkim-materiale-biologicznym/

[33] https://lexlege.pl/ustawa-o-prawach-pacjenta-i-rzeczniku-praw-pacjenta/

[34] https://lexlege.pl/ustawa-o-swiadczeniach-opieki-zdrowotnej-finansowanych-ze-srodkow-publicznych/

[35] https://lexlege.pl/ustawa-o-informatyzacji-dzialalnosci-podmiotow-realizujacych-zadania-publiczne/

interoperability, taking into account the principle of equal treatment of different IT solutions, Polish Standards and other standardisation documents approved by the national standardisation body.

As a result of implementation of DIRECTIVE (EU) 2019/1024 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 20 June 2019 on open data and the re-use of public sector information [36] the Member States were obligated to enact national implementations in this field. Consequently, in 2021 the law "on open data and re-use of public sector information"[37] was announced. The introduced law does not change much in the field of sharing medical data. However, it introduces some changes to the reuse of scientific data. Firstly, by introducing the definition of research data and the obligation to share them if they were generated with public funds. At the same time, the Minister of Education and Science was indicated as the body responsible for the implementation by preparation of detailed guidelines in the form of policy in this area—at the time of writing this text, work is still in progress. Another important issue arising from the new law is the appointment of the minister competent for computerization, which is developing the "Data Opening Program"—a continuation of the previous responsibility of the Ministry of Digitization, which has been dissolved in the meantime. One of the six pillars of the Program is: "Stimulating the market for re-use of cultural resources and scientific data". As part of this document, it was recommended that scientific data should be made available through thematic repositories, which have been intensively developed at universities in recent years—as examples Polish Platform of Medical Research.[38] On the other hand, in the document there was also identified the factors negatively affecting the use of data—the multitude of available registers. This may lead to a situation where scientific data repositories, which have been intensively developed in recent years, apply individual standards, which in turn will hinder interoperability and data exchange between individual systems. It will ultimately translate into difficulties in searching for data—the need to search each of the repositories separately. Among others further obstacles were indicated legal—lack of sufficient legislation on data sharing, competency—the lack of properly qualified personnel. The document also sanctions the participation of Poland in the European Open Science Cloud ("EOSC"). The report on the implementation of the program for 2021 indicates the creation of an association of six universities that will represent Poland in the EOSC and become responsible for the implementation in the country.

Another road map is "HEALTHY FUTURE STRATEGIC FRAMEWORK FOR THE DEVELOPMENT OF THE HEALTH CARE SYSTEM FOR 2021-2027, WITH A PERSPECTIVE UNTIL 2030." [39] issued by the Ministry of Health. In terms of Digital Health, the document focuses mainly on e-services provided to patients, doctors or medical entities, technical equipment of facilities with adequate IT infrastructure. Building medical knowledge, developing methods of collecting and sharing data is not a priority. Based on the strategic documents presented earlier, a silo landscape emerges at the ministerial level—documents and guidelines are created in separate departments, probably without any attempt to coordinate work. According to the conclusions of the report "Digital Health Implementation approach to Pandemic Management" [Digital Health Implementation approach to Pandemic Management G20], this is not an approach that may herald failure in implementing an effective digital health system. Which requires coherent coordination of work at the national level. The

[36] https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32019L1024&from=PL

[37] https://isap.sejm.gov.pl/isap.nsf/download.xsp/WDU20210001641/T/D20211641L.pdf

[38] https://ppm.edu.pl/index.seam?lang=en&cid=269887

[39] https://www.gov.pl/web/zdrowie/zdrowa-przyszlosc-ramy-strategiczne-rozwoju-systemu-ochrony-zdrowia-na-lata-2021-2027-z-perspektywa-do-2030

WHO issued similar recommendations [Global strategy on digital health 2020–2025, WHO].

It is also important to note that in 2019 the Polish Medical Research Agency (MRA) will be established. The main scope of the Agency is to increase the potential of non-commercial clinical research especially for new treatment methods in oncology, cardiology and rare diseases areas. The MRA has been created by law (Act of 21/02/2019 about *Medical Research Agency, Journal of Laws No. 447*[40]). Noteworthy is the fact that from 2022 The MRA has implemented the biobanking requirement activity for all clinical trials which are sponsored by the agency, where the blood sample is taken from a patient. Moreover, the biobanking must be performed according to the *Quality Standards for Polish Biobanks (QSPB).*[20,21] Additionally, in 2023 the MRA has announced the call for Digital Medicine Centres, where Biobanks as necessary units are also included and will be financed. However, it is strictly defined that the biobanking process must be carried out within ISO 20387:2018 and QSBP.[20,21] Thus, the Polish Biobanking Network membership based on unified and harmonised standards sustainability can assure that the fulfilment of the highest regulation proposed by national or governmental authorities will be achieved.

9 Digitization of Genomics Data in Poland

Sharing of data was the primary domain of Biobanks in Poland. Although biobanks have just begun to emerge in Poland in the beginning of the twenty-first century. However, from the origination they started to play a significant role in the sample and data sharing ecosystem of Polish science. In 2017 the BBMRI-ERIC Polish Node was established as well as BBMRI.pl consortium.[41] The initiative joined 7 entities involved in biobanking. One of the project goals was to implement IT System for samples discovery and data sharing, integration with BBMRI-ERIC directory,[42] creation of unified BIMS and integration with HIS, setting up a gate for information exchange between biobanks and national registries. Due to insufficient legal framework the last task was not even started. Integration of BIMS and HIS system was performed as a Proof of Concept and paused at this stage. First three tasks were completed. The unified BIMS is designed to support data/information exchange with API interface; there was also developed Central Platform dedicated to performing queries for data collected in central repository as well as in federated ecosystem—created with software installed in biobanks and fed with data directly from local BIMS. The consortium did not only focus on technical aspects and took challenges in changing the ELSI landscape, among others there was proposed the code of conduct based on GDPR art. 40—"Polish code of personal data processing by biobanks in Poland".[43] Currently works of the consortium is held up due to a pause in funding.

Another initiative for creating infrastructure for data sharing is "Polish Genomic Map in open access—digitization of biomolecular resources of the Biobank Lab University of Lodz" project.[44] The idea is to set up Polish node of Federated European Genome-Phenome Archive (EGA)[45,.46] This infrastructure will be compliant with EU guidelines "as open as possible as closed as necessary". It provides Public Key Infrastructure (PKI) encryption of datasets submitted to the repository. Access to the data is available under approval by the Data Access Committee (DAC). DAC can be set up by the Principal Investigator or the Institution. The Polish instance will be connected to Central EGA discovery service—providing an interface for researchers looking for data.

[40] https://eli.gov.pl/api/acts/DU/2019/447/text.pdf

[41] Witoń M. et al.; Biopreserv.Biob.; 2017, 15, 3

[42] Holub P.; Biopreserv.Biob.; 2016, 14, 6

[43] Krekora-Zając D.; Front. Genetics: ELSI in Science and Genetics; 2021; 12

[44] Marciniak B. et al.; Current Topics in Biophisics, 2022, 43, ISSN 2084-1892, p.32

[45] Lappalainen, I. et al.; Nat Genet, 2015, 47

[46] Mallory A.F. et al.; Nucleic Acids Research, 2021, 50, D1, 7.

Thanks to EU funding, the Digital Poland funding scheme was provided to support ventures in the area of digitization. Beneath there are mentioned some projects that were supported and shared medical data and resources.

Digital Brain—main goal of the project is to digitise and share in an open access collection of brains stored by the biobank of Institute of Psychiatry and Neurology.

OpenCardio—main goal of the project is to disseminate the digitised results of pulmonary embolism diagnostics by creating a specialised digital platform openCARDIO and digitization of science resources on venous thromboembolism.

Medical Data Bank—in this case the project is performed by Lodz University of Technology and Institute of the Polish Mother's Memorial Hospital in Lodz the aim is to digitise one million histopathology samples and share them with connected medical records.

Although the Digital Poland funding stream is the great source for supporting digitization initiatives there is at least one serious oversight. Program became very popular and plenty of repositories raised a great variety of data. Unfortunately, there weren't any general standards introduced. So, at the end there is a lot of data available, but the problem is lack of standard communication protocol or API introduced. Therefore, in future there might be problems with data interoperability and/or harmonisation. Also, a single search entry point might be problematic to implement– each repository needs to be queried individually.

The mentioned ventures should be considered as bottom-up initiatives performed by the scientific community. At the time of writing this text there is no systematic approach on a national level that would promote data sharing. There are even not defined any regulations that would oblige scientists or academia/institutions performing scientific research funded from public money for publishing data in open repositories.

One of the main sponsors of Polish science is National Science Center, during 10 years of its existence, it is estimated to have spent about 1,000,000,000 PLN (250,000,000 USD) for granting projects in which Human Biological Material was used—on average 93 projects per year (based on analysis of available projects abstracts on NSC web page—years 2014–2020). At the end of March 2023, in scientific repositories there were deposited 30 data sets—by Polish institutions or regarding Polish population DbGap—22 datasets, EGA—8 datasets. Which indicates a significant gap between the genomic data generated and data available.

On the other hand, there are some top-bottom initiatives that focus on accessing HIS and health registries to combine data and use them in scientific ecosystems or decision supporting tools. These approaches are supported with law regulations or policies established on a national level. At this point these initiatives do not focus on genomic data.

National Cancer Registry set up by Polish Ministry of Health[47]— In the form of a web-based platform that aggregates information about cancer diagnosis, it can be fed with data directly from HIS system or manually by doctors. Data from the registry are then aggregated in a data warehouse and are available through a web interface to scientists or medical personnel.

National registry of Rare Diseases[48] is the next initiative that is planned to be set up in the near future to provide a transparent system for collecting information from HIS and provide aggregated data for policy creation.

The situation is slowly changing, in 2023 the Medical Research Agency (MRA) has announced the call for Digital Medicine Centers. The idea is to combine Hospitals, Biobanks Academia, entities running non-commercial clinical research, facilities providing genome sequencing services and facilities performing analysis (with proven experience in AI) in one regional node. The idea is to generate and collect for further re-use as much data connected with sample and donor as possible. This also includes genomics data. In the first phase there is planned creation of 10 such

[47] https://isap.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=WDU20120001497

[48] https://isap.sejm.gov.pl/isap.nsf/download.xsp/WMP20210000883/O/M20210883.pdf

regional nodes. In the call there are no strict requirements how the cooperation needs to be performed nor which standards to be used. Actually, there are some recommendations, for instance suggestions to use HL7 FHIR standard for data interchange, qualification of personnel that need to engage into the project realisation. General rule is to set up connectivity between HIS and interface that would allow sharing or discovery samples and related data. There is also a need to provide IT infrastructure that would be used to perform federated analysis. The regional centre was left free to use any technology they found relevant and compatible with already existing infrastructure. In the next phase there is planned setting up a central hub which will coordinate data flows between regional centres and provide discovery services for scientists.

10 Summary

In contemporary Poland, the situation regarding broadly understood digitization, innovation in medicine, development of approaches and solutions based on AI is not particularly imperfect and/or neglected. We can be proud of some impressive implementations. We have both clinical and scientific achievements. There are dynamically developing institutions whose mission is to influence decision-makers so that the development of modern technologies encounters as few obstacles as possible. Despite this, we still struggle with various problems, due to which we remain less developed than the giants of digitization, such as Asian countries, Israel or even Estonia, which is the closest to us geographically, culturally and historically. The barriers result from the condition of the Polish healthcare system, which was problematic even without the context of innovation and digitalization. Consequently, this is reflected in the approach to medical education as well as in the attitude of healthcare professionals towards solutions which are considered new and unknown.

The trend of a significant data increase and collection in biobanks is also becoming more pronounced. Starting from clinical data, anthropometric, diagnostic data, it is worth pointing out that international standards determine the critical amount of data only from pre-analytics/processes. This settled the necessity of professional development of the IT infrastructure in each biobank and its proper supervision and protection by competent personnel. These data are increasingly noticed by the regulator and research funding communities. However, it is important that they are made available and used in a controlled way while maintaining the full range of data quality and according to FAIR principles. The availability of a variety of best practice documents, recommendations, policies and procedures supports the availability and use of biological material and related data, giving a major impetus to the global use of biological resources for scientific research and the exploitation of their potential in the innovative research sector. However, it is equally critical to have a regulatory package that will clearly define the possibility of using data, and how to transfer it securely for R&D purposes, including using it in an efficient and secure AI or Machine Learning research. There is also a need for broad social education in this area in order to objectively present the benefits and risks of the increasing volume of data being generated. Biobanks therefore appear as a key element of research infrastructure not only as institutions managing biological material but also as operators of data repositories. Data from both the health sector and science. In this respect, biobanks can use their skills to build relationships of trust with donors/patients/participants.

All the information presented in this chapter, referring both to the case description itself and presented issues which shall be improved, are summarised as digital divide determined challenges for future actions in the context of policy makers and decision makers and stakeholders (Table 1).

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Table 1 Summary of factors related to digital divide

What reduces the divide?	What are the causes of the divide?	What was studied/reported?
Examples of successful implementations of AI-based solutions in the polish healthcare system Active institutions promoting the use of AI in healthcare (with relevant documents available for the general public)	Still low level of practical use of AI in healthcare Still low level of awareness about both: potential benefits as well as the actual contexts in which AI in healthcare may be successfully implemented Chaos in data collection in the polish healthcare system resulting from the nature and the amount of generated data as well as from low awareness Lack of formal education in the field of innovative medicine	Reports such as "AI is not Sci-fi", "Whitepaper on AI in clinical practise" or "Top disruptors in healthcare" Survey related to both the believes as well as substantive aspects of the use of AI in healthcare
Highly complex and developed area of biobanking		Numerous documents and regulations addressing material and data management within biobanks.

Potential of Digital Health Solutions in Facing Shifting Disease Burden and Double Burden in Low- and Middle-Income Countries

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Abstract

The changes in global health have fueled the concept of disease burden, and the process of how a shifting disease burden leads to a double burden has been observed in low-income countries (LIC) and lower-middle-income countries (LMIC) for the last few decades, replicating a trend experienced by high-income countries (HIC) in the previous century. Adding to the burden of communicable, maternal, neonatal, and nutritional diseases, non-communicable diseases (NCD) are becoming more prevalent due to socio-economic development that changes lifestyles in an aging population resulting in significant increases in life expectancy. The shifting disease burden drives healthcare systems to change accordingly to provide an adequate response. In the meantime, unsolved problems of inequality, shortage of medical personnel, and high prevalence of infectious diseases remain significant, putting massive pressure on the limited resources of healthcare systems in LICs and LMICs.

This is where digital health brings its promising potential, firstly to better understand the disease burden itself for an accurate conception of the health risks for the population, secondly to develop new solutions that will improve the efficiency of the current healthcare ecosystem, alleviating constraints and overcoming the lack of resources, and finally to provide better health outcomes for individuals as a customer-centric solution. Applications like health information technology (health IT) with electronic health records (EHR) offer an inclusive perspective on a patient's total health and access to all healthcare providers, insurers, and other healthcare stakeholders. Mobile applications and wear-

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ables empower and engage patients in self-care management while real-time monitoring, collection, and exchange of their health status provide a continuous image of their health. Such solutions used together can build a strong history of a patient's health status, and the data can then be used in conjunction with other data, such as genomics, etc., for early detection of many kinds of diseases, providing space and time for rapid treatment through personalized and precise medicine that works better for each individual, going towards more preventive care and wellbeing, which is particularly effective in managing NCDs. On the other hand, telehealth, using digital information and communication technologies, has already proven its usefulness in dealing with communicable diseases, as recently seen during the COVID-19 pandemic, while improving healthcare access and cost for rural, remote, and marginalized communities. The applications vary and are constantly updated as new technologies emerge, with numerous interrelated factors driving the changes.

This chapter studies LMICs in particular as they are the most strained and impacted by the double burden and provide us with insights into the challenges and the opportunities that emerge with digital health solutions as contenders. Amongst LMICs, Vietnam is an interesting case due to its rapid socio-economic growth that brings homegrown solutions to the local and foreign markets, while facing important health and inequality issues. As such, in dealing with the double burden and particularly for LMICs, digital health promises to be the answer for gaining equitable and universal access to high-quality healthcare that is both cost-effective and affordable. In highlighting this, indicative examples will be presented to illustrate the point.

Keywords

Shifting disease burden · Double burden · Digital health · Health ecosystems · Low-and-middle income countries (LMIC)

1 Shifting Disease Burden in Low- and Middle-Income Countries

Disease burden refers to the human and economic costs resulting from poor health. Human costs refer to the gap between an ideal situation of living in old age with good health and the actual situation where health is impacted by disease, injury, disability, and premature death. The economic costs are the financial expenses related to healthcare and loss of productivity/labor incurred due to illness for individuals, households, healthcare systems, and society in general. Disease burden enables the evaluation and understanding of the relative importance of disease and disability for the entire population. A better understanding of which condition poses the greater threat to society allows policymakers and public health practitioners to allocate resources optimally for better health outcomes.

Besides maternal, neonatal, and nutritional diseases or injuries, diseases are often referred to as communicable diseases or non-communicable diseases (NCDs). NCDs, such as heart disease, stroke, cancer, diabetes, or chronic lung diseases, are the leading causes of death worldwide. On the other hand, communicable diseases, such as HIV/AIDS, tuberculosis (TB), malaria, viral hepatitis, sexually transmitted infections (STD), reemerging diseases and neglected tropical diseases (NTD), remain the leading causes of death in low-income countries (LIC).[1] Globally, NCDs accounted for 60.8% of all deaths in 2000 and rose to 73.6% in 2019, whereas communicable diseases accounted for 30.7% of all deaths in 2000 and decreased to 18.4% in 2019 (Fig. 1). However, in recent times, the COVID-19 pandemic had a strong impact on the burden of communicable diseases and due to its associated complications for people at high risk, impacted the burden of NCDs too.

Taking cardiovascular disease as an example of the NCDs, even though its general decreasing trend may paint a positive picture, there remains

[1] https://www.who.int/our-work/communicable-and-noncommunicable-diseases-and-mental-health

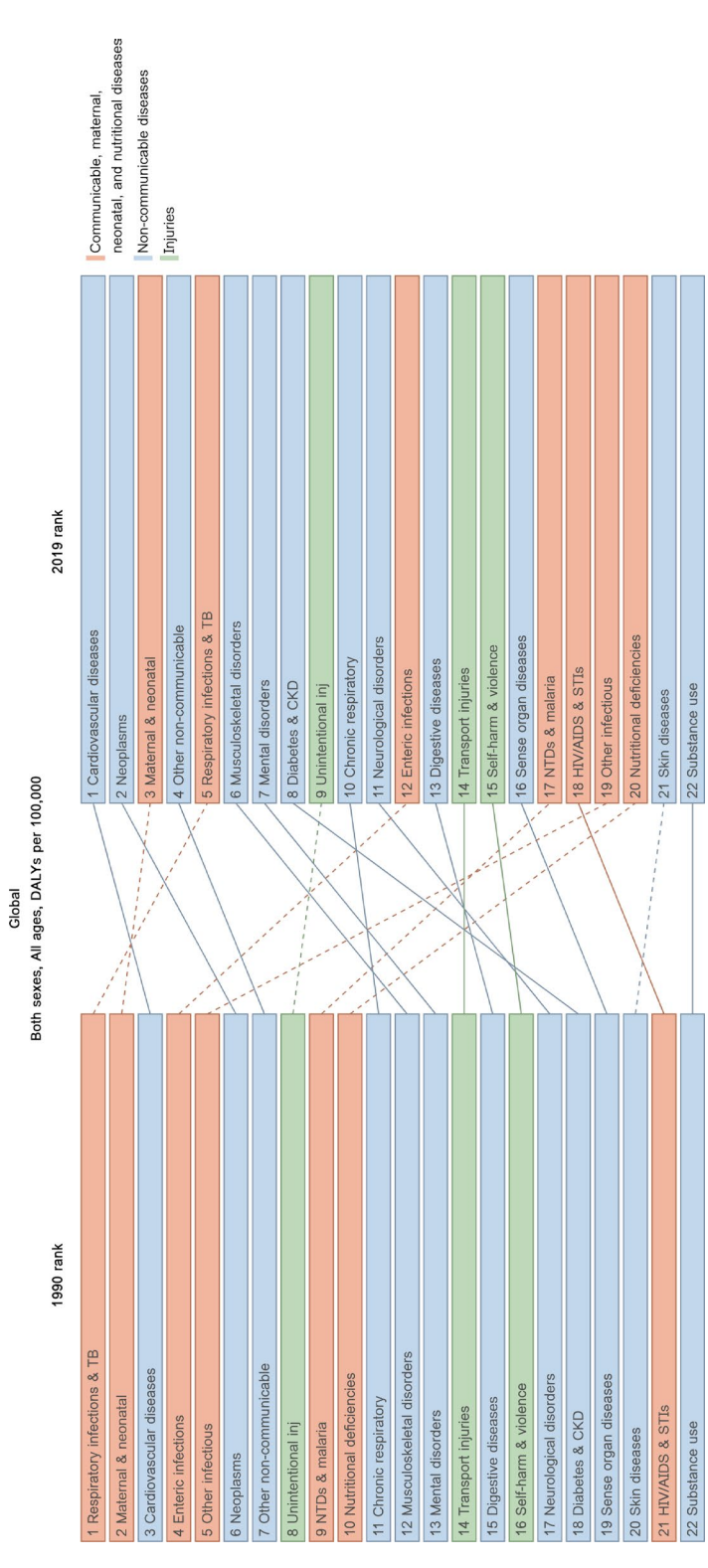

Fig. 1 Leading 22 Level 2 causes of global DALYs (1990 and 2019), all ages for both sexes combined. Lines between time periods connect causes; solid lines show increases or stagnation in ranks, and dotted lines show decreases in ranks. TB tuberculosis, CKD chronic kidney disease, NTDs neglected tropical diseases, HIV/AIDS human immunodeficiency virus/acquired immunodeficiency syndrome, STI sexually transmitted infections excluding HIV. (Source: GBD Compare, IHME Viz Hub (healthdata.org))

a crucial disparity between developed and developing nations. As a result, health policymakers must create preventive programs and improve patient care, specifically in developing countries.[2]

Thus, with tight global budgets for health and research spending, a better resource allocation is necessary to improve health outcomes effectively. Furthermore, in any given country, evaluating disease burden at the local level is critical to provide the needed population health information for national and local governments to make targeted and efficient public health policies and programs.

To obtain precise insights into the roots of disease burdens, healthcare policymakers must consider both fatal and non-fatal outcomes of each disease and their risk factors. This requires utilizing data on causes of death, prevalence and incidence rates of various conditions, and risk factor prevalence and exposures within the population while incorporating statistical models to create a holistic picture of health trends without bias or inconsistency.

Between 1990 and 2019, the shift in disease burden was observed worldwide, with NCDs increasing in the ranking of disability-adjusted life years (DALYs) per 100,000 people globally. On the other hand, communicable, maternal, neonatal, and nutritional diseases are showing a downward trend, particularly thanks to improving health and living standards in LICs and LMICs. Meanwhile, NCDs are on increasing trends in terms of rankings, highlighting the shifting disease burden throughout time (Fig. 1).

The shift is significant in LICs, LMICs, and to some extent in upper middle-income countries (UMIC) as well, but it is mainly in LICs and LMICs that communicable diseases remain prevalent. However, thanks to international and national programs, numerous investments and improvements have brought a decline in mortality and the spread of diseases such as AIDS, TB, malaria, or NTDs. Between 2000 and 2019, this shift can mainly be seen in Africa, the Eastern Mediterranean, and South-East Asia, where many LICs and LMICs are located. Overall, UMICs and HICs (as seen in the Americas, Europe, and Western Pacific) are experiencing a minimal ratio of communicable, maternal, perinatal, and nutritional conditions (Fig. 2). Nevertheless, a global pandemic like COVID-19 brings unprecedented changes to all regions, requiring collaborative efforts in tackling its impact on the state of communicable diseases.

Whereas NCDs were traditionally associated with HICs, more than 75% of all NCD-related deaths occur in LMICs, with about 80% of all cardiovascular disease-related deaths occurring in LMICs. In 2000, 171 million people were estimated to have diabetes, and 2/3rd of them were living in HICs, but by 2030, WHO predicts that developing countries will have about 284 million people with diabetes. Amongst the most affected countries will be China and India, which respectively had 20.8 million and 31.7 million cases of diabetes back in 2000.

NCDs increase due to interrelated trends, including the decreasing share of deaths from communicable and infectious diseases thanks to better nutrition, public health and medicine, longer life expectancy, and population ageing. This shift in disease burden is also known as the epidemiological transition; the leading causes of disease and death are shifting from infectious and acute diseases to chronic and degenerative diseases. NCDs share four major risk factors: tobacco use, physical inactivity, the harmful use of alcohol, and unhealthy diets.[3] All are becoming more common in LMICs due to economic growth and increased purchasing power, the changing lifestyle, particularly from urbanization (often unplanned) and its corresponding sedentary behavior, and changes in nutritional intake due to food market globalization that have

[2]Masaebi, F., Salehi, M., Kazemi, M. et al. Trend analysis of disability-adjusted life years due to cardiovascular diseases: results from the global burden of disease study 2019. *BMC Public Health* 21, 1268 (2021). https://doi.org/10.1186/s12889-021-11348-w

[3]https://www.who.int/health-topics/noncommunicable-diseases#tab=tab_1

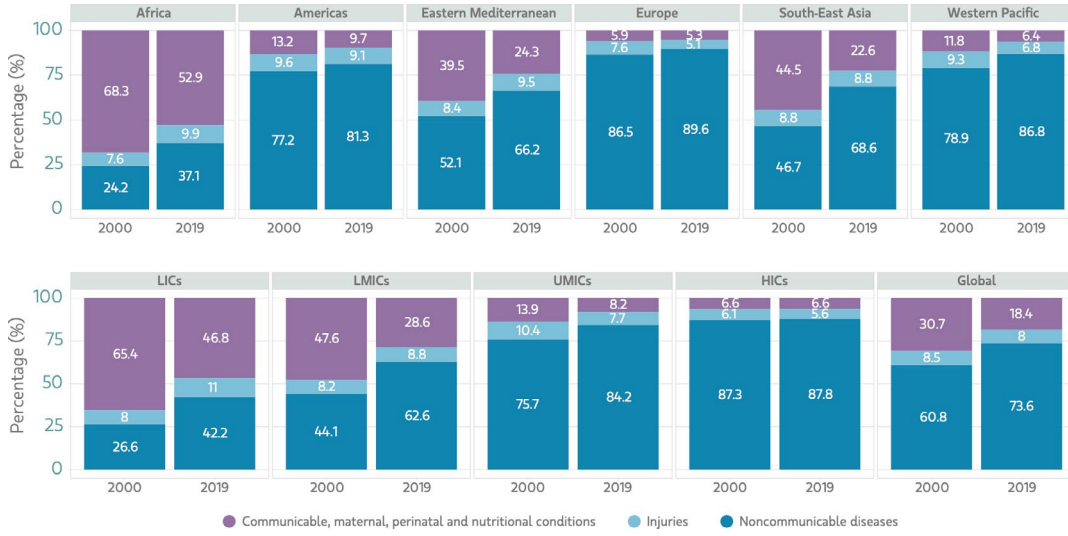

Fig. 2 Composition of causes of death by WHO region, World Bank income group, and global, 2000 and 2019. (Source: World Health Statistics 2022, Monitoring health for the SDGs, WHO)

brought unhealthy food consumption.[4] Environmental degradation, climate change, growing inequality, and air quality are other important factors that increase the burden of NCDs.

The shifting in disease burden happens predictably in part; throughout history, diseases have existed, evolved, and spread, and scientific advances have helped to study and understand these patterns for better health. Even newly named or rare diseases have been intensively investigated. Additionally, the patterns of diseases in developing countries can be found to slowly replicate those experienced in the developed world over the last century. This allows health policymakers and healthcare providers to anticipate upcoming challenges and prepare accordingly, while creating opportunities for investment in other areas of healthcare, shifting the focus from communicable diseases to NCDs.

Nevertheless, this shift remains multidirectional and cannot always be predicted easily, with radical, even surprising changes. A globalized and integrated world creates globalized disease patterns; societies worldwide suffer from more or less the same afflictions. Regular outbreaks of new diseases, such as COVID-19, can disrupt the global healthcare system and require a new response. Many diseases are induced by climate change too, which is becoming more and more of an alarming issue worldwide. Multidrug-resistant bacteria are slowly becoming more prevalent, becoming one of the most significant issues that medicine faces without any one-for-all solution; well-known pathogens evolve with time, eventually outpacing scientific knowledge and technologies.

As such, this shifting disease burden is one of the most impactful factors shaping the future of medicine, along with the development and adoption of new technologies (Fig. 3)[5]; and they are influenced by a multitude of socio-environmental drivers: increasing life expectancy, decreasing fertility rates, rising customer expectations and demands, growing inequality, human migration, climate change, resource scarcity, and declining quality of food and lack of nutrients.

[4] https://www.scielosp.org/article/bwho/2004.v82n7/556-556/

[5] https://www.translinkcf.com/wp-content/uploads/2022/06/Translink-Report_Alternative-Futures-for-Healthcare.pdf

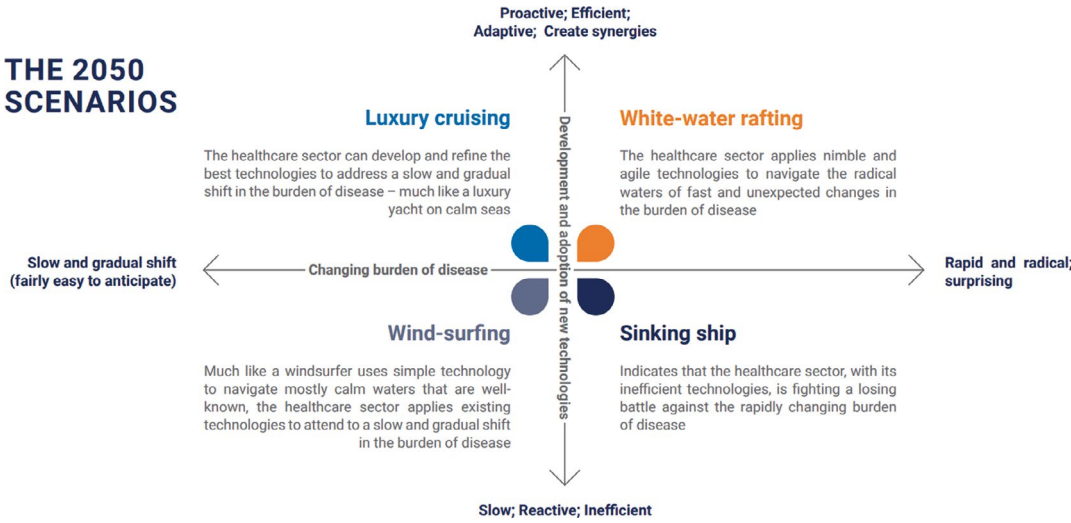

Fig. 3 The 2024 Alternative Futures for Healthcare, four scenarios based on two key drivers ("Changing burden of diseases" and "Development and adoption of new technology"). (Source: Translink Corporate Finance and Institute for Future Research)

1.1 Double Burden

The Southeast Asian region is now experiencing a rapid demographic transition, with the ratio of the aged population continuously becoming more critical, with the overall Asian region expected to have 456 million seniors aged 65 or older by 2025, representing 10% of its population.[6]

With a shifting disease burden, communicable diseases remain a significant cause of death. Thus, the double disease burden is very relevant in the region, resulting in complex socio-economic and healthcare challenges for the governments and local communities. Double disease burden occurs due to a substantial prevalence of both communicable and NCDs. This rapid shift of disease burden leaves the region even more unprepared and lacking in resources. Despite general progress in living standards and healthcare, communicable diseases have had periodic rises, mainly due to solid urbanization and often inefficient healthcare systems that cannot cope with the increasing demand. On the other hand, the general progress in living standards and healthcare has also increased life expectancy, which increases NCDs amongst the older population (in LMICs, populations aged thirty-five and older).[7]

This resulting double disease burden is a common characteristic of many developing countries and can lead to a vicious cycle that could impede economic growth due to loss of economic activity. Such changes reflect the socio-economic development of the countries and progress made in controlling and curbing infectious diseases. The pace at which the populations are aging worsens the burden of NCDs in LMICs, putting a critical strain on the entire health ecosystem. HICs had longer to adjust while their populations aged, but developing countries went through this shift in a much shorter period.

With the strong urbanization rate in LMICs, bringing them into the globalized world, there is an increase in NCDs, creating similarities in disease patterns to HICs. However, the weakness and inefficiency of the healthcare system in LMICs do not allow it to control communicable

[6] https://www.mckinsey.com/industries/healthcare/our-insights/the-future-of-healthcare-in-asia-digital-health-ecosystems

[7] Lower-Income Countries That Face The Most Rapid Shift In Noncommunicable Disease Burden Are Also The Least Prepared

diseases fully, leaving them to co-exist with the increasing rate of NCDs, and a creating a double burden of disease. Furthermore, NTDs are still affecting the poorest populations the most, and amongst developing countries, it happens too often to populations that are living in geographically remote areas, ethnic minorities (EM), or marginalized groups, which exposes them to an intense vulnerability to an even greater range of diseases. In addition, other NCDs are also of public health importance such as renal, endocrinal, neurological, hematological, hepatic, gastroenterological, musculoskeletal, skin, and oral diseases; mental disorders; disabilities, including blindness and deafness; violence and injuries. NCDs and their risk factors are also linked to communicable diseases, maternal and child health, reproductive health, aging, and social, environmental, and occupational determinants of health, that puts LMICs in a particularly challenging situation.

Hence, there is a strong need for a systemic and integrated response to the current needs of healthcare systems in developing countries that are often focused on short-term care rather than long-term care and preventive measures. As a result, with cases of multiple comorbidities occurring more frequently, there is an increasing demand for high-quality healthcare and long-term solutions.

2 What Digital Health Can Bring to the Table

Numerous forces worldwide have been driving significant changes in healthcare towards a consumer-centric digital health model: shifting demographics, consumer and patient demand and expectations, financial burden, the inefficiency of legacy healthcare infrastructure, and most importantly, availability of and advances in digital technologies that have become essential for daily life. This is particularly true in Asia as it is now undergoing the more prevalent Asian Century, with the larger economies becoming stronger global players. At the same time, other countries are moving up to become MICs and LMICs, such as Vietnam, and the aforementioned factors are reaching new heights in the region. In 2021, it was estimated that digital health impacts more than a billion lives and could create up to $100 billion in value in Asia by 2025.[8]

With the rapid development of digital technologies, there are more and more applications to every aspect of health and healthcare, leading to the umbrella term of digital health, that encompasses eHealth, health information technology (health IT), mobile health (mHealth), wearable devices, telemedicine and telehealth, and precise and personalized medicine, among others.

Health IT refers to the general use of hardware, software, and other electronic infrastructures to process, store, manage, and exchange health information (clinical, administrative, and financial) between patients, providers, payers, and quality monitors. Electronic Health Records (EHR) go beyond Electronic Medical Records (EMR) as the latter is principally a digital version of the traditional paper charts, keeping all the medical and treatment history of the patients in one practice. In contrast, the former goes beyond encompassing the patient's total health to provide an inclusive perspective on the patient's care and health status that can be shared with the whole healthcare ecosystem. With the high penetration of devices such as smartphones, tablets, etc., and their capabilities, it is evident that mobile communication technology is leveraged for healthcare: patients' self-care through health apps, real-time monitoring, collection of clinical health data, exchange of healthcare information, training and collaboration of health workers. Branching from mobile health (as wearable devices are often connected to mobile devices, using the Internet of Technology (IoT) solutions), these devices are used to collect, transmit, and analyze personal health data through smart sensors: fitness trackers, smart watches, ECG monitors, blood pressure monitors, biosensors, etc. Telemedicine and telehealth, representing remote clinical services and the broader scope of

[8] https://www.mckinsey.com/industries/healthcare/our-insights/the-future-of-healthcare-in-asia-digital-health-ecosystems

remote healthcare (including non-clinical services), respectively, use digital information and communication technologies to access and deliver healthcare services remotely without any in-person visits, and were particularly useful during the COVID-19 pandemic. Telemedicine can improve access to rural, remote, and marginalized communities, and along with e-pharmacy services, can broaden access to primary care for underserved populations and maintain continuity of care. Precision and personalized medicine leverages genomics, big data analytics, and population health to help clinical decisions for disease prevention, diagnosis, and treatment for a more accurate, precise, proactive, and impactful outcome. Digital tools facilitate personalized healthcare through data-rich decision-making based on a comprehensive history and follow-up in many healthcare touchpoints. It sits at the forefront of being a consumer-centric digital solution while promising better approaches to diseases such as cancer, neurodegenerative diseases, and rare genetic conditions.

Digital health ecosystems are built to be consumer-centric by bringing together a network of healthcare providers, applying digital tools to analyze patients' needs and direct them toward the appropriate provider based on their behavioral, social, and health data, all supported by digital technologies that enable the exchange of information between healthcare providers. Indeed, using digital health applications, patients and their healthcare providers can cooperate in a consistent and ongoing healthcare process toward seamless and cost-effective medical care without lining up in a crowded waiting room or missing the golden periods of diagnosis and treatment. By reducing the fragmentation of care, digital health solutions improve patient safety and quality of care. More significantly, with a health-related database, policymakers and providers can leverage real-time information to enhance the quality of healthcare and better understand the current health situation in the population and, hence, the disease burden.

According to WHO and UNDP, digital technologies have proven potential to deliver better patient care and enhance health outcomes through better medical diagnosis, data-based treatment decisions, digital therapeutics, clinical trials, self-management of care and patient-centered care; increased revenue for health centers; more quality data for policy and decision-makers; reduced cost for patients; development of health workers through e-learning by creating more evidence-based knowledge, skills and competence; all while striving to provide equitable and universal access, with quality that is cost-effective and affordable.[9,10]

In facing a shifting disease burden and a double burden, as seen in the case of LMICs, shortcomings are exposed in relation to healthcare systems due to weak infrastructures and a lack of resources, leaving them unprepared for long-term care and preventive measures as the focus remains on short-term care due to the current and recent history of dealing mainly with communicable diseases, and these challenges are further aggravated by the lack of accessible quality healthcare.

One of the most significant weaknesses of healthcare systems in LMICs is infrastructure, resulting in a state of unpreparedness when faced with the double burden. Clinical settings are typically centralized in urban, populated areas with comparatively higher-income populations, which limits access to high-quality healthcare services and leads to inequality. The cost of transportation and follow-up due to distance breaks healthcare provider and patient connections in most cases. Without following up, NCDs become unmanageable, leading to life-threatening complications. Also, without interactions between medical staff and patients, trustworthiness and engagement cannot be built. Telemedicine solves the long commute issue, saves patients' time and money, and reduces pressure on overcrowded hospitals. With a strong network of hospitals equipped with telehealth, high-quality healthcare can be centralized in critical areas and accessed remotely on demand. Virtual consultations and remote patient monitoring demonstrated their usefulness

[9] Global strategy on digital health 2020–2025 WHO.

[10] https://www.undp.org/blog/what-role-can-digital-play-africas-health-challenges

in COVID-19 time and can be expanded into many infectious disease management programs to timely respond against communicable diseases by effectively limiting human-human contact. However, LMICs struggle due to limited resources, further aggravated by the double burden. It is challenging for them to build a sustainable healthcare system that can be highly efficient and help with cost-saving, and could then free resources for better allocation. This is where digital health solutions can help reduce costs, that becomes particularly significant in the long term. For example, health IT systems such as an EHR will help healthcare providers access patient data quickly, improving efficiency and reducing costs while standardizing the flow of information in the entire healthcare ecosystem, enabling a holistic perspective on the patient's health. With the patient's history available for the physician, a long-term patient-physician relationship is quickly built, with new information being integrated at each step, helping early recognition of problems before possible health issues become unmanageable, leading to unnecessary spending by patients and a strained workforce for healthcare providers.

The challenges that come from the double burden of disease can be addressed by digital health solutions in both of its two core components. Communicable diseases normally require acute care with expediting access but limited transportation and human contacts. The COVID-19 pandemic proved the power of digital tools in sharing information and communication, tracing contacts and mapping cluster development, supporting healthcare services, and accelerating the development and implementation of vaccination programs. Data collected can be used for epidemic control and disease model prediction, helping national, regional, and international collaborative efforts in eradicating communicable diseases. NCDs, on the other hand, need high-quality care over time by closely monitoring patients' health, engaging patients in treatment courses, and in many cases, modifying and engaging patient behavior towards wellness. There are many digital chronic disease management platforms that provide services to manage patients' conditions, home-based lab services, e-pharmacy services, and medicine taking. In terms of prevention, mobile apps with health devices can track customers' daily step counts, food consumption, heart rates, blood oxygen level, etc. Recommendations for better routines, changes in behavior, or early detection of abnormalities are available to improve wellness. As targeted by WHO, digital health has the potential to help achieve important goals by prioritizing and supporting the prevention and control of NCDs at all levels through international cooperation, which is facilitated through better data sharing and exchange. In turn, this strengthens the global, regional, and national agendas, building partnerships across sectors and collaborating in their efforts. It can also enhance healthcare systems and create health-promoting environments for better cooperation between healthcare providers and patients, leading to monitoring NCD trends and determinants.

Digital tools can help reduce disease burden through prevention by promoting wellness. Wearable devices give personalized recommendations on healthy routines and keep track over a long period of time to shape good behaviors. Moreover, health-support devices facilitate an early warning system for prevention and detecting abnormalities, which is the key to the early diagnosis of diseases. By detecting changes to an individual's health status very early, they improve therapy outcomes, save costs and resources, prevent hospitalization, and relieve the burden on healthcare systems. For people at risk of cardiovascular events, early detection of abnormalities in asymptomatic individuals can prevent premature death, heart failure, or ischemic stroke.[11] Supporting diagnosis at an early stage, many AI-augmented diagnostic tools are used by physicians and health technicians to quickly and precisely catch the damages and show their use cases in improving treatment outcomes and reducing the economic burden. Furthermore, advanced diagnosis tools can effectively manage symptoms that are beyond the average level of physicians'

[11] https://www.who.int/health-topics/cardiovascular-diseases#tab=tab_1

skills, resulting in improved clinical performance and greater accessibility to optimal healthcare for all patients. This can also alleviate the workload of the healthcare workforce and decrease disparities in their proficiency capabilities, which improves the service quality.

Digital health promises to alleviate the strain on healthcare ecosystems while providing holistic perspectives and improvements, leading WHO to harness its potential "to accelerate global attainment of health and wellbeing."[12]

At the micro level, the advancements and implementation of digital health solutions allow for a better insight into the social, behavioral, and environmental determinants of health, providing healthcare providers with a greater understanding of individual preferences, values, interactions, and exposures. This can create long-term partnerships for creating healthy behaviors and environments while delivering targeted preventive and acute care for better health outcomes. As this valuable information and data circulate safely and securely within the healthcare system, from healthcare providers to commercial players, insurance companies, and governmental agencies, it becomes possible to go beyond health behavior and self-awareness to provide on-demand health information and education, and promote accountability with social support networks, health coaches, and providers.

When such digital health solutions are equitably implemented and effectively used at the macro level, they can help prevent, mitigate, and reduce inequalities in access, quality, and cost. For healthcare providers, knowledge transfer and management become more feasible, improving the workforce's skills and capabilities, thus upgrading the overall infrastructure and resources. In addition, the aforementioned data can provide analysis into identifying behavioral risks, monitoring patterns and trends of diseases for evaluation and understanding of the relative importance of disease and disability for the entire population, and a better understanding of which condition poses the more significant threat to society, allowing policymakers and public health practitioners to allocate resources optimally for better health outcomes.

3 The Case of Vietnam

Vietnam, the world's 38th largest economy (according to GDP in current prices, as of October 2022[13]), is one of the countries successfully transitioning from being amongst the poorest nations into a LMIC, resulting from the Đổi Mới reforms of 1986 that opened up the economy to the international market and trade. Since then, the country has experienced rapid economic development, a growing population, poverty alleviation, and an increasing share of the middle class as the nation reached LMIC status in 2009. Over the last two decades, pre-COVID-19, it enjoyed an average annual GDP growth rate of 6.5%,[14] and emerging from this pandemic crisis, its GDP grew by 8.02% in 2022. With a population of 98 million people in 2021, Vietnam is the 15th most populated country in the world and currently benefits from its demographic status of a golden population structure, with 70% of the population being of working age (18–65 years old) (Fig. 4), contributing to its economic development. The country's rising living standards have increased life expectancy at birth to 75 years.[15] However, population growth is now floating at 0.8% per year,[16] leading to an aging population since 2015. Vietnam is among the fastest aging countries, with an expected shift towards an aged population from 2035 onwards.[17]

[12] https://www.who.int/health-topics/digital-health#tab=tab_1

[13] https://www.imf.org/external/datamapper/NGDPD@WEO/VNM

[14] https://data.worldbank.org/indicator/NY.GDP.MKTP.KD.ZG?end=2019&locations=VN&start=1999

[15] https://data.worldbank.org/indicator/SP.DYN.LE00.IN?locations=VN

[16] https://data.worldbank.org/country/vietnam

[17] https://www.worldbank.org/en/country/vietnam/publication/vietnam-adapting-to-an-aging-society

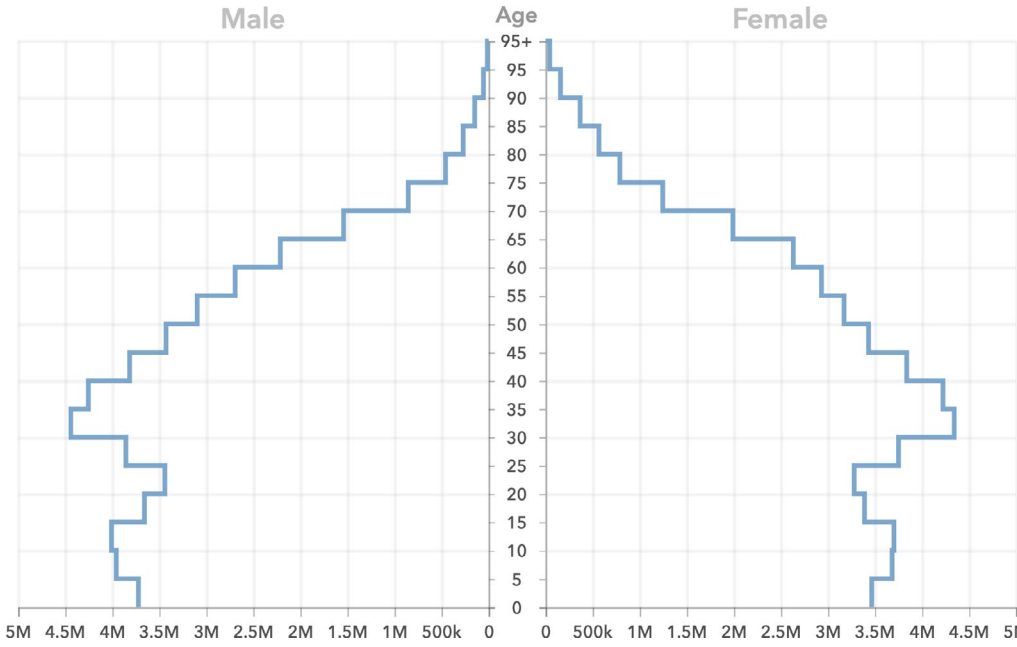

Fig. 4 Vietnam population age structure, 2023. (Source: Population Forecasting, IHME Viz Hub (healthdata.org))

Rising living standards and the population structure brought an essential shift in its healthcare landscape and increased healthcare expenditures due to surging demand for high-quality healthcare and private healthcare providers, namely by the strong middle-income class; but in the longer term, the healthcare structure will be tested as the population ages. Another factor behind this shift in the healthcare landscape, which is also impacted by the country's economic development, is the shifting disease burden from communicable diseases to NCDs, that requires long-term healthcare solutions. The substantial increase in NCDs is due to people increasingly adopting unhealthy habits: from a sedentary lifestyle due to urbanization, decreasing levels of physical activity due to new transportation forms such as motorbikes, dietary changes due to the globalization of fast food, and high levels of smoking tobacco and drinking alcohol. For example, in 2018, the total alcohol consumption per capita (liters of pure alcohol consumed by 15+ years of age) was 8.7 liters, and in 2020, 24.8% of the population aged 15 years or older smoked tobacco on a daily or non-daily basis.

As a result of its economic development, Vietnam has experienced rapid advances in technology and the country's overall infrastructure has improved. The entire population has access to electricity, 73.2% is connected to the internet through 156 million cellular mobile connections (a single individual may have more than a single subscription) with an average median download speed of 35.14 Mbps. Amongst internet users (between the age of 16 to 64), 97.6% own a smartphone, 64% own a laptop/desktop computer, 35.2% own a tablet, 29.9% own a smartwatch/wristband, and 18.6% own a smart home device. This same part of the population also spends an average of 6 h 38 m using the internet, with 76.95 million active social media users spending an average of 2 h 28 m on social media.[18] This demonstrates the digital literacy of the Vietnamese population and how the internet is core in both daily life and across all sectors, laying solid foundations for digital development and adoption of innovative technologies. In parallel, Vietnam is pursuing rapid growth in mobile communications technologies while shifting

[18] https://datareportal.com/reports/digital-2022-vietnam

towards cloud-based services, moving toward becoming a digital nation by 2030. This is set out by the National Programme for Digital Transformation's aim to "develop a digital government, digital economy, and digital society and to establish Vietnamese digital technology enterprises capable of going global," as declared by the Prime Minister of Vietnam in 2020. The objective is to become one of the 30 leading digital nations in the world, driving forward Vietnam's socio-economic development and national competitiveness through innovation, and it is expected that such goals will have a significant impact on the development of digital health solutions.

However, the country is still facing challenges of multidimensional inequalities, categorized into four different areas, that are interrelated: income and asset, life and health, education and learning, participation, influence, and voice. Focusing on the first three areas (due to their significant impact on health) based on a report by Oxfam,[19] as of 2016, wage inequality accounts for the largest share at 46.2% of total income inequality. In contrast, for total consumption inequality, it was mostly non-food consumption and housing. A significant disparity in all areas is due to the substantial gap in living standards between the Kinh (the largest population in Vietnam) and ethnic minorities (EMs): EMs account only for 15% of the total population but represent 73% of the poor.

Regarding life and health, inequality is differentiated by ethnic groups, regions, and income groups due to four main drivers. First, there is unequal access to healthcare due to the distance to healthcare centers for high-quality care, and a lack of healthcare providers (0.82 physicians and 1.34 nurses per 1000 residents). Second, despite impressive progress, there remains unequal access to maternal and child healthcare, with child mortality rates varying significantly depending on the region. Third, poor households have unequal access to clean water, adequate sanitation, and good nutrition, especially in densely populated areas with EMs, raising the risks of communicable diseases spreading. Finally, social and cultural norms influence many practices, negatively impacting their health and living standards.

Government expenditure and external financial support for healthcare have tended to decrease over time, and the Vietnamese government has gradually reduced funding for public hospitals, making them financially autonomous. During COVID-19, medical facilities were overcrowded, and resources stretched thin, overloading the entire healthcare system. As such, inequality issues can potentially disrupt the continuity and consolidation of developments and achievements made in healthcare in the past years. It should be noted that the healthcare system in Vietnam, from primary to tertiary, is structured by four administrative levels: commune (health centers from both public and private sectors), district (general hospitals and preventative health centers from both public and private sectors), provincial (general and specialty hospitals, preventive health centers, from both public sectors, and secondary medical schools), and national (general and specialty hospitals, preventative health centers, from both public and private sectors, and medical and pharmaceutical universities and colleges).

With compulsory education in primary school only, the enrolment rate starts to drop at higher levels, including high school and college. Urban areas have a significantly larger enrolment rate than rural areas, 51.8% compared to 33.6%, and the enrolment rate also has a strong correlation with the education level of the household head and the household's economic status, namely for EMs. On the other hand, the quality of infrastructure, facilities, equipment, and teaching activity varies greatly depending on regions, even between the main site and the satellite site of the same school, with poorer conditions being prevalent in geographical locations mainly occupied by EMs.

With such solid developments and existing inequality, Vietnam is a prime LMIC where digital health solutions offer opportunities to advance the healthcare ecosystem further and improve health outcomes of the population in general.

[19]Research Report: Multidimensional Inequality in Vietnam

3.1 Toward a More High-Income Patient Profile

Boosted by the country's socio-economic development, the middle class has grown significantly in Vietnam and is expected to continue growing, from 10% of the population in 2015 to an estimated 50% by 2035.[20] This growing middle class, along with its rising living standards, is also correlated with the increase in digital literacy and results in a greater demand for high-quality healthcare, private healthcare providers, and the incorporation of digital health services.

Leveraging the development of infrastructure and in response to the demand, private hospital networks have seen rapid growth, with some hospital chains such as Hoan My and Vinmec also achieving international standards such as Joint Commission International (JCI) accreditation. As these hospitals use more advanced health management systems and deliver advanced digital health solutions, high-income patients increasingly adopt digital health for better healthcare outcomes. Patients' trust in such services increases over time upon satisfaction with the quality, guaranteed through transparent governance and improving the local standards to international best practices. In parallel, digital tools also enable better patient engagement and trust, with more and improved direct communication between patients and healthcare providers, telemedicine, and encrypted EHR. Even public hospitals have started adopting digital health solutions, enhancing operational efficiency and medical outcomes, with more than 92% of them outsourcing to local IT companies such as FPT, Link Toan Cau, and Dang Quang to develop digital solutions for their facilities.

Telemedicine is beneficial because it alleviates the strain on physical medical infrastructure and avoids the spread of infections. It also allows patients more freedom with the timing and location of their consultations which is particularly advantageous if they have tight schedules due to their occupations. It avoids draining the resources of the provincial and national hospitals, resulting in better efficiency and cost-saving, as the Vietnamese strongly prefer these hospitals over communal health centers that remain highly underutilized. As resources are better allocated to new tools to track health outcomes for long-term healthcare in a move away from short-term care due to the shifting disease burden, high-income patients' demand is growing for better interventions for faster recovery, preventive solutions, and wellbeing in general. Precision and personalized medicine, leveraging AI and ML technologies, deliver early screening of possible health risks by combining genomic data and clinical histories, offering rapid treatments at early stages, and promoting behavioral change for better health outcomes.

Nevertheless, with the local healthcare sector experiencing capacity constraints and sometimes unable to provide the standards demanded by high-income patients, a significant portion of these opt for healthcare solutions in other countries, such as Thailand, Malaysia, Singapore, Japan, or the United States of America. The main reasons why patients choose treatment abroad include the healthcare quality and service, the qualification and experience of the healthcare professionals, the availability of medicines and treatments, and the reputation of healthcare facilities. The amount spent on medical tourism amounts to two billion USD yearly.

Given the opportunities from socio-economic and technological development and facing the challenges of a double burden and inequality, Vietnam is now in a prime position to adopt digital health solutions to meet the increasing healthcare needs of the population, to face the double burden, and provide equitable and universal access, with high quality that is both cost-effective for providers and affordable for patients. This has led the Government to set out an agenda for bringing digital transformation to its healthcare industry, working in a quadruple helix model (government, businesses, academic institutions, and society) that makes up the entire healthcare ecosystem.

[20] ("Digital Health in Vietnam: A Guide to Market," Austrade, July 2019.)

3.2 Local Digital Health Solutions: Indicative Examples

Various local players, from private healthcare providers to universities, startups, and offshore software developers, have taken advantage of the favorable factors resulting from the strong socio-economic and technological developments to develop digital health solutions for both the local and foreign markets, ranging across numerous aspects of the healthcare system. While many digital health solutions already exist in the market (often from HICs), they are often too costly for local implementation and integration in the local healthcare ecosystem remains challenging without compatible infrastructures.

Many mobile applications are used for tracing and monitoring infections to help control and prevent outbreaks of communicable and infectious diseases, e.g., COVID-19 with Bluezone and Ncovi (Vietnam's medical communication information system), and support HIV-infected people committed with antiretroviral (ARV) treatment. In addition, messaging services such as Messenger, WhatsApp, Viber, Zalo, etc., have been used for low-cost options to monitor diarrhea and influenza or update the COVID-19 pandemic status. Meanwhile, high-quality and advanced healthcare systems have been established to provide more precise and personalized medicine, and are gradually marking the transition towards preventive healthcare and wellbeing in order to better cope with NCDs.

3.2.1 VieVie Healthcare Co., Ltd: Telemedicine for Diagnosis and Patient Care Management

VieVie Healthcare Co., Ltd is a telemedicine company that was launched in 2017, with investment by Clermont Group (a private investment group based in Singapore), which also owns the Hoan My Medical Corporation, one of the largest private healthcare networks in Vietnam. Through the partnership between VieVie and Hoan My Medical Corporation, the former's digital health services and solutions are fully integrated into the hospital network. VieVie offers an online telemedicine platform established as a marketplace that connects both patients and doctors: providing space for patients to communicate with doctors for video call consultations and other primary care services, while doctors can expand their portfolio by signing up on the portal.

Like other telemedicine platforms around the world, this solution proved its efficiency during the COVID-19 pandemic by limiting human-to-human contact and alleviating crowding and constraints in hospitals while maintaining healthcare activities remotely, in turn promoting accessibility.

3.2.2 Hanoi Medical University Hospital (HMUH): Telehealth in Action

The Hanoi Medical University is the oldest modern university in Vietnam, founded in 1902 by the French during the French colonization, and it is now the most prestigious medical university in the country. Stemming from its long history, the university and its hospital enjoy a vast depth and breadth of knowledge and practice rooted in excellence.

During the COVID-19 pandemic, HMUH showed strong initiative in digital health solutions by being the first to launch a telehealth program on April 18th 2020. By leveraging its educational roots and live streaming on Facebook and YouTube, it provided free education, open and accessible for everyone, to raise awareness about COVID-19, getting people working together and learning from each other. With more centers joining such activities, learning becomes more beneficial through network effects, raising awareness of the pandemic (and of communicable and infectious diseases in general), and helping to bring it under control.

As Vietnam lacks medical resources, the disparity in medical examination and treatment qualifications between commune/district and provincial/national poses a difficult problem for the Vietnamese health sector. Provincial and national hospitals are overloaded whereas commune and district doctors have little opportunity to improve their professional qualifications because of a lack of patients. Expanding telehealth to clinical services will enable experts

from provincial and national hospitals to give advice in real-time on difficult cases that cannot be reached in district hospitals as immediate medical response is needed. This helps to mitigate complications and risks while saving time. As collaborative work becomes feasible, local healthcare providers can learn from experts, improving their knowledge and experience and improving patients' trust in local healthcare facilities. This will reduce overcrowding in the larger hospitals and help the experts have more time to research new knowledge and advanced treatments, corresponding to the shifting disease burden. For doctors, every telehealth session is a valuable clinical learning session. Each online medical examination has thousands of viewers and tens of thousands of reviewers. Because of the apparent benefits, HMUH intends to implement Continuous Medical Education (CME) via telehealth and obtain permission from the Ministry of Health to issue a CME certificate for each telehealth session. This will be the simplest and most effective way for doctors to learn, especially young doctors, and will help raise the general standard of the entire healthcare ecosystem.

3.2.3 Finizz: Outpatient Clinics and Health Tech

Finizz is a startup founded in 2015 in Ho Chi Minh City as a platform for booking consultations, aiming to address the lack of information in the Vietnamese healthcare industry, and connecting people in need with healthcare providers. With over 30,000 medical facilities registered in the country, the platform generates thousands of monthly appointments for healthcare and beauty care in a highly efficient manner. In addition, the platform provides information on clinics, doctors, hospitals, diseases, drugs, etc., that is constantly updated for the best accuracy possible. To satisfy diverse search needs, this is complemented by a 24/7 online question-answering service. As people move into the middle class, less concerned by communicable diseases but facing more NCDs, information becomes crucial for increased awareness and healthcare engagement. Having more accessible information is one step towards dealing with the double burden.

3.2.4 BuyMed & Thuocsi: Pharmaceutical Supply Chain

In Vietnam, pharmacies commonly operate by purchasing drugs from unlicensed agents. This poses great risks for the whole healthcare ecosystem, consumers, and patients. As a result, healthcare providers often spend a great amount of time sourcing drugs, which further aggravates the problems due to lack of resources when dealing with health issues.

BuyMed, founded in 2017, tackles this issue as a business-to-business (B2B) pharmaceutical distribution marketplace, leveraging technology to solve fraud issues and promote verification in pharmaceutical supplies. It has connected over 2000 healthcare providers with verified suppliers. Thuosci.vn, founded in 2018, is one of the most successful startups in medical technology and services, operating as a platform that includes a website and mobile application for providing and distributing drugs and pharmaceuticals to more than 1000 pharmacies and clinics across the country. Building on its success, it is currently expanding its distribution network further to neighboring countries in South-east Asia, such as Cambodia.

3.2.5 mHealth for Increasing Immunization Rates at Low Cost in Vietnam

Low rates of completed childhood immunization can be a major health issue that can escalate with time, affecting the burden of disease and the general population health. Although Vietnam claims a high immunization coverage rate of 95% (based on the diphtheria-tetanus-pertussis (DTP3) vaccine as a key indicator of immunization program performance), the system is highly inefficient due to its reliance on a paper-based system to administer, monitor, and report vaccines and immunizations. This also leads to possible errors in data recording and reporting, potentially impacting vaccine stocks, resulting in a child missing a vaccine and contracting a disease that could have been prevented. Hence the actual immunization coverage rate may not be accurate at regional levels.

A digital solution was developed in 2012 called the Digital Immunization Registry System

(ImmReg) to replace the old paper-based system. ImmReg is a web-based application (for both computers and mobile phones) that tracks the vaccination status of children, and in which immunization data can be recorded and accessed in real-time. With the addition of an auto-SMS system integrated in 2017 (in cooperation with Vietel and taking advantage of the growth of mobile networks for mHealth) , reminders can be sent via SMS to caretakers for the required vaccinations to be administered on time. As a result, workload burden is reduced, cost-saving is increased, data recording accuracy is improved, and most importantly, immunization rates and timing are improved. With a strengthened quality and effectiveness of immunization programs, it will be beneficial for the healthcare system to integrate this system into the national health IT and adopt it for other healthcare programs (i.e., maternal and child health, nutrition or infectious disease control), boosting overall efficiency and minimalizing health issues that can be prevented by vaccines.

3.2.6 Ominext Joint Stock Company: Promoting Primary Care

By digitizing the medical and healthcare systems, the information technology system is fundamental for moving away from analog and legacy approaches.[21] Ominext Group[22] brings a holistic and integrated expertise capable of developing and implementing various systems for areas related to hospitals & clinics, treatment & examination, medicine, welfare, and patient services, all as a cost-effective, project-based, and labor outsourcing development solution.

Established as an offshore software development company providing mainly for the Japanese market, the group has been able to provide for the needs of the Japanese market with its aging population and digital transformation efforts in all industries, by building on the ability to provide outsourced software development at a cheaper cost against high labor costs and a shortage of skilled workforce in Japan. There are three main factors contributing to Japanese longevity: equity, the government's strong intervention, and universal health coverage. With the country pushing for the concept of Society 5.0, Japan's digital health is technology-based, human-centered, and aims for wellness and personalization. The group integrates its extensive knowledge of medical and healthcare systems with technology systems ranging from cloud systems, big data, server and system development and maintenance, image analysis, IoT, and AI to blockchain, leading to the development and deployment of over 250 systems in over 7000 hospitals/clinics and 3000 pharmacies, all in alignment with security and regulatory frameworks, from ISO to Japanese governmental guidelines.

Since 2018, with advances in the digitization of the medical & healthcare industry in Vietnam, Ominext Group has expanded its operations locally in Vietnam through its subsidiaries to provide medical & healthcare services by creating a safe, modern, and reliable healthcare ecosystem. With Ominext's knowledge and experience from having operated in Japan, building a thorough understanding of the healthcare ecosystem and health situation in a highly developed country, it can bring valuable insights to a developing country like Vietnam, helping prepare for the future of health as the country pursues its growth and deals with the shifting disease burden.

3.2.7 Institute of Gastroenterology and Hepatology

Institute of Gastroenterology and Hepatology (IGH), established in March 2018, is a scientific and technological organization for intensive research and training in digestive and hepatobiliary issues. In adopting a patient-oriented, digital health solution, IGH opts for mHealth through mobile applications, such as GERDcare or a colonoscopy bowel preparation application, to help bridge the gap between physicians' instructions and patients.

For digital health solutions that are doctor-oriented, AI tools can be used for clinical diagnosis in a move towards high-quality precise and personalized medicine. Commercial products already

[21] https://www.adlittle.com/jp-en/insights/report/hospital-information-systems-digitally-enabled-era

[22] https://www.ominext.com/

exist (Fuji Film and Medtronic), but tend to be costly and require compatible infrastructure from the same providers, and need continuous updates. With resources already limited, it is more viable for institutions to develop their own in-house solutions as the development can be controlled and the technology owned, providing flexibility in integration and decoupling and, most importantly, reducing the cost for primary care facilities. Such projects begin with building a database from scratch, with big data from and for Vietnamese people, training the system to tag possible issues for diagnosis while promoting ongoing communication between the IT and data science teams. The collected data will be used for further studies and educational purposes, supporting primary care. However, there are important challenges: building the database is time-consuming (1 year for setting up the standards and training for judgment), and resources remain limited, even for in-house development. While the side-product can be used for training programs, with the data being used for education and investigation, the whole study remains at a very early stage.

3.2.8 Vinmec

Vinmec is a non-profit healthcare system established in 2012 as a subsidiary of Vingroup (the largest conglomerate in Vietnam). It currently operates seven international-standard hospitals. With the aim to improve patient outcomes and advance healthcare in Vietnam, Vinmec has been working to continuously deliver international standards through advanced healthcare models, research, and embraced digitization to improve and create new solutions that also correspond to the increasing consumer demand.

To deliver a value-based and patient-centric care, Vinmec implemented P4 medicine, with the emphasis on personalized, predictive, preventive, and participatory care, employing various digital tools, such as AI and big data, for advanced healthcare activities that include genetic testing and molecular diagnosis. These practices enable the tailoring of treatments for individual patients, a desirable procedure for high-income patients and for better healthcare outcomes in tackling NCDs in particular.

To support the management, research, and services, Vinmec has undergone significant digital transformation. A notable example is its in-house developed mobile application, MyVinmec, to provide patients with a convenient healthcare experience, from booking appointments to telehealth, medical records, test results, and prescription refills. Reducing waiting times and improving patient engagement, it enables patients to track their longitudinal medical history, marking the transition from looking after illnesses and their treatment to preventive care and wellbeing. Meanwhile, for the practitioners, this increases efficiency and alleviates resources, allowing better focus on other advanced healthcare activities. In addition, the hospital group has adopted a picture archiving and communication system (PACS) to digitize the traditional films, providing instant access to medical images, which coupled with AI-assisted X-ray diagnostics, helps diagnose conditions rapidly and accurately. Outside of these two major actors, Vinmec has also established a digital connection with healthcare insurance providers, allowing insurance claims to be processed directly in less than an hour, further boosting the efficiency for all stakeholders.

4 Conclusion

LICs and LMICs face a particular set of interrelated challenges. Despite the socio-economic development they may be enjoying, strong inequalities persist on many levels that tend to impact the population's health negatively. The general healthcare ecosystem remains underdeveloped, with a weak infrastructure and a lack of resources. On the other hand, due to various drivers, the countries experience a shifting disease burden, with an increase in NCDs while communicable diseases remain prevalent, leading to a double burden. In turn, this double burden adds pressure to the already strained healthcare ecosystem, stretching resources thin and challenging the infrastructures. The result is that healthcare providers and policymakers will be unable to get the best results when tackling the double burden,

which is the central issue. This will fuel further inequalities, which may ultimately impede socio-economic development. This situation may result in a vicious cycle that worsens the situation on all fronts.

Fortunately, other factors exist that can help avoid such a vicious cycle by alleviating these difficulties. Many of these will be fueled by digital health that offers various solutions to help tackle the shifting disease burden and double burden, while improving the healthcare ecosystem and responding to the increasing demands of customers and patients. These solutions help provide equitable and universal access to quality healthcare, that are both cost-effective and affordable, and can turn the potentially vicious cycle into a virtuous cycle, leading to further socio-economic growth. It was for this reason that indicative examples were presented in this chapter, these are not the only ones that exist but are used simply to illustrate the point.

For this to become a practical reality, it is essential to first gain a deep understanding of the health inequalities and how digital health may prevail in this area. In the next chapter we will explore this theme in more depth.

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Health Inequalities and Availability: Needs and Applications

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Abstract

The limited access to high quality healthcare in Low- and Middle-Income Countries (LMICs) creates disparities and challenges. In such nations, health outcomes are inevitably influenced by the scarce geographic distribution of health providers and the often unbearable cost of quality services. Regardless of improvements in global life expectancy and mortality rates due to scientific and medical breakthroughs in the modern world, LMICs do not experience similar progress. To bridge the healthcare gap, a coordinated global effort to transfer medical knowledge to developing countries through the digitalization of medicine, in the form of adopting and implementing electronic health records (EHRs) or telemedicine is imperative. This chapter initially explores how the concepts of healthcare inequality and inequity are exerted and provides examples of how medical digitalization is implemented in LMICs. International and national responses to health inequalities that are impacting digitalization efforts and the role of human rights towards achieving the effective and widespread provision of high-quality healthcare services are also addressed.

Keywords

Healthcare inequalities and inequities · Medical digitalization in LMICs · Marginalized and disadvantaged populations · The right to health · mHealth · Electronic Health Records (EHRs) · Sustainable Development Goals (SDGs) · Healthcare systems

1 Introduction

Inaccessibility to healthcare services in Low- and Middle-Income Countries (LMICs) (World Economic Outlook Update 2013; Word Data 2022) has a detrimental impact on the standard of living and quality of life of their citizens. Addressing this challenge effectively requires comprehending and addressing the specific needs and applications of healthcare, medicine, and medical research in these regions. Limited healthcare access and high costs are the key factors that contribute to deficiencies in the provision of effective health services and perpetuate poverty among marginalized and disadvantaged popula-

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tions (Smith 1999). Global income inequality contributes to healthcare provision disparities, with approximately 71% of the world's population living in countries with high levels of inequality and where out-of-pocket payments for healthcare are a common practice (Gottret and Schieber 2006). Urbanization further contributes to growing disparities within cities, where wealth and modern infrastructure coexist with severe deficiencies in proper healthcare. Consequently, this societal gap generates a healthcare gap directly affecting the overall quality of life in citizens of developing nations. Therefore, despite global improvements in life expectancy (Crimmins 2015), infant mortality rates, and cancer outcomes, these positive trends are not uniformly observed globally (Fauconnier 2019; Roser et al. 2013).

To bridge the healthcare gap, LMICs cannot rely solely on their own resources. A coordinated global effort that will advance key components and digitalization mechanisms of existing healthcare systems is a critical step to ensure that LMICs can keep pace with the rest of the world in providing satisfactory healthcare services and extend their involvement in scientific excellence. In this regard, it is essential to highlight the several needs of such healthcare systems, including the establishment of suitable infrastructures, enhancement of the healthcare workforce, increase in health education and awareness, and adoption of relevant digitalization mechanisms such as EHRs, telemedicine, and healthcare mobile applications. Strategic implementation of such requirements is crucial to effectively address the specific challenges faced by these countries. Likewise, it is essential to address the issue of digital literacy of the population, particularly among healthcare professionals. While this chapter focuses on medical digitalization mechanisms, it is important to note that physical infrastructures, including medical equipment and hospitals, are essential components of this endeavor, as they play an equally significant role in achieving the equitable provision of healthcare services and supporting the effective implementation of these digital mechanisms.

This chapter initially explores how the concepts of healthcare inequality and inequity are exerted and provides examples of how medical digitalization is implemented in LMICs. International and national responses to health inequalities that are impacting digitization efforts and the role of human rights towards achieving the effective and widespread provision of high-quality healthcare services are also addressed.

2 The Concepts of Health Inequality and Inequity: Their Role and Impact

The concepts of ***health inequality*** and ***health inequity*** play a vital role in the global effort to support LMICs in achieving satisfactory healthcare services and improving healthcare systems. These concepts have gained broad recognition and are addressed by various international organizations, such as the World Health Organization (WHO) (WHO 2023), United Nations Development Programme (UNDP) (Kivioja et al. 2023) and United Nations Children's Fund (UNICEF) (UNICEF 2016). Health inequalities, as defined by WHO *"are the differences in health status between groups of people which are important, unnecessary, unfair, unjust, systematic, and avoidable by reasonable means. They can be observed between populations and groups within populations and as a gradient. They can also be observed between countries and regions. They are linked to social, economic, and environmental conditions, the conditions in which we are born, grow, live, work and age"*. On the other hand, *"health inequities are differences in health status or in the distribution of health resources between different population groups, arising from the social conditions in which people are born, grow, live, work and age. Health inequities are unfair and could be reduced by the right mix of government policies" (*World Health Organization 2023*).*

The distinction between healthcare inequalities and inequities stems from their underlying causes and the implications they have on fairness and justice in healthcare. Failure to comprehend

the concept of health inequity in LMICs can perpetuate systemic disparities, hinder policy responses, misallocate resources, erode social cohesion, impede economic development, and undermine international cooperation (Andermann 2016). For example, maternal and child health disparities remain prevalent in LMICs due to limited access to healthcare services, malnutrition, low educational attainment, and poverty (World Health Organization 2015). Likewise, disproportionate rates of the prevalence of infectious diseases such as HIV/AIDS, tuberculosis, and malaria, persist among disadvantaged populations (World Health Organization 2021). Noncommunicable diseases, including cardiovascular diseases, diabetes, and cancer, disproportionately impact marginalized groups on top of an underlying gender dimension (Namasivayam et al. 2012). Moreover, exposure to environmental health hazards, such as air and water pollution, poses additional health risks in communities where relevant regulations or monitoring are not a state priority (UN DESA 2020; Scheil-Adlung and Kuhl 2011). To this end, recognizing and proactively addressing health inequities is crucial for addressing deep-rooted health disparities.

While the concepts of healthcare inequality and healthcare inequity are closely related and are often used interchangeably, they have distinct roles in promoting understanding and impacting the development of healthcare policies, particularly in LMICs. This includes the introduction and implementation of digitalization mechanisms in medicine. Introducing the concept of equity as a core value in the digitalization of medicine, we can actively promote social responsibility, inclusivity, and ethical practices in the digital health domain (Yao et al. 2022). Equity may serve as a motivation for societies, policymakers, and stakeholders to not only promote the digitalization of medicine but also to consider and prevent any adverse effects that may arise from technological interventions (Yao et al. 2022). Emphasizing equity in digitalization efforts plays a crucial role in creating more just and inclusive healthcare systems. Thus, to narrow the healthcare gap, it is crucial to comprehend the role and impact of each concept. This understanding will enable policymakers and healthcare stakeholders to advance appropriate and targeted interventions and policies.

3 International and National Responses to Health Inequalities

Despite the acknowledgement of the distinction between health inequalities and health inequities in several published documents, there is lack of sufficient reflection regarding this issue in the international and national responses aimed at tackling these challenges. Efforts to address health inequalities have been evident at both the international and national levels since the 1980s (Albert-Ballestar and García-Altés 2021). Due to the complexity of the factors contributing to this challenge, no single solution is available, and it is now clear that collaborative efforts are needed from world citizens, private entities, and a plethora of government sectors such as finance, economics, social welfare, and healthcare (World Health Organization 2023). To strengthen these collaborative efforts, international and national organizations work together with governments for creating and implementing policies aiming to deliver the essential conditions for a healthy living environment. The United Nations and WHO play a critical role in coordinating global initiatives and in supporting the global community to gain access to data from various sources that revealed and produced renewed evidence about the magnitude of health inequalities and the disparities that are on the rise (Barreto 2017).

In 2015 the United Nations adopted 17 Sustainable Development Goals (SDGs) as a universal call to action towards eradicating poverty, protecting the environment, and enhancing the quality of life for all people worldwide with a 15-year plan to achieve them (United Nations 2023). Each goal is accompanied by a set of indicators that aim in measuring progress made in the 193 countries that have agreed to work toward achieving the goals, and a report on global and national progress is released annually. The SDGs serve as a framework for addressing health and

social inequalities on a global, national, and local level. All the goals aim to address the root causes of health inequalities in such sections as poverty, justice, peace, climate change, and environmental degradation. Significantly, one adopted goal focuses directly on health (SDG3 *Good Health and Wellbeing*), and among others a target (3.8) has been set for it to achieve Universal Health Coverage (UHC) for all including financial risk protection, access to quality essential health-care services and access to safe, effective, quality, and affordable essential medicines and vaccines (UN 2022).

In addition, WHO created a Health Equity Policy Tool (2019) to assist Member States and partners in monitoring, implementing, and enhancing policy actions to address the five identified fundamental conditions for a healthy living (including access to health care services), ultimately leading to a reduction in health inequalities (World Health Organization 2023). Furthermore, WHO regional offices (e.g., Europe (World Health Organization | Regional Office for Europe 2023), Pan-American (Pan American Health Organization (PAHO) 2023), and Africa (World Health Organization | Regional Office for Africa 2023)) have examined the primary causes of health inequalities in their regions, evaluated the available factors contributing to these inequalities, and launched regional programs to target them.

Even though most countries have not given health inequalities a prominent position on their political agenda, numerous policy suggestions have been put forward on an international and national level and available evidence has been utilized for incorporating actions into country healthcare policies that in some cases were able to partially diminish inequalities (Barreto 2017; Mackenbach 2020).

4 Digitalization Levels and Initiatives

While LMICs actively strive to address health inequalities and improve healthcare access, quality, and cost-effectiveness, the digitalization of medicine and healthcare stands as a crucial factor. However, the availability of digitalization in these countries depends on various factors including limited internet accessibility and bandwidth, funding, availability of experts, and policy support. Nonetheless, once digitalization and new technologies such as EHRs, telemedicine, and healthcare mobile applications are successfully implemented, many of these challenges could be overcome (Holly et al. 2022; Devi et al. 2020).

A crucial step towards achieving digitalization is to replace the traditional paper-based health records with Electronic Medical Records (EMRs) and thereinafter to EHRs. This shift is expected to reduce bureaucracy, and operational costs, and contribute towards achieving effective healthcare. Electronic systems offer numerous advantages like scalability, backups, enhanced security, time efficiency, consistent layouts, clear audit trails, and version history (Mathioudakis et al. 2016). They address concerns regarding the availability and accessibility to services like scheduling appointments, accessing medical records and obtaining medical advice. For example, effective access to medical records in many countries can often be challenging due to inefficient technologies or limited funding. Therefore, the development of cost-effective health information systems (HIS) (Koumamba et al. 2021) and integration of the information through an EHR, along with the establishment of regulations for data privacy and security will consequently elevate patient healthcare (Akwaowo et al. 2022).

One of the most significant benefits of digitalization is its potential to increase access to healthcare services. Telemedicine is a cost-effective technology compared to traditional in-person visits and can help bridge the gap and increase access to healthcare services. In particular, 3.4 billion people (around 45% of the global population) who live in rural areas of LMICs can have access to medical care by using telemedicine tools or applications, and dedicated support is further available for chronic patients through at-home monitoring systems (Ftouni et al. 2022). Telemedicine can also help in resource allocation with higher effectiveness, by minimizing the number of unnecessary visits and tests, while

putting high-risk patients who need timely intervention in priority (Lupton and Maslen 2017; Combi et al. 2016).

Another significant mechanism is the development of healthcare mobile applications (mHealth) designed for various purposes, including clinical reference, telemedicine, health management, and to track wellness and fitness levels (Ventola 2014). These applications improve patient engagement through mobile apps or text messaging, reduce the risk of misdiagnosis, provide immediate access to care, offer automated reminders, enhance data management by integrating with EHRs, and enable real-time monitoring through healthcare Internet of Things (IoT) implementations (Dendere et al. 2019). These apps contribute to personalized healthcare by allowing patients to access their medical records, communicate with healthcare providers, and manage their health conveniently and efficiently.

In addition, the significant challenge posed by the limited accessibility of many LMICs to essential medications can be addressed through digitalization, especially for the improvement of supply chain management. Inevitably, digitalization maintains a crucial role in ensuring transparency and accountability for supply chain procedures, mitigating potential delays and inefficiencies, and in preventing the illicit diversion of drugs to the black market (Beaulieu and Bentahar 2021).

Rwanda is an example of a country that made significant investments in electronic health infrastructure, including the implementation of electronic medical records and a national health information exchange. Such interventions include the mHealth RapidSMS and the TRACnet platforms, which allow healthcare workers to collect and share healthcare data in real-time and to track disease outbreaks and monitor patients' health, respectively. This advancement has enabled healthcare providers to access patient health information from anywhere in the country and has improved the quality of care for patients. Kenya is a developing country that also implemented several digital health initiatives, including the National Hospital Insurance Fund (NHIF) mobile platform, which allows patients to access healthcare services and make payments through their mobile phones. Moreover, Kenya has brought forward additional solutions, such as the application of several mHealth initiatives, including the mPedigree platform, which enables patients to use their mobile phones for verifying the authenticity of their medications (Hategeka et al. 2019; Kizito et al. 2013).

In conclusion, the importance of digitalization for medicine/healthcare cannot be overstated. Healthcare systems have the potential to be revolutionized through the application of digital technologies for improving healthcare access and enhancing health outcomes. While there are many promising initiatives aimed at promoting digitalization in healthcare, there is still a long way to go in terms of achieving universal access to digital health services in LMICs. All countries, irrespective of income levels, must continuously invest in digital technologies to improve their healthcare systems by ensuring adequate funding to develop and maintain a digital health infrastructure and align with current technological advancements (Drury et al. 2018). Addressing the barriers to digitalization in healthcare will require a collaborative effort among governments, healthcare providers, and other stakeholders, as well as a commitment to ensuring that the benefits of digitalization are accessible to all.

5 Human Rights as a Supportive Mechanism to the Digitalization of Medicine in LMICs

Human rights are universally applicable and can play a key role in advancing equity in LMICs through the digitalization of medicine. States assume obligations and duties under international law to respect, to protect and to fulfil human rights by ratifying international treaties and conventions. The principle of universality is a core principle of human rights recognized and endorsed by the international community (UN 1948). Universality ensures that human rights apply to all individuals, irrespective of their nationality, race, gender, religion, or any other

characteristic and varying levels of development, political systems, and socio-economic conditions of countries (UN 2023). Human rights also enshrine other principles such as indivisibility, equality, and non-discrimination, participation, accountability, transparency, rule of law, and human dignity. These principles provide a just and fair regulatory framework to facilitate responsible and ethical utilization of digital technology in medicine and biomedical research. Such a framework is critical in these countries, where the vulnerabilities within their populations and healthcare systems are significantly diverse and more pronounced than elsewhere in the world. The right to health and the right to private life, for example, can be instrumental in narrowing the healthcare gap through the digitalization of medicine and biomedical research.

The right to health stands out as one of the most significant human rights and it is recognized as a fundamental human right under international law by several international human rights instruments (UN 1948, 1966a). Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR) recognizes 'the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.' This includes the right to access quality healthcare services, medicines, and facilities without discrimination, as well as the right to information related to health, participate in decision-making about one's health, live in a healthy environment and have an adequate standard of living. The right to health plays a crucial role to the digitalization of medicine and biomedical research by embedding relevant human rights principles into the regulatory frameworks. By doing so, it would promote effective and proper digitalization of medicine in LMICs, aligning with core values and standards. The rights to health and digitalization of medicine are mutually supportive. Digitalization can contribute to the implementation of this right by improving access, quality, and affordability of healthcare services. Significantly, it ensures that the benefits of digitalization are accessible to all, with particular attention to marginalized and disadvantaged populations.

The right to private life assumes particular significance in the digital era, where health data can be easily accessed and shared, necessitating special safeguards and attention for LMICs. Article 17 of the International Covenant on Civil and Political Rights (ICCPR) explicitly states 'No one shall be subjected to arbitrary or unlawful interference with his privacy, family, home or correspondence, nor to unlawful attacks on his honor and reputation' (UN 1966b). Similarly, the right to respect for private life is guaranteed at the European level under Article 8 of the European Convention of Human Rights (ECHR) (1950). In May 2018, the General Data Protection Regulation (GDPR) (2016) was put into effect providing comprehensive data protection in Europe and establishing principles for processing of health data. Digitalization of medicine raises ethical, legal, and social issues (ELSI) that require careful consideration. These concerns encompass issues related to data privacy and security, the potential for bias and discrimination in algorithms and decision-making, and the need to ensure that digital health technologies are accessible and affordable for all individuals.

Both the right to health and the right to privacy are important in the global efforts to narrow the healthcare gap. To promote and implement digitalization in medicine, it is imperative to establish a regulatory framework rooted in human rights principles. Such principles ensure the responsible and ethical use of digital technology in medicine and biomedical research, while fostering its acceptability due to the universal applicability of human rights. In addition, concerns regarding data protection and informed consent in the utilization of digital technology can be effectively addressed and at the same time they will promote trust within the society.

6 Conclusion

Moving towards the era of precision and personalized medicine, the concept of digitalization in medicine, and in extent of biomedical research, inescapably becomes critical. As LMICs employ smart, user-friendly, and interoperable digital

solutions to bolster healthcare services, matters of inequality and inequity impede LMICs from being at the forefront of modern advancements. Consequently, such barriers create gaps in the application of medical services despite the efforts accounted for by relevant coordinating organizations. It is imperative that to achieve a certain degree of backbone digitalization in healthcare services, LMICs must instigate a holistic and multileveled approach. This involves engaging all key components and digitalization mechanisms discussed in this chapter, requiring a coordinated global effort from various stakeholders and patient advocacy groups and necessitating the establishment of a regulatory framework to safeguard the responsible and ethical utilization of the digital world in medicine by being essentially based on human rights' principles. Additionally, the concept of health equity should be embedded as a fundamental principle to bring recognition towards the obligation of states worldwide to provide equal opportunities for individuals in attaining optimal health outcomes, regardless of their social or economic status, and at the same time in fostering a fair and inclusive society that ensures access of citizens to healthcare services on an equitable basis. Therefore, it is emphasized that the adoption of policies based on social equity to achieve a high level of medical digitalization capacity, significant strides can be made in narrowing the existing healthcare gap. Such holistic approaches will in turn enable policymakers and healthcare stakeholders to develop and implement targeted and personalized interventions, to ultimately accomplish and maintain accessible, equitable, and ethically responsible healthcare systems in the developing world.

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Needs of Healthcare and Medical Research Digitization in Developing Countries: Digital Health Infrastructure

Olivier Vandenberg and Zisis Kozlakidis

Abstract

Digital health and digitization in healthcare have only accelerated by the recent COVID-19 pandemic. LMIC settings face a unique complexity of healthcare challenges, where digital health infrastructure is likely to ameliorate at least part of the existing pressures. However, persistent infrastructure challenges provide a barrier to implementation. Therefore, key considerations have to be taken into account for key structural needs: firstly, the likely greater impact of digitalization in LMICs on primary healthcare, and as such the design of systems to support smaller, inter-connected units; secondly, the tropicalization of equipment, that can bely opportunities for co-development of digitalization applications under a universal health coverage system; and thirdly, the greater availability of field performance studies in LMICs, that would eventually inform future funding and support models. The digitization of healthcare in LMICs will be context-driven, and as such different implementation models are likely to emerge. Taking the key considerations above into account, such models can be further optimized to respond to the national/regional healthcare needs and pressures.

Keywords

Health infrastructure · Digital infrastructure · Low-and middle-income countries (LMIC) · Structural needs · Tropicalized equipment

1 Introduction

The recent pandemic has demonstrated the fragility of global healthcare systems, especially in Low-and Middle-Income countries (LMICs). The need to strengthen LMIC healthcare systems' resilience is not a new concept, but has existed for a number of decades (Mabey 2004), summarized in 2009 in a seminal publication by the World Health Organization (WHO) on 'Systems thinking for health systems strengthening' (De Savigny and Adam 2009). This concept was iterated through the recent infectious disease

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outbreaks in LMICs in recent years, for example, during the Zika (Duchin 2016) and Ebola (Kluge et al. 2018; Kruk et al. 2015) virus outbreaks. However, it is important to note that within LMICs these infectious disease outbreaks exist in addition to other considerable infectious disease threats, namely malaria, tuberculosis (TB) and Human Immunodeficiency Virus (HIV) to cite a few (Hogan et al. 2020). Moreover, it has been predicted that a substantial increase of non-communicable diseases will also be anticipated in LMICs, for example, for cancer predicting a rise from ca. 05m deaths in 2020 to about 1m deaths by 2030 (Ngwa et al. 2022). Therefore, the development of digital health infrastructure has to address acute pressures, and more than likely be able to cover multiple overlapping needs within the existing healthcare systems.

Further pressures originate from changes in the nature of health care delivery itself (for example a greater shift on remote care), government and payer initiatives, the attitude of insurance organizations, consumer education and expectation, and rapid changes in technology. Altogether, the increasing needs and diverse pressures have prompted a push to consolidate biomedical laboratory analyses, where resources and services are centralized and serve a large(r) population for purposes of enhanced efficiency, increased standardization, and potentially earlier time to results (Vandenberg et al. 2020). This trend is universal and has been exhibited in high-income countries, as well as LMICs, though more intensely in the former (Mochon and Santa 2016).

Initial considerations included diagnostic costs, privatization, and scarcities of appropriately qualified personnel, as consolidating capacities could allow for technical scaling-up of offered services (Vandenberg et al. 2018). However, secondary benefits have also emerged, supported by the increasing digitalization, including for example integrated databases linked to regional/national reporting systems, as well as more easily managed biorepositories (Aisyah et al. 2023). The current prospective manuscript highlights the key needs of healthcare and medical research digitalization in LMICs relating to the digital health infrastructure.

2 Persistent Infrastructure Challenges

In high-income settings, consolidation of clinical services and lean approaches have been promoted for a number of years, in conjunction with clinical utility (Samuel and Novak-Weekley 2014; Miller et al. 2019). Similar initiatives were reported for LMICs; however, they were fewer by comparison (Shah et al. 2020; Micah et al. 2020). The challenges in the implementation of change, or even more of a systemic transformation, in LMIC healthcare are many and persistent. In the case of digitalization, they can be grouped in challenges relating to: infrastructure, equipment, consumables, human resources, available pathways to embed within routine healthcare, political priorities and governmental structures (Ombelet et al. 2018). A number of those will be specifically covered in subsequent chapters (e.g., Chap. 21 on the technical challenges; Chap. 23 on governance, etc.). The focus of the current chapter would be on the design of the digital health infrastructure so as to reflect current and future needs.

As highlighted previously, building capacity for clinical laboratories, for example, needs to include data management capacities, which currently remain under-resourced. For example, the lack of a fit-for-purpose and open-source laboratory information management system software is of particular concern, and has not been addressed even during the COVID-19 pandemic. Thus, without actions to improve information technology infrastructure and data management systems, ongoing efforts to develop capacity in LMICs are unlikely to realize their full potential (Turner et al. 2021). Furthermore, a digital technology or application transposed directly within and LMIC context may not operate as effectively as anticipated (by comparison to high-income contexts), as the local healthcare needs, clinical parameters (Alp and Rello 2019), and even relative abundance of infectious agents (Budayanti et al. 2020) may be different, hence exerting a distinctly local combination of needs and pressures. Moreover, emerging technologies and platforms are more easily assimilated in bigger laboratories, leaving

the smaller ones (e.g., in peri-urban or rural settings) at risk of being left behind (Vandenberg et al. 2020). New and usually quite complex technologies already require (multiple) accreditation levels to comply with European Conformité Européenne (CE) or American Food and Drug Administration (FDA) guidelines, thus the implementation capacity within many LMIC settings is prohibitive.

3 Identifying the Key Structural Needs

As digital health interventions and electronic clinical decision support algorithms (CDSAs) in primary healthcare is identified by the WHO as key accelerators in achieving the 20,230 Sustainable Development Goal 3 of ensuring good health and wellbeing for all, digitalization should enable the emergence of small scale, cost-effective, semi-autonomous and decentralized clinical laboratories within LMICs.

Most large urban centers in LMICs have a healthcare structure that spans primary to tertiary healthcare facilities. While the capacity may be limited, and the local population under-served, the healthcare structure exists and has a blueprint for directional growth at each healthcare provision level (Nugraha et al. 2017; Massoud 2008). Digitalization can enable further expansion at the primary healthcare level, i.e., the entry point to healthcare for the majority of the population (Rawat et al. 2023). Smaller scale units can be created, operated by basically trained staff that are digitally connected with larger units that provide the support as and when required. This cost-effective approach has been implemented for some existing initiatives as a way of scaling-up (Bhattarai et al. 2022; Rodriguez-Villa et al. 2020). Such approaches can be adapted to accommodate inexpensive and robust techniques. The digitalization aspect will provide the necessary standardization of service provision and connectivity with other services, while the infrastructural focus will be centered on technical components such as accessibility to digital applications and to cloud/internet infrastructures. Of course, implementation of digitization initiatives between different tiers of healthcare is more complex than within the same tier (Eboreime et al. 2019). Thus, adequate pre-intervention planning, understanding, and engaging the various interests across the governance structures are key to improving the potential adoption and successful implementation.

The second key structural need for digital health infrastructure is the availability of 'tropicalized' equipment consumables and techniques, i.e., that would be able to operate within the technical challenges of LMICs without compromising the quality of the technical output (Tran 2016; Sankaran et al. 2010). This is process that can often be considered as 'reverse-innovation' or 'bottom-up' innovation (Trimble and Govindarajan 2012), where available core technologies are available on-site in LMICs, and undergo iterative rounds of co-design, adaptation and improvement so that aspects are optimized for the local operational contexts. In some cases, such a process can also result in the local production, disposal and/or distribution of resulting product variants (Naseri 2022; Sankaran et al. 2010). There are of course additional requirements, beyond the co-design process, such as the understanding of non-expert user and training requirements, so that the need for future technical support can be estimated. The use of digital health by non-expert users through the innovative smartphone algorithm using point-of-care testing at district hospital level has already demonstrated its added value in the clinical management of children suffering from febrile illnesses, in particular by improving the rational use of antibiotics (Keitel and D'Acremont 2018; Tan et al. 2023).

Finally, a key point is the need for field performance studies on LMICs for implementation of digitalization applications. The existing data, though very interesting, is incomplete and piecemeal within regions, reflecting the vertical programs driving such initiatives, as opposed to a broader healthcare system view (Keitel and D'Acremont 2018; Tan et al. 2023; Lazuardi et al. 2021). While individual solutions are unlikely to engage a wide adoption within an

entire country/region, network-enabled solutions are more likely to succeed. Such field performance studies would address the ability of digitalization applications to meet end-users' expectations by fulfilling ASSURED criteria (Affordable, Sensitive, Specific, User-friendly, Rapid and robust, Equipment-free and Deliverable to end-users), as recommended by the WHO (Tamrat et al. 2022; Luogaa et al. 2019). Another utility of field performance studies is the informing of policy makers regarding projected costs. For example, the integration within a universal healthcare service or a cycle of independently-funded low supply/low demand, represent only two of the many potential funding approaches that can be implemented. The availability of information is likely to lead towards a better-suited funding model for the digitalization approaches implemented.

4 Conclusions

The advent of digitization in healthcare is a universal phenomenon that has only been accelerated by the recent COVID-19 pandemic. LMIC settings face a unique complexity of healthcare challenges, where digital health infrastructure is likely to ameliorate at least part of the existing pressures. However, persistent infrastructure challenges provide a barrier to implementation (both adoption and diffusion) for many digitalization implementations. Therefore, key considerations have to be taken into account. These are the identification of key structural needs: firstly, the likely greater impact of digitalization in LMICs on primary healthcare, and as such the design of systems to support smaller, interconnected units; secondly, the tropicalization of equipment, that can bely opportunities for co-development of digitalization applications under a universal health coverage system; and thirdly, the greater availability of field performance studies in LMICs, that would eventually inform future funding and support models. The digitalization of healthcare in LMICs is both a necessity and inevitability, however, the digitalization will be context-driven, and as such different implementation models are likely to emerge. Taking the key considerations above into account, such models can be further optimized to respond to the national/regional healthcare needs and pressures.

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Digitization of Healthcare in LMICs: Challenges and Opportunities in Data Governance and Data Infrastructure

Zisis Kozlakidis, Jennifer Kealy, and Marianne K. Henderson

Abstract

The increasing digitization of healthcare in LMICs is an ongoing process that occurs at different rates and with variable impacts on the patient populations of different countries. The healthcare data infrastructure has to overcome the local milieu of challenges, and while addressing those, any implementation effectiveness would depend on the different regulatory and legal frameworks extant at each location. The examples used in this chapter come primarily from the Americas (as a representative global snapshot), and highlight the relative lack of regulations specific to digital healthcare applications, as well as use of healthcare data. A major challenge includes the acute need for digital education of the professional and wider population. Despite the above, the COVID-19 pandemic has sharpened the national focus on healthcare digitization, interconnectivity of stakeholders and interoperability of available systems. It is hoped that these aspects, now that they have risen to the top of the agenda, will be addressed in a constructive and effective manner, taking into consideration tailor-made approaches, optimizing the resources deployed to enhance the countries' digital ecosystems.

Keywords

Data infrastructure · Healthcare data · Data governance · Low-and middle-income countries (LMIC) · Techquity

1 Introduction

One of the lasting legacies of the recent COVID-19 pandemic for healthcare is the rapid increase of digitalization that was implemented alongside other major advancements, such as mRNA vaccines development. In terms of economic sustainability, digitization technologies have become more critical post-pandemic (Nandi et al. 2021), with businesses demonstrating high technology adoption and online presence surviving, while for small/medium enterprises with lack of digitization the pandemic increased vulnerability, especially for individuals and family businesses (Bartik et al. 2020). In the field of

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healthcare, digitalization was brought to the forefront. A dedicated G20 global digital health summit in 2020 produced the Riyadh declaration (Al Knawy et al. 2020), a landmark consensus statement for the future directions on digital health (Al Knawy et al. 2022). Further details on the Riyadh declaration and how this has driven digitalization forward in Saudi Arabia are provided in Chap. "The Emergence and Growth of Digital Health in Saudi Arabia: A Success Story" of this book.

Approximately 30% of the world's data volume is currently being generated by the healthcare industry. By 2025, the compound annual growth rate of data for healthcare is expected to reach 36%. That's estimated by some to be 6% higher than industrial manufacturing, 10% higher than financial services (Coughlin et al. 2018). In the USA, as well as Canada, COVID-19 accelerated the healthcare digitisation process, as the pandemic necessitated additional investments in public health infrastructure for diagnosis, tracing and reporting purposes. However, the digitisation process had already started and was on solid foundations. Specifically, the 2009 HITECH Act, allowed the majority of USA hospitals and ambulatory care practices to introduce and incorporate a basic level of electronic healthcare record (HRE) use. Subsequent years focused on interoperability and in enabling electronic access to health data (Adler-Milstein 2021). Taken together, these actions have catalyzed private-sector digital health efforts, which have expanded in scale and scope (Rock Health 2023), complementing the public health sector investment in healthcare research (Baumgart 2020).

However, healthcare digitalization has not been equally attempted and available globally. Chapter "Biobank Digitization in Low-Middle Income Countries (LMICs): Current and Future Technological Developments" of this book provides a scoping review on the digital divide based on technological development and availability, and how infrastructural requirements are an important limiting factor to such digitalization attempts. The term "techquity" is frequently used to describe this overall digital divide. Techquity is defined as the strategic development and deployment of technology in healthcare and health to achieve health equity (Shelton 2021), having four core components: (i) education, (ii) data trust, (iii) measurability and (iv) explainability (Rhee et al. 2021). In this chapter, we will focus on the aspects of techquity that relate to the data trust, and how this is interlinked with the existing data infrastructures. Many of the examples will relate to low- and middle-income countries (LMICs) in Latin America, highlighting the diversity of context, approaches, challenges and opportunities.

2 Healthcare Data Infrastructure

In general, healthcare data infrastructure follows a similar pattern in most locations (Ozaydin et al. 2020). Healthcare data is collected continuously in four distinct areas: (i) administrative, (ii) clinical data (including imaging and -omics data), (iii) decision-support systems that provide interoperability with (i) and (ii), and (iv) research data and data analytics platforms, that rely on interoperability primarily with (ii) and (iii) and less so with (i). While the impact of the pandemic has touched all four areas of healthcare data infrastructure; the relative impact on each aspect was highly dependent on the local context. Thus, digitalization in healthcare, as well as the impact of the pandemic on healthcare data infrastructure are highly variable globally.

For example, in Brazil, the main healthcare databases are generated by the Brazilian unified national health system [Sistema Único de Saúde (SUS)] (de Mello Jorge et al. 2010), classified into: (1) epidemiological, used for surveillance and research; (2) administrative, used for accounting; and (3) clinical, used to store the patient data (Souza et al. 2016). In addition, data relevant to healthcare is also generated and managed by other departments, such as the Ministry of social development, for provision of social services, and others, summarized by Ali et al. (2019). In Mexico, the Coordination of the

National Digital Strategy (CNDS), as part of the Office of the President of Mexico, is responsible for designing, establishing and maintaining the national digital infrastructure for the objective of securing the country's innovation and development (Arpi n.d.), in coordination with the National Commission for Bioethics (de Chavez et al. 2017). The latter provides qualified directions and guidelines in the manner in which healthcare data is used and can be used, for example, providing advice on the regulation and governance of artificial intelligence (AI) in healthcare. Mexico and Brazil offer the two most advanced such examples in the Americas, beyond the USA and Canada (Tentori et al. 2020). For the remaining countries in the Americas, the healthcare data infrastructure is more fragmented, i.e., with fewer integrated systems within a unified healthcare system, and in some cases such infrastructure may be entirely absent (Curioso 2019). Thus, this part of the world offers a representative image of the global picture.

3 Healthcare Data Policy and Governance

In 2019 the World Health Organization (WHO) published the "Global strategy on digital health 2020–2025", endorsed by the 73rd World Health Assembly [decision WHA73 (Monraz-Pérez et al. 2021)] (World Health Organization (WHO) 2021), and echoed in the "Plan of Action for Strengthening Information Systems for Health 2019–2023" published in the same year by the Pan American Health Organization (PAHO) (Pan American Health Organization (PAHO) 2019). In this global view, digital health is positioned as the game changer for effective healthcare delivery, in particular within developing economies, where mobile connectivity is transforming local markets and capacities rapidly (however, there has not been an estimate as yet, on the level of completion/adoption of this global strategy). Four guiding principles were outlined to orient the global strategy towards the appropriate and sustainable adoption of digital health technologies within the contexts of national health sector and strategies (Table 1).

However, as part of the implementation of the digital health strategies, the consensus is that legal and ethical frameworks will be created, supporting and regulating the emerging sets of healthcare activities, as well as the novel fields of the healthcare market (World Health Organization (WHO) 2021; Thomason 2021). For example, to harness existing datasets, abundant medical data would need to be made readily accessible to researchers and the private sector, under defined conditions of access, sharing and use. Additionally, the emergence and persistence of healthcare data marketplaces will be an inevitable outcome to making healthcare data accessible and interoperable. Thus, important questions remain, such as the monetization of healthcare data, secondary use of healthcare data, and return of incidental findings. These all require, if not a legal framework, a set of national guidelines linking to the wider healthcare provision. As an example of monetization, the value of healthcare data has been calculated in real-terms by Roche's acquisition of Flatiron, the latter combining extensive sets of patient data, an electronic healthcare record (EHR) as well as an oncology platform. Based on the published records, a value of USD 950 per patient record was estimated as part of the agreement (Thomason 2021; Wayman and Hunerlach 2019). However, such an invest-

Table 1 The four guiding principles of the WHO's Global strategy on digital health 2020–2025

	Principle
1	Acknowledge that institutionalization of digital health in the national health system requires a decision and commitment by countries.
2	Recognize that successful digital health initiatives require an integrated strategy
3	Promote the appropriate use of digital technologies for health
4	Recognize the urgent need to address the major impediments faced by least-developed countries implementing digital health technologies

ment formulates the exception of healthcare data monetization currently rather than the rule, perhaps limiting further such transactions by the lack of relevant legal frameworks.

4 Observed Regulatory Challenges

In the Americas, in particular Latin America, healthcare systems are highly fragmented between public and private institutions, with the quality of healthcare systems generally considered superior in private institutions. The overall investment in Latin America's public healthcare systems is estimated to be low, as compared to other global regions, resulting to an even greater inequity in care (including digital healthcare) across public and private institutions (Kanavos et al. 2019; Atun et al. 2015; Organisation for Economic Co-operation and Development (OECD) 2020). This was further accentuated during the COVID-19 pandemic, where Latin America recorded over 27% of the cumulative global death toll (Ezequiel et al. 2021; Camacho-Leon et al. 2022). Therefore, the creation of a regulatory framework as a support tool for the digitalization of healthcare and the development of techquity, based on local capacities and addressing local needs, is critical. Having said that, a number of challenges remain.

Most Latin American countries (notable exceptions are Bolivia and Honduras) have some form of regulation regarding healthcare data, telemedicine, and patient data protection (Camacho-Leon et al. 2022). These laws tend to be expanded in their implementation to encompass digital healthcare applications; however, they are not specifically designed to address those emerging challenges and opportunities, and can lead to regional interoperability restrictions. For example, Mexico does not have specific regulations for telemedicine, even though over 5.5 m telemedicine consultations were reported in 2020 alone (Monraz-Pérez et al. 2021), and has been included in public policies since 2015 with accompanying published guidelines and recommendations by the national Ministry of Health. In June 2020, a document titled "Contact unit for remote interconsultation (UCID) Mexico: attention to chronic diseases" was published, which consolidates guidelines on teleconsultation and promotes the use of telemedicine in the treatment of chronic diseases (Aizenberg 2023). However, this still falls short of consolidating the expertise of a decade of digital health implementation and provision within a legal framework. Camacho-Leon et al. provide an excellent narrative review of the current status, where it becomes evident that the example from Mexico is a typical one for the region (Camacho-Leon et al. 2022). Importantly, the lack of a dedicated and/or updated legal framework impedes the sharing of healthcare data across jurisdictions. In the short-term this may put patient data confidentiality into question, and in the longer-term may be a critical limiting factor in addressing techquity, as inability to share healthcare data means that these populations would be under-represented in the global databases.

It is important to note that regulation is a challenge linked to a matrix of challenges that would need to be considered/addressed concurrently. For example, for digital healthcare such challenges would be the: unrealistic expectations, biased and non-representative data, inadequate prioritization of equity and inclusion across the population entailing the risk of exacerbating health care disparities, low levels of trust regarding the use of healthcare data, and inadequate evaluation of implemented initiatives. The USA National Academy of Medicine has produced a high-level document describing many of those challenges in detail and how they could be addressed both in isolation as well as part of a wider approach (National Research Council 2009).

5 Local Context

Finally, the pandemic demonstrated the importance of local context in relation to the effectiveness of implemented digital healthcare. Specifically, a number of Latin American coun-

tries (Perú, Argentina, Bolivia, Chile, Ecuador, México, Colombia and Brazil) and the Inter-American Development Bank deployed digital applications for the surveillance of viral transmission through testing and tracing. However, they collaborated with private companies and/or universities in each country, resulting in the release of different platforms (Benítez et al. 2020). However, these platforms did not perform as well as originally anticipated due to poor reach and limited effectiveness of mobile technologies, as well as the inability of Latin American healthcare systems to provide follow-up services. Additionally, the massive population surveillance assumed a different dimension than similar efforts in Europe and North America, with heightened concerns regarding the protection of personal data and the balance of public health demands with democratic rights (Waisbord and Segura n.d.; Segura 2022).

6 Opportunities

While many challenges in pursuit of techquity exist, there are also opportunities. Technology, when diffused and utilized equitably, democratizes access to information and can bridge existing knowledge gaps or misinformation. It acts as an effective countermeasure to the digital divide, the latter providing unequal access to, and utilization of, healthcare, predominantly affecting individuals who are hard to reach, or from certain racial and/or from specific socio-economic population groups. Despite the advancement in accessing digital services, the digital divide persists (Vogels 2021). For infrastructure operators, the main challenge to addressing the digital divide remains the economic feasibility of creating and maintaining networks in areas with low population density and/or high geographic fragmentation. However, there are a number of novel wireless technologies, e.g., mmWave Cellular Networks, that can help to address this need, providing a much cheaper alternative and thus, bridging the digital divide (Zhang et al. 2021, 2022). These technological developments can act as an impact multiplier when implemented with supportive regulatory frameworks, however, implementation is still lacking.

The acute need for training and building the digital literacy capacity of healthcare professionals in Latin America (Luna et al. 2014), presents a unique opportunity to design and provide capacity-building activities that could reach very large numbers of professionals. For example, PAHO developed virtual courses (e.g., "eHealth for Managers and Decision Makers"; "Access and Use of Scientific Information on Health", and others) available through the Virtual Campus of Public Health, and already accessed by thousands (Novillo-Ortiz et al. 2016). The pandemic has highlighted this need for education across many different populations of data producers and data users, and as a result such courses have now been created and multiplied, widening their reach and hopefully their impact (Curioso 2019).

7 Way Forward

The COVID-19 pandemic has revealed the usefulness of digital healthcare to many governments across the world to deliver healthcare utilizing different operating models, e.g., increased remote monitoring of patients and teleconsultations (Jazieh and Kozlakidis 2020), but also as a tool to confront inequities in access to healthcare in their respective countries (Brewer et al. 2020). Digital healthcare services and collected data have been clearly interpreted not just as a set of siloed services, but also as foundational infrastructure for research activities within healthcare. For example, biobanking emerged as a foundational research infrastructure that can be utilized in times of healthcare crises (Henderson and Kozlakidis 2020). Taken together with the experiences of LMICs, in particular in Latin America (Ács et al. 2022), they can offer the following points for the way forward:

- Access to reliable infrastructure remains a key component upon which digitization of healthcare is based. Thus, further investment in digital infrastructure remains a critical need.

- Access to digital applications is not tantamount to utilization; addressing the digital literacy aspects is a pre-requirement for the impactful operation of digital technologies.
- The interconnections between different stakeholders (i.e., clinical professionals, patients, entrepreneurs, individuals, and governments) in the digital economy brings important interoperability challenges to digital platforms.
- Therefore, there is an acute need to provide clear regulatory frameworks for the emerging digitization in healthcare, including provisions for data access, sharing, utilization (including for secondary use) and reporting.

8 Conclusion

The increasing digitization of healthcare in LMICs is an ongoing process that occurs at different rates and with variable impact on patient populations in different countries. On the one hand, the healthcare data infrastructure has certain high-level similarities, but has to overcome the local milieu of challenges (including local and national political challenges, not covered in this chapter). On the other hand, even if the healthcare data infrastructure is fully addressed, digitization implementation effectiveness would depend on the different regulatory and legal frameworks. The examples used in this chapter come primarily from the Americas (as a representative global snapshot), and highlight the relative lack of regulations specific to digital healthcare applications, as well as use of healthcare data. Additionally, challenges include the acute need for digital education of the professional and wider population. Despite the above, the COVID-19 pandemic has sharpened the national focus on healthcare digitization, interconnectivity of stakeholders and interoperability of available systems. It is hoped that these key areas, now that they have risen to the top of the agenda, will be addressed in a constructive and effective manner, taking into consideration tailor-made approaches, addressing the local contexts and optimizing the resources deployed to enhance the countries' digital ecosystems.

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Long-Term Digital Storage and Usage of Research Data: Data Pooling

Svetlana Gramatiuk and Karine Sargsyan

Abstract

In the quickly evolving field of scientific research, securing, utilizing, and maintaining access to large datasets over extended periods is very important. This chapter examines the challenges connected to the long-term digital storage and use of research data, focusing on data pooling. Because of the increasing amount and complexity of data generated in biomedical research, finding a storage solution that is scalable and sustainable is significant. Creating robust data governance frameworks, addressing data security and privacy issues, and defining the roles of data stewards in biomedical research programs are critical steps. Based on the principles of the Open Science, this chapter supports a structured approach to ensure the authenticity, accuracy, and reliability of biomedical data for long-term access. In addition, integrating biomedical datasets offers new opportunities for collaborative analysis and promotes synergies between translational, and clinical research. This chapater emphasizes the importance of strategic decisions concerning data retention policies that require collaboration with funding agencies, research communities, and established repositories for the long-term development of scientific knowledge.

Keywords

Digitization · Healthcare · Data pooling · Long-term digital storage · Low-and middle-income countries (LMIC) · Artificial intelligence (AI)

1 Introduction

Based on data from the University of South California, by 2025, minimum 465 data points per person will be created daily. The total capacity of world data currently is about 45 zettabytes (ZB), 41 times more than crystals of salt in the oceans. Furthermore, while not all newly generted data will necessitate long-term storage, IT specialists forecast that by 2025, about 7.6 ZB will be required, compared to about 1.2 ZB in 2020. The progress of patient and healthy populations medical and health data is linear, and data like imaging and electronic medical records

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(EMR) have a specific growth pattern, generating challenges and opportunities for healthcare productivity. This appraisal of almost 80 megabytes per year per patient mirrors the increasing volume and complexity of the long-term storage of health information (Bakos et al. 2018; Chodacki et al. 2016; Morgan and Janke 2017). Several vital mechanisms are obvious when inspecting the wide-ranging structure for the long-term digital storage and consumption of medical research data. These important elements comprise the Data Management Plan (DMP), the Standards for Digital Imaging in Medicine, SNOMED CT, ICD-11, Health Level Seven (HL7), and usage of Artificial Intelligence (AI) technologies (Simms and Jones 2017). At the same time, professionals face a considerable volume of patient data demanding trustworthy storage infrastructure. Thus, healthcare organizations worldwide must invest in scalable and safe storage solutions to adapt to the growing data load, and archiving of outdated electronic health records (HER). Compliance with data storage and regulatory requirements is essential (Simms et al. 2017; Williams et al. 2017). For example, integrating and understanding data from outdated EHR systems can take time and effort. If funding is secured for data storage infrastructure in many countries, the issues of effectively extracting relevant information from large data sets still requires attention.

Data protection issues are at the center of all the aspects mentioned above. With the growth of patients' data volume, maintaining confidentiality and the safety of medical information becomes increasingly important. Health organizations should introduce reliable cybersecurity measures to protect sensitive data on patients from unauthorized access and violations (Stephens et al. 2015). This policy is facilitated by the commitment to data protection rules (for example, HIPAA in the United States). Suppliers of medical services should constantly update their security protocols and comply with developing standards.

Given the epidemiological challenges during the COVID-19 pandemic, actively archiving data solutions such as tracking disease outbreaks, getting up-to-date information on treatments and vaccines, tracking patient diagnoses, and supporting the growth of telemedicine, the role of health data has never been more significant. The active archiving solution aligns with the evolving expectations in healthcare IT by ensuring secure, accessible, and compliant storage of historical patient records. This archiving method supports patient care continuity and enhances data management efficiency within healthcare organizations (Fig. 1).

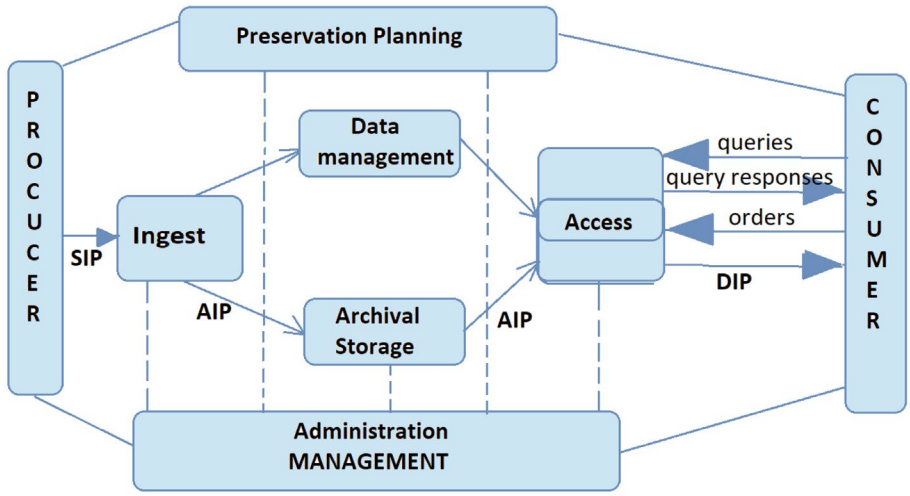

Fig. 1 A model for data management effectiveness in healthcare organizations

Long-term digital storage and usage of research data, especially in data pooling, involves several considerations to ensure the integrity, accessibility, and usability of the data over an extended period (Michener 2015; Schnell 2015; National Library of Medicine 2013). The key aspect is scalability and performance. Databanks should be customized to handle large volumes of data and provide high performance. Scalability allows it to grow effectively with increasing data volume and number of users. Implementing a scalable platform for processing and managing biomedical data will help make research more efficient while ensuring data security and accessibility for many users.

One example is a real-time medical data collection system for medical laboratories (using a laboratory information management system), which reduces errors, minimizes extra work, and ensures data and metadata integrity. Another notable example would be Submission Information Packages (SIPs) for clinical trials, patient registries, and other human subjects' studies, where using Common Data Elements (CDEs) is a strategic approach. Developing SIP for clinical research and patient registers, including CDE, can significantly improve the standardization and harmonization of data, which, in the future, will enhance the quality of data and promote cooperation and joint use of research initiatives (Williams et al. 2017; O'Reilly 2018; Kazic 2015).

CDEs are standardized terms, definitions, and guidelines for data collection in clinical trials. They aim to ensure uniformity and consistency in data collection and presentation, facilitating comparison and sharing of data between different studies and organizations. Examples of CDEs used in the clinical and biomedical fields include Big Data biobanks and repositories. For instance, CDEs can define standards for describing genetic variants, sequencing methods, and other parameters, as well as multicentred studies, which help ensure consistency of data collected across clinical sites, making it easier to analyze and compare results available through the National Institutes of Health (NIH) CDE resource portal (Rubinstein and McInnes 2015).

Applying CDE in such contexts provides a standardized and unified approach to data collection, improving research findings' accuracy, consistency, and transferability. It also enhances the efficiency of research processes and facilitates data sharing between research groups and organizations. Furthermore, using online collaboration tools to map reported terms to a preferred ontology is common in biomedical research and other fields. Such tools enable effective collaboration between researchers and help ensure consistency and uniformity in the use of terminology (Williams et al. 2017; Simms and Jones 2017). Ontologies establish standard terminology and definitions for use in a given field (International Classification of Diseases), which ensures uniformity in understanding and communication. Ontologies are widely used in AI systems in healthcare to train machines, support decision-making in developing new drugs, and search for target cells.

Implementing the biomedical dataset model provides new data integration, analysis, and discovery capabilities, which help advance fundamental, translational, and clinical research. Assessment of data resources needs and ensuring their protection is essential in defining data characteristics, storage requirements, and security measures to protect confidentiality and data integrity. Effective data management includes understanding the data lifecycle, from collection and processing to storage and long-term access. The Open Information Archive model provides a structured approach to data management and long-term preservation. Application of this model promotes the conservation of the authenticity, accuracy, and reliability of biomedical data, providing standards for long-term access (Simms et al. 2017; Ravagli et al. 2017; Leonelli 2017; Navale et al. 2018).

In summary, effective data management is becoming a key element in contemporary science, where large volumes of data require careful planning and management. Below we discuss the key parameters that determine the effective operation and development of long-term digital storage and research data usage.

2 Data Management Plan (DMP)

The first step is a formal document, the data management plan (DMP), which outlines the strategies and procedures for managing research data throughout its lifecycle. It serves as a roadmap for researchers and research teams, providing a structured framework for organizing, storing, documenting, and sharing data. The primary goals of a DMP include ensuring the integrity, accessibility, and long-term preservation of research data, as well as facilitating compliance with ethical, legal, and institutional requirements (Kirlew 2017).

Key components typically included in a DMP are data architecture, data models, data generated, data quality checks, data governance, project overview, data types and formats, data collection and processing methods, ethical and legal considerations, data ownership and responsibility, data storage and backup, data security, data sharing, and access, data preservation.

Leading funding and research agencies, including the National Institutes of Health (NIH), the National Science Foundation (NSF), the Centres for Disease Control and Prevention (CDC), and the Agency for Toxic Substances and Disease Registry. (ATSDR) require medical researchers to submit a DMP for funding decisions. The DMP assures sponsors that data loss prevention strategies, regular backups, protection against losses due to hardware failures, and other precautions are in place (Data Storage Best Practices 2018). The DMP facilitates the planning and standardization of metadata, improving data quality, making it easier to interpret and compare, and ensuring better reproducibility. DMP development includes consideration of long-term data storage and access issues, which is essential to ensure data safety and future use.

A typical example of a DMP is a text document written as a detailed narrative. These documents include various guidance documents and templates for DMP production (NNLM National Network of Libraries of Medicine), and the first generation of tools to facilitate DMP production have been created and are widely available (Goodman et al. 2014; The NNLM website 2020; Navale and Bourne 2018). Examples of the first generation of DMP tools could be simple online forms offered by universities or funding agencies to help researchers develop data management plans for their projects. Later generations of tools have become more complex, integrated, and focused on advanced data management capabilities.

The second generation of DMP tools aimed to make them "machine-accessible" or "machine-readable." These tools focused on automating data management processes and integrating with information systems, contributing to more efficient data processing and use. The tools used semantic technologies and data formats such as RDF (Resource Description Framework) to present information in machine-readable form. Integration with other information systems, such as data repositories, library catalogs, or project management systems, was done (Ohno-Machado et al. 2017). Standardized protocols like API (Application Programming Interface) enabled interoperability with other applications and systems. As data management requirements and standards have evolved, new DMP tools have begun to include more detailed and in-depth information.

Moreover, the DMP plays a vital role in the grant application evaluation process and post-award evaluations, although this role may need to be better defined and understood. However, not all guidelines for scoring Research Proposals (RPPs) explicitly mention DMPs, although data-sharing plans can be a required element of proposals. The reasons may be varied, and this may depend on the country, organization, or specific area of study. Understanding the importance of DMPs and their inclusion in the NCD assessment process is just beginning to gain traction, and in the future, such documents may more clearly highlight the role of DMPs (Corpas et al. 2018; Jagodnik et al. 2017).

In terms of specific examples, the Interdisciplinary Earth Data Alliance (IEDA) is an organization that provides infrastructure for storing, processing, and sharing geoscience data. They support tools and resources for researchers

to ensure accessibility and management of data in the field. IEDA provides researchers with the ability to generate a data compliance report based on an NSF (National Science Foundation) award number; this is likely because NSF often sets data management standards and requirements for projects they fund, as well as part of the "Results" preliminary support for NSF" in subsequent proposals, but, again, it is unclear how much weight they are given in the evaluation process.

In another example, Canada's Tri-Agency Statement of Principles for Digital Data Governance emphasizes researchers' obligations in developing and adhering to DMPs. However, the Canadian Institutes of Health Research needs to include DMPs in its evaluation criteria. However, given the growing significance of effective data administration in scientific research, organizations may want to review their policies and criteria in line with evolving standards and practices (Rubinstein and McInnes 2015).

The development of second generation DMP tools in response to the changing requirements of funding agencies and the generalized learnings from the first generation of tools represents a logical development in the field of data management in scientific research. Creating a "meta-DMP," or tool that provides consistent guidance irrespective of an agency's specific reporting requirements, has several potential benefits: universality, flexibility, automation, compliance with updates, training and support, integration, and performance tracking.

For example, maDMP, according to Simms and Jones 2017, can help predict data storage costs (Williams et al. 2017; Simms and Jones 2017). The proposed formal machine-readable document allows data exchange between different objects through the entire data life cycle. maDMP's emphasis on metadata, such as quantity and type of data, regardless of storage location, allows for evaluating the time-varying cost of storing such data. A standard has yet to emerge, although several use cases exist.

Creating such a tool could address the challenges posed by the diversity of requirements from different agencies and make it easier for scientists to develop and manage data management plans.

3 Data Standards and Documentation

Data standards and documentation are crucial for ensuring accurate, consistent, and interoperable healthcare information in the medical and hospital sector. Health Level Seven (HL7): HL7 is a widely used international standard for exchanging, integrating, sharing, and retrieving electronic health information. It defines a framework and common standards for messaging, clinical documents, and interoperability. HL7 develops standards for exchanging information in various areas of health care, including clinical, administrative, and financial aspects. These standards are essential in supporting interoperability between different information systems, ensuring a normalized and structured exchange of information.

Examples of standards developed by HL7 are:

1. HL7 v2 (Health Level Seven Version 2) is a standard for healthcare messaging. It transfers data between different systems, such as electronic medical records (EMR) systems and patient management systems.
2. HL7 CDA (Clinical Document Architecture). A standard for structuring clinical documents such as case reports and patient histories to ensure standardized exchange.
3. HL7 FHIR ehe standard is focused on providing a faster and more flexible exchange of information in healthcare, especially in web and mobile applications.
4. HL7 v3 (Health Level Seven Version 3) is designed to solve data interoperability problems and define a standard healthcare model.

International Classification of Diseases (ICD): The ICD is a standard system for classifying diseases, conditions, and health-related problems. It provides a common language for global reporting and monitoring health conditions. It is important

to consider the International Classification of Diseases (ICD) as an example of standardization of data and documents as part of the long-term digital storage and usage of research data systems. It is a standard developed by the WHO to classify and code different diseases and health conditions. It is used worldwide for uniform documentation of diseases, health statistics, and medical and health information exchange. The latest version of ICD-11 was adopted by the 72nd World Health Assembly in 2019 and entered into force on January 1, 2022 (Annex 3.8 of the Reference 2019).

The International Classification of Diseases, Eleventh Revision (ICD-11), is an updated classification system covering various aspects of diseases, including their diagnosis, treatment, research, and statistics. The ICD-11 classification deals with various aspects, such as using research data systems for long-term digital storage. Such elements may include coding diseases in research data to uniquely identify diseases in long-term data storage and use systems, providing a uniform and standardized way to represent medical concepts.

Systems using ICD-11 can monitor morbidity, mortality, and other aspects of population health over the long term. Classification allows the creation of standardized reports and analysis of trends. The use of ICD-11 can help with this by unifying the way diseases are classified. In systems for long-term storage and use of research data related to medical research, ICD-11 can serve as a basis for structuring and analyzing data related to various diseases (ICD-11 2022).

The Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT) is a comprehensive, multilingual clinical terminology used in healthcare and clinical research. It is a standardized coding system for representing and exchanging clinical information globally. SNOMED CT facilitates precise and standardized health information exchange across healthcare settings and systems (Vuokko et al. 2023; Cangioli et al. 2023).

SNOMED CT and ICD are two different standards addressing different aspects of healthcare. Still, they can interact and complement each other across multiple health information systems. SNOMED CT is more detailed and designed to describe clinical concepts, while the ICD is more often used for statistics, classification, and coding underlying diseases.

The primary goal of SNOMED CT is to provide standardized codes to describe diseases, procedures, symptoms, and other clinical concepts. SNOMED CT incorporates the Fully Qualified Ingredient (FQI) concept to characterize drug products with great detail. SNOMED CT provides standardized terms for clinical decision support, semantic search, and data analytics in healthcare. Concepts are organized into hierarchies, allowing for a more granular representation of clinical information. The hierarchy enables the classification of concepts based on broader or narrower relationships.

Each concept in SNOMED CT is associated with one or more human-readable terms or clinical descriptions. These descriptions represent the concept in an understandable way to healthcare professionals. SNOMED CT allows for creating post-coordinated expressions, combining multiple concepts to represent complex clinical situations. This feature enhances the specificity of clinical coding. SNOMED CT is designed to support multiple languages, making it a versatile terminology for international use. SNOMED CT covers various clinical domains, including anatomy, clinical findings, and procedures. This comprehensive coverage makes it suitable for representing diverse aspects of healthcare. SNOMED International maintains SNOMED CT, a not-for-profit organization that oversees its development, distribution, and ongoing updates. It is widely used in electronic health records (EHRs), health information exchange, clinical research, and other healthcare-related applications to ensure standardized and interoperable representation of clinical information. SNOMED CT promotes unambiguity and standardization in medical terminology, enabling more efficient data exchange, system interoperability, and semantic accuracy in healthcare (ICD-11 2022; Vuokko et al. 2023; Cangioli et al. 2023; HIMSS Adoption Model for Analytics Maturity (AMAM) 2023; Cheemalapati et al. 2016).

Additionally, using standardized methods and formats reduces the risk of data loss due to technology obsolescence. Long-term storage of data by standards ensures data stability and reproducibility. Standardized systems are more flexible and can be easily updated or expanded, allowing to adapt to new requirements, technologies, and standards without significant costs. The overall standardization of data and documents creates a sustainable basis for the long-term storage and use of research data, ensuring its integrity, availability, and relevance over an extended period.

4 Clinical Document Architecture (CDA)

Developed by the Health Level Seven (HL7) initiative, Clinical Document Architecture (CDA) provides a standardized format for storing and sharing clinical information. Over 20 long-term periods of storage and use of research data, the CDA architecture offers a structured form for presenting medical information. CDA allows for storing data in organized ways that influence subsequent data access, retrieval, and analysis.

- Every CDA document begins with a Clinical Document, the root element of the entire document.
- The document header contains metadata such as document ID, document type, creation date, patient ID, and other attributes.
- The CDA is divided into sections, each containing specific clinical information. For example, a section with medical history and laboratory results may exist.
- There is structured clinical information in the document's central part. This section contains structured data, such as tables, lists, and other elements in a specific format.
- A record is a specific piece of information within a section. It contains primary data such as test results, diagnoses, procedures, and other elements.
- The document's body may also contain textual information and unstructured content necessary for additional comments or descriptions.

The CDA architecture includes standardized semantic elements such as LOINC, SNOMED CT, and others, which provide a more precise and unambiguous understanding of document content. Semantic elements are essential for the accuracy and consistency of data during long-term storage (Hart et al. 2016; Ghatnekar et al. 2021; Blackley et al. 2019). CDA can embed contextual information such as patient IDs, healthcare facility information, timestamps, and other details. Contextual information ensures that data is complete and correct for future compliance. CDA is often used in patients' electronic records to present clinical information, ensuring medical research continuity in digital medical institutions.

The structured CDA format can store additional metadata and tags that periodically identify research data, which is essential for subsequent analysis, meta-analysis, and re-use of data. CDA can be included in a strategy for secure data storage, ensuring the integrity and confidentiality of health information throughout its lifespan. CDA enables interoperability between different areas of health and healthcare, which is essential for the exchange and sharing of research data on a large scale.

The application of CDA in long-term storage and use of research data provides semantic standards of clarity and capability with existing progressive information trends. Being a document markup standard and defining the structure and semantics of "clinical documents," it has defining characteristics: persistence, control, authentication, and integrity. The clinical document continues to exist in an unmodified state for a period determined by local and regulatory requirements. The internal rules of the organization regulate the storage of the document.

The CDA standard's requirements and uses focus on creating standardized, structured, and semantically interoperable clinical documents.

Requirements:

1. The first requirement for a CDA is that its format is structured, and the document must contain specific sections and elements to ensure consistency and understanding of the data.

2. CDA includes using standardized terminologies and encoding to ensure semantic interaction, including codes for procedures, diagnoses, drugs, and other items.
3. An essential factor in creating context and identifying healthcare stakeholders is that the CDA contains information about the document's source (e.g., healthcare organization) and patient.
4. CDA provides a means to embed clinical context into the document, including information about the physician, dates of procedures, and laboratory results.
5. CDA can support various documents such as examination reports, case histories, treatment plans, and others, making it versatile for multiple clinical scenarios.

The use of ready-made solutions and platforms that support the CDA standard, such as EHR and other tools, already have been implemented byhealthcare organizations, ensuring integration of the CDA standard with existing healthcare systems and information technologies, such as electronic medical records, hospital management systems, etc. (HIMSS Adoption Model for Analytics Maturity (AMAM) 2023; Ghatnekar et al. 2021; Blackley et al. 2020).

Automated tools (template auto-completion and electronic forms integration) are used to create, transmit, and store CDA documents. Creating simple and intuitive user interfaces for CDA is the basis for users to help users quickly adapt to new technologies. Providing feedback and the availability of a technical support mechanism for users will help solve potential technical problems and provide assistance if necessary. Attraction to decision-making for all interested parties, including medical and technical personnel and the administration, will help to ensure broad support and understanding of the importance of implementing the standard.

The CDA may include links to external resources such as images, files, or other documents. Despite its many advantages, clinical document architecture has its limitations, making it difficult to use in long-term storage and use of research data.

5 Digital Imaging and Communications in Medicine (DICOM)

The Digital Imaging and Communications in Medicine (DICOM) standard provides a critical framework for systems for the long-term storage and use of research data in the medical field. DICOM provides a standardized format for storing and exchanging medical images, including data such as X-rays, magnetic resonance imaging (MRI), computed tomography (CT), and other methods. A single format makes processing, analyzing, and visualizing these images more accessible (Ghatnekar et al. 2021; Blackley et al. 2019; Blackley et al. 2020; Gottlieb et al. 2021). DICOM includes metadata standards, including patients about patients, information about the device, and date and time that provide context and semantic information for medical images, which is essential for correctly interpreting and using data. DICOM provides interoperability with health information systems, EHRs, and other systems, making integrating medical images into the overall information flow easy (Torab-Miandoab et al. 2023).

DICOM provides frameworks and guidelines for long-term storage and archiving of medical images and includes standards for data backup, recovery, and long-term availability. DICOM provides mechanisms to ensure the confidentiality and security of health data, including encryption and authentication mechanisms, which are essential to comply with laws and protect sensitive health information. The DICOM standard is regularly updated and expanded to meet needs and emerging technologies in the field of medical imaging, ensuring long-term adaptation to new requirements and technological innovations.

DICOM defines a messaging protocol. The DICOM protocol is compatible with the control of the transmission and the Internet protocol, which allows the objects of the DICOM application to communicate via the Internet. Examples of DIMSE are N-SET (Attribute Setting), C-STORE (Store), C-FIND (Query/Retrieve), C-MOVE (Query/Retrieve), C-GET (Query/

Retrieve), C-ECHO (Verification), N-GET (Attribute Retrieval). These service primitives allow devices to communicate with each other, send and receive requests, transfer data, and manage various aspects of health information on a DICOM network. Each service primitive has its format and structure, defined in the DICOM standard.

DICOM servers and archives are a third option. DICOM servers provide the infrastructure for storing, retrieving, and transmitting medical images in DICOM format. These servers can be deployed as local systems in medical institutions or as part of cloud-based DICOM archives, providing centralized and convenient access to medical data.

Each of these implementations of the DICOM protocol has its characteristics and applications. Software packages typically provide rich medical image processing and analysis capabilities, while built-in support in medical equipment provides transparency to end users. DICOM servers and archives offer the infrastructure for efficient storage and exchange of large volumes of medical data. DICOM's internal mechanisms are continually updated to support new types of medical devices. As technology advances, new types of equipment may appear, such as more advanced scanners, tomographs, and MRI machines, and internal mechanisms must be adapted to communicate with these devices.

With improvements in power and image processing algorithms, DICOM's internal mechanisms were implemented to support more complex applications critical for diagnostics and analysis. With the development of 3D visualization and virtual reality technology, the internal mechanisms of DICOM have expanded to algorithms for data exchange and processing, which is especially important for surgery and diagnostics. Due to increasing cybersecurity threats, DICOM's internal mechanisms have sometimes worked out to ensure the confidentiality, integrity, and availability of health data. In some cases, DICOM's internal mechanisms can support integration with artificial intelligence systems, allowing machine learning and AI algorithms to analyze medical data. Furthermore, DICOM provides standardized formats for telemedicine consultations and remote exchange of medical images, which are increasingly important in modern healthcare. Overall, DICOM plays a crucial role in ensuring standardized, efficient, and secure storage and use of medical images in the long term.

6 Documentation in Healthcare. Electronic Health Records (EHR) Documentation

Healthcare documentation, especially EHRs, plays a crucial role in long-term digital storage and usage of research data systems. EHRs comprise various data on patient patient information, including medical history, laboratory results, diagnoses, treatments, and other data. This comprehensive information is a valuable source for long-term research and analysis.

EHRs can provide long-term data storage by ensuring information security for many years, which is essential to assure data availability for subsequent research and monitoring. EHRs often includes standardized formats and terminology, such as HL7 and LOINC, which facilitates collecting and integrating data from various sources (Corpas et al. 2018; Vuokko et al. 2023; Cangioli et al. 2023; HIMSS Adoption Model for Analytics Maturity (AMAM) 2023; Cheemalapati et al. 2016; Tohmasi et al. 2021).

With aggregated data from EHRs, it is possible to monitor and analyze the health of a population over time. It helps develop public health plans and make strategic decisions. EHRs may include mechanisms to maintain security and privacy standards, essential from an ethical and legal compliance perspective when dealing with health information. Clinicians often encounter several challenges related to the usability of existing EHRs, as developers and vendors not always actively engage clinicians to understand their needs to create more user-friendly, efficient, and intuitive solutions. Updates and modifications to EHR systems must consider end-user feedback to ensure optimal usability and improve

the efficiency of healthcare staff (Cangioli et al. 2023; HIMSS Adoption Model for Analytics Maturity (AMAM) 2023; van Buchem et al. 2021; Wang et al. 2021).

One possible solution is to create personalized interactions between humans and computers with an automated AI system. This interaction can optimize EHR functionality for a context-sensitive adaptive documentation process, which only requires human influence to assist the machine when necessary. Implementing AI in EHRs can manifest in various ways, for example in predicting complications and risks.

A relevant example is the development of AI-based recommendation systems that provide doctors with personalized recommendations on treatment selection, drug dosage, and other medical issues. The most common use of AI in EHRs is analytics to monitor patient wait times and optimize appointment scheduling to reduce delays and improve service.

These examples demonstrate how implementing AI in EHRs can potentially improve the quality of patient care in the future by enabling more accurate diagnoses, personalized treatment, and streamlined healthcare workflows.

The above components' combined implementation and effective interaction create an integrated system that facilitates long-term health data storage, management, and use. The integrative system advances modern research methods, improves patient care, and builds the basis for future innovations in healthcare.

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Possible Process Optimization: Innovative Digital Health Implementation Models

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Abstract

The digitization in healthcare faces challenges in LMICs. The success of digital tools depends on having a workforce capable of designing, implementing, and maintaining such tools. Relevant training of professional staff and familiarisation with new tasks are crucial processes for the optimization of digital tools' performance. In the broader context, interdisciplinary and interprofessional healthcare interventions often focus on outcomes such as length of stay, readmission rates and/or mortality. However, the effects of digital health interventions on these outcomes have been inconsistent in low-and middle-income countries. The current chapter discusses identified challenges in different digital health implementation models. Addressing these challenges and conducting further research and evaluation can contribute to successfully implementing digitization and process optimization in healthcare settings, leading to improved patient outcomes and quality of care.

Keywords

Process optimization · Low-and middle-income countries (LMIC) · Digital health · Innovation · Implementation models

Abbreviations

AGV	Automated Guided Vehicles
AMPATH	Academic Model Providing Access to Healthcare
BPIS	Biometric Patient Identification System
CDS	Clinical decision support
CPOE	Computerised physician order entry
CRF	Case report form
DEPEND	Digital Feedback Engagement in Primary Care
DGHS	Directorate General of Health Services

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DHIS2	District Health Information Software 2
DIAL	Digital Impact Alliance
EDI	Electronic Data Interchange
EHR	Electronic Health Record
eLMIS	Electronic Logistics Management Information System
HIA	Health Impact Assessment
HIE	health information exchange
HISP	Health Information Systems Programme
HIV	Human Immunodeficiency Virus
HMIS	Health Management Information System
HPLC	high-performance liquid chromatography
IoT	Internet of Things
IT	information technology
LMICs	low- and middle-income countries
MIMIC-III	Medical Information Mart for Intensive Care III
MS	mass spectrometry
MTaPS	Medicines, Technologies, and Pharmaceutical Services
mTrac	Mobile Tracking System
NGOs	Non-governmental Organizations
NHS	National Health Service
NPT	Normalisation Process Theory
OpenSRP	Open Smart Register Platform
PASP	Patient Admission Scheduling Problem
PHI	Protected Health Information
PIH	Partners in Health
REDCap	Research Electronic Data Capture
RFID	Radio Frequency Identification
SC	Supply Chain
SCM	Supply Chain Management
SOFA	Sequential Organ Failure Assessment
STX	Smile Train Express

1 Introduction

Process optimization in healthcare refers to improving healthcare processes and systems to increase efficiency, reduce waste, and enhance patient outcomes. In healthcare, a process can be defined as a sequence of interrelated tasks or activities that aim to achieve a specific healthcare goal, such as diagnosing and treating a patient, managing a chronic condition, or providing preventive care. The digitalization of process optimization in healthcare has the potential to significantly improve healthcare outcomes by increasing efficiency, reducing errors and redundancies, and improving patient access to healthcare services. However, it is essential to ensure that digital tools are implemented to protect patient privacy and security and that healthcare providers are appropriately trained to effectively use these tools.

Optimization of limited healthcare resources utilising digital technologies might provide significant advantages to low- and middle-income countries (LMICs). Finding the optimal way to handle the sophisticated healthcare requirements of hospitalised, mostly multimorbid medical patients is a global issue. The quality of health services should be measured by their efficacy, safety, and focus on the needs of the patients. For the advantages of quality health care to be realised, health services must be timely, equitable, integrated, and efficient. On the other hand, fundamental logistic and organisational aspects of medical hospital care have been prioritised less than treating particular diseases.

Digitalization has the potential to offer substantial benefits to the optimization of healthcare processes in LMICs. Nonetheless, a number of challenges must be overcome to guarantee the successful implementation and adoption of digital tools in these settings.

Benefits of digitalization in LMICs:

- Improved access to healthcare. Digital tools such as telemedicine and mobile health apps can help bridge gaps in healthcare access in LMICs, particularly in remote or underserved areas (World Health Organization 2021).
- Increased efficiency. Digital tools can automate routine tasks and improve data management, reducing the time and resources needed to manage healthcare processes (Olu et al. 2019).
- Enhanced patient outcomes. Digital tools can improve the accuracy and completeness of

Widespread	Pilot	Research
• Electronic health record-based tools • Healthcare scheduling optimization • Supply chain management for medicines • Patient registries	• Data-driven optimization of logistics and procurement • Biometric systems • Counterfeit drug testing and detection	• Automated completion or analysis of medical records • Patient feedback collection and analysis • Quality/Performance improvement analytics

Fig. 1 Healthcare process optimization applications on scaled, pilot and research stages

patient health information, leading to better diagnosis and treatment decisions (Attia et al. 2019).
- Cost savings. Digital tools can help reduce the costs associated with healthcare processes, such as paper-based record-keeping and administrative tasks (World Health Organization 2019).
- Increased collaboration. Digital tools can facilitate communication and cooperation between healthcare providers, improving care coordination and patient outcomes (Wannheden et al. 2022).

Challenges of digitalization in LMICs (World Health Organization 2021):

- Infrastructure limitations. Many LMICs lack the infrastructure to support digital tools, such as reliable electricity and internet access.
- Limited resources. Healthcare providers in LMICs may lack the resources or expertise necessary to implement and utilise digital tools effectively.
- Limited digital literacy. Patients and healthcare providers in LMICs may have limited experience with digital tools and require additional training and support.
- Data privacy and security. Digital tools may raise concerns about data privacy and security, particularly in LMICs where regulations and infrastructure to support secure data management may be lacking.
- Integration with existing systems: Digital tools may need to be integrated with existing healthcare systems, which can be complex and require significant resources.

Overall, despite the fact that digitalization can significantly improve healthcare process optimization in LMICs, there are still a number of obstacles to be resolved before these technologies can be successfully adopted and implemented. Addressing these challenges will require collaboration between healthcare providers, policymakers, and technology providers to ensure that digital tools are tailored to the needs and context of LMICs.

Several process optimization solutions have already acquired widespread implementation in a broad spectrum of industries. Some are now being piloted on a limited basis, and others are still in the initial phases of research. Figure 1 shows several process optimization technologies in three stages of development (Chowdhury and Pick 2019).

2 Electronic Health Record-Based Tools

Electronic Health Record (EHR) is a permanent electronic record of patient health information created by one or more encounters in any healthcare setting. EHR is a patient's official health documentation maintained over time by the provider and shared among various facilities and organisations. It may include all relevant administrative and clinical information required for that person's treatment by that provider, such as

demographics, progress notes, issues, treatments, vitals, past medical histories, vaccinations, laboratory results, and radiology reports (Resource Center – All Resources | HIMSS 2023). EHR systems have been used by many healthcare institutions throughout the globe owing to their various advantages over traditional paper charts. Consequently, transitioning from paper to electronic charting has become a priority for several healthcare facilities that previously utilised paper documentation. Implementing a comprehensive healthcare data management system with a solid case has been found to enhance healthcare quality through facilitating fast data extraction (Xu et al. 2016), improving clinical research (DeShazo and Hoffman 2015; Adane et al. 2019) and clinical practice communication (Xu et al. 2016; Bookman et al. 2017; Lakin et al. 2016; Halpern et al. 2016; Weber and Kohane 2013), minimising medical errors (Adane et al. 2019), standardising medical documentation (Adane et al. 2019; Plantier et al. 2017; DesRoches et al. 2008), and raising the standard of healthcare services (Jawhari et al. 2016). Clinical decision support (CDS) tools, health information exchange (HIE) and computerised physician order entry (CPOE) systems are three specific features that show significant promise in improving the efficacy of healthcare and decreasing costs at the healthcare system level.

A CDS system assists the expert in making choices about patient care by delivering the most recent data on a therapeutic agent, cross-referencing a patient's allergy to a medicine, and flagging probable drug interactions and patient difficulties. These aspects contribute to the provider's ability to deliver patients the most effective care possible. As a result of the expanding medical knowledge, each of these capabilities now offers a mechanism through which maintenance may be provided far safer and more effectively. One may anticipate that some medical mistakes will be avoided as the number of CDS systems in use increases and that the patient will, on the whole, get the treatment that is both more effective and safer as a result (Sutton et al. 2020).

HIE is exchanging patient-level electronic health information across organisations, which may lead to significant improvements in healthcare delivery. HIE may eliminate expensive duplicate tests done because one provider does not have access to clinical information held at another provider's site by allowing for the secure and possibly real-time interchange of patient information. HIE allows for the interaction of this information through EHRs, which may lead to significantly more cost-effective and high-quality care (Walker et al. 2005).

CPOE systems are intended to substitute a hospital's paper-based ordering system by enabling consumers to electronically make the full spectrum of orders, retain an online prescription administration record, and monitor modifications made to orders by successive staff. In addition, devices provide safety notifications triggered when an unsafe order (for instance, a request for duplicate prescribed medications) is submitted, as well as clinical decision assistance to direct clinicians to less costly options or choices that better correspond to hospital guidelines (Connelly and Korvek 2022).

Despite the adoption of EHR systems by numerous medical institutions in high-income countries, implementing EHR software in healthcare facilities in LMICs remains a significant challenge due to financial constraints, lack of necessary technological infrastructure, and limited access to software training (Why sub-Saharan Africa 2023; Akhlaq et al. 2016; Ajami and Bagheri-Tadi 2013).

Nonetheless, it is crucial to implement EHR-based tools in LMICs because they can improve the quality of care, reduce medical errors, and improve overall healthcare outcomes. To introduce EHR-based instruments in LMICs, the following actions can be taken (Archer et al. 2021; Fraser et al. 2005; Ohuabunwa et al. 2016):

1. Evaluation of the current state of health information technology (IT) infrastructure in the target LMICs: determination of the availability of hardware, software, internet connectivity, and other necessary resources for EHR implementation.
2. Development of a solid understanding of the local healthcare system, including its struc-

ture, processes, and data needs and involvement of key stakeholders, such as healthcare providers, administrators, policymakers, and patients, to determine their unique needs and obstacles.

3. Investment in training and capacity-building programs for building local health IT expertise: train healthcare professionals, IT specialists, and other relevant personnel in EHR implementation, data management, and system administration. This contributes to the sustainability of EHR implementation and upkeep.
4. Adaptation of EHR systems to local requirements: numerous off-the-shelf EHR systems may not meet the specific needs of LMICs, by collaboration with vendors or developers to adapt EHR systems to local protocols, dialects, clinical guidelines, and data standards, and development or modifying EHR modules, interfaces, and reporting tools may be required.
5. Establishment of data governance and privacy policies, including developing robust data governance frameworks to address concerns regarding privacy, security, and confidentiality, assuring compliance with local data protection regulations and international standards and establishing data sharing, access control, and informed consent policies.
6. Enhancement of health information exchange, including promoting interoperability among healthcare facilities and systems to enable the seamless exchange of health data and implementing standards to facilitate data sharing and integration across various EHR platforms.
7. Pilot project implementation and scalability: it is recommended to start with small-scale pilot programs to evaluate the feasibility and efficacy of EHR implementation in particular settings or regions, followed by an evaluation of the outcomes, lessons learned, and difficulties encountered during the pilot phase. Based on the findings, the implementation strategy and the development of a scalable plan for expanding EHR adoption across the nation or region should be modified.
8. Assuring infrastructure readiness: strengthening the IT infrastructure by enhancing internet connectivity, power supply, and hardware availability and utilising mobile technologies, such as smartphones and tablets, to overcome infrastructure limitations in remote or resource-constrained areas.
9. Training the users and providing ongoing support by conducting comprehensive training programs for healthcare professionals to ensure they are proficient in using EHR systems effectively and providing ongoing technical support to address any problems encountered during the implementation and post-implementation phases.
10. Monitoring and evaluation by establishing mechanisms to monitor the impact of EHR implementation on healthcare delivery, patient outcomes, and system performance, continuously evaluating the benefits and challenges of EHR adoption and making the necessary adjustments to optimise its efficacy.

Innovative transition tools based on electronic health records are necessary to decrease unequal resource distribution and significantly improve the clinical needs of hospitalised medical patients.

Despite this, several studies indicate that businesses wishing to install EHR software at healthcare institutions in LMICs must take a highly personalised strategy due to the substantial variation in hospital and government policies.

Below are some examples of open-source EHR platforms that LMICs can use.

2.1 Smile Train Express (STX)

Smile Train Express (STX) is an EHR system developed by Smile Train, a charity focused on cleft lip and palate treatment. Smile Train, the largest cleft charity in the world with more than two decades of experience collaborating with healthcare facilities in LMICs, devised a cleft treatment EHR system and disseminated it to

their partner institutions (Louis et al. 2018). It aims to overcome barriers associated with EHR implementation by minimising technological requirements and simplifying the documentation of patient's Protected Health Information (PHI) (Louis et al. 2018). The primary purpose of STX is to track cleft surgical data, enabling Smile Train and its partner institutions to collaborate in developing quality improvement and safety plans to enhance and standardise cleft surgical care (Louis et al. 2018). To receive funding for cleft surgeries, all Smile Train-partner institutions are obligated to enter surgical cases into STX within 31 days of the procedure and actively engage in quality improvement and safety practices (Louis et al. 2018). Case entry can be completed during patient encounters or at a later date as long as the healthcare data is uploaded to the STX cloud-based patient record database on a monthly basis. In some Smile Train-partner institutions, STX has evolved from a quality improvement tool to the primary medical documentation medium (Louis et al. 2018).

The studies suggest that the implementation of STX has impacted medical documentation practices at some partnered institutions (Ferry et al. 2021; Nutley et al. 2013; Hernández-Ávila et al. 2013). However, the integration of STX into clinical workflows at most institutions has likely been limited due to regulations and guidelines established by governing bodies. The findings emphasise that organisations aiming to implement EHR software in healthcare facilities within LMICs need to adopt a highly individualised approach. This is necessary because of the considerable variability in hospital and governmental policies within LMICs. The studies highlight the importance of understanding and adapting to each institution's specific regulatory and policy contexts to successfully implement EHR systems in LMIC settings.

2.2 OpenMRS

OpenMRS, released in 2004, has become one of the most widely used open-source EHR systems LMICs (Serda et al. 2011). It was designed for resource-constrained environments and has been implemented globally in healthcare facilities. The software is supported by an extensive network of developers and implementers contributing to its ongoing development.

OpenMRS was initially developed by researchers, developers, and public health professionals at Regenstrief Institute and Partners in Health (PIH) for the AMPATH project in Kenya (Seebregts et al. 2009). Its early implementations focused on HIV and TB patient management in Kenya, Rwanda, and South Africa (Seebregts et al. 2009). Today, OpenMRS is utilised in various use cases and care settings, including secondary and tertiary facility-based health records management, primary healthcare, telemedicine, HIV care, tuberculosis management, non-communicable disease management, maternal and child health, reproductive health, Ebola response, and cancer care (Verma et al. 2021).

The platform was designed to be scalable across multiple countries and use cases, multilingual, and capable of functioning in challenging environments with limited internet access and low technology adoption (Wolfe et al. 2006). It is an open-source application with a robust data model, basic EHR functionality, and the ability to add new features through modules (Wolfe et al. 2006).

OpenMRS has been recognized as a "Global Good," indicating its role as a sustainable and scalable medical records solution in LMICs (Digital Square 2023). As governments and funders increasingly promote open-source technology, including Global Goods, this study aims to analyse the reach, utilisation, impact, and return on investment of OpenMRS as a Global Good (Digital Square 2023). It also seeks to identify key challenges and unmet needs to guide continued investment in the platform.

2.3 DHIS2

DHIS2 is a web-based open-source platform primarily used as a Health Management Information System (HMIS) (About DHIS2 – DHIS2 2023). It is the largest HMIS platform in the world and

is presently used by 73 low- and middle-income countries, affecting approximately 2.4 billion individuals (About DHIS2 – DHIS2 2023). Moreover, DHIS2 is in use across more than 100 countries, including programs run by non-governmental organisations (NGOs) (About DHIS2 – DHIS2 2023). Globally coordinated by the HISP Centre at the University of Oslo (UiO), the development of the DHIS2 software is a global collaborative effort. HISP, which stands for Health Information Systems Programme, is a network consisting of 17 in-country and regional organisations (About DHIS2 – DHIS2 2023). These organisations provide ongoing direct support to ministries and local implementers of DHIS2, ensuring its effective utilisation and implementation (About DHIS2 – DHIS2 2023). DHIS2 is an open-source platform for health management information systems, serving numerous countries worldwide and benefiting a significant portion of the global population. The collaboration and support provided by the HISP network further contribute to its successful implementation and development (About DHIS2 – DHIS2 2023).

Some papers suggest that DHIS2 has value for Health Impact Assessment (HIA) in low-resource settings by standardising data collection processes and improving reporting rates and accuracy (DHIS2 as a tool for health 2023; Byrne and Sæbø 2022). However, there are obstacles to effectively using DHIS2 data for HIA. The key challenges identified include limitations in data quality, analysis, and access (DHIS2 as a tool for health 2023). Multiple platforms operating independently across different ministries, sectors, or organisations can hinder a comprehensive understanding of health conditions. To address the challenges, additional funding and cross-institutional collaboration are needed to integrate platforms, promote national stewardship of DHIS2, and establish shared understandings of data through data dictionaries, metadata packages, and formal processes for integrating systematic data collection into global health monitoring and evaluation frameworks (DHIS2 as a tool for health 2023). Efforts are also required to build human resource capacity for HIA, including training for data cleaning, analysis, and visualisation (DHIS2 as a tool for health 2023). Furthermore, expanding accessibility to DHIS2 data through public web portals can enhance the value of DHIS2 for HIA and evidence-based health policy, ultimately improving health outcomes (DHIS2 as a tool for health 2023).

In summary, DHIS2 offers numerous advantages for LMICs, including its cost-effectiveness, customizability, scalability, and data standardisation features. However, technical requirements, data quality, sustainability, and system complexity must be addressed to successfully implement and utilise DHIS2 in LMICs. Close collaboration with stakeholders, adequate investment in infrastructure and capacity-building, and continuous support are essential for maximising the benefits of DHIS2 in resource-constrained settings.

3 Healthcare Scheduling Optimization

Healthcare scheduling optimization refers to the process of using advanced techniques and algorithms to optimise the scheduling and allocation of resources in healthcare settings. It aims to improve operational efficiency, patient outcomes, and resource utilisation while considering various constraints and objectives.

Healthcare scheduling research is crucial for optimising costs, improving patient flow, and efficiently utilising hospital resources. In recent decades, there has been an increasing number of systems that use metaheuristic methodologies to automate the search for optimum resource management in healthcare. The focus has primarily been solving healthcare scheduling problems such as patient admission scheduling (Ceschia and Schaerf 2012), nurse organising issues, and operating room scheduling/surgical scheduling (Di Martinelly et al. 2014). These methods aim to provide timely treatment administration and maximise the utilisation of available hospital resources.

3.1 Patient Admission Scheduling Problem

Patient Admission Scheduling Problem (PASP) is a complex combinatorial problem involving scheduling patients within specific time slots to optimise management competency, patient comfort and safety, and overall medical care (Abdalkareem et al. 2021). The problem aims to allocate patients to appropriate beds in relevant departments, considering their specific medical needs and restrictions (Abdalkareem et al. 2021). In some hospitals, a centralised admission office handles the assignment of patients to beds by coordinating with different departments in advance (Abdalkareem et al. 2021). However, in other cases, the responsibility of patient admission is decentralised, leading to a lack of overall knowledge and information among departments (Abdalkareem et al. 2021). This decentralised approach can result in suboptimal occupancy of beds, with some departments facing a shortage of available beds while others have extra beds (Abdalkareem et al. 2021). Efficiently solving the patient admission scheduling problem requires developing strategies and algorithms considering various factors, including patient needs, department capacities, and medical restrictions. By addressing this challenge, hospitals can improve bed allocation, optimise resource utilisation, and ensure that patients receive appropriate care in a timely manner (Abdalkareem et al. 2021).

Several software solutions available for patient admission scheduling are designed explicitly for LMICs. Here are a few examples:

- **Open Hospital:** Open Hospital is an open-source hospital management system with patient admission scheduling features. It was designed to be adaptive and configurable to the requirements of LMICs (Open Hospital 2023). Open Hospital offers functionalities for managing patient appointments, bed allocation, and resource utilisation. It aims to provide affordable and efficient solutions for healthcare facilities in resource-constrained settings (Open Hospital 2023).
- **MedScheduler:** MedScheduler is a web-based scheduling software designed for healthcare facilities in LMICs. It offers features for managing patient appointments, tracking bed availability, and optimising schedules based on various factors (New Innovations – GME Details 2023). MedScheduler aims to improve efficiency and patient flow in healthcare facilities with limited resources (New Innovations – GME Details 2023).
- **mHealth applications:** Mobile health (mHealth) applications, particularly those developed for LMICs, often include features for patient appointment scheduling and management (mHealth App Development 2023). These applications can be accessed through smartphones or feature phones, allowing healthcare providers to schedule patient admissions, send appointment reminders, and track patient flow (mHealth App Development 2023).

3.2 Nurse Scheduling Problem

Generating nursing schedules is a crucial task requiring significant time and effort from managers. It involves efficiently allocating nurses to shifts, considering a range of constraints such as shift timings, holidays, leaves, and unexpected events (D'souza et al. 2021).

Nursing scheduling software, a health rota or roster software, is crucial in healthcare environments for efficiently allocating nurses to shifts while considering various constraints (D'souza et al. 2021). These software solutions help automate the process of creating and managing nursing schedules, considering factors such as shift timings, holidays, leaves, and emergencies (D'souza et al. 2021). By using nursing scheduling software, managers can optimise the allocation of nurses, ensure appropriate coverage, and improve overall workforce management (D'souza et al. 2021).

Examples of nursing scheduling software include ROTA, NurseGrid, and Schedule360 (D'souza et al. 2021; NurseGrid 2023;

Schedule360 2023). These software options offer various features and functionalities to streamline the nursing scheduling process and improve overall workforce management in healthcare settings.

As an example of utilising roster software in LMIC, the Hong Kong Health Authority operates an AI-based tool developed by the City University of Hong Kong to generate staff rosters that meet various constraints (Nurse Rostering 2023). These constraints include staff availability, preferences, working hours, operational requirements, and regulations. Implemented across 40 public hospitals, the tool manages the scheduling of over 40,000 staff members. The introduction of this system has resulted in increased productivity, improved staff morale, and enhanced service quality. The tool is perceived as fair, saves managers' time, and provides valuable insights into working patterns and resource utilisation, benefiting overall management efficiency (HA: Nurse Rostering 2023).

3.3 Operating Room Scheduling/ Surgical Scheduling

The operating room theatre is a critical component of the healthcare sector, significantly influencing hospital performance. It involves a specialised combination of personnel and equipment, and each surgery requires preoperative and postoperative preparations. However, managing and scheduling the operating room theatre is challenging due to various constraints and stakeholder preferences. Furthermore, limited resources and the growing demand for surgical services have prompted the development of improved approaches for room scheduling. These approaches aim to effectively manage the operating room theatre by implementing different strategies and methodologies (Abdalkareem et al. 2021).

Several examples of operating room scheduling/surgical scheduling software are suitable for LMICs. Here are a few examples:

- **SurgiDat:** SurgiDat is a web-based operating room management system for resource-constrained settings. It helps hospitals and surgical centres optimise operating room scheduling, manage patient flow, track surgical instruments, and monitor performance indicators (SurgiDat 2023).
- **Surgimate**: Surgimate is a comprehensive surgical scheduling software that helps streamline the entire surgical workflow, from preoperative planning to postoperative follow-up. It allows hospitals and surgical centres to efficiently manage their surgical resources, schedule surgeries, track patient information, and generate reports (Surgimate 2023).

These software solutions can help healthcare facilities in LMICs overcome the challenges associated with operating room scheduling, optimise resource utilisation, and improve the efficiency of surgical services. Evaluating each software's specific features and suitability for the local context is essential before implementation.

4 Supply Chain Management for Medicines

The healthcare supply chain (SC) has been described as the information, supplies, and finances associated with acquiring and transferring products and services from the supplier to the end user of products and services from the supplier to the end user in order to improve clinical outcomes and control costs (Schneller and Smeltzer 2006). Due to the unique nature of health services, the supply chain is not limited to physical products (drugs, pharmaceuticals, medical devices, health aides, and other products) but also includes patient flow (The management of the supply 2023). According to Turhan and Vayvay (n.d.), healthcare supply chain management (SCM) the healthcare supply chain differs from that of other industries due to its propensity for misalignment, high costs for healthcare providers, and reliance on third parties. The healthcare supply chain is decentralised, lacking (financial or contractual) coordination mechanisms between physicians, hospitals, and patients, and is subject to substantial regulatory pressure (Dobrzykowski 2019).

Digitalization plays a crucial role in transforming healthcare supply chain management. By leveraging technology and digital tools, healthcare organisations can enhance efficiency, transparency, and coordination throughout the supply chain process (Beaulieu et al. 2021). Digital platforms and software solutions are also used to automate procurement processes, streamline supplier management, and optimise distribution logistics. These tools facilitate automated ordering, invoice processing, and payment systems, reducing administrative burdens and improving operational efficiency (Beaulieu et al. 2021).

The concept of SC digitalization encompasses a range of technologies, including both traditional and advanced ones. Conventional technologies like electronic data interchange (EDI), electronic catalogues, radio frequency identification (RFID), and automated guided vehicles (AGVs) (Bechtsis et al. 2017; Morenza-Cinos et al. 2019) are now integrated into the broader concept of digitalization, alongside newer technologies such as cloud computing, IoT, big data analytics, 3D printing (Kosmol et al. 2019), blockchain (Chang et al. 2019), and artificial intelligence (Ehie and Ferreira 2019). However, there is still a need for a standard definition of terms like big data within the context of SC digitalization.

These technologies offer the potential to enhance supply chain management by enabling real-time synchronisation of material and information flows, personalised production (Büyüközkan and Göçer 2018), and improved flexibility and agility (Seyedghorban et al. 2019). However, their adoption would require restructuring the roles of actors within the supply chain and the development of necessary skills to effectively use the tools and analyse the vast amounts of data generated. To fully benefit from these new technologies, organisations should prioritise developing deployment plans and ensuring they have the required skills and capabilities before rushing into their acquisition. This approach, suggested by Hartley and Sawaya, emphasises the importance of adequate preparation to fully leverage the potential of digitalization in the supply chain domain (Hartley and Sawaya 2019).

Constructing effective SCM systems in LMICs can be complicated due to limited infrastructure, insufficient institutional frameworks, and resource constraints. Nonetheless, there are a number of strategies and approaches that can aid in enhancing supply chain administration in LMICs.

The eLMIS, which stands for Electronic Logistics Management Information System, is an innovative and cost-efficient solution for managing health data (Usaid 2015). Its implementation in Zambia and Tanzania has enhanced commodity security and improved health outcomes for the population (Strengthening Health Systems 2023). In healthcare programs, the availability of an adequate quantity and quality of health products is crucial for meeting patient needs and achieving better health outcomes. To address this challenge, Zambia and Tanzania collaborated to develop the eLMIS, a comprehensive system encompassing various major health programs in the countries. By establishing a connection between health facilities and the central store, the eLMIS enables the collection and real-time distribution of logistics data. This information plays a vital role in supply chain management by providing insights into the utilisation and demand for medicines, thereby facilitating the provision of uninterrupted supplies to patients.

Bangladesh's Directorate General of Health Services (DGHS) faced challenges in health supply chain management, including the lack of an integrated inventory management system and tracking capabilities, mainly when COVID-19 emerged in the country, USAID Medicines, Technologies, and Pharmaceutical Services (MTaPS) collaborated with DGHS to develop a comprehensive COVID-19 eLMIS based on an existing eLIMS (Digitalization of COVID-19 Commodities 2023). MTaPS initially established a basic online reporting system and trained around 500 health workers. This enabled centralised tracking of emergency commodity stock levels at health facilities and distribution centres. By April, the DGHS, central administration, suppliers, and beneficiaries received daily updates on

emergency commodity stocks, with 99% of COVID-19-dedicated health facilities reporting regularly. Recognizing the need for an expanded inventory management system, MTaPS and DGHS upgraded the reporting system into a comprehensive COVID-19 eLMIS. This enhanced system included a quantification tool for real-time stock information, which is crucial for timely procurement and distribution decisions at the central level. The eLMIS was gradually implemented in a phased rollout after user acceptance testing and facility assessments. The collaboration between MTaPS and DGHS in developing the COVID-19 eLMIS helped overcome the supply chain crisis. The system improved the visibility, tracking, and reporting of emergency commodity stocks, facilitating informed decision-making at the central level.

5 Patient Registries

Patient registries are systematic databases that collect standardised data on a specific population affected by a disease, condition, or exposure (McGettigan et al. 2019). These registries follow patients over time, gathering information on their demographics, medical history, treatment outcomes, and other relevant factors (McGettigan et al. 2019). Patient registries have the potential to provide valuable data for regulatory decision-making, particularly when evaluating treatments for rare diseases (McGettigan et al. 2019). The digitalization of patient registries refers to the process of transitioning from paper-based or manual record-keeping systems to electronic platforms for data collection, storage, and analysis (Digital Health and Patient Registries 2023). The digitalization of patient registries offers numerous advantages, including improved data quality, efficient data management, advanced analytics, and enhanced collaboration (Digital Health and Patient Registries 2023). By leveraging digital platforms, patient registries can maximise their potential to inform clinical practice, support regulatory decision-making, and contribute to research and healthcare improvement (Digital Health and Patient Registries 2023).

The digitalization of patient registries in LMICs can bring significant benefits to healthcare systems, despite their unique challenges. Here are a few examples of digitization efforts for patient registries in LMICs:

- **OpenSRP (Open Smart Register Platform)—**OpenSRP is an open-source mobile health platform developed by the Digital Impact Alliance (DIAL). It has been used in LMICs, such as Bangladesh, Zambia, and Kenya, to digitise patient registries and improve data collection and reporting for maternal and child health. OpenSRP enables community health workers to register patients, track vaccinations, monitor growth, and provide personalised care through mobile devices (OpenSRP—Open-source smart register platform (SRP) 2023).
- **REDCap (Research Electronic Data Capture)—**REDCap is a web-based platform for building and managing online surveys and databases (Harris et al. 2019). It has been used in LMICs for digitising patient registries in various research studies and clinical trials. REDCap enables data entry, storage, and analysis while ensuring data security and privacy. It can be customised to meet specific registry requirements and utilised in countries like Ethiopia and Uganda (Harris et al. 2019).

6 Biometric Systems

Biometric systems are computer-based systems that use unique physical features, such as fingerprints, facial characteristics, or iris patterns., to identify individuals. These systems have gained widespread use in recent years for various applications, including access control, border control, and identity verification (Committee NRC (US) WB et al. 2010a).

One of the main advantages of biometric systems is that they provide a higher level of security than traditional authentication methods, such as passwords or PINs. Individual biometric characteristics are difficult to duplicate or forge, making them practical for preventing unauthorised

access. Biometric systems can also be more convenient for users, as they do not need to remember passwords or carry additional authentication devices (Nigam et al. 2022).

Several biometric systems exist, including fingerprint, facial recognition, and iris scanners. Each type of system has specific advantages and disadvantages and the appropriate method for a particular application will depend on its specific requirements and constraints (Guennouni et al. 2019).

Fingerprint scanners are one of the most widely used biometric systems. They capture an image of the fingerprint and analyse the unique patterns and ridges present in the fingerprint. These systems are relatively inexpensive, easy to use, and accurate, making them suitable for various applications. Fingerprint scanners can be used for multiple purposes, including access control, attendance tracking, and financial transactions (Maltoni et al. 2022).

Facial recognition systems use artificial intelligence and machine learning algorithms to analyse the unique characteristics of a person's face, such as the shape and size of the eyes, nose, and mouth. These systems are highly accurate, but they can be affected by changes in appearance, such as facial hair or makeup, and they may be less accurate for people of certain ethnicities (Li et al. 2020). Facial recognition systems have been used for various purposes, including identifying criminals, detecting terrorists, and tracking the movement of individuals (Robbins 2021).

Iris scanners use a camera to capture an image of the iris, the coloured part of the eye surrounding the pupil. The unique patterns in the iris are then analysed to identify the individual. Iris scanners are highly accurate and resistant to changes in appearance, but they may be more expensive and complex to implement than other biometric systems. Iris scanners have been used for various purposes, including access control and identity verification (Daugman 2004).

Biometric systems can potentially revolutionise how we authenticate ourselves and access services and resources. However, there are also potential privacy and ethical concerns associated with these systems (Cooper and Yon 2019). For example, biometric data collected by these systems may be stored and used for purposes beyond the original intent. There is a risk of discrimination based on the characteristics being measured. Biometric systems may cause false positives and negatives, raising concerns regarding their reliability and accuracy (Committee NRC (US) WB et al. 2010b).

To address these concerns, organisations adopting biometric systems need to consider the following factors (Ratha et al. 2001):

- Privacy: Organisations should implement appropriate safeguards to protect the privacy of individuals and ensure that biometric data is only used for the intended purpose.
- Accuracy: Organisations should ensure that biometric systems are accurate and reliable and have processes to address false positives and negatives.
- Ethical considerations: Organisations should consider biometric systems' potential implications and implement appropriate safeguards to prevent discrimination based on measured characteristics.

In the healthcare sector of LMICs, biometric systems are increasingly used for client registration and identification to improve healthcare service delivery, reduce fraud, and ensure accurate patient records. Here are a few examples of biometric systems used in LMICs healthcare:

- **Aadhaar (India):** The Aadhaar system in India is one of the most significant biometric identification projects globally. It uses a combination of fingerprint, iris, and face recognition to assign residents a unique 12-digit identification number. Aadhaar has been widely used for various government services, including social welfare programs, banking, and healthcare (Home – Unique Identification Authority of India 2023).
- **Biometric Patient Identification System (Kenya):** The Biometric Patient Identification

System (BPIS) was implemented in Kenya to improve patient identification in healthcare facilities. The system utilises fingerprint biometrics to identify patients and link them to their medical records accurately. It helps prevent medical errors, ensures continuity of care, and reduces the risk of misidentification (Anne et al. 2020).

- **Mother and Child Tracking System (India):** India implemented the Mother and Child Tracking System (MCTS), which utilises biometric identification to track and monitor the health of pregnant women and children. The system captures biometric data, including fingerprints and photographs, to create unique individual identification records. This facilitates targeted healthcare interventions and ensures proper delivery of maternal and child health services (India's Mother and Child Tracking System 2023).

In conclusion, biometric systems have the potential to increase security and convenience for a variety of applications. However, organisations must consider these systems' potential privacy, accuracy, and ethical issues and implement appropriate safeguards to protect individuals' rights and interests.

7 Counterfeit Drug Testing

Counterfeit drugs are a significant public health threat, as they often contain incorrect or harmful ingredients, leading to serious health consequences for those who consume them (Kon and Mikov 2011). One important factor contributing to the proliferation of counterfeit drugs is the increasing availability of online pharmacies. These pharmacies often sell drugs not approved by regulatory agencies and may be fake or of substandard quality. Enhancing online surveillance and enforcement efforts to educate consumers about the risks of purchasing drugs from unverified sources is essential to address this issue. To combat the problem, it is crucial to optimise the testing of counterfeit drugs to ensure that they are accurately identified and removed from circulation (Islam and Islam 2022).

One approach to optimising counterfeit drug testing is using advanced analytical techniques. These techniques, such as high-performance liquid chromatography (HPLC) and mass spectrometry (MS), can provide detailed chemical analyses of drugs and identify any discrepancies or deviations from the expected composition. These techniques are also susceptible, allowing for detecting even small amounts of counterfeit material (Martino et al. 2010a).

Another way to optimise counterfeit drug testing is by using reference standards. These standards, carefully calibrated and validated samples of known drugs, can be used to compare the quality and purity of tested drugs. By using these standards, laboratories can more accurately determine whether a drug is counterfeit (Martino et al. 2010b).

In addition to these analytical techniques, several approaches can be taken to optimise the overall process of counterfeit drug testing. For example, establishing a well-coordinated network of laboratories to conduct testing can help to ensure that samples are analysed efficiently and effectively. Additionally, implementing quality management systems and training programs can help ensure testing is performed according to established protocols and standards (Implementation of a Quality Management System n.d.).

Another critical factor in the fight against counterfeit drugs is the development of innovative technologies for tracking and tracing the supply chain. These technologies, such as blockchain and RFID tagging, can help ensure that medications are authentic, properly stored, and handled during transportation. Implementing these technologies can reduce the risk of counterfeit medicines entering the supply chain and reaching consumers (Zakari et al. 2022).

Several regulatory measures can be taken to prevent counterfeit drugs from entering the market. For example, strengthening intellectual property protection for branded drugs can help to reduce the profitability of counterfeiting, as it

becomes more difficult for counterfeiters to pass off their products as genuine articles. Additionally, increasing penalties and enforcement efforts for those who produce or distribute counterfeit drugs can deter would-be counterfeiters (WHO Member State Mechanism 2023; 1 in 10 medical products in developing countries 2023).

Effective collaboration between government, industry, and other stakeholders is also essential in the fight against counterfeit drugs. Working together, sharing information and resources, and developing more comprehensive strategies for addressing this complex problem is achievable (WHO Member State Mechanism 2023; 1 in 10 medical products in developing countries 2023).

Combating counterfeit drugs requires a multifaceted approach that involves advanced technologies, scientific excellence and collaboration. By taking these steps, reducing the risks posed by these dangerous products and protecting public health is possible.

While specific software solutions for counterfeit drug testing may vary across different countries and regions, here are a few examples of counterfeit drug testing software used in LMICs:

- **PharmaSecure** is a software platform that helps combat counterfeit drugs by providing unique identification codes on drug packaging. Patients or healthcare providers can send a text message with the code to a designated number, and they receive an immediate response confirming the product's authenticity. This solution has been implemented in several LMICs, including India, Nigeria, and Kenya (PharmaSecure 2023).
- **mPedigree** is a mobile-based anti-counterfeiting solution that enables patients and healthcare providers to verify the authenticity of medicines through a unique scratch-off code on the drug packaging. By sending the code via SMS, users receive an instant response indicating whether the product is genuine. The mPedigree platform has been deployed in countries like Ghana, Kenya, and Nigeria (Rasheed et al. 2018).
- **Sproxil** is a mobile verification solution that employs scratch-off labels with unique codes on drug packaging. Users can send the code via SMS or use a smartphone app to verify the authenticity of the medicine. Sproxil has been used in several LMICs, including Nigeria, India, and Kenya, to combat counterfeit drugs (Johnston and Holt 2014).

These examples highlight some of the software solutions that have been deployed in LMICs to address the issue of counterfeit drugs. It should be emphasised that the deployment of these technologies can differ depending on the unique requirements, regulations, and available resources of each country or region.

8 Automated Completion or Analysis of Medical Records

With the growth and global adoption of EMR systems in medical healthcare, vast quantities of information have become available, necessitating the investigation of alternative methods for maximising the utility of these massive datasets (Sun et al. 2018). Automated completion or analysis of medical records refers to the use of technology and algorithms to assist in the process of completing or analysing patient medical records. This approach aims to streamline and enhance the efficiency of healthcare documentation and data analysis (Sun et al. 2018). Automated filling and analysis of medical records possess the capability to enhance the efficiency and quality of healthcare documentation, facilitate data-informed decision-making, and enable thorough examination of patient information. However, it is essential to ensure patient data's accuracy, privacy, and security when implementing these automated systems (Ozonze et al. 2023). The automation of medical records completion and analysis is a subject of continuous research and development, and its widespread use may not be prevalent at the current time. While there have been advancements in natural language processing, machine

learning, and data analytics techniques for medical record automation and analysis, the implementation and adoption of these technologies in healthcare settings vary.

Below are presented a few examples of research studies related to the automated completion or analysis of medical records:

- Using the Medical Information Mart for Intensive Care III (MIMIC-III) dataset, which contains a diverse range of healthcare data, conducted an experimental investigation into the utilisation of machine learning techniques to create predictive models for sepsis. These models considered vital signs, laboratory test results, and demographics as predictive features for sepsis. The experiment results demonstrated that the machine learning models outperformed the commonly used Sequential Organ Failure Assessment (SOFA) and Quick SOFA (qSOFA) scoring systems at the time of sepsis onset. This suggests that the machine learning models have a higher overall performance in predicting sepsis compared to the traditional scoring systems (Camacho-Cogollo et al. 2022).
- Evaluation of automated electronic case report form (CRF) data entry from EHRs explored to assess the feasibility and benefits of automated data transfer from EHRs to electronic CRFs in a clinical trial for hospitalised COVID-19 patients. Drawing on these discoveries, the study reached the conclusion that automated EHR-to-CRF data transfer had the potential to significantly reduce the effort required by study personnel while improving the accuracy of the data in CRFs. Implementing automation in data transfer can enhance efficiency, reduce errors, and enhance the quality and safety of clinical trial data collection (Cheng et al. 2023).

These examples highlight the ongoing research efforts to develop and validate automated completion or analysis techniques for medical records. While these studies demonstrate the potential benefits of automation in healthcare, it should be acknowledged that the field is still in a state of development, and additional research is necessary to enhance and validate these approaches prior to their broad implementation in clinical settings.

9 Patient Feedback Collection and Analysis

Collecting patient feedback digitally offers numerous advantages, including leveraging existing communication channels, collecting data more efficiently, and gathering real-time insights. Digital methods, such as online surveys, QR codes, and social media, provide healthcare organisations with a broader reach and faster data collection beyond the immediate episode of care. While traditional post-visit or post-discharge surveys provide valuable information about the patient experience, digital listening strategies enhance and deepen patient insights. These strategies enable healthcare organisations to stay attuned to real-time data, capturing feedback on specific touchpoints and adventures throughout the patient journey. By utilising digital channels, healthcare providers can access a broader range of patient feedback and gain actionable insights to improve the quality of care (Von Wedel et al. 2022).

The DEPEND study research paper explores the implementation of a digital feedback intervention in the English National Health Service (NHS). The study found that healthcare staff viewed digital feedback positively, finding it attractive, quick to complete, and easy to analyse. However, patient perspectives varied depending on their familiarity with digital technology. Some patients encountered barriers such as a lack of visibility of the feedback system, concerns about privacy, limited digital literacy, and technical difficulties. The level of engagement with digital feedback varied across sites due to workload pressures, perceptions of roles and responsibilities, and ongoing organisational

changes. The concentration of mental health service users with digital feedback was influenced by their relationships with staff and their health status. The study emphasised the importance of considering local contexts, different patient groups, and organisational leadership when implementing digital feedback methods. Involving patients in the change process and adaptation of the intervention was crucial for successfully integrating digital feedback into routine practices. The application of the Normalisation Process Theory (NPT) provided a comprehensive understanding of the actions and interactions of staff and patients involved in the implementation (Ong et al. 2020).

Several examples of digitalization of patient feedback collection and analysis in LMICs have emerged in recent years:

- **Interactive Voice Response (IVR) Systems:** IVR systems collect patient feedback via phone calls. In India, the National Rural Health Mission implemented a toll-free IVR system where patients can share their feedback on healthcare services, including cleanliness, staff behaviour, and availability of medicines (Swendeman et al. 2015).
- **mHealth Apps:** Mobile health applications have been developed to collect patient feedback and assess healthcare quality. For instance, in Uganda, the mTrac app allows patients to report on the availability of medicines, quality of care, and health worker performance through SMS-based surveys (Cummins 2015).

These examples highlight the diverse approaches taken to digitise patient feedback collection and analysis in LMICs. However, it is crucial to consider the specific context and infrastructure challenges of each LMIC when implementing digital patient feedback systems. Collaboration between stakeholders, including governments, healthcare providers, technology experts, and patients, is crucial for successful implementation and sustainability.

10 Quality/Performance Improvement Analytics

Quality/performance improvement analytics refers to the process of using data analysis and evaluation techniques to assess, monitor, and enhance the quality and performance of healthcare systems, processes, and outcomes. It involves collecting and analysing data related to various quality indicators and performance metrics to identify areas for improvement and implement evidence-based interventions. The digitalization and process optimization of quality/performance improvement analytics bring several benefits to healthcare organisations enabling healthcare organisations to make data-driven decisions, improve operational efficiency, enhance patient outcomes, and foster a culture of continuous quality improvement (Martin et al. 2023).

In LMICs, there is a growing interest in leveraging quality/performance improvement analytics tools to enhance healthcare delivery. The availability and adoption of specific devices may vary across different countries and settings. It should be emphasised that the accessibility and adoption of these tools in LMICs can be influenced by factors such as infrastructure, financial resources, and local capabilities. Additionally, ongoing research and innovation in LMICs continue to contribute to developing context-specific tools and approaches for quality/performance improvement analytics.

11 Conclusion

The adoption of digitalization measures in healthcare, such as electronic medical records, faces challenges in LMICs. The success of these tools depends on having a workforce capable of designing, implementing, and maintaining the systems. Limited human resources can hinder the effective management of these technologies. Additionally, if digitalization introduces a new service rather than replacing an existing system,

it may strain health workers, requiring additional training and recruitment.

Data training and expertise are crucial for process optimization tools. Good data leads to good outcomes, while insufficient data can have negative consequences, such as misallocating resources. User-friendly platforms and ensuring data interoperability are essential for success. However, the increasing use of "people analytics" has been criticised for potentially dehumanising work and may not effectively increase productivity or optimise practices.

Tools that support process optimization do not provide immediate relief or diagnosis but aim to improve back-end processes, freeing up time and resources for healthcare workers. Over the medium to long term, these tools can increase capacity and support quality research through enhanced data collection.

In the broader context, interdisciplinary and interprofessional healthcare interventions often focus on outcomes such as length of stay, readmission rates, mortality, or functional status. However, the effects of such interventions on these outcomes can be inconsistent. While some improvements in interprofessional collaboration have been associated with reduced complications of care, interventions confined to the inpatient setting may not reduce readmissions or mortality rates. The generalizability of results can be limited due to differences in healthcare systems and standards of care.

There is a need for further validation and research on interventions to optimise patient flow, discharge processes, and overall patient management. Consensus on performance benchmarking data and needed interventions are lacking, hindering quality improvements. Standard sets and patient-reported outcome measurement systems can help assess the impact of diagnostic and therapeutic steps on patient outcomes. Prospective time-series analyses and randomised controlled trials can also be valuable study designs in investigating the effects of transition-changing interventions.

Additionally, the availability of anonymized patient-level data from clinical trials can enhance research and accountability and avoid duplication of trials. It is important to prevent "data dumpsters" by linking data to relevant documentation and analyses. Furthermore, the costs and benefits of novel interventions need to be carefully evaluated, considering the additional resource deviation they may require.

Addressing these challenges and conducting further research and evaluation can contribute to successfully implementing digitalization and process optimization in healthcare settings, leading to improved patient outcomes and quality of care.

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Digitalization in Preclinical Research: Advancements and Implications

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Abstract

Digital technologies are omnipresent and have influenced the entire continuum of preclinical research activities both in high-income countries and low-and middle-income countries. This chapter describes the many different aspects of preclinical research and how it is affected by digitization. These include the digital tools and technologies in preclinical research, the ways in which digitization enhances data management in preclinical research, as well as experimental design in preclinical research.

Keywords

Preclinical research · Digital health · Electronic data capture · Data integration · Laboratory information management systems (LIMS) · Machine learning

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1 Introduction

Digitization has been transforming various fields, and preclinical research is no exception. The use of digital technologies in preclinical research has become increasingly common and has had a significant impact on the way research is conducted, managed, and analyzed. Preclinical research refers to scientific investigations conducted in the laboratory or animals before testing new therapies or interventions in humans. It encompasses a wide range of studies aimed at understanding the safety, efficacy, and mechanisms of action of potential treatments.

Digital technologies are playing an increasingly significant role in transforming preclinical research methodologies. These technologies offer a wide range of tools and approaches that enhance data collection, integration, and analysis. By integrating diverse data sources, such as genomics, proteomics, other -omics, and imaging data, researchers can gain deeper insights into disease mechanisms and treatment responses. Moreover, digital tools enable *in silico* approaches, virtual screening, and computational modeling, accelerating the drug discovery and optimization process. Adopting digital technologies in preclinical research holds great promise for improving efficiency, reproducibility, and the discovery of novel therapeutics.

As preclinical research consists of multiple complex topics and sub-areas, within this chap-

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ter, it will be divided it into the following fields: dedicated to Drug Discovery and Development, Disease Modeling and Pathophysiology, Safety and Toxicology Assessments, and Pharmacokinetic-Pharmacodynamic modeling and analysis.

Preclinical research consists of a series of labor-extensive steps and requires a thoughtful analysis to identify and optimize lead compounds with desirable properties for subsequent evaluation in clinical trials. The preclinical drug discovery may vary based on the specific therapeutic area, target, and research objectives, but a general, structured framework outlining the key components can be presented with the following phases (Mahajan et al. 2020; Cook et al. 2014; Vogel and Maas 2016; Li and Wang 2019):

I. **Target Identification and Validation.**
   Preclinical drug discovery begins with the identification and validation of a target molecule(s) or pathway(s) that plays a critical role in the disease process. This involves understanding the underlying biology of the disease and establishing the relevance of the target in the context of the therapeutic goal.
II. **Hit Identification and Lead Optimization.**
   Once a target is identified and validated, the focus shifts to finding potential drug candidates or "hits" that interact with the target. High-throughput screening (HTS) and virtual screening are commonly employed to identify compounds that show activity against the target. Subsequently, lead optimization involves refining and modifying the initial hits to improve their potency, selectivity, and other desirable properties.
III. ***In vitro* and *In vivo* Testing**.
   Preclinical drug discovery involves extensive *in vitro* and *in vivo* testing to evaluate the pharmacological effects, efficacy, safety, and toxicity of the lead compounds. *In vitro* assays and cell-based models are employed to assess target engagement, cellular activity, and initial toxicity screening. Animal models, such as rodents or non-human primates, are used to assess the pharmacokinetics, efficacy, and safety of lead compounds in a more complex biological setting.
IV. **Pharmacokinetics and Pharmacodynamics Modeling and Analysis.** Understanding the pharmacokinetic and pharmacodynamic properties of lead compounds is critical in preclinical drug discovery. The pharmacokinetic properties of lead compounds are evaluated, including absorption, distribution, metabolism, and excretion (ADME). The pharmacodynamics are focused on the analysis of how lead compounds interact with the target and produce the desired effects
V. **Safety and Toxicology Assessment.**
   Preclinical drug discovery includes comprehensive safety and toxicology assessments to evaluate the potential adverse effects of lead compounds. This involves conducting a range of toxicity studies, including acute toxicity, repeated-dose toxicity, genotoxicity, and safety pharmacology assessments, to identify potential risks or side effects associated with the compounds.
VI. **Data Analysis and Decision-making.**
   Throughout the preclinical drug discovery process, data analysis plays a vital role in informing decision-making. Researchers analyze and interpret the data generated from various experiments and assays to assess the efficacy, safety, and suitability of lead compounds for further development.
VII. **Regulatory Requirements.**
   While preclinical drug discovery primarily focuses on understanding the properties and effects of lead compounds, there is also an awareness of regulatory requirements and considerations. Preclinical data generated during this phase lay the foundation for regulatory submissions and serve as a basis for advancing compounds into clinical trials.

Digitization plays a significant role in accelerating the drug discovery and development processes. By leveraging digital tools and technologies, researchers can streamline data

collection, analysis, and collaboration, leading to more efficient identification of potential drug targets and optimization of lead compounds. Additionally, digitization enables virtual screening, computational modeling, and data-driven decision-making, expediting the design and evaluation of drug candidates, ultimately reducing costs and time-to-market for new therapies.

2 Digital Tools and Technologies in Preclinical Research

2.1 Overview of Key Digital Tools and Technologies Utilized in Preclinical Research

In the context of data management in preclinical research, digitization refers to the adoption and integration of digital technologies and tools to transform how data is collected, stored, analyzed, and shared. It involves leveraging digital platforms, software applications, and automated processes to streamline data management workflows, enhance data quality, improve accessibility, and enable more efficient and informed decision-making.

2.2 Electronic Data Capture (EDC) Systems for Efficient Data Collection and Management

Digitization in preclinical research data management encompasses several key aspects, including the fundamental one—Electronic Data Capture (EDC). Thanks to digitization, traditional paper-based data collection methods can be replaced, partly or fully, with electronic data capture systems. This allows for the direct entry of data into electronic forms or databases, reducing errors, improving data quality, and enabling real-time data available for analysis.

EDC systems eliminate the need for manual data entry from paper forms, reducing transcription errors and saving time. Researchers can directly enter data into electronic forms or databases, streamlining the data collection process. Moreover, EDC systems provide built-in data validation checks and data range validations, minimizing errors and ensuring data integrity. Required fields, data format checks, and logical checks can be implemented in electronic forms, prompting researchers to enter accurate and complete data. This helps maintain high-quality data for analysis and decision-making. With EDC systems, data is instantly available for analysis and monitoring to all those that have received the relevant regulatory and ethical clearance. Researchers can access real-time data and track study progress, enabling timely decision-making and intervention as and when required. This real-time access to data improves the overall efficiency of preclinical research studies and helps in identifying trends or issues promptly. EDC systems enable remote data capture, allowing researchers to collect data from multiple sites or participants located in different geographical locations. This flexibility eliminates the need for physical visits or manual data transfer (partly or fully), reducing logistical challenges and potential errors associated with data collection.

Data security and privacy play a pivotal role during extensive and longitudinal preclinical studies, EDC systems offer robust security measures to protect sensitive research data through access controls, encryption, and audit. These systems adhere to regulatory guidelines, such as the Health Insurance Portability and Accountability Act (HIPAA) and Good Clinical Practice (GCP) standards.

2.3 Laboratory Information Management Systems (LIMS) for Streamlined Data Organization and Integration (Cucoranu 2016; Brusniak et al. 2019; Kumuthini et al. 2020)

Digital platforms that are fundamental to managing and organizing various aspects of laboratory operations and data were developed as Laboratory Information Management Systems (LIMS).

LIMS facilitates the management of preclinical research data within laboratory settings through tracking of samples, recording of experimental data, management of protocols and workflows, and integration of data from various instruments and sources. They provide a centralized and standardized approach to data management, ensuring consistency and efficient retrieval of information.

There is a wide range of LIMS platforms available on the market with a broad range of customization options according to the end-users' needs. The LIMS systems are designed to be adaptable and extendable, making them suitable for both small and large research laboratories where multidisciplinary scientists collaborate on the engineering of compounds for potential therapeutic applications from creation to preclinical experiments.

What is important, LIMS allows researchers to track and manage samples throughout their lifecycle, from acquisition to disposal. It provides features to record sample details, such as storage location, sample type, and associated metadata. By automating sample tracking, LIMS minimizes errors, improves traceability, and facilitates easy retrieval of samples when needed.

Recording and storing experimental data generated during preclinical research within LIMS includes data from assays, tests, measurements, and observations. Researchers can enter data directly into the system or integrate LIMS with instruments to automatically capture data, eliminating manual entry errors and ensuring data accuracy.

As standardization of the experiments and processes is fundamental for providing accurate, real-life results, LIMS allows the creation of protocols, specifying step-by-step procedures and instructions for different experiments. Having this functionality, LIMS ensures adherence to protocols, promotes consistency in data collection, and allows for easy replication of experiments.

As the importance of high-throughput technology grows every year in the field of preclinical research, instrument integration is recognized as an integral part of LIMS to facilitate the seamless integration of data generated by various laboratory instruments and equipment. This integration enables the automatic capture and storage of instrument-generated data, reducing the risk of data transcription errors and simplifying data management. Instruments such as spectrophotometers, chromatography systems, and robotics can be connected to LIMS, enabling direct data transfer and reducing the human error connected with this process.

LIMS also plays an important role in Quality Assurance in preclinical research. By incorporating regulatory standards and internal quality control procedures, LIMS facilitates adherence to Good Laboratory Practice (GLP) guidelines, data integrity, and audit trials. LIMS assists in managing documentation related to regulatory compliance, including sample chain of custody, quality control records, and Standard Operating Procedures (SOPs).

As reporting is particularly important to track the quality and progress of preclinical research, LIMS often includes tools for generating customizable reports and performing basic data analysis. Researchers can extract relevant data subsets, create graphical representations, and perform basic statistical analysis within the LIMS environment and integrate with external data analysis tools for more comprehensive analysis.

2.4 Cloud-Based Storage and Computing Solutions for Secure and Scalable Data Management (Willard et al. 2016; Berman 2012; Ngiam and Khor 2015)

The way how preclinical research data is managed and analyzed was revolutionized by cloud-based data storage solutions. Cloud platforms offer robust security measures, including encryption, access controls, and regular backups, ensuring the confidentiality and integrity of research data. Researchers can store large volumes of data in the cloud without the need for

expensive on-site infrastructure, reducing on-site infrastructure costs and associated administrative burden. Moreover, these types of storage solutions provide scientists with convenient and universal access to their data from anywhere with an internet connection. This accessibility facilitates seamless collaboration among research teams, allowing multiple users to access, share, and work on the same data simultaneously. It promotes real-time collaboration, streamlines communication, and enhances productivity.

What is important, to maintain data redundancy and backup within preclinical research using the cloud-based solutions, research data is replicated and stored across multiple servers and data centers, ensuring high availability and reducing the risk of data loss due to hardware failures or natural disasters. Automated backup processes provide an additional layer of data protection, enabling easy data recovery in case of accidental deletion or system failures.

Cloud-based storage solutions facilitate data integration and interoperability from various sources, such as laboratory instruments, electronic medical records, or external databases, in a centralized cloud environment. This integration allows for comprehensive analysis and correlation of diverse datasets, leading to more meaningful insights and discoveries.

Moreover, cloud computing provides researchers with the access to powerful computational resources for data analysis and processing. Scientists can leverage cloud-based computing environments to perform complex data analyses, simulations, and modeling without the need for extensive on-site computational infrastructure. Cloud platforms offer high-performance computing capabilities, enabling researchers to process large datasets and perform computationally intensive tasks efficiently.

Cloud computing platforms offer scalability, allowing researchers to scale up or down their storage resources based on their needs. Researchers can easily accommodate growing data volumes without investing in additional hardware or infrastructure. This scalability offers cost-effective solutions and flexibility in managing preclinical research data compared to maintaining on-premises infrastructure. Researchers can avoid repeated upfront investments in hardware, maintenance costs, and software licenses. Cloud services typically operate on a pay-as-you-go model, allowing researchers to pay only for the resources they consume, making it a more cost-effective option for preclinical research data management and analysis.

2.5 Data Analysis and Visualization Tools for Deriving Meaningful Insights from Preclinical Data (Park et al. 2019; Tian and Greenberg 2019; Tomczak and Czerwińska 2018; Sutherland and Rahman 2017; Campillos and Kuhn 2019; Cheng et al. 2019; Wang et al. 2018)

Digitization empowers researchers to employ advanced computational methods, machine learning algorithms, statistical tools, and data visualization techniques for comprehensive analysis and interpretation of preclinical research data. These capabilities enable researchers to uncover valuable insights, identify patterns, discover relationships, and effectively communicate their findings, ultimately advancing scientific knowledge and contributing to developing novel therapeutic approaches.

Digitization enables the application of computational methods and machine learning algorithms to analyze preclinical research data. These advanced techniques can handle large datasets, identify complex patterns, and discover hidden relationships that may not be apparent through traditional data analysis approaches. Moreover, computational methods, such as data mining, clustering, classification, and predictive modeling, allow scientists to uncover valuable insights, make data-driven decisions, and generate hypotheses for further investigation.

Statistical tools are crucial in preclinical research as they enable researchers to analyze data, test hypotheses, evaluate treatment efficacy, and make evidence-based decisions, ensuring robust and reliable scientific findings. These tools help quantify uncertainty, assess significance, and establish the credibility and integrity of research outcomes. Digitization provides access to a wide range of statistical tools and software that facilitate robust analysis of preclinical research data. Having such digital tools, researchers can apply statistical methods, including hypothesis testing, regression analysis, survival analysis, and multivariate analysis, to assess the significance of findings and draw valid conclusions. These tools enable researchers to evaluate the above mentioned steps involved in treatment efficacy, measure variability, determine statistical significance, and assess the impact of various factors on research outcomes.

With digitization, researchers can analyze preclinical research data to identify patterns and discover relationships. By examining data across different variables, time points, or experimental conditions, scientists can uncover correlations, dependencies, and trends that may inform their understanding of disease mechanisms, treatment responses, or biological interactions. This information can guide further experimentation, target selection, or refinement of research hypotheses. By exploring data across different variables, time points, or experimental conditions, researchers can detect recurring trends, associations, and dependencies that may be critical for understanding disease processes and treatment outcomes. These patterns can provide important clues for further investigation and guide the development of targeted interventions.

Moreover, digitization facilitates the exploration of relationships within preclinical research data. By conducting correlation analyses, regression modeling, or other statistical techniques, researchers can uncover connections between different variables or factors. For example, they may identify a correlation between a specific biomarker level and treatment response or observe how certain experimental conditions influence the expression of genes of interest. These relationships help researchers understand the underlying biology and can direct future research efforts.

What is important, the research hypotheses based on the analysis of preclinical data can be refined thanks to digitization. By gaining insights into patterns and relationships, researchers can refine their understanding of disease mechanisms or treatment targets. For example, if data analysis reveals a consistent association between a particular molecular pathway and disease progression, researchers may refine their hypothesis to focus on that pathway for further investigation. This iterative process of hypothesis refinement contributes to the advancement of preclinical research.

As target selection is a critical step in preclinical research and drug development, digitization plays a vital role in this process, supporting the identification and selection of potential therapeutic targets. By analyzing preclinical research data, researchers can identify molecules, pathways, or biological targets that are strongly associated with disease processes or treatment responses. This information helps guide the selection of targets for further investigation or drug development, enhancing the efficiency and effectiveness of preclinical research efforts.

Digitization allows researchers to analyze preclinical research data to identify potential therapeutic targets. By examining various types of data, such as genomic, proteomic, or phenotypic data, researchers can uncover molecules, pathways, or biological targets that are strongly associated with disease processes or treatment responses. For example, through transcriptomic analysis, researchers may identify genes that are differentially expressed in disease states compared to healthy conditions. These differentially expressed genes can serve as potential targets for further investigation.

Digitization enables the integration of diverse datasets from various sources, including public databases, in-house experiments, and literature. By combining and analyzing multiple datasets, researchers can gain a comprehensive view of the

molecular landscape associated with a particular disease or biological process. This integration allows for the identification of potential targets that exhibit consistent patterns across different datasets, increasing confidence in their selection.

Computational methods and machine learning algorithms are leveraged by digitization to analyze complex datasets and identify potential therapeutic targets. These techniques enable the exploration of large-scale data, uncovering hidden patterns and associations that may not be apparent through traditional analysis methods. For example, machine learning algorithms can identify molecular features or signatures that are predictive of disease progression or treatment response, guiding the selection of targets with high potential for therapeutic intervention.

Prioritization of potential targets is strongly supported by digitization based on various criteria, such as target druggability, relevance to disease mechanisms, and feasibility of intervention. By integrating data from preclinical studies, clinical trials, and biomedical literature, researchers can assess the evidence supporting the potential therapeutic value of a target. Additionally, digitization facilitates the validation of potential targets through *in vitro* and *in vivo* experiments, further confirming their suitability for drug development.

Digitization allows for the analysis of complex target networks and interactions within biological systems. By examining the relationships between potential targets and their associated pathways or networks, researchers can gain insights into the broader biological context and potential cross-talk between different targets. This understanding is crucial for selecting targets that can modulate key disease-related processes or pathways.

By leveraging digitization, researchers can streamline the process of target selection in preclinical research. The analysis of diverse datasets, integration of multiple data sources, and application of computational methods enable the identification and prioritization of potential therapeutic targets with higher precision and efficiency, ultimately enhancing the success rate of drug discovery and development.

3 Enhancing Data Management in Preclinical Research Through Digitization

Efficient data management is crucial in preclinical research to ensure accurate, secure, and accessible data throughout the research process. Digitization offers numerous advantages in data management, streamlining workflows, and improving overall research efficiency. This section focuses on the benefits and strategies of enhancing data management through digitization in preclinical research.

3.1 Importance of Robust Data Management in Preclinical Research

Robust data management in preclinical research is crucial for maintaining data integrity, ensuring reproducibility, complying with regulatory standards, protecting data security, and enabling effective data analysis and decision-making. By implementing rigorous data management practices, researchers can maximize the value of their research data, accelerate scientific discoveries, and contribute to the advancement of knowledge in the field of preclinical research. Preclinical research generates vast amounts of data, ranging from experimental results to imaging data, genomic data, and clinical observations. By implementing standardized data collection protocols, proper documentation, and quality control measures, robust data management minimizes errors, enhances data accuracy, and ensures the reliability of research findings. Moreover, robust data management promotes research reproducibility and transparency. Well-managed and properly documented data allows other researchers to reproduce experiments, validate findings, and build upon existing knowledge. Transparent data management practices, such as data sharing and open science initiatives, facilitate collaboration, promote cross-validation, and enable the scientific community to verify research outcomes.

It is important to remember that preclinical research involves sensitive data, including patient information, animal model data, and experimental results. Robust data management ensures compliance with regulatory standards and ethical guidelines, such as the HIPAA and the General Data Protection Regulation (GDPR). Adhering to these standards protects the privacy and confidentiality of research subjects and prevents potential legal and ethical implications. Effective data management addresses data security concerns and ensures the protection of preclinical research data from unauthorized access, loss, or corruption. Implementing secure data storage, backup systems, and access controls safeguards data integrity.

Preclinical research generates valuable data that may have long-term significance. Robust data management includes appropriate data archiving, version control, and data retention policies. Proper documentation and retention of research data ensure its availability for future reference, meta-analyses, and potential re-evaluation. Preserving research data over time enhances the integrity and legacy of preclinical research. Effective data management facilitates data analysis and data-driven decision-making in preclinical research. Well-organized and accessible data allows researchers to perform comprehensive analysis, apply statistical methods, and derive meaningful insights. This supports evidence-based decision-making, hypothesis generation, and the identification of potential therapeutic targets or lead compounds.

3.2 Role of Digitization in Improving Data Accuracy, Integrity, and Accessibility

Digitization plays a vital role in improving data accuracy, integrity, and accessibility in preclinical research. It enables standardized data collection, enhances data tracking and version control, promotes data sharing and collaboration, and ensures the security and confidentiality of research data. By leveraging digital tools and platforms, researchers can have greater confidence in the quality and reliability of their data.

Digitization minimizes errors and improves data accuracy through automated data capture and standardized data entry. Digital tools also often include data validation checks and built-in quality control measures to ensure the accuracy and completeness of data.

What is particularly important in preclinical studies, digitization ensures data integrity by providing mechanisms for data tracking, version control, and audit trails. With digital platforms and systems, researchers can easily track and document any changes made to the data, maintaining a transparent record of data modifications. This enhances data integrity, allowing researchers to trace the evolution of the data and verify the accuracy of the results.

Moreover, digitization promotes data standardization and adherence to data governance principles. Through digital platforms and data management systems, researchers can define standardized data collection protocols, data dictionaries, and metadata standards. This ensures consistency and uniformity in data collection across studies, making it easier to compare and integrate data from different sources or experiments.

The accessibility of preclinical research data is promoted by digitization through enabling centralized and secure storage, retrieval, and sharing. Cloud-based storage solutions provide researchers with the ability to access data from anywhere, at any time, facilitating collaboration among geographically dispersed teams.

Robust security measures to protect the confidentiality and privacy of preclinical research data are crucial to secure data storage and it is possible through encryption, user access controls, and authentication mechanisms to safeguard data from unauthorized access or breaches.

Reliable data backup and disaster recovery mechanisms are possible thanks to digital platforms and cloud-based storage solutions that automatically backup data, preventing data loss due to hardware failures or unforeseen events. This ensures data continuity and reduces the risk of losing valuable research data.

3.3 Integration of Diverse Data Sources and Data Standardization for Enhanced Collaboration

Digitization promotes data standardization, facilitating enhanced collaboration in preclinical research. By integrating datasets from various sources, researchers can gain a comprehensive understanding of complex biological processes, foster interdisciplinary collaborations, and leverage the expertise of multiple research teams. The integration and standardization of data enhance reproducibility, support cross-domain insights, and enable meta-analyses, ultimately advancing preclinical research and improving the translation of research findings into clinical applications.

Digitization enables the integration of data from various sources, such as genomics, proteomics, imaging, clinical observations, and electronic health records. By consolidating these diverse datasets, researchers gain a comprehensive view of the research landscape, uncovering potential correlations and insights that may not be apparent when analyzing individual datasets in isolation. Integration of diverse data sources promotes a multidimensional understanding of disease mechanisms, treatment responses, and therapeutic targets.

Collaborative Data Analysis is facilitated by digitization by providing a unified platform for researchers to access and analyze integrated datasets. Digital tools and platforms support data sharing, enabling multiple researchers to work simultaneously on shared datasets. This collaborative approach promotes cross-disciplinary collaborations, fosters knowledge exchange, and leverages the expertise of different research teams, enhancing the quality and depth of data analysis and interpretation.

Data standardization and interoperability, promoted by digitization, enable easier integration and analysis of datasets from different research groups or institutions. Standardized data formats, metadata, and data dictionaries ensure consistency in data collection, annotation, and representation across studies. This standardization facilitates data sharing, meta-analyses, and comparison of results, allowing researchers to build upon existing knowledge and accelerate scientific discoveries.

In turn, integrated and standardized data promote research reproducibility. By sharing well-documented and harmonized datasets, researchers can replicate experiments, validate findings, and verify the robustness of research outcomes. The ability to access and analyze integrated datasets enhances transparency, encourages open science practices, and supports the reproducibility of preclinical research studies, reinforcing the reliability and credibility of research findings.

Integration of diverse data sources enables researchers to gain cross-domain insights, fostering interdisciplinary collaborations and expanding the understanding of complex biological processes. For example, combining genomic and imaging data may reveal correlations between genetic variations and phenotypic characteristics. Integrating clinical data with preclinical research findings can help bridge the translational gap, facilitating the identification of potential therapeutic targets and informing clinical trial design.

What is important, digitization facilitates data harmonization for meta-analysis, enabling researchers to pool and analyze large-scale datasets from multiple studies. Meta-analyses conducted on integrated datasets, provide valuable insights into population-level trends, treatment responses, and predictive factors in preclinical research.

3.4 Real-Time Data Availability and Monitoring for Timely Decision-Making

Real-time data availability and monitoring are essential components of digitization in preclinical research, enabling researchers to make quicker decisions. Instant access to preclinical research data eliminates delays associated with manual data collection and processing. Researchers can enter data directly into electronic systems, making it immediately available for analysis and monitoring. This real-time access

to data reduces the time lag between data collection and decision-making, enabling researchers to respond promptly to emerging trends, unexpected observations, or critical events.

What is important, digital platforms and data management systems enable continuous monitoring of preclinical research data. Researchers can set up automated alerts and notifications based on predefined criteria, allowing them to stay informed about key metrics, data trends, or experimental milestones. Continuous data monitoring facilitates proactive decision-making by identifying potential issues or deviations in real time, allowing researchers to intervene promptly and adjust experimental protocols, treatment strategies, or study designs as needed.

Moreover, real-time data availability facilitates the early identification of trends, patterns, and emerging insights in preclinical research. By analyzing data as it becomes available, researchers can detect subtle changes or correlations that may indicate the efficacy of a treatment, the progression of a disease, or the need for adjustments in experimental conditions. Early identification of such trends enables researchers to make timely decisions regarding the continuation, modification, or termination of a study, potentially saving time, resources, and effort.

Rapid response to safety and efficacy signals in preclinical research has been made possible thanks to the real-time data availability and monitoring. Adverse events or unexpected treatment responses can be promptly detected, allowing researchers to take immediate actions, such as adjusting dosages, modifying experimental protocols, or initiating additional safety assessments. Timely decision-making based on real-time data helps ensure the welfare of research subjects and improves the overall quality and validity of preclinical research outcomes.

Digitization enables iterative experimentation and optimization of preclinical research. Real-time data availability allows researchers to analyze preliminary results and make informed decisions regarding the next steps in the research process. This iterative approach facilitates the fine-tuning of experimental designs, treatment regimens, or data collection methods based on ongoing data analysis and evaluation. By continuously optimizing research parameters, researchers can enhance the efficiency, accuracy, and success rate of preclinical studies.

4 Digitization and Experimental Design in Preclinical Research

Through leveraging digital tools and technologies, digitization plays a crucial role in improving experimental design in preclinical research. It enables virtual screening, which involves using computational methods to identify potential therapeutic targets and screen large libraries of compounds. Through virtual screening, researchers can prioritize and select target molecules or pathways for further investigation, saving time and resources compared to traditional screening methods.

Moreover, digitization facilitates *in silico* modeling and simulation, using computer-based algorithms and simulations to predict and evaluate the properties and behaviors of molecules. These methods can be applied to optimize drug candidates, assess pharmacokinetics, simulate protein-drug interactions, and predict the potential efficacy or toxicity of compounds. *In silico* modeling allows researchers to make informed decisions regarding experimental designs and prioritize compounds for further preclinical evaluation.

The data-driven experimental design can be improved by leveraging existing data to inform future research directions. By analyzing preclinical research data, researchers can identify patterns, correlations, and trends that can guide the design of subsequent experiments. This data-driven approach helps optimize experimental parameters, improve the efficiency of studies, and increase the likelihood of obtaining meaningful results.

Importantly, digitization supports high-throughput screening (HTS) and automation, allowing researchers to rapidly test a large num-

ber of compounds or samples, even utilizing robotic platforms and digital interfaces in a high-throughput manner. This automation improves efficiency, minimizes human error, and enables the screening of vast compound libraries or biological samples.

Digital platforms and LIMS streamline experimental workflow management in preclinical research. These systems provide centralized repositories for protocols, sample tracking, and data management. Researchers can efficiently track experimental progress, monitor resource utilization, and ensure adherence to standardized protocols, promoting consistency and reproducibility in experimental design. The optimization of sample size and statistical power in preclinical studies can be made through computational methods and statistical tools, when researchers can perform power calculations and sample size estimations based on desired effect sizes, variability, and statistical significance thresholds. This optimization ensures that experiments are adequately powered to detect meaningful effects and reduces the need for unnecessary animal use or resource allocation (Hagan et al. 2019; Rodgers and Levin 2017; Ruusuvuori et al. 2018; Tanoli et al. 2019).

4.1 Utilizing Digital Tools for Experimental Design and Protocol Optimization (Gao et al. 2020; Morrissey et al. 2016; Rodgers and Levin 2017; Tung and O'Brien 2017; Williamson et al. 2009)

Utilizing digital tools for experimental design and protocol optimization in preclinical research offers several advantages, including improved efficiency, increased accuracy, and data-driven decision-making. Digital tools enable virtual screening and molecular modeling techniques to predict the interactions between molecules and their targets. Researchers can use computational methods to assess the binding affinity, selectivity, and potential off-target effects of compounds. This information aids in the design of experiments and the selection of promising compounds for further evaluation, reducing the time and cost associated with traditional screening methods.

Thanks to digitization, a wide range of statistical analysis software is available to perform power calculations, sample size estimations, and statistical hypothesis testing. By leveraging these tools, researchers can optimize their experimental designs by ensuring sufficient statistical power to detect meaningful effects and reduce the risk of false positives or negatives.

Digital tools, such as Design of Experiments (DOE) software packages, assist researchers in designing efficient and robust experiments. These tools help determine the optimal combination of factors, levels, and interactions to achieve the desired experimental objectives while minimizing variability and resource utilization. By systematically exploring the experimental space, researchers can identify key factors influencing outcomes and optimize experimental conditions.

Data visualization and analysis capabilities enable researchers to explore and interpret complex datasets. Visualization tools allow for the graphical representation of experimental results, facilitating the identification of trends, patterns, and outliers. Data analysis software offers various statistical and computational algorithms to analyze experimental data, extract insights, and derive quantitative measures of effect size or significance.

Moreover, LIMS platforms facilitate experimental design and protocol optimization by providing centralized management of protocols, samples, and data. As described above, researchers can document and share experimental protocols, track sample information, and record experimental outcomes within the LIMS. This centralized system enhances collaboration, standardization, and reproducibility, ensuring consistency in experimental procedures across research teams.

Digital tools enable iterative design and feedback loops, allowing researchers to refine experimental protocols based on initial results or pilot studies. By continuously analyzing and integrat-

ing data generated during the course of the research, researchers can adapt their experimental designs to optimize parameters, adjust treatment regimens, or modify sample selection criteria. This iterative approach increases the efficiency and success rate of preclinical experiments.

4.2 Digital Platforms for Sample Tracking, Experimental Workflows, and Protocol Management (Danziger et al. 2018; Li et al. 2019; Ratner 2010; Tarca et al. 2016; Zhang et al. 2019)

Digital platforms enable researchers to track samples throughout the preclinical research process. These platforms provide functionalities for assigning unique identifiers to samples, recording sample information (such as collection date, storage conditions, and experimental group), and tracking sample movement and usage. With barcode or Radio Frequency Identification (RFID) technologies, researchers can easily scan and update sample information, ensuring accurate sample tracking and minimizing human errors. Digital platforms also support inventory management, allowing researchers to monitor stock levels, expiration dates, and reordering of supplies.

Moreover, digital platforms facilitate the management of experimental workflows, ensuring efficient and standardized processes. Researchers can create digital protocols that outline the step-by-step procedures, equipment requirements, and data collection points for each experiment. These protocols can be accessed, followed, and documented digitally, providing consistency and reproducibility across experiments and research teams. Digital platforms also allow for the integration of data capture instruments, such as automated analyzers or imaging systems, streamlining data acquisition and minimizing manual data entry.

Thanks to digital platforms, it is possible to maintain centralized repositories for storing, sharing, and version-controlling experimental protocols. Researchers can access up-to-date protocols, ensuring consistent implementation of procedures across studies and reducing the risk of protocol deviations. These platforms support collaboration by allowing multiple researchers to work on protocols simultaneously, enabling real-time updates and annotations. Digital protocol management ensures accessibility, traceability, and proper documentation, enhancing transparency and facilitating the replication of experiments.

The integration of data generated from various sources and instruments is supported by digital platforms. Researchers can import and link data files, including images, raw data, and metadata, to specific experiments or samples within the platform. This integration simplifies data retrieval, enables cross-referencing, and facilitates downstream analysis. Some digital platforms also offer built-in data analysis tools or integration capabilities with third-party analysis software, allowing researchers to perform data processing, visualization, and statistical analysis within the platform itself. Examples of digital platforms for sample tracking, experimental workflow management, and protocol management include Electronic Laboratory Notebooks (ELNs), LIMS, and cloud-based research management platforms.

4.3 Use of Virtual Screening and *in Silico* Methods for Target Identification and Compound Selection (Ertl et al. 2000; Friesner et al. 2004; Schneider et al. 1999; Shoichet 2004; Wang et al. 2005; Willett et al. 1998)

Virtual screening and *in silico* methods have become valuable tools in preclinical research for target identification and compound selection. These computational approaches offer efficient and cost-effective ways to prioritize and evaluate potential drug candidates. Virtual screening involves the computational screening of large chemical databases or libraries to identify molecules that have a high probability of binding to a specific target of interest. This process typically

utilizes molecular docking algorithms to predict the binding affinity and pose of small molecules against the target's three-dimensional structure. By virtually screening millions of compounds, researchers can prioritize a subset of molecules for further experimental evaluation.

Both ligand-based and structure-based approaches are employed within virtual screening methods. Ligand-based methods involve comparing the chemical features and properties of known active compounds against the target to identify structurally similar molecules. Structure-based methods rely on the target's three-dimensional structure to predict the binding affinity and interactions of small molecules. These approaches provide complementary strategies for target identification and compound selection.

Pharmacophore modeling is a technique used in virtual screening to identify the essential structural features required for a molecule to interact with a target. By analyzing the active compounds and their common chemical features, a pharmacophore model is generated, representing the key interactions necessary for activity. This model can then be used to screen compound libraries and identify molecules that match the pharmacophore, aiding in target identification and compound selection.

Virtual screening and *in silico* methods also include Quantitative Structure-Activity Relationship (QSAR) Analysis involves the development of computational models that correlate the chemical structures of compounds with their biological activities. By training QSAR models on known activity data, researchers can predict the activity of new compounds against a target. These predictions guide compound selection by identifying molecules with a higher likelihood of desired activity, reducing the need for extensive experimental testing.

To evaluate the pharmacokinetic and toxicological properties of compounds, the Absorption, distribution, metabolism, excretion, and toxicity (ADMET) prediction models are used. By using computational algorithms, researchers can predict parameters such as solubility, permeability, metabolic stability, and potential toxicities. ADMET prediction aids in compound selection by identifying candidates with favorable drug-like properties and reducing the risk of failures in later stages of drug development.

In silico methods can also be employed to identify potential new uses for existing drugs. By analyzing databases of known drugs and their interactions, researchers can identify off-target effects and explore new therapeutic indications. This approach of drug repurposing offers a cost-effective strategy for identifying candidates with established safety profiles and known pharmacokinetics.

Virtual screening and in silico methods significantly accelerate the early stages of drug discovery by reducing the number of compounds for experimental testing, optimizing the selection of lead candidates, and providing insights into the structure-activity relationships. However, it is important to note that these computational approaches are hypothesis-generating tools and still require experimental validation.

4.4 Application of Machine Learning Algorithms for Predictive Modeling and Simulation Studies (Cherkasov et al. 2014; Cramer et al. 2020; Ekins et al. 2007; Sliwoski et al. 2014; Wallach et al. 2015)

Machine learning algorithms are increasingly being applied in preclinical research for predictive modeling and simulation studies. These algorithms have the ability to analyze complex datasets, identify patterns, and make predictions or classifications. Predictive models that estimate various outcomes in preclinical research can be built with the use of machine learning algorithms. For example, these algorithms can predict drug efficacy, toxicity, pharmacokinetic properties, or biological activity based on input features such as chemical descriptors, genomic data, or experimental results. By training the algorithms on known data, they can learn patterns and relationships to make accurate predictions on new or unseen data.

Machine learning algorithms play a significant role in the Structure-Activity Relationship

(SAR) Analysis, which is an essential part of drug discovery. These algorithms can learn from chemical structures and their corresponding activities to identify key features associated with a compound's activity against a particular target. SAR models built using machine learning can aid in compound selection, design, and optimization by predicting the activity of new compounds based on their structural similarity to known active compounds.

The process of toxicity prediction can be also supported by machine learning algorithms. By training on data that contains information about chemical structures and corresponding toxicological outcomes, these algorithms can learn to classify compounds into toxic and non-toxic categories. Toxicity prediction models can help prioritize compounds for further experimental evaluation, thus reducing the cost and time associated with toxicity testing. Moreover, machine learning algorithms can be employed in predicting potential interactions between drugs. By analyzing the chemical structures, pharmacokinetic properties, and known drug-drug interaction data, these algorithms can identify pairs of drugs that are likely to interact. This information aids in predicting potential adverse drug reactions and guiding the selection of drug combinations for further investigation.

Simulation studies also open novel opportunities to use machine learning algorithms for the prediction of the behavior of complex biological systems. The assistance of machine learning algorithms in integrating and analyzing diverse datasets from multiple sources is becoming recognized. These algorithms can automatically extract relevant features from large datasets and identify the most informative variables for predictive modeling. Feature selection techniques enable researchers to focus on the most influential factors and reduce the dimensionality of data, thereby improving the efficiency and accuracy of predictive models.

It is important to note that the successful application of machine learning algorithms in preclinical research requires high-quality and well-curated datasets, appropriate feature engineering, validation, and interpretation of results.

5 Implications of Digitization on Preclinical Research Outcomes

The implications of digitization on preclinical research outcomes are significant and wide-ranging. It is widely recognized that digitalization streamlines various aspects of preclinical research, including data collection, analysis, and collaboration. Automated data capture, electronic data storage, and real-time data availability reduce manual effort, minimize errors, and improve overall efficiency. This leads to faster experimentation, data processing, and decision-making, ultimately accelerating the pace of preclinical research (Arrowsmith 2013; Casadevall and Fang 2016; Leek and Peng 2015; Lynch 2008; Taylor et al. 2015).

Digitization is an important milestone in improving data accuracy, integrity, and traceability. Electronic data capture systems and standardized data entry protocols ensure consistent and error-free data recording. Digital platforms enable data validation, audit trails, and version control, enhancing data quality and reproducibility. This ensures that research outcomes are based on reliable and trustworthy data. Advanced data analysis techniques, including machine learning, statistical modeling, and data visualization have been made possible thanks to digitalization. By harnessing these computational methods, researchers can derive deeper insights, uncover patterns, and make data-driven decisions. Advanced data analysis facilitates the identification of novel relationships, biomarkers, or therapeutic targets, enhancing the overall outcomes of preclinical research.

As previously stated, digital platforms enable seamless integration of data from diverse sources, such as genomics, proteomics, and imaging. This integration facilitates multidisciplinary collaboration, as researchers can easily share, access, and analyze integrated datasets. Collaborative data analysis promotes cross-validation, knowledge exchange, and interdisciplinary discoveries, leading to more comprehensive and impactful research outcomes. Moreover, digitization promotes reproducibility and transparency in

preclinical research. Electronic protocols, SOPs, and version-controlled documentation ensure consistent experimental procedures and facilitate protocol sharing. Digital platforms also allow for the sharing of raw data, analysis code, and research findings, promoting transparency and reproducibility of research outcomes.

As cost reduction and resource optimization play an important role in sustainability of preclinical research, digitization through electronic data storage reduces the need for physical storage space and decreases administrative overhead. Computational modeling and simulation techniques can reduce the number of experiments required, saving time, resources, and animal models. Digitalization also enables virtual collaborations and remote access to data, reducing travel and infrastructure costs.

6 Conclusion

The introduction of digital technologies has influenced the entire continuum of preclinical research activities. This chapter describes the many different aspects of preclinical research and how it is affected by digitization. These include the digital tools and technologies in preclinical research, the ways in which digitization enhances data management in preclinical research, as well as experimental design in preclinical research. These aspects are universal and applicable both in high-income countries and low-and middle-income countries, though the relevant rate of implementation may differ, depending on the local context of implementation.

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Digitization of Clinical Pathways in Low- and Middle-Income Countries

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Abstract

The digital revolution has transformed many industries, and healthcare is no exception. In low- and middle-income countries (LMICs), digitization of clinical processes can improve healthcare delivery, patient outcomes, and healthcare system efficiencies. This chapter examines the current state of digitization of clinical pathways in LMICs and highlights the challenges and opportunities in accordance with its implementation. It also examines the impact of digital technologies on various aspects of clinical pathways, such as diagnosis, treatment, monitoring, and follow-up. The potential benefits and risks of digitization are discussed, including data security, privacy, and fairness issues. Based on a review of the relevant literature, the chapter aims to provide an insight into the potential of digitization to revolutionize healthcare in LMICs.

Keywords

Digital healthcare · Digitisation · Low-and middle-income countries (LMIC) · Clinical pathway · Follow-up · Remote monitoring

1 Introduction

In recent years, the digital revolution has transformed how healthcare is delivered, managed, and accessed worldwide. While high-income countries have digitized healthcare, low- and middle-income countries (LMICs) face unique challenges and opportunities in digitizing clinical pathways. Despite resource constraints, LMICs recognize the potential of digitization to improve clinical workflows, healthcare delivery and fill existing gaps in patient care. This chapter examines the digitization of clinical pathways in LMICs and highlights the opportunities, challenges, and potential impact on health outcomes.

LMICs are rapidly adopting digital technologies to address various socioeconomic challenges. Digitization offers many opportunities to help these countries improve their healthcare, education, governance, and economic develop-

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ment. The health infrastructure and lack of resources in LMICs pose significant challenges to providing adequate health services to their populations. The World Health Organization (WHO) and the United Nations (UN) have highlighted the key challenges related to the limited health infrastructure, shortage of health workers, and insufficient access to quality health care in these regions.

LMICs often face significant limitations in their healthcare infrastructure, which include a lack of modern healthcare facilities, limited availability of medical equipment, and inadequate healthcare management systems. These shortcomings can hamper the delivery of timely and effective health services to vulnerable populations. In addition, the situation is exacerbated by the lack of medical professionals. Many LMICs struggle to attract and retain qualified health workers, including doctors, nurses, and other health workers. This shortage of skilled professionals results in increased workloads and lower quality of care, limiting the ability to meet healthcare needs. The WHO (2018a, b) highlighted the problem of limited health infrastructure and shortage of health workers in LMICs. These problems prevent these countries from building and maintaining sound health systems and hamper their ability to provide adequate health services to their citizens.

Inadequate access to quality medical services is one of the main problems. In LMICs, a significant portion of the population faces barriers to accessing quality healthcare services. Financial constraints, geographical remoteness, and inadequate transportation infrastructure are the main factors limiting these regions' healthcare access. As a result, many people lack access to timely healthcare, and leading organizations and various stakeholders are investing in developing healthcare infrastructure, strengthening the healthcare workforce, and implementing policies that ensure equal access to quality healthcare services for all LMIC citizens.

2 Gaps in the Clinical Pathways also Affect the Digitization Process

Health systems in LMICs face numerous challenges in providing effective and timely care to their populations. Two notable gaps in clinical care pathways that significantly impact service delivery in LMICs are fragmented care systems, poor coordination, inefficient referral processes, lack of coordination and late care. In several LMICs, healthcare systems are fragmented, involving many public and private healthcare providers with limited coordination and communication between them. This fragmentation often leads to duplication of effort, inefficient resource allocation, and fragmented patient care. As a result, patients may have difficulty navigating a complex healthcare system, leading to suboptimal health outcomes and increased healthcare costs (Baker et al. 2018a, b). A lack of coordination among healthcare providers in LMICs can further exacerbate problems in chronic disease management and continuity of care. Patients may find it difficult to access different levels of care, such as primary, secondary, and tertiary care, leading to delays in diagnosis and treatment. In addition, poor communication between first responders and professionals can disrupt the smooth care flow.

Inefficient referral processes and delayed assistance: The referral process in many LMICs can be slow and inefficient, delaying patients' access to specialized care. Primary care providers often lack clear guidelines for appropriate referrals, and referral pathways can be confusing and bureaucratic. As a result, patients can experience significant waits before seeing a specialist or receiving primary diagnostic testing and treatment (Bazemore et al. 2018a, b). Delays in the referral process can lead to disease progression, worsening of symptoms, and higher In addition, in rural or remote areas where access to specialized health services is limited, late referral can have serious consequences for patients and make

it challenging to treat complex diseases adequately. LMICs should focus on improving healthcare coordination and implementing effective referral processes to fill these gaps in clinical care pathways. This can be achieved by developing integrated healthcare systems that facilitate collaboration between different healthcare providers, including the public and private sectors. Additionally, investments in health infrastructure, staff training, and public health initiatives can further strengthen health systems in LMICs, improve patient outcomes, and ensure equitable access to quality health services.

Digital Healthcare Solutions. The uptake of digital health solutions in LMICs offers enormous potential to improve the accessibility, quality, and efficiency of healthcare. Telemedicine, mHealth applications, and electronic health records can help to close the gap between patients and healthcare providers, especially in remote areas. In addition, artificial intelligence (AI)-based diagnosis and data analysis can aid disease surveillance and personalized treatment, improving health outcomes (Smith and Johnson 2020).

e-Government Services: Digitalization has the potential to revolutionize health public services in LMICs through e-Government initiatives. Online portals, digital payment systems, and e-voting can simplify administrative processes and increase transparency and accountability in governance. This can increase citizen engagement and participation, ultimately contributing to inclusive development (Rahman and Khan 2021).

Digital education and e-learning. The introduction of digital technologies in education can provide access to quality learning resources and promote skills development in LMICs. E-learning platforms, open educational resources (OER), and digital classrooms can empower learners and teachers by removing barriers to education (Li and Patel 2019).

Financial Inclusion and Digital Payments. Integrating digital payment systems can significantly improve financial inclusion in LMICs. Mobile banking, digital wallets, and fintech solutions can provide previously unbanked populations access to formal financial services, contributing to economic growth and poverty reduction (Gupta and Singh 2022).

The possibilities of digitization in LMICs are large and diverse. By harnessing the power of digital technologies, these countries can overcome traditional barriers to development and accelerate progress at different healthcare system levels. However, challenges such as digital infrastructure, digital literacy, and data protection need to be addressed to realize digitalization's full potential in LMICs.

*Mobile health (mHealth) technolo*gies also play an essential role in digitizing clinical workflows in LMICs. In recent years, mobile phone usage has reached unprecedented levels in LMICs, owing to the increasing availability of affordable smartphones and reliable mobile networks. This surge in cell phone penetration presents a unique opportunity to apply mHealth technologies in clinical practice to address the health challenges these resource-constrained regions face. Thus far, potential benefits and applications of mHealth technologies in LMICs focus on remote consultations and patient follow-up. The GSM Association (commonly referred to as 'the GSMA' or Global System for Mobile Communications, originally Groupe Spécial Mobile) is a non-profit industry association representing the interests of mobile network operators worldwide, and has reported consistently on the potential of mHealth technologies, as for example in the GSMA Comprehensive Report on Pervasive Mobile Phone Penetration and Use in Low- and Middle-Income Countries (2021). In addition, Michael et al. (2019) provide valuable information on the use of mHealth applications for remote consultation and patient monitoring. The study shows how mHealth can help physicians bridge geographic distances and reach underserved populations. Additionally, mHealth apps offer the potential to increase public and patient engagement and adherence to treatment plans through timely reminders and educational resources. These technologies could facilitate

telehealth services by allowing healthcare professionals to remotely counsel and monitor patients, especially in hard-to-reach areas with limited access to medical facilities. Introducing mHealth technologies into clinical practice can revolutionize healthcare in LMICs. However, challenges such as digital infrastructure limitations and data security issues need to be addressed to fully realize the potential of mobile medical applications to improve health outcomes and facilitate the access to quality healthcare in LMICs.

*Telemedicine and teleconsultatio*n services have become transformative clinical solutions for LMICs, offering innovative ways to break down geographic barriers and expand access to healthcare. This section examines the use of telemedicine and successful teleconsultation initiatives in LMICs, drawing on crucial references, namely "Expanding Telemedicine to Break Geographic Barriers" (Sood et al. 2018) and "Successful Teleconsultation Initiatives in LMICs" (Labrique et al. 2017). Geographical barriers have long hampered the equitable delivery of health care in LMICs, often resulting in remote and underserved populations not having adequate access to health services. Sood et al. (2018) emphasize the potential of telemedicine to fill this gap. Using digital communication technologies, telemedicine can bridge distances and bring virtual medical consultations, diagnosis, and treatment to patients regardless of their geographic location. Expanding telemedicine services has shown promising results in reducing healthcare inequalities, ensuring timely medical intervention, and improving health outcomes in LMICs.

In addition, Labrique et al. (2017) highlight successful teleconsultation initiatives that have significantly contributed to healthcare delivery in LMICs. These initiatives used mobile technology, internet connectivity, and telecommunications infrastructure to connect patients in remote areas with skilled health workers in urban centers or specialized health facilities. Through real-time audio and video consultations, teleconsultation services have simplified remote diagnosis, medical consultations, and treatment plans, optimizing resource allocation and improving patient management in resource-constrained environments.

The convergence of telemedicine and teleconsultation services has paved the way for cost-effective and efficient healthcare solutions in LMICs. These technologies have strengthened primary healthcare systems and facilitated collaboration between healthcare providers, allowing them to share experiences and knowledge over long distances. Despite problems with limited internet connectivity and technological infrastructure in some regions, the introduction of telemedicine and teleconsultation services has shown promising potential for increasing access to healthcare, reducing healthcare costs, and improving the quality of care in LMICs.

Thus, such services have become tools to transform clinical pathways in LMICs, remove geographic barriers, and expand access to healthcare. The success of teleconsultation initiatives in low- and middle-income countries highlights the potential of such technological interventions to revolutionize healthcare delivery in resource-constrained settings and contribute to more equitable and efficient healthcare systems worldwide. As technology advances, more research and investment in telemedicine are needed to maximize its impact on health outcomes in LMICs and beyond.

Electronic health records (EHRs) have become a revolutionary tool in healthcare and offer significant potential to improve data availability and quality. In LMICs, implementing EHR systems in clinical practice has gained attention as a means to improve healthcare delivery and patient outcomes. The integration of EHR into clinical pathways in LMICs can be seen two landmark studies: Implementation of EHR Systems to Improve Data Availability and Quality (Rajbhandari et al. 2020) and Successful Implementation of E HR in Resource-Constrained Environments (Fraser et al. 2021).

Rajbhandari et al. (2020) showed that introducing EHR systems in LMICs can significantly improve data availability and quality. By digitizing medical records and streamlining data management, electronic health records give healthcare

professionals real-time access to critical patient information. This accessibility facilitates timely decision-making and enables efficient and personalized patient care. In addition, electronic health records facilitate data standardization, improving data quality, increasing research capacity, and supporting evidence-based practice. Fraser et al. (2021) provided valuable information on the successful implementation of EHR in resource-constrained environments and highlighted the feasibility and benefits of implementing EHR systems in LMICs. The study underscores the importance of addressing issues such as limited infrastructure, internet connectivity, and lack of human resources. Successful implementation of EHR in LMICs requires tailored solutions that include scalable and cost-effective technologies with a focus on ease of use and training of healthcare professionals.

However, implementing digital clinical pathways in LMICs is challenging. These issues include funding constraints, interoperability, and privacy concerns. A lack of financial resources can impede the large-scale implementation of EHR, thereby impeding the widespread adoption of digital clinical pathways. Interoperability between different EHR systems and healthcare organizations is critical for effective data sharing and care delivery, but it can be challenging to achieve in all healthcare organizations. In addition, ensuring privacy and data security remains a priority when moving to digital systems to maintain patient trust and comply with regulatory requirements.

EHRs offer significant opportunities to improve healthcare in LMICs by improving data availability, quality, and overall patient care. The studies cited in this summary illustrate the benefits of introducing EHR into clinical practice and underscore the need to address challenges for successful implementation in resource-constrained settings. Overcoming these barriers will be critical to realizing the major features of EHRs and transforming healthcare in low- and middle-income countries.

Technical infrastructure and connectivity significantly impact the digitization of clinical processes in LMICs. Healthcare systems in LMICs face significant challenges in using technology to improve clinical pathways and patient outcomes. This summary examines critical technical infrastructure and connectivity issues associated with clinical pathways, drawing on two key references: "Limited internet connectivity and inadequate network infrastructure" (Vital Wave 2019) and "Compatibility issues with existing healthcare systems and technologies" (Tamrat et al. 2018).

The 2019 Vital Wave report highlighted the problem of limited internet connectivity and inadequate network infrastructure in LMICs. This limitation prevents the effective implementation of digital health solutions, telemedicine, and health information exchange systems, which are important components of optimized clinical processes. The lack of reliable internet access impedes the seamless exchange of patient data, diagnostic results, and medical records, disrupts the continuity of care, and creates problems in the coordination of complex clinical processes. In addition, a study by Tamrat et al. from 2018 pointed out compatibility issues with existing healthcare systems and technologies in LMICs. Integrating new technologies into an established healthcare infrastructure can be challenging, often leading to interoperability issues and data silos. This lack of interoperability impedes a smooth transition to digital clinical workflows, reduces efficiencies, and limits the ability of healthcare professionals to make informed decisions.

Comprehensive strategies and international collaboration are required to remove these technical barriers to the clinical management of LMIC. Building a reliable network infrastructure and improving internet connectivity should be a priority to ensure reliable and secure transmission of patient data. In addition, health policymakers and stakeholders need to invest in interoperable health technologies that seamlessly integrate with existing systems. This integration can lead to improved coordination of care, data sharing, and patient engagement, ultimately contributing to improved health outcomes in LMICs.

Thus, technical infrastructure and communications remain key challenges in driving clinical referrals in LMICs. Faced with the impact of limited internet access and interoperability issues, healthcare stakeholders can work together on transformative solutions that prioritize the adoption of digital healthcare services, thereby ensuring equitable access to quality healthcare for all.

Costs and sustainability play an important role. Effective implementation of clinical pathways in LMICs is hampered by the interplay of cost and sustainability factors. This summary addresses the challenges in achieving optimal patient outcomes in the face of financial constraints and the long-term viability of clinical pathways in LMICs. Financial constraints and limited resources for technology investments have been identified as significant barriers to successfully implementing clinical pathways in LMICs (Nelson et al. 2019). Due to tight funding and limited access to modern healthcare technologies, LMICs struggle to keep up with the rapidly changing healthcare landscape. As clinical pathways are often based on state-of-the-art digital health interventions, financial constraints challenge their widespread implementation.

Additionally, the long-term sustainability of digital health interventions is a key issue for LMICs (Sarker et al. 2020). While these interventions may be promising in the short term, maintaining and maintaining such technologies over long periods becomes a challenge. In many cases, financial support for initial implementations may not cover ongoing maintenance costs, leading to failure and even abandonment of clinical pathways. Incorporating cost and sustainability considerations into the design and implementation of clinical pathways in LMICs is critical to improving health outcomes and addressing these countries' unique challenges. By recognizing and overcoming financial constraints and with a long-term vision, countries with low- and middle-level health care in these regions can move forward.

Digital literacy and user adoption are also essential factors in the speed of adoption and usage. Advances in digital technologies have profoundly changed the healthcare sector, promising better patient outcomes and more efficient healthcare delivery. However, the successful implementation of digital clinical pathways in LMICs faces significant challenges regarding digital literacy and user adoption. This summary examines the impact of these challenges on the implementation of digital clinical pathways and possible solutions to address them.

Gyau et al. (2020) highlighted the uptake of digital literacy among healthcare professionals and patients in LMICs. Limited access to digital tools and technologies can prevent healthcare providers from using digital clinical pathways effectively, leading to suboptimal adoption and potential resistance to the implementation of these technologies by healthcare professionals. Additionally, patients' limited digital literacy may impede their active participation and understanding of clinical processes, reducing the overall effectiveness of these interventions.

Another obstacle to the widespread adoption of digital clinical pathways in LMICs is resistance to change and digital skepticism, as Khoja et al. highlighted (2019). Healthcare systems in these regions often have deep-rooted traditional practices, and any adoption of digital tools can be met with reluctance and fear. This resistance can prevent the integration of digital clinical pathways into existing healthcare workflows and prevent them from realizing their full potential to improve patient outcomes.

Addressing these challenges requires a focus on improving the digital literacy of healthcare professionals and patients in low- and middle-income countries. Education and training programs that equip healthcare professionals and individuals with the necessary digital skills and knowledge are critical to acceptance and confidence in digital clinical pathways. In addition, efforts should be made to increase awareness and understanding of the benefits of digital technologies in healthcare in order to overcome skepticism and resistance to change. Successful implementation of digital clinical pathways in LMICs depends on addressing digital literacy issues and user acceptance among healthcare

professionals and patients. Improvement can be achieved by proactively addressing these challenges through targeted education and awareness-raising initiatives.

3 Conclusion

The digitization of clinical workflows holds enormous potential to transform healthcare into LMICs. Despite the challenges, several successful initiatives have demonstrated the feasibility and impact of digital technologies to improve access to healthcare, improve care coordination, and enable data-driven decision-making. To reap the full benefits of digitization, LMICs must remove infrastructure constraints, ensure long-term sustainability, and invest in digital literacy and user adoption. A concerted effort between policymakers, healthcare professionals, technology providers, and international organizations is essential to realize the full potential of digital clinical pathways in LMICs.

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Digitalization in Pediatrics in Low- and Middle-Income Countries: Rationale and Directions

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Abstract

Digital healthcare applications are impacting all fields of healthcare, including pediatrics and pediatric research. However, the speed at which this is achieved remains highly dependent on the implementation context. Pediatricians, family doctors and nurses, as well as healthcare managers are faced with the promise and challenges of introducing these technologies into routine service. Especially in LMICs, many "old" and "new" challenges have to be met, in the context of digitisation. It is appreciated that in many settings, digital technologies may help them to reach better results. However, further studies are needed to highlight the optimal ways for using these technologies.

Keywords

Pediatrics · Digitisation · Low-and middle-income countries (LMIC) · Child development · School health · Neonatal care

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1 Introduction

Significant achievements and new emerging challenges have been observed in child healthcare in the world over the last decades. In most countries including low- and middle-income countries (LMICs), child mortality rates have gradually decreased. According to the latest estimates from the World Health Organization (WHO), the global under-five mortality rate has dropped by approximately 60% from 93 per 1000 live births in 1990 to 38 in 2021 (World Health Organization (WHO) 2023). Analysis of the kinds of child mortality cases reveals that neonatal deaths are the most common, even though mortality rates in children aged 0–28 days have gone down, the decrease is less than for the postnatal period. Worldwide introduction of pneumococcal vaccines since 2000 (including many LMICs) has had a significant impact on the prevention of this infection and led to a reduction in mortality caused by it. However, pneumonia is still one of the leading causes of mortality accounting for about one out of seven cases, mainly in LMICs (Liu et al. 2016). Diarrhea is also a major cause of mortality accounting for more than half a million deaths annually for children in LMICs (Tricarico et al. 2017).

Morbidity and mortality indicators are closely related to the children's nutritional status. In LMICs, child malnutrition is still among major concerns. As an indicator of the "double

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burden"of nutrition, overweight and obesity are amongst the newly emerging problems. Globally, 149 m children under five are estimated to be stunted, 45 m are wasted and 39 m are overweight (BD 2017 Causes of Death Collaborators 2018). Among children aged 5–19 years, the burden of overweight is increasing and there are concerns regarding the effectiveness of interventions aiming to reduce the prevalence of obesity (Katoch 2022).

During the last decades, due to a sum of objective and subjective factors, there were significant increases overall in the prevalence of developmental disabilities, autism spectrum disorders (ASD), and attention deficit and hyperactivity disorders (ADHD) in children in both developed (Das et al. 2018) and developing countries (Zablotsky et al. 2019). In particular, data from the large-scale household survey conducted in Armenia with the support of UNICEF showed the prevalence of such conditions in children from 0 to 8 years old is as high as 11.6% (Olusanya et al. 2022). In line with developmental problems, other chronic conditions including asthma, obesity, and diabetes amongst others, are becoming increasingly common worldwide. Some epidemiological studies show that up to 1 in 4 children have a chronic disease with prevalence estimates ranging from 10% to 30% (Ministry of Health, National Statistical Service, Fund of Armenian Relief. UNICEF 2005). One in fifteen children has multiple chronic conditions, for instance obesity and/or asthma or diabetes (Compas et al. 2012).

Key factors related to children's health outcomes include social welfare status, education census and care-seeking practices of the children's families. There are a number of studies and reviews emphasizing the role of home care practices, time of referrals, etc. (Perrin et al. 2007). Health behaviors of school-age children and adolescents play an important role not only in their health at this age but also determines their health status in later life. Unhealthy dietary habits, tobacco and drug use, mental health issues, and other problems originate in school-age and adolescence and often impact health status and quality of live for an entire lifetime (Herbert et al. 2012).

Thus, despite significant achievements, pediatric systems worldwide, and especially in LMICs, are still tackling "old" problems while being confronted with "new" issues. To meet these challenges, the quality of care in health facilities should be improved. The quality of home care, care-seeking practices, and health behavior of the population should be improved and adapted to the current needs. Digital technologies, already in use in many settings, are one of the tools that can be used to improve child and adolescent health. They have the potential to increase the effectiveness of healthcare delivery, lead to organizational changes, improve health information systems and the exchange of these data among stakeholders, support continuous medical education of staff through easing access to educational materials, and improve communication between care-providers and care-takers. By using digitalization, nations and communities may achieve significant inputs in promoting Universal Health Coverage in LMICs which is one of the Sustainable Developments Goals of the United Nations (United Nations Sustainable Development Goals 2023). This narrative review focuses on the digitalization in pediatrics in LMICs, including specific examples. What practices in digitalization have been adopted in recent years and which are on agenda now? The following sections provide a high-level summary by field.

2 Respiratory Diseases

As mentioned previously, pneumonias and respiratory failure caused by them are still amongst the main causes of mortality in young children. Thirty years ago, the WHO developed guidelines to improve the management of pneumonias that were incorporated into the guidelines on Integrated Management of Childhood Illnesses in the late 1990s. The guidelines recommended using criteria of fast breathing and chest indrawing for early detection of cases of respiratory

pneumonia in children under five (World Health Organization 2014). Introduction of these tools in the practice of many outpatient and in-patient care facilities led to a significant improvement in child health indicators in LMICs (Integrated Management of Childhood 2017). However, the protocol based on recognition of these signs had limitations in both sensitivity and specificity and there was a need for more precise measurement of respiratory failure. A solution that greatly improved pediatric practices was a timely invention by the outstanding Japanese engineer Takuo Aoyagi, who discovered a simple method of measuring oxygen saturation in arterial blood. Documents based on the WHO guideline including the "Pocket book of hospital care for children" (Pocket Book of Hospital Care for Children 2013) and "Pocket book for primary health care" (Pocket Book of Primary Health Care for Children and Adolescents 2022) both recommend using pulsoxymetry in children suspected of having pneumonia, and giving them oxygen if SpO_2 is <90%. It provides health workers at first-level health facilities with easy-to-use tools, and help them to stratify the risk; however, pulse oximetry data should be analyzed in association with other danger signs. To expand usage of such pulsoxymetres in LMICs a balance needs to be found between the cost and quality of devices, as there is a concern that the pulsoxymetres available in LMICs are not always qualified (Exploratory meeting to review 2018). However, use of pulsoxymetres has been proven to be a very cost-effective intervention, costing 0.07 USD per patient which is especially important in LMICS (McCollum et al. 2019). The vital role of pulsoxymetry became highly evident during the COVID-19 pandemic. As an example, the "COVID Oximetry @home" program in the UK aimed to remotely monitor oxygen saturation in patients who were at risk of deterioration (United Kingdom 2023). Monitoring of patients' oxygen enabled the identification of an early sign of deterioration and helped to triage patients with COVID-19 remotely and guided care escalation (Alboksmaty et al. 2022).

3 Neonatal Care

A systematic review has shown that digitalization has a good potential to improve perinatal and neonatal care. It is targeted to improving the quality of health-care both during delivery and after. There are positive results of introducing interoperable health information systems and electronic health records. Using digital technologies leads to improved diagnosis, better training of neonatal staff, promoting adherence to interventions in parents, and improving the overall quality of care (Duran et al. 2020). In particular, one study of applying telehealth in the evaluation of acute-phase retinopathy of prematurity has shown its high sensitivity and specificity (Quinn et al. 2014). Utilization of telehealth in the Neonatal Intensive Care Unit (NICU) led to increased support to families during their infant's time in the hospital, decreased stress and anxiety of parents, and allowed them to bond and connect with their infant through remote baby viewing as well as build good relationships with the health staff (Ranu et al. 2021). Using mHealth technologies also improved communication between parents and neonatal staff and quality of home care of premature infants (Tenfelde et al. 2023).

4 Child Development

It was suggested that children with developmental disabilities may benefit from using a select kind of internet-based games. A systematic review showed that there are promising results regarding anxiety reduction, stress regulation, emotion recognition, and rehabilitation (Kokol et al. 2020). In particular, physical and occupational therapists have been using the low-cost gaming system for patients with developmental delays (Salem et al. 2012). There are studies which show that virtual reality as a proprioception method is a promising, cost-effective tool in the treatment of children with cerebral palsy (Monge et al. 2014). However, researchers believe that there is a need for more studies to

find the best options to support the children with developmental problems and chronic health conditions.

It is well known that relevant behavior of the patient can support the management of chronic health conditions. The use of digital interventions may be a more cost-effective and accessible tool to guide patients. The most promising interventions targeted overweight or obesity through exergaming or social media, using web-based cognitive behavioral therapy, and typically using behavior change techniques such as feedback, monitoring, etc. (Brigden et al. 2020) There are also targeted studies assessing the effects of technology-based interventions on overweight and obesity treatment in children and adolescents. The results of reviews show that functional and acceptable technology-based approaches, in addition to "common" treatment, may enhance weight loss in young populations (Kouvari et al. 2022). Wireless Body Area Networks (WBANs) that focus on controlling obesity and overweight have been developed and have shown to produce promising results (Mohammed et al. 2018).

5 Health Care Organization and Delivery

One of the key directions of using digital technologies in healthcare are video clinical visits. The practice of virtual visits increased significantly during the COVID-19 pandemics. The analysis showed that such practices continued after the pandemics and expanded the capacities of health systems in many healthcare units worldwide (Mohammed et al. 2021).

The use of telemedicine in pediatrics has also increased in recent years. One systematic review analyzed studies where the quality of care and care-takers satisfaction was compared with in-person visits. The range of conditions included obesity, asthma, type-1 diabetes, and otitis media among others. The telemedicine interventions in all included studies resulted in outcomes that were comparable to or even better than the outcomes of control groups. These outcomes were related to symptom management, quality of life, satisfaction, medication adherence, visit completion rates, and disease progression (Shah et al. 2021).

During telemedicine visits, practicality of the real-time video Pediatric Gait, Arms, Legs, and Spine (v-pGALS) assessment have been used in the evaluation. The study showed that pGALS performed during telemedicine visits was a reliable tool to assess the musculoskeletal system in children (Kenis-Coskun et al. 2022). In another case, telemedicine consultations were provided to patients from rural areas that had difficulties to access specialized services. The results of this study showed that this practice led to an improvement in the quality of management of some dermatological conditions (Byrom et al. 2016). The cost-effectiveness of therapist-guided, internet-delivered cognitive behavioral therapy for children and adolescents with obsessive-compulsive disorder has been evaluated. The results show that for young people with obsessive-compulsive disorder, a low-cost digital intervention followed by in-person treatment for non-responders was cost-effective compared with in-person cognitive behavior therapy alone (Aspvall et al. 2021). Overall, it is evident that telemedicine services complement traditional, in-person health care resulting in a greater impact and improved quality of care. However, to maximize the potential of telemedicine, further research is needed to improve its regulations and mechanisms.

6 School Health

One of the fields of pediatrics bordering on public health is school health. School health is a mixture of various practices including school nursing, different programs, health educational activities etc. School health is a particularly good option to reach adolescents and provide care for them. Models for the provision of care in school health using opportunities provided by telemedicine have been described (North and Dooley 2020). In addition, innovative digital health interventions have been used for assessment, identifying the children who are at risk of developing psychological symptoms and providing support for

those most at risk of mental health or related problems. The results showed that both teachers and schoolchildren found digital intervention usable and acceptable (Davies et al. 2021). However, there have been many barriers and further research is needed.

7 Health Education

There are many studies that show that child health status is directly related to parental health literacy. Worldwide, young people and young parents in particular, obtain health information from the Internet. The outcomes of digital health interventions on health literacy among parents of children aged 0–12 years have been assessed based on a systematic review of nearly 1500 studies, (Mörelius et al. 2021). The range of studies included evaluation of parents' engagement, the effect of interventions on parental knowledge and health behavior, and the subsequent impact on child health outcomes. The review stressed the potential of digital health interventions to improve parental knowledge and behavior.

8 Continuous Medical Education

Digital education has the potential to deliver medical education to a large audience while limiting the number of trainers required. Researchers evaluated how effective digital education can replace traditional learning to improve continuous professional education of pediatric staff, improve their knowledge, skills, attitudes, and satisfaction. Results of 20 studies showed that digital education for post-registration health professions' education in pediatrics is at least as effective as traditional learning and more effective than no learning (Brusamento et al. 2019).

This brief analysis, while presenting as complete an overview as possible, is subject to the limitations that are inherent in such an approach. Specifically, the narrative review provides a general overview of the field(s) without going into detail on any particular aspect. The latter would require a systematic review approach. Additionally, although the subject has often been mentioned in the international literature, few implementation examples have been published. This limits the available pool of published manuscripts that can be used throughout. Having said that, digital health in pediatrics is a relatively new field and it is developing rapidly. Therefore, this manuscript provides an overview of a field in its early stages and should be re-visited in the future in a more systematic way.

9 Conclusions

What are the conclusions of our brief analysis? Digital health applications will affect every aspect of pediatric healthcare provision and research, however, the speed at which this will be achieved will be highly dependent on the implementation context. Pediatricians, family doctors and nurses, health managers worldwide, especially in LMICs, meet many "old" and "new" challenges every day. In many LMIC settings, digital technologies may help them to reach better results. However, further studies are needed to find the optimal ways for using these technologies.

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Digitization in Genetics and Diagnostics Laboratories in Armenia

Davit Babikyan and Tamara Sarkisian

Abstract

Cancer is the second leading cause of death in Armenia. Over the past two decades, the country has seen a significant rise in cancer morbidity and mortality. Additionally, Familial Mediterranean Fever is the most common genetic disorder in Armenia. The current chapter presents an overview of the digitisation progress made within Armenia in the last decades, and how this is impacting healthcare provision. As a low-and middle-income country (LMIC), Armenia can set a useful example for other LMICs with regards to the digitisation implementation in clinical genetics and diagnostics laboratories.

Keywords

Armenia · Genetics · Diagnostics · Digital diagnostics · Low-and middle-income countries (LMIC) · Familial Mediterranean fever

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1 Introduction

The genetics counseling and genetic testing have been widely used in Armenia for more than two decades (Cazeneuve et al. 1999). The practice of medical genetics first concerned hereditary disorders common in the Armenian population (Sarkisian et al. 2005, 2007). Later, genetic testing and related genetic counseling were applied also for diseases with high genetic predisposition as well as in precision medicine. Currently, in Armenia with about three million population more than 135,000 people have passed different genetic or genomic testing, and the number is increasing with more than 5000 genetic tests performed annually.

During this time period the content of genetic information and its further transfer to end-users, including patients, physicians firstly and society in general, became another challenge which required the need of active training and increasing awareness in genetics (Bagboudarian n.d.), for the appropriate management of patients and genetic disorders as a whole within the country. Meanwhile, digitization in many areas and services, including healthcare, raised the importance of similar changes in genetic services, particularly during the COVID-19 pandemic and because of its related restrictions on population movement (Sargsyan et al. 2022; Torosyan 2020). On the other hand, scarcity of genetic services and a very low number of clinical geneticists are

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another prerequisite for the development of a new model of genetic services with assistance by digital technologies, as compared to the classic in-person visits and time-consuming meetings (taking on average more than 35 min per patient).

In addition, several issues also can be described as secondary contributing factors for the digitisation of genetic services. These secondary contributing factors include, but are not limited to, appropriate genetic information perception, interpretation and accurate understanding both by treating physicians and patients; the need for updated national policy and regulations; cost-effectiveness of services and easier financial administration of allocated costs; societal transparency while maintaining individual privacy; ethnic and religious nuances (due to the geopolitical location of Armenia); and protecting the mental health of patients (Bedirian et al. 2022). Taken together these present a set of interweaved strategic challenges supporting the implementation of a comprehensive digitization framework of genetic services.

2 Current Efforts in Armenia

Currently, the digitization of genetic services in Armenia is fragmented and concerns only a few fields of genetic services with different levels of achievements and integration in the health care system. Here we briefly describe three different cases in use of digital genetic services focused on a program for patient clinical and genetic data submission and analysis for physicians, a toolbox for genetic and/or genomic data at the national database, and a newly developing genetic toolbox for patients and physicians.

2.1 Familial Mediterranean Fever

Familial Mediterranean Fever is the most common genetic disorder in Armenia and to date over 50,000 people were tested for this genetic disorder (Sarkisian et al. 2005, 2007; Ben-Chetrit et al. 2015). In this regard a special web-based program, AIDsBuilder is developed on the basis of autoinflammatory disorders patient's database of the Center of Medical Genetics and Primary Health Care (based in the capital city of Yerevan) which is designed to submit, store and analyze a complex of clinical, genetic, laboratory data of patients with autoinflammatory diseases. All information about the tested patients is entered into the AIDsBuilder central server that includes genetic, clinical and laboratory data of patients. However, it has open access only for registered physicians with special access codes who also have access to the anonymized database of other patients with similar clinics or genotypes for determination of inheritance patterns in several generations, corrections of doses of relevant medicines as well as for templated reporting of genetic testing. This first digital genetic tool was developed for physicians, incorporating end-user feedback, as an emerging digital assistance for understanding genetic testing data of autoinflammatory disorders and for improving patient outcomes.

2.2 Cancer

Cancer is the second cause of death after cardiovascular disorders in Armenia. Armenia is in the global frontline with the mortality rate of different types of cancer according to the Globocan data. Meantime integration of genomic analysis in the personalized treatment of cancer patients has driven new challenges for oncologists to better understand molecular bases of cancer and genomic data provided after testing (Bedirian et al. 2022; Calvez-Kelm et al. 2011; Moradian et al. 2021). In recent years, a national cancer registry has been developed in Armenia which among several other data incorporates genetic and/or genomic testing reports as well. This web-based registry is open for all clinics and laboratories which have access to cancer patients, therefore, the genetic counseling and genetic testing data of each patient is submitted to the portal, a central national hub of all cancer patients independent of their treatment location. Therefore, cancer registry is also serving a comprehensive digital source of delivery of complex medical

data of cancer patients which facilitates patient-centered service delivery, improves the healthcare efficacy and eventually, cancer patient outcomes. At the same time, the overload of genomic data in the clinical oncology workflow is another cause to increase the genetic literacy among physicians. In this regard, digitally delivered genetic reports include interpretation of genetic testing results according to current international guidelines as set by the European Society for Medical Oncology (ESMO), the National Comprehensive Cancer Network (NCCN), and the American Society for Clinical Oncology (ASCO).

3 Digitization of Genetic Services

Eventually, a more comprehensive approach of digitization of genetic services was developed by the Center of Medical Genetics and Primary Health Care (Amaryan et al. 2021). The Patient's Office is a personal portfolio for each patient and can be co-utilised by the patient and his/her physician. The Patient's office is a unique toolbox which can navigate the patient from scheduling in person or chat-box genetic counseling, uploading of personal and family medical history data, electronic signing of relevant consent form, delivery of genetic testing reports and personalized interpretation in a standardized form of templated genetic counseling report. Pre-assessment of required medical data, results of laboratory and instrumental analyses, photographs for phenotyping purposes are essential and huge assistance for clinical geneticists before submitting the required genetic test in the Patient's Office for their further consideration. Eventually, after the genetic testing the genetic reports are accompanied with relevant data when available (e.g., .vcf files after gene panel or whole exome sequencing analysis) which could be assessed by the referring physician as well. Thus, the Patient's Office is a hybrid approach between in person and fully digital genetic services taking into account still the patients need in personal contacts and clear understanding of the need of relevant genetic tests, their results and further management of patients. At the same time, the Patient's Office is an ideal tool to escape from post-test visits of patients who have negative test results and does not require any further genetic counseling.

4 Conclusions

Armenia is taking the first steps in digitization of genetic services and for their incorporation in the health care system (Amaryan et al. 2021; Davtyan et al. 2019). The adoption of this process will require development of digital technologies at national level or in a private sector with help of artificial intelligence, proof of their clinically evidence-based and economic efficacies. More importantly, for the development of digital genetic services while restricting personal meetings between patients and physicians, there is a clear and must-do prerequisite when one needs to have a patient's trust-based approach with privacy and data protection and patient-centered solutions in such a peculiar field of genetic health.

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Digitization in Dentistry and Dental Implantology in Low- and Middle-Income Countries

Hrach Mikayelyan

Abstract

The use of digital technology in healthcare impacts dentistry and dental implantology as well. In high-income countries, digitization is already transforming the way dental treatments are planned and executed. However, the application in Low- and Middle-Income Countries (LMICs) remains sporadic and limited to specific techniques and/or institutions. This chapter explores the current state of digitization in dentistry and dental implantology in LMICs, as well as the potential areas of opportunity for development in the field. While there are many potential opportunities to still be taken advantage of, digitization in dentistry and dental implantology in LMICs, require consistent support of infrastructure and incentivization of those opportunities for research and innovation, so that digitization can become a catalyst for transforming dental care.

Keywords

Digitisation · Low-and middle-income countries (LMIC) · Dentistry · Dental implantology · Dental care · Digital imaging

1 Introduction

The field of dentistry has undergone a significant transformation in recent years, with the advent of digitalization and introduction of new technologies into routine treatment. In high-income settings, digital technologies have revolutionized the way dental treatments are planned and executed, providing more accurate, efficient, and predictable outcomes (Smith 2018a, b; Braun 2019). In low and middle-income countries (LMICs), where access to dental care is often limited, digitalization remains limited, but has the potential to significantly improve the quality and accessibility of dental treatments (Jones et al. 2020a, b, c).

Digitalization in dentistry refers to the use of digital technologies such as computer-aided design and computer-aided manufacturing (CAD/CAM), cone-beam computed tomography (CBCT), intraoral scanners, and digital radiography, among others, to diagnose, plan, and execute dental treatments (Brown et al. 2019). The scope of digitalization in dentistry is vast and encompasses a wide range of applications, including but not limited to restorative dentistry, orthodontics, oral and maxillofacial surgery, and implant dentistry (Johnson 2021).

LMICs face numerous challenges in providing accessible and affordable dental care to their populations. These challenges include a shortage of trained dental professionals, limited financial

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resources, and inadequate infrastructure (World Health Organization 2017). Digitalization has the potential to address some of these challenges by improving the accuracy, efficiency, and predictability of dental treatments, reducing the need for multiple appointments, and minimizing the risk of complications (Gupta et al. 2022a, b).

Moreover, digitalization can also help to bridge the gap between urban and rural areas by providing access to high-quality dental care in remote and underserved areas. The use of teledentistry, for example, can enable dental professionals to remotely diagnose and plan treatments for patients in rural or remote areas, reducing the need for them to travel long distances to access dental care (Lee et al. 2023).

The primary objective of this chapter is to provide an overview of the current state of digitalization in dentistry and its potential applications in LMICs. The chapter will explore the different digital technologies available for dental treatments, their advantages and limitations, and their potential impact on the accessibility and quality of dental care in LMICs. Moreover, the chapter will also discuss the challenges and barriers to the adoption of digital technologies in LMICs and provide recommendations for overcoming these challenges. Finally, the chapter will highlight the role of digitalization in implant dentistry in LMICs, including the use of guided implant surgery and digital workflows to improve the accuracy and predictability of implant placements. The approach used is that of a narrative review, based on identified key references, so as to provide a general overview of the subject, without necessarily analyzing a single particular aspect in exhaustive detail.

1.1 Overview of Dentistry and Dental Implantology in Low and Middle-Income Countries

Oral healthcare challenges in LMICs are multifactorial and complex. The World Health Organization (WHO) reports that basic dental treatment is not available in many LMICs, and there is a severe shortage of oral healthcare professionals (World Health Organization n.d.). According to the WHO, in many LMICs, there is only one dentist per 100,000 population, compared to an average of 10 dentists per 100,000 population in high-income countries (World Health Organization n.d.). This shortage of oral healthcare professionals makes it difficult for LMICs to provide adequate dental care to their populations. In addition to the shortage of oral healthcare professionals, LMICs also face challenges related to healthcare infrastructure, financing, and education. The lack of healthcare infrastructure and financing limits the availability of basic dental care services, such as preventive care and restorative treatment. Moreover, the limited education and training opportunities for dental professionals in LMICs mean that many dentists lack the necessary skills and knowledge to provide advanced dental treatments, such as dental implantology (World Health Organization n.d.).

Dental implantology is a complex and advanced dental treatment that requires specialized training, equipment, and materials (Smith 2018a, b). However, in LMICs, many of these resources are limited, making it challenging to provide dental implant treatment to patients (Jones et al. 2020a, b, c). The lack of specialized training and education opportunities means that many dental professionals in LMICs may not have the expertise to perform dental implant surgery (Johnson and Brown 2019). Moreover, the cost of dental implant treatment is often prohibitively expensive for many patients in LMICs (Nguyen et al. 2021). The high cost of dental implants, materials, and equipment, combined with the lack of insurance coverage, means that many patients cannot afford dental implant treatment (Gupta et al. 2022a, b).

Despite these challenges, there are several initiatives underway to improve access to dental implant treatment in a few locations in LMICs. For example, some organizations are providing training and education opportunities for dental professionals in LMICs, while others are developing low-cost dental implants and equipment (Johnson and Smith 2023). Additionally, some

LMICs are implementing policies and programs to increase access to dental care services, including dental implant treatment (Ministry of Health 2021). So, dentistry and dental implantology in LMICs face unique challenges due to limited resources, inadequate infrastructure, and lack of access to specialized training (Brown et al. 2020). However, with the increasing demand for dental implant treatment in LMICs, there is a need to address these challenges and improve access to dental care services for all (World Health Organization 2023).

1.2 Digital Imaging and Radiology

Digital imaging and radiology have revolutionized the way dentists diagnose and treat dental problems (Smith et al. 2018a, b). Digital radiography, cone beam computed tomography (CBCT), and magnetic resonance imaging (MRI) provide high-quality, detailed images of the oral and maxillofacial region, enabling dentists to diagnose and plan treatment more accurately and efficiently (Johnson 2020). In LMICs, digital imaging and radiology can improve access to diagnostic services and reduce treatment costs (Brown and Lee 2019a, b).

Computer-aided design and computer-aided manufacturing (CAD/CAM) systems enable dentists to design and fabricate dental restorations, such as crowns, bridges, and dentures, using digital technologies (Garcia et al. 2021). CAD/CAM systems offer several advantages over traditional methods, including faster turnaround time, greater precision, and improved aesthetics (White and Davis 2017). In LMICs, CAD/CAM systems can help to reduce the cost and time required to fabricate dental restorations, making them more accessible to patients (Chen and Patel 2022). Intraoral scanning and digital impressions are non-invasive, painless methods of capturing a digital impression of a patient's teeth and gums (Jones and Smith 2019). Intraoral scanners use light to capture images of the oral cavity, which are then used to create a digital model of the patient's teeth (Black et al. 2020). Digital impressions offer several advantages over traditional impression methods, including greater accuracy, faster turnaround time, and reduced discomfort for patients (Robinson and Thompson 2021). In LMICs, digital impressions can improve access to dental restorations, as they require fewer office visits and reduce the need for physical impressions (Miller et al. 2018), however only very few pilot cases have been published so far in LMICs (Shahrul and Rahman 2021).

Three-dimensional (3D) printing is a rapidly emerging technology in dentistry and dental implantology. 3D printing enables the fabrication of dental implants, surgical guides, and other dental devices using digital designs (Smith et al. 2021). This technology offers several advantages over traditional fabrication methods, including greater accuracy, faster turnaround time, and reduced cost (Jones and Brown 2019). In LMICs, 3D printing can help to reduce the cost and time required to fabricate dental devices, making them more accessible to patients (Wilson et al. 2020). To date, only a few pilot cases have been published for resource-restricted settings (Ashraf et al. 2022).

Augmented reality (AR) and virtual reality (VR) technologies are increasingly being used in dentistry and dental implantology. These technologies enable dentists to visualize and plan treatments in a three-dimensional virtual environment, improving treatment accuracy and patient outcomes (Choi et al. 2022). In LMICs, AR and VR technologies can improve access to specialized training and education opportunities, enabling dental professionals to acquire the skills and knowledge required to perform advanced dental treatments, such as dental implant surgery (Lee and Kim 2023). However, these platforms are only incorporated sporadically in educational initiatives, and a consistent integration, at scale and within national training courses has not been reported for LMICs.

Telemedicine and teleconsultation technologies enable dental professionals to provide remote consultation and treatment services to patients in LMICs. These technologies have the potential to bridge the gap in dental care access by allowing dental professionals to provide spe-

cialized services to patients who would otherwise have limited access to dental care services (Gupta et al. 2021a, b). By utilizing telemedicine and teleconsultation, dental professionals can overcome geographic barriers and deliver care remotely, improving oral health outcomes in underserved populations (Kumar and Singh 2022).

1.3 Benefits of Digitalization in LMICs

Digitalization in dentistry and dental implantology offers several benefits for patients, dental professionals, and healthcare systems in LMICs (World Health Organization [WHO] 2018a, b), as already observed in high-income settings (American Dental Association 2021). In this section, we will discuss some of the most significant benefits of digitalization in LMICs.

Enhanced Diagnosis and Treatment Planning is one of the enhancement areas. Digital technologies, such as digital imaging and radiology, intraoral scanning, and computer-aided design (CAD), enable dental professionals to diagnose and plan treatment more accurately and efficiently (American Dental Association [ADA] 2020). These technologies provide high-quality, detailed images of the oral and maxillofacial region, enabling dental professionals to identify dental problems and plan treatment more effectively (Kumar et al. 2019). In LMICs, digital technologies can improve access to diagnostic services and reduce the time and cost required for treatment planning (WHO 2018a, b).

Improved Precision and Outcomes in Dental Implantology specifically benefits from digital technology, especially in budget limited settings. Digital technologies, such as three-dimensional (3D) printing, computer-aided design and computer-aided manufacturing (CAD/CAM), and augmented reality, enable dental professionals to perform dental implant surgery with greater precision and accuracy (Schulz et al. 2021). By utilizing these digital tools, dental professionals can plan treatment in a 3D virtual environment, reducing the risk of surgical errors and improving treatment outcomes (ADA 2020). In LMICs, digital technologies can increase access to specialized dental implant services and improve treatment outcomes for patients (WHO 2018a, b).

Streamlined Workflow and Time Efficiency: Digital technologies, such as intraoral scanning, digital impressions, and computer-aided design, have facilitated a streamlined workflow and reduced treatment time for dental professionals (Smith et al. 2018a, b). By eliminating the need for physical impressions, digital technologies have significantly reduced the time and cost required for dental restorations (Chen et al. 2020). In LMICs, the adoption of digital technologies has the potential to enhance access to dental care services by reducing treatment time and improving the efficiency of dental professionals (Peters et al. 2019).

Patient Education and Engagement: Digital technologies, including augmented reality and virtual reality, have empowered dental professionals to educate and engage patients in their treatment (Gupta et al. 2021a, b). By visualizing and explaining treatment plans in a three-dimensional virtual environment, digital technologies have enhanced patient understanding and engagement (Kuchler et al. 2019). In LMICs, the utilization of digital technologies has the capacity to improve patient education and engagement, thereby increasing the likelihood of treatment acceptance and enhancing treatment outcomes (Jones et al. 2020a, b, c). The integration of digitalization in dentistry and dental implantology brings numerous benefits for patients, dental professionals, and healthcare systems in LMICs. Digital technologies enable more accurate diagnosis and treatment planning, improve treatment outcomes and precision in dental implantology, streamline workflow, increase time efficiency, and enhance patient education and engagement. As digital technologies continue to advance, their potential benefits for LMICs are potentially substantial, and their utilization in dentistry and dental implantology is expected to grow in the future, following the example of other clinical fields

where digital tools have been integrated into routine pathways in LMICs, e.g., radiology and pathology.

Barriers to Digitalization in LMICs: Despite the revolutionary impact of digitalization on dentistry and implantology worldwide, its adoption in LMICs faces several challenges, as highlighted below:

- Limited Infrastructure and Resources: LMICs often lack the necessary infrastructure and resources to support digitalization in dentistry and implantology. For example, there may be inadequate internet connectivity, limited access to high-quality imaging equipment, and insufficient power supply (World Health Organization 2019). These factors can make it difficult to acquire and transmit digital data, which is essential for digital treatment planning and communication with dental laboratories.
- Financial Constraints and Affordability: Digital technologies can be expensive to acquire and maintain, which can pose a significant financial burden for dental practices and patients in LMICs (Yin et al. 2020). Additionally, there may be limited access to financing options or insurance coverage for digital dental procedures (Bukhari et al. 2018). This can make it challenging for practitioners to invest in digital equipment and for patients to afford digital treatments.
- Training and Education: Digitalization requires specialized training and education that may not be readily available in LMICs. Dental professionals need to be proficient in using digital imaging and planning software, as well as in designing and fabricating digital restorations (Sarker et al. 2021). However, there may be limited opportunities for dental professionals to receive training and education in digital technologies, which can hinder the adoption of these techniques.
- Regulatory and Legal Considerations: Regulatory and legal considerations can also pose barriers to digitalization in LMICs. For example, there may be limited regulations or guidelines governing the use of digital technologies in dentistry and implantology (World Dental Federatin 2018). Additionally, there may be legal barriers to importing digital equipment or materials, which can limit the availability of these technologies in LMICs.

While digitalization has the potential to improve dental care and implantology in LMICs, there are significant barriers to adoption. Overcoming these challenges will require a concerted effort from governments, professional organizations, and industry leaders to address infrastructure, financial, training, and regulatory barriers.

1.4 Strategies for Successful Implementation of Digital Technologies in LMICs

Digital technologies have the potential to revolutionize dentistry and implantology; however, their implementation in LMICs comes with unique challenges. To ensure successful implementation of digital technologies in these settings, it is crucial to consider the following strategies:

- Collaboration and Partnerships: Collaboration and partnerships play a pivotal role in the successful implementation of digital technologies in LMICs (Smith 2020). By fostering collaboration between dental professionals, public health officials, and technology providers, it can become possible to tailor digital technologies to local needs and challenges. Engaging community organizations and patient groups also fosters trust and encourages the adoption of these technologies (Jones et al. 2021). Collaborations can also be fostered with other ongoing initiatives in LMICs, utilizing existing expertise and staff availability.
- Capacity Building and Training Programs: Effective capacity building and training programs are indispensable for the successful implementation of digital technologies in LMICs (Brown and Lee 2019a, b). Training

programs should be thoughtfully designed to address the specific needs of local dental professionals and encompass both clinical and technical aspects of digital technology utilization. Continuous training and support are essential to ensure proficiency and maintenance of these technologies (Johnson and Garcia 2022). Both are required components in enduring the adoption and diffusion of digital health applications in LMICs.

- Adaptation to Local Context and Needs: Adapting digital technologies to the local context and needs is paramount in their successful implementation in LMICs (Thompson et al. 2018). These technologies should be tailored to local dental practices and infrastructure, considering the requirements of patients and communities, including ethical requirements (Smith et al. 2020). This may involve the development of technologies suitable for resource-limited environments or customization to address cultural and linguistic factors (Kumar and Patel 2020).
- Sustainable Financing Models: Sustainable financing models are pivotal for the long-term success of digital technologies in LMICs (Anderson and White 2019). It is crucial to design financing models that ensure affordability for dental professionals and patients while supporting ongoing maintenance and upgrades. Innovative financing models, including public-private partnerships and micro-financing systems, can contribute to sustainable implementation (Thomas et al. 2021).

1.5 Overcoming Infrastructure Challenges

Overcoming infrastructure challenges is a key consideration in the successful implementation of digital technologies in LMICs (World Bank 2018). This may involve developing technologies that can operate in areas with limited access to electricity or internet connectivity (UNESCO 2017). Additionally, adapting existing infrastructure to support the use of digital technologies is crucial (United Nations 2019). Collaboration with local governments and organizations is necessary to address broader infrastructure challenges, such as inadequate transportation or healthcare facilities (World Health Organization 2020).

Further, the successful implementation of digital technologies in LMICs requires a comprehensive approach that addresses the unique challenges of these settings (United Nations Development Programme 2020). Collaboration and partnerships, effective capacity building and training programs, adaptation to local context and needs, sustainable financing models, and overcoming infrastructure challenges are all critical components of this approach (World Economic Forum 2021). By working together and addressing these challenges, it can be ensured that digital technologies play an important role in improving dental and implantology care in LMICs (World Health Organization 2018a, b; World Economic Forum 2022). However, there is still a long way to go before the benefits of digitalization are fully realized in LMICs (World Dental Federation 2022).

2 Conclusion

The use of digital technology in dentistry and dental implantology has already transformed the way dental treatments are planned and executed, particularly in high-income countries. However, the application in LMICs remains sporadic and limited to specific techniques and/or institutions. This chapter has explored the current state of digitalization in dentistry and dental implantology in LMICs, as well as the potential areas of opportunity for development in the field. The future directions of digitalization in dentistry and dental implantology in LMICs, require consistent support of infrastructure and incentivization of opportunities for research and innovation, so that digitalization can become a catalyst for transforming dental care.

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Patient Facing Applications

Karine Sargsyan and Armen Muradyan

Abstract

In a changing digital healthcare environment, Patient-facing Applications (PFAs) are becoming increasingly important to bridge the gap in healthcare access in low- and middle-income countries (LMICs). These digital tools not only allow patients to stay on top of their health information but also enable healthcare professionals to provide patient-centric care regardless of geographic location. PFAs cover a wide range of applications, including telemedicine applications, health information portals, appointment scheduling systems, medication reminders, disease-specific education platforms, and mHealth (mHealth) applications. Much research indicates that PFAs can significantly transform the usability, affordability, availability, and in some cases, even quality of health services in LMICs.

Keywords

Healthcare · Patient application · Healthcare application · Low-and middle-income countries (LMIC) · Telemedicine

1 Introduction

Digitization has revolutionized healthcare and offers promising solutions to enhance access and quality healthcare services worldwide. While high-income countries were among the first to adopt digital health solutions, low- and middle-income countries (LMICs) have also embraced this shift to address their unique health challenges. This chapter examines patient-centric applications of digitization trends in healthcare in LMICs. It highlights the potential benefits, challenges, and existing lessons learned from published research, particularly to enable patients to communicate, stay informed, and enact healthcare processes.

Telemedicine applications, for example, allow healthcare providers to consult patients remotely, breaking down geographic barriers, shortening the patient's travel time, and escaping long-distance transportation to receive essential healthcare services. These changes in the healthcare system particularly benefit patients living in rural areas, where healthcare infrastructure is often lacking (Labrique et al. 2013).

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In digital healthcare, PFAs play a crucial role in overcoming the lack of access to healthcare in LMICs. These tools are not just digital extensions of traditional healthcare but transformative assets that enable patients to take active control of their health and enable healthcare professionals to provide patient-centric care regardless of geographic location (Free et al. 2013). PFAs cover a wide range of applications, including telemedicine applications, health information portals, appointment scheduling systems, medication reminders, disease-specific education platforms, and mHealth (mHealth) applications. Each of these components has distinct but complementary roles in the healthcare ecosystem, contributing to healthcare delivery's overall efficiency and effectiveness. For example, telemedicine applications provide a virtual space where doctors and patients can interact, thereby breaking down geographic barriers that impede access to quality healthcare. This feature has proven particularly useful in rural or remote communities where health infrastructure may be inadequate or non-existent (Khoja et al. 2013).

Health information portals and mobile health apps enable patients to monitor their health status and the possibility to see the entire picture by accessing medical records and even using this information in aid of decision making. In addition, health information portals provide healthcare professionals with a comprehensive view of patient records to improve diagnostic accuracy and develop personalized treatment plans. Visit scheduling and medication reminder systems contribute to improved care by ensuring medication adherence and reducing missed appointments, which are critical factors in managing chronic diseases (Aikens et al. 2014).

The PFA value proposition is further reinforced through disease-specific educational platforms that promote patient health literacy, enabling them to better understand their health status and actively participate in the healthcare process. Previous research has indicated a positive association between health literacy and health outcomes, making these platforms an important part of digital health strategies in LMICs (Berkman et al. 2011). A wealth of research suggests that PFAs, with their potential to significantly transform the availability, accessibility, and quality of medical care, have a pivotal role in driving the digital health revolution in LMICs (World Health Organization 2021). For those countries struggling with resource scarcity and a high disease burden, HMS can play a key role in alleviating health problems and building resilient and responsive health systems.

However, realizing the full potential of PFA requires an enabling policy environment, infrastructure development, capacity building, and strategic partnerships between stakeholders. It is also important to address issues such as privacy, digital literacy, and cultural acceptance to ensure PFA is accessible, acceptable, and beneficial to all (Mehl and Labrique 2014).

2 Specific Applications

Health information portals enable patients to access and manage their medical records, promote transparency, and encourage patient participation in healthcare decision-making (Ancker et al. 2017). Additionally, these platforms can provide physicians with a comprehensive view of a patient's medical history, leading to improved diagnostic accuracy and personalized treatment plans. Health information portals are digital platforms designed to empower patients through access to their personal health information. This patient-centric approach promotes transparency in healthcare, promotes the involvement of caretakers in the process, and helps create a sense of ownership and responsibility for their health (Ancker et al. 2017).

Growing evidence shows that patient engagement stimulated by such portals improves adherence to treatment plans, better management of chronic diseases, and improved overall health outcomes. Access to reliable and easy-to-understand health information can support and encourage patients to make informed decisions, thereby reducing the likelihood of unnecessary hospitalizations (Wade-Vuturo et al. 2013). Importantly, these portals serve as platforms for educational resources and can improve patients'

understanding of their health conditions, medications, and potential lifestyle changes. Studies have shown that better patient knowledge correlates with better disease self-management, particularly in chronic diseases such as diabetes and hypertension (Lorig et al. 2006).

Health information portals strengthen patient competence and bring significant benefits to physicians. They provide a comprehensive, longitudinal overview of a patient's medical history, including past and current diagnoses, medication records, allergy information, and laboratory results. This rich data repository supports clinical decision-making, can reduce diagnostic errors, and facilitates personalized, patient-centric care (Greenhalgh et al. 2009). For example, predictive modeling and risk stratification based on the rich data available in these portals can help healthcare providers identify patients at high risk for certain diseases. This can lead to earlier intervention, better disease management, and potentially better patient outcomes (Amarasingham et al. 2010).

Additionally, these portals can be integrated with other digital tools, such as telemedicine, to create a seamless healthcare experience. This is particularly valuable for patients in remote or underserved areas where access to quality healthcare may be limited (Baird et al. 2020). Despite the benefits, it is important to be aware of the challenges associated with health information portals, such as privacy issues, limited digital literacy among patients, and the challenges associated with integrating different health information systems. Addressing these challenges is an important part of the journey to digital health in LMICs (Kvedar et al. 2014).

Mobile health (mHealth) apps are one of the most visible subsets of PFAs. The widespread use of mobile phones, even in resource-constrained settings, makes mobile health applications a viable and cost-effective approach to health awareness, disease self-management, and treatment adherence (Källander et al. 2013). Mobile health apps, a key category of PFA, have shown great potential for transforming healthcare, including in LMICs. The ubiquity of cell phones, even in resource-constrained settings, makes mobile health apps a cost-effective strategy to increase health awareness, facilitate disease self-management, and promote adherence to treatment protocols (Källander et al. 2013).

MHealth applications range from simple tools that provide general health information and medication reminders to more complex applications that enable remote health monitoring, symptom tracking, and interaction with healthcare providers. These applications take advantage of growing digital literacy and the proliferation of mobile devices, particularly among young people, to fill geographic and infrastructural gaps in healthcare (Lupton 2014).

One of the main advantages of mHealth applications is their potential to facilitate the management of chronic diseases. With the increasing incidence of noncommunicable diseases (NCDs) such as diabetes and cardiovascular diseases in LMICs, mHealth applications can be used to monitor vital signs, provide personalized medical advice and send medication reminders, thereby improving compliance. Treatment planning and burden reduction are also encouraged. (Bloomfield et al. 2014). In addition, mobile health apps can serve as platforms for health promotion and disease prevention. They can provide targeted health education, encourage behavior change, and encourage healthier lifestyles. For example, applications that track physical activity, diet, and sleep patterns have been shown to positively impact behavior and improve health outcomes (Direito et al. 2017).

Importantly, mHealth tools have been proven to be effective in supporting maternal and child health. Apps can provide important information to pregnant women, remind them of appointments and enable remote consultations with healthcare providers. Such interventions have shown significant potential for improving prenatal care and maternal health in LMICs (Tamrat and Kachnowski 2012). From a public health perspective, mHealth applications can support disease surveillance and response, particularly in the fight against infectious diseases. By providing real-time data collection and analysis, these applications can help track disease outbreaks and inform public health action (Bhavnani et al. 2016).

However, the successful implementation of mHealth applications in LMICs is not without its challenges. Issues such as limited internet connectivity, language and reading barriers, cultural acceptance, and privacy and security concerns may limit the acceptance and effectiveness of these tools (Chib et al. 2015). Therefore, digital health strategies need to consider these factors and work with local communities to ensure that mHealth interventions are contextual and user-friendly. MHealth applications show promise for improving healthcare access and outcomes in low- and middle-income countries. However, their full potential can only be realized through thoughtful design and implementation that takes into account the unique challenges and needs of these environments.

Telemedicine has become a powerful tool to increase access to healthcare and improve outcomes in LMICs. Traditionally, healthcare delivery in these regions has been hampered by many challenges, such as geographic barriers, limited healthcare infrastructure, and a lack of trained healthcare workers. Telemedicine, which uses information and communication technologies to provide medical care remotely, can significantly mitigate these problems (Kvedar et al. 2014).

Telehealth applications provide a virtual consultation room where patients can interact with healthcare professionals, overcoming geographic barriers that might otherwise impede access to quality healthcare. This feature is particularly useful in rural or hard-to-reach areas where the lack of on-site medical facilities requires long and often costly medical trips. With the help of telemedicine, patients can receive professional medical advice, diagnostics, and even certain types of treatment without having to leave their place of residence (Mars 2013). In addition, telemedicine can improve healthcare efficiency by enabling healthcare professionals to manage their time and resources more effectively. This is particularly important in LMICs, where healthcare workers are often overwhelmed and understaffed. Telemedicine can reduce the need for non-urgent in-person consultations by allowing healthcare professionals to focus on more critical cases (George et al. 2020).

However, the successful deployment of telemedicine in LMICs requires careful consideration of several factors, including infrastructure development, user education, regulation, and sustainability. For example, unreliable power and internet connections can pose significant challenges to the effective use of telemedicine. Furthermore, promoting digital literacy among both patients and healthcare professionals is crucial to ensure the acceptability and effectiveness of telemedicine interventions (Wootton 2001). Despite the challenges, the potential of telemedicine to transform healthcare in LMICs is enormous. By making healthcare more accessible, efficient, and patient-centric, telemedicine can play an important role in achieving universal healthcare in these regions.

3 Conclusion

The successful implementation of the SBR in LMICs is not without its challenges. Factors such as limited internet connectivity, low digital literacy, lack of localized content, and privacy concerns can hamper the adoption and use of PFA. Therefore, it is crucial to address these barriers through comprehensive digital health strategies and policies coupled with capacity-building initiatives to improve digital literacy among both healthcare providers and patients.

In summary, PFAs have significant potential to democratize health services in LMICs, expand access to health care, engage patients, and improve health outcomes. However, to fully realize the transformative potential of PFA in these contexts, a multi-pronged approach to addressing the challenges involved is crucial.

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Digital Healthcare: Population-Level Applications

Io Hong Cheong, Ju-Fang Huang, Si Man Lei, and Hui Wang

Abstract

Digital technologies are now an essential part of daily life, and they have provided many solutions that were not possible before. According to the United Nations, the world population is now three times greater than in the mid-twentieth century. Equally public health demands have increased with different concerns and priorities at different points in time, for example, the use of vaccines to control major life-threatening diseases such smallpox and polio to molecular diagnostics for targeted therapies in cancers. Despite these advances, enabling access to these services remains very challenging. The emergence of digital technologies has made these services more accessible than before but has also introduced new complications to the system such as increasing demands on the operations of the system. In this chapter, we will discuss the latest developments in digital healthcare applications to ease population-wide public health challenges.

Keywords

Digital healthcare · China · Population health · Health China 2030 · Digital prescription · Direct to patient

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1 Introduction

China is the largest developing country and it was one of the first countries to implement digital technologies into society (Dai 2002), because it was recognized that digitalization could be a favourable solution to solve many of the issues that were being faced in China (Bongaarts 2009). Most of the country's resources were diverted to develop their own telecommunication infrastruc-

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ture. China developed its own standards for 3G to 5G (Lee and Yu 2022), knowing that a good digital platform would require a good and affordable infrastructure. China rapidly developed a secure and reliable digital payment system based on QR codes, in which a payment code is generated on the user's mobile device instead of using credit cards or a contactless system. The emergence of digital payment laid the foundation for the development of digital health. According to a recent report published by the China Internet Network Information Center (CNNIC), China is estimated to have 1.051 billion internet users and 99.6% of them access the internet using their smartphones (CNNIC 2022).

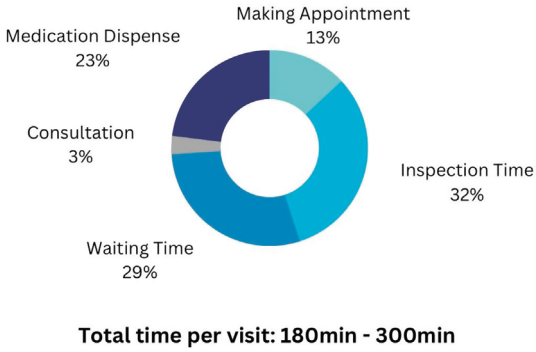

Fig. 1 Shows the average time spent for a typical visit to a hospital in China

Before digital solutions were implemented, hospital patients had to go through a series of steps to access treatment: making an appointment, waiting for consultation, consultation, inspection with diagnosis and payment with therapy. Figure 1 shows that the average time spent for a single visit to hospital was between 180 and 300 minutes on average and only 3% of this total time was spent in consultation. The lack of communication between patients and doctors caused major trust issues nationwide. There are currently 1100 internet hospitals registered in China and it is estimated that over 60% of second tier hospitals or above have online services. Figure 2 shows how internet hospitals changed the overall user experience compared with the previous system. The following sections introduce some background on the development of population-based applications in China.

At the beginning, digital health services were limited to the provision of information and payment functions. This eased the pressure on infor-

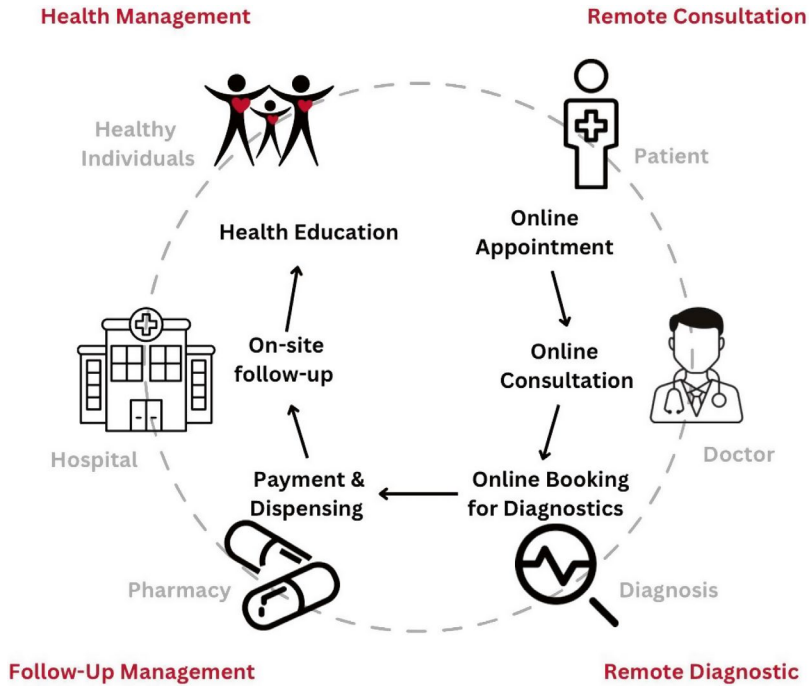

Fig. 2 Shows areas where digitalization has changed the patient interaction with healthcare services

mation counters, cashiers and accountants, and shortened queues for those who need to use the services. However, the benefits of digitalization were not fully exploited in the medical system. Technologies such as electronic medical records and online appointment systems were not popular with the management of the hospitals. Implementing new technology into the existing system creates concerns about how operations in the hospitals will be affected, especially since most of the hospitals in China are relatively large in terms of capacity due to the large population. A failure in the system can potentially be disastrous, therefore, many pilot tests were carried out to demonstrate that the new technology would work, and also to address the changes that would accompany the transition (Liang et al. 2020).

2 Digitization Period

In 2009 the Ministry of Health (presently known as the National Health Commission) published a guiding opinion about the execution of an appointment based reservation system in hospitals (China 2009). Since then, China has tested many digital solutions including digitised medical records, online appointments system, image information sharing, remote consultation, and online prescriptions etc. Many software developers emerged to create apps because of this, but the lack of uniform standards in these apps created a lot of challenges. For example, different branches of hospitals under the same institutions initiated different digital solutions at different times and settings, which resulted in many different apps that could not connect to each other. Users also became very tired by the endless registration process, and a lot of the work reverted to manual processes. Eventually, some apps were developed that provided solutions for such settings, for example, WeDoctor (also known as Weiyi) and Ding Xiang Yuan. Most of these platforms are informative in nature, and there are very few clinical applications. In addition to the developments in hospitals, in 2000 many cities began to set up demonstration zones to allow online purchase of non-prescription medications. Since then, the State Food and Drug Administration (SFDA) (presently known as the National Medical Products Administration) has issued regulations and monitoring systems to further define online medication services such as the business qualifications, service areas, standards, and specialised qualifications for targeted groups (Administration 2007). Despite small market occupancy, platforms started targeting pharmaceutical consumers.

As the coverage and speed of the internet increased, the increase in connectivity enabled the possibility of remote consultations. However, such consultations were not considered to be fully legitimate or recognised. In 2014, there was an official guiding opinion published by the National Health and Family Planning Commission with guidance on promoting remote medical consultation services (China 2014). The paper stated that remote consultation is limited to the referral from one medical institution to another. This is because the authorities could foresee chaotic impacts if remote consultation started from individuals to professionals. Instead, they preferred to start with two medical professional categories, who are under regulatory control. Such progress received much attention in the market, and a lot of the focus began to shift to how to move forward by proposing different future regulatory models and plans for how they should be set up. Meanwhile, the development of online medication purchases was a lot more complicated. There were a lot of illegal trading activities on the market, unlicensed entities or individuals sold registered or unregistered medications or licensed entities sold medications online that required prescriptions. The authorities understood that digital health would be incomplete if online medication services were not operated in a regulated manner. However, the areas of control exceeded the health authority's coverage. After careful evaluation by the authorities, it was concluded that a healthy growth of online medication services would require the control of information technology, commercial business regulatory, cyberspace information management, police, and medication registration information. Hence, the first joint notice targeting illegal online selling of medications was published in 2013, the paper was published jointly by five departments: SFDA, Cyberspace Administration of China, the Ministry

of Industry and Information Technology, the Ministry of Public Security and the State Administration for Industry and Commerce. At the same time, SFDA agreed to allow some of the more established and developed areas like Shanghai and Guangdong Province to have medication services on a third-party platform.

In addition to this development, informatics infrastructures such as cloud computing, artificial intelligence and big data created links between online and offline settings. The Opinions of the General Office of the State Council on Promoting the Development of "Internet plus Health Care" allowed hospitals to have the name "Internet hospitals" affiliated with their original registered name. This allowed them to give remote consultations and health management consultations for follow-up patients with certain common or chronic diseases (Council 2018). It also allowed a qualified third-party app to connect its services to these internet hospitals. Later in the same year, the term and concept of "Internet Hospital" were further defined (National Health Commission, 2018a, b, c), allowing online general practitioner registrations and follow-up of certain common or chronic diseases. The documents also limited the service to non-first-time patients. Later in 2016 strategic documents Health China 2030 listed digital health services as one of the national strategic goals (Tan et al. 2017). Immediately, many previously established third-party apps formed Internet Hospitals, and interestingly, some medical institutions closed their offline consultations. At the time of writing, according to the statistics from the National Health Commission, traffic for online medical consultations has increased 20 times, consultations with treatments have increased 17 times and those needing prescriptions has increased 10 times in the last 5 years.

3 Present Developments

At present, online medical services can be classified as either Business to Business (B2B), Business to Consumer (B2C) or Online to Offline (O2O). B2B and B2C are the most popular bases for the platforms. In hospitals, digitalization of healthcare led to the progression of prescription services to a direct-to-patient (DTP) model. This model has since further evolved into three different applications:

(i) **Prescriptions within the hospital**

Digitalization for prescriptions within the hospital is the most common service provided by internet hospitals. Upon approval from the pharmacist, prescriptions are delivered to the patient's home address. This service does not have any direct commercial value, but rather it is an added-value service. This model functions within the hospital's information system (HIS) unit and does not involve any external platform. In contrast to conventional offline hospitals, this model demonstrates the capacity of internet hospitals, where users do not have to visit the hospital and regular follow-up can be done via smartphone, prescriptions can be issued upon approval by HIS, users can pay within the HIS, the approved and paid prescriptions are then transferred to the pharmacy for approval and the medication will then be dispensed and dispatched to users by logistics. Despite its capacity, this model is not always preferred by many because social medical insurance limits the potential financial margin for such services, and it creates a much bigger demand on the hospital workers.

(ii) **DTP through online shops**

DTP through online pharmacy stores is how users mainly request specific medication products, then a doctor assesses if the user is apt to use such products (whereas the model described previously requires a prior consultation with a doctor). Once approved, this information will be transferred to internet hospitals and a prescription is issued and delivered to the user. This model has relatively larger financial initiatives compared to (i), so many of the procedures are very reproducible. However, the platform sets a lot of commercial rules, and often the entry requirements for such business are very demanding. Therefore, it is very difficult for one to copy such a model.

(iii) **Outsourcing of prescriptions**

This is a model that evolved recently. Internet hospital prescriptions are outsourced to a plat-

form that connects to online pharmacies. The platform checks the availability of the items in their shops and users can then view a list of shops that have the required medication in stock. Upon approval, the medication can be collected from the store or delivery can be arranged. For this system to function effectively, hospitals and pharmacies must use similar pharmacopoeia. This solution diverts the demands into pharmacies closer to the users.

4 Emerging Industries from Digital Health

The traditional medical industry in China can be divided into three parts: an upper stream that consists of medical device manufacturers and pharmaceuticals; a medium stream that comprises the offline hospitals that provide medical services; and a downstream that comprises the users that pay for these services that can be divided further into governmental expenses, public health expenses, personal expenses, and patient expenses. Internet hospitals increase the proportion of personal and patient-related expenses. Industries related to these developments include applications designed for making appointments and consultations, personal health management, online pharmacy shops, tools for doctors (including patient management and sustain educational app), digital payment applications (including commercial and social insurances), AI services (including imaging, diagnostic and medical record services) and digitised information services.

5 Case Study—Ping An Health

Ping An Health is an application developed by the Ping An Group which was originally an insurance company. The group initially had its own team of in-house doctors that then became the core of its health application. The application makes most of its profit from the consumer healthcare sector. Their source of customers is from personal, insurance, enterprise, and offline hospitals. In addition to the in-house doctors, they have taken advantage of remote consultation to acquire specialists from other parts of the country and abroad that led to the rapid growth of online health malls. The data gathered allows them to accurately target specific groups and this creates opportunities for advertising income within the app. From 2016 to 2020, the number of doctors in the app increased about three times from 797 to 2247 and currently there are 400 million registered users (one third of the population). While the group will continue to focus on its B2C customers, it is also looking to optimise the O2O user experience (Fig. 3).

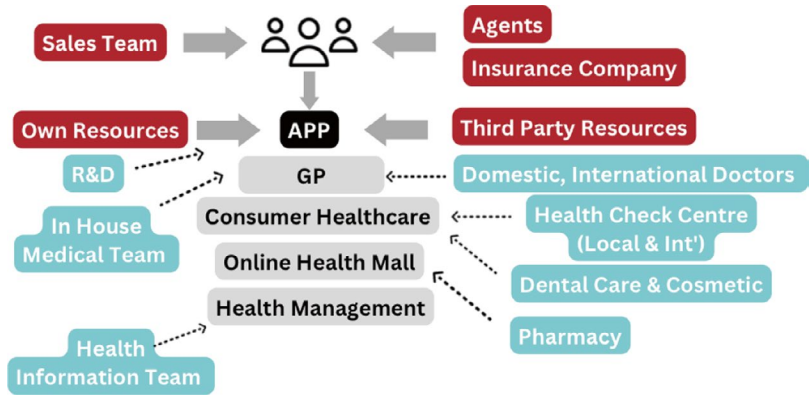

Fig. 3 Shows the operational model for Ping An Health App

6 Limitations and Differences

Despite the big improvements and advances that digitalization brings, the following limitations have been observed through personal communications to frontline workers (anecdotal evidence meriting systematic future investigation). According to CNNIC, only one in five elderly people (over 60 years old) can complete online purchases and search for information online independently (CNNIC 2022). Many patients with chronic diseases have already developed routine habits and are unwilling to change to a digital platform. The lack of understanding of digital technologies creates a sense of insecurity and uncertainty for these users, so acceptance of new technology within certain groups requires additional education and communication to enable them to make the transition. In addition, the medication that the doctor wants to prescribe is not always listed in the directory.

It was also noticed that different sectors had different focuses. At the initial stage, public healthcare providers such as hospitals focused on building internal information systems, their primary aim being to transform the information they already had, whereas the applications platform focused more on providing guidance, doctors' background, focus groups on specific diseases and user review experience. Eventually, the public sector will move on to remote services such as imaging, pathologies, consultations, and surveillance, whereas the applications will focus more on promoting the concept of preliminary consultation to the public as a tool for light consultation. At the later stage, it was observed that the public sector focused on providing medical services via Internet hospitals and transformed some of its offline services to online. Meanwhile, the applications focused on the integration of medical services, insurance and pharmacies, the purpose of this being to optimise the distribution of resources.

The differences between the digital health services provided by applications and information transformed within hospitals are that applications: (i) optimise the distribution of healthcare resources, (ii) empower digital healthcare services using tools such as AI-assisted systems to improve efficiency and capability, and (iii) connect multiple parties such as healthcare, medical insurance, pharmaceuticals, and diagnostics to avoid platform overlaps.

7 Future Perspectives

The Health China 2030 framework is designed to transform the medical healthcare landscape from diseases focus to a general health focus. The role of population-level applications is to act as backbone support to build a personalized health profile that enables more personalised health management solutions based on more accurate data generated. It is likely that offline medical settings will follow the trend of digitalization. The challenges are the connectivity and interactions between the three systems (hospitals, insurance, and pharmacies). The circuit of appointments, consultations, medication dispensaries and follow-up visits should be completed in a seamless fashion. Thus, integration of the three systems is the key to closing the gaps in the circuit. Furthermore, basic knowledge about digitalization technologies should be taught in schools to increase future understanding and acceptance of these platforms.

8 Conclusion

Based on the experience gained, it was concluded that population-level applications targeted different digital health services at different developmental stages. At the initial stage, most services were mainly information-based, such as information for appointments, online pharmacies with limited items, and basic operational information. The scope of applications was relatively small. Eventually, the manual appointment system was transformed to an online appointment system because telephone appointment systems were very well established, and it was easiest for users to adapt to this transition. For the near future, and once the online appointment system becomes established, it will be possible to use the system

for preliminary consultations to reduce the pressure on the frontline. These services are accumulating in number and scope, and networks of digital wards are forming that will eventually become internet hospitals. Because the size of these virtual entities is so big, there will be heavy discussion on regulation and policies on this subject, that will enable population-level applications to grow in the right direction according to their capacities.

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Digitalization of Healthcare in LMICs: Digital Health and the Digital Divide Based on Technological Availability and Development

Ruzica Biga, Sven Nottebaum, Zisis Kozlakidis, and Symeon Psomiadis

Abstract

Digitization in healthcare has been an ongoing trend for several decades, strengthened by the acute needs presented by current health areas such as the COVID-19 pandemic, non-communicable diseases, and the mental health crisis. While in many cases technological development has been a conduit for reducing healthcare inequalities, in others it has had the opposite effect. One of the reasons for the sub-optimal impact of technology has been the digital divide, in other words the lack of technological availability and development. This chapter is a scoping review that identifies the key factors in recent scientific literature that relate to the root causes of the digital divide. Key aspects such as connectivity, digital literacy and accessibility have been firmly mentioned through most of the identified publications. Also, through the scoping review recommendations were identified. This chapter has highlighted the diverse factors affecting the digitization of healthcare in relation to the digital divide, as well as the potential actions that can mitigate this divide based on digital technology availability and development.

Keywords

Digitisation · Healthcare · Low-and middle-income countries · Mhealth · Techquity · Digital literacy · Digital divide

1 Introduction

The use of digital platforms has increased significantly over the past two decades. Hospitals have moved beyond the initial investments that were limited to Electronic Health Records and/or Virtual dispensaries, towards a more holistic view of digitalization in healthcare. The latter includes a view of a digital environment, where the different data streams can be integrated or connected in ways that reflect local and national needs and priorities. Furthermore, digital health has been recognized as a technological approach that can address the gap between urban and rural populations (Marcin et al. 2016) and between

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high-income and Low-and Middle-Income Countries (LMICs) (Labrique et al. 2018). At the same time, a few publications have voiced concern that digitalization may actually be widening the gap in needs and capacities between different healthcare systems (Dorsey and Topol 2016; Scott Kruse et al. 2018; Yao et al. 2022). In the case of LMICs, it is easy to point to the challenges relating to infrastructure as the main barrier to digitalization implementation in healthcare. However, the digital health divide does not simply exist due to the connectivity or not to an internet line. Instead, the reasons for digitalization implementation are complex (as with many other specialized technologies) and intertwined, the result of a combination of persistent healthcare, social, economic, and political factors. Thus, technological availability and development provide an important entry point but should not be seen in isolation or removed from the local context in which digitalization takes place.

Several chapters within this book focus on infrastructural aspects in relation to digitalization of healthcare in LMICs, for example Chap. "Digitization of Physical Health Data in Low- and Middle-Income Countries" on the 'Infrastructure needs, risks and opportunities', Chap. "Proliferation, Ingestion, and Interpretation of Health Data in Low-and Middle-Income Countries (LMICS)" on 'Future sustainability' of digitalization, etc. Complementing the above-mentioned chapters, the question in this chapter is uniquely viewed through the lens of the digital divide and how technological availability and development can create additional challenges or promote sustained growth and development. The current chapter has been structured as a scoping review as it seeks to present an overview of a potentially large and diverse body of literature pertaining to a broad topic. Some of the specific thematic groups that have been identified can form the basis of future systematic reviews, with a sharpened and more specific focus.

2 Methodology

A scoping review of the literature was done, to map out the gaps regarding digital health and the digital divide based on technological availability and development. Studies and articles that describe these gaps were identified from two databases: PubMed and EBSCOhost. The search was done on February sixth, 2023, using the search terms (digital health or digital medicine or electronic health or ehealth or digital health care or mhealth) AND (digital divide or digital gap or digital inequality or digital inequalities or digital inclusion), since inception of the databases and only published in English. The results of the databases and manual searches were exported into EndNote. Duplications were removed using EndNote-based methods as reported previously (Bramer et al. 2016) and double-checked manually. Two reviewers (RB and SP) independently screened by the following eligibility criteria: (i) detailed discussion of the digital divide, at least within a section of the publication; (ii) detailed discussion of digital health implementation, technology and/or policy. Non-English articles, commentaries, and posters were excluded. The difference of opinion between the reviewers was resolved by a discussion with a third party (ZK). The chapter was reviewed and edited in its entirety and independently by a third party (SN), for any potential misalignments. The study screening processes are shown in Fig. 1. The thematic grouping of the identified articles was conducted following a similar methodology, RB and SP conducting the thematic groupings independently and any difference of opinion resolved by ZK as a third party.

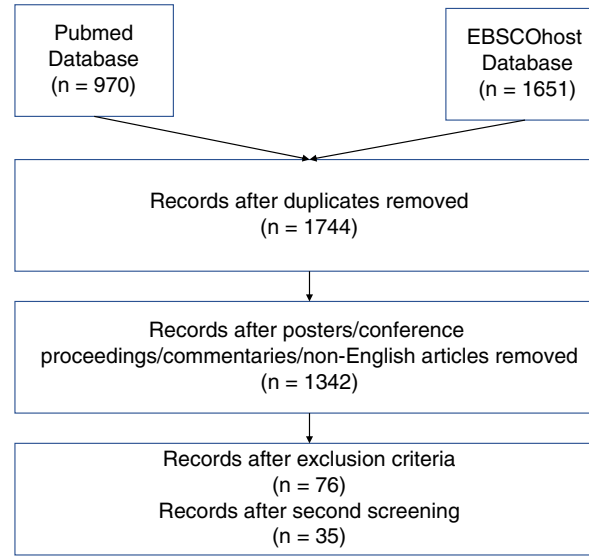

Fig. 1 PRISMA graph of the scoping review for the current book chapter

3 Results

Search results: From the PubMed database, 970 articles were retrieved, 50 were chosen on the first screening (reading abstract) and these were reduced to 31 articles on the second screening (reading the main body of the article). From the EBSCOhost database, 1651 articles were retrieved, 878 were excluded as were duplicates with those identified by PubMed, resulting in 774 unique articles. Twenty-six articles were chosen on the first screening (reading the abstract), reduced further to 4 articles on the second screening (reading the main body of the article). Thus, 35 articles were used in this scoping review, and all have been included within the references of this chapter. It is interesting to note that most of the identified articles had simple mentions of the search terms in passing and thus the observed high attrition rate, however, very few dedicated a specific section or any detailed forethought on the topic. The retrieved articles have been divided in the thematic groups presented below.

3.1 Affordability and Cost of Technology (Saeed and Masters 2021; Paccoud et al. 2021; Jiang and Liu 2020; Bayard et al. 2022; Freeman et al. 2022; Haenssgen 2018; Nagler et al. 2013; Kemp et al. 2021)

A low social-economic status (SES) is a determining factor for the availability of technology and digital health. Populations with lower incomes face more challenges in access to and are less likely to adopt digital health technologies, which may lead to more severe health inequalities. This observation is supported by the fact that there is an income gradient associated with having access to telehealth. What is more, it was shown that socially disadvantaged groups of patients tend to be excluded from technology-based intervention research primarily based on their lack of access to computers and/or mobile phone devices.

3.2 Device Type (Marcin et al. 2016; Freeman et al. 2022; Arcury et al. 2020; Giansanti and Veltro 2021; Graetz et al. 2018; Reddy et al. 2022; Graetz et al. 2016; Frutos et al. 2022; Patel et al. 2022; Lama et al. 2022; Scott Kruse et al. 2018; Greenberg et al. 2018; Schrauben et al. 2021; Broffman et al. 2023; Moon et al. 2022; DeGuzman et al. 2020; Sanders et al. 2013; Zhang 2022; Toscos et al. 2019; Singh et al. 2022)

People living in rural areas and areas with higher levels of poverty are disproportionately affected, and they are more likely to be reliant on the use of lower-performing devices, such as smartphones, as opposed to PCs or tablets, for internet usage. With access to digital health only via mobile phone, many patients accessed mobile-only virtual services less frequently than those who used computers since there are applications with only computer-based access or applications that are less able to operate natively on several platforms and/or lower-performing devices. A statistically significant correlation was found between having a personal computer and internet access and patient health record use. These factors contribute to the difficulties in performing and the probability of completing remote consultation visits. These articles provide evidence for the links between digital health utilization and computer characteristics and the quality of the device. For example, once people own a certain hardware (Like PC or tablet) they're more likely to be more computer literate than mobile-only patients. However, this does not mean that device performance affects the utilization of digital health tools, as modern healthcare applications function on multiple platforms and devices in an effort to capture the widest used base possible.

3.3 Connectivity (Bayard et al. 2022; Freeman et al. 2022; Reddy et al. 2022; Graetz et al. 2016; Patel et al. 2022; Lama et al. 2022; Scott Kruse et al. 2018; Greenberg et al. 2018; DeGuzman et al. 2020; Toscos et al. 2019; Mackert et al. 2016)

Many countries cannot embrace the latest healthcare innovations due to geographical restrictions or a lack of consistent internet connectivity. Unequal access to high-speed or broadband internet service and digital health itself magnifies disparities and limits access to web-based patient portals across patient sub-populations, especially in already disadvantaged groups that are typically hard to reach. Furthermore, a limited number of digital health infrastructure providers highlights gaps in digital health availability. Residents with a lesser ability to obtain and afford access to a fixed broadband signal exhibited limited skills in utilizing technology.

3.4 Accessibility (Saeed and Masters 2021; Haenssgen 2018; Piers et al. 2023)

Digital health expansion could improve the quality of life; however, the digital divide could exacerbate disparities, especially among people with disabilities. Communication disabilities represent an obstacle to accessing technologies; in particular, deafness needs to be acknowledged. Nonetheless, disabilities that cause difficulties in accessing these tools need to be taken into account. One current major barrier to digital health access for people with disabilities is the design of digital health technologies, whether those are provided through websites or applications, which has accessibility issues that prevent people with disabilities from being able to utilize

these technologies. It has also been shown that disparities in the digital divide largely influence patients with mental health/psychological disorders.

4 Digital Literacy (Paccoud et al. 2021; Jiang and Liu 2020; Bayard et al. 2022; Freeman et al. 2022; Nagler et al. 2013; Kemp et al. 2021; Frutos et al. 2022; Scott Kruse et al. 2018; Toscos et al. 2019; Sayed and Mamun-ur-Rashid 2021; Masucci et al. 2006; Kim and Kim 2010; Choxi et al. 2022; Gordon and Hornbrook 2018; Kumar et al. 2019)

One of the common barriers to adopting digital healthcare is a lack of technological experience or familiarity. It has been shown that the quality of digital health services depends both on patients' and providers' familiarity with the medium of communication. One of the identified issues is that medical personnel are not adequately trained or experienced in fully utilizing the technological capabilities available to them. On the other hand, people with limited technology skills may be reluctant to use or unable to access technology to acquire health information on their phones. And even feel left behind with digital health, despite having access to a computer or smartphone. Having low skills in using a cell phone or computer represents a significantly lower use of digital health services. Additionally, it was shown that interest in and successful use of the digital health system were not correlated to any other factor (age, gender, education level, or ownership of a computer) but to skills in technology use. Low digital literacy was related to increased anxiety about using digital health.

4.1 Health Literacy (Kemp et al. 2021; Arcury et al. 2020; Graetz et al. 2018; Reddy et al. 2022; Schrauben et al. 2021; Moon et al. 2022; Singh et al. 2022; Mackert et al. 2016; Piers et al. 2023; Sayed and Mamun-ur-Rashid 2021; Gordon and Hornbrook 2018)

Knowledge of digital health (even in general terms) positively and significantly influences the use and acceptance of digital health services. It was shown that the use of digital health tools has been consistently lower in patients with low health literacy. Moreover, they were less likely to be perceived as easy or useful. The ability and confidence to use digital health technologies to obtain health information and advice decline with age and are less prevalent among ethnic minorities. Furthermore, a study identified that only less than a third of internet and smartphone users have proficiency in the use of digital health technologies, and an even smaller fraction have adequate digital health literacy. It has been shown that health literacy can be improved by digital health technology itself, which will enhance patients' participation in digital health care.

4.2 Cultural Barriers (Yao et al. 2022; Haenssgen 2018; Kemp et al. 2021; Reddy et al. 2022; Sayed and Mamun-ur-Rashid 2021)

Even within regions with full access to technologies, uneven access to technologies was found due to cultural barriers. Discriminating societal norms and restrictive cultural beliefs, in addition to poor health literacy, weave together a web of cultural barriers, in which the hardest-hit groups are females. In some regions where women have low socioeconomic status (SES), they are dis-

couraged from going on the web and do not have access to cell phones. In addition, female sex is correlated with a decreased probability of completing a digital health visit or compliance with remote counseling/monitoring. A great number of sociocultural factors related to institutional, economic, cultural, and educational barriers negatively impact women's physical well-being and their access to appropriate health-care services in developing countries. Furthermore, language barriers (including translation inaccuracies) can play an important role in digital health's utility.

5 Discussion

Several of the identified articles, beyond the description of barriers and different challenges relating to digital health and the digital divide, provided accompanying potential solutions (Bayard et al. 2022; Reddy et al. 2022; Zhang 2022; Liang 2012; Bashshur et al. 2020). These can be summarized in the 9 points shown below:

1. It is necessary to minimize the cost of scaling up the technology by developing modalities that are feasible, affordable, and acceptable to the people and the community.
2. A digital health site in a rural public library would enable greater access to digital healthcare services by removing obstacles caused by insufficient residential broadband access. The library serves as a proxy example for state-sponsored public service, where existing access opportunities can be identified.
3. If markets with competitive internet service providers fail to bring bandwidth and equipment to geographically isolated areas, then the respective governments should consider implementing policies to cover the gap.
4. To provide equitable access to care, legislation supporting reimbursement of digital health services is crucial.
5. To address disparities and increase accessibility of digital health, it is necessary to have a program that provides underserved communities with information technology education and training to improve its use, alongside improved digital infrastructure, and strategic resource allocation. Importantly, even though targeting underserved communities, this support should be available to all who want to make use of it.
6. Having a mobile-accessible patient health record can help engage patients in managing their health through convenient and timely access.
7. mHealth interventions should employ phone features that are accessible and familiar to the target audience to avoid denying intervention benefits to those with low mobile phone literacy and therefore widening health disparities.
8. A framework within healthcare organizations that should include standardized protocols for effective deployment of digital health to triage patients at the point of need and the efficient use of relevant technological innovations.
9. Primary healthcare facilities are the entry point to healthcare for the largest part of LMIC populations. Thus, they should be enabled to provide wider access to digital health information to disseminate the best resources that would maximize adoption and long-term use.

This summary of recommendations from the identified manuscripts reflects well the priorities set by the G20 health meeting in 2020, resulting in the 'Recommendations from the Riyadh Global Digital Health Summit' of 'Riyadh declaration' (Al Knawy et al. 2020). Even though the declaration focused on infectious diseases, as opposed to a wider healthcare view (also due to the G20 meeting taking place during the height of the COVID-19 pandemic), there are marked similarities. For example, the fourth recommendation mentions exactly "Ensure that countries prioritize digital health, particularly improving digital health infrastructure and reaching digital maturity". A further, more detailed breakdown of these recommendations has gone a step further, placing strong emphasis on community participation and action in digital health to build resilience in healthcare systems as a whole and establish the foundation for effective prevention, preparedness, and response to healthcare pressures (Al

Knawy et al. 2022), complemented by appropriately trained leadership (Al Knawy and Kozlakidis 2021; Al Knawy 2021). Additionally, emphasis was placed on techquity, i.e., the strategic development and deployment of technology in health care and health to achieve health equity, and system transformation (Al Knawy et al. 2022). It is anticipated that further granularity will be achieved in years to come, linking policy recommendations to actions and measurable outputs, aimed to address the digital divide, technological development and availability.

6 Conclusion

Digitization in healthcare has been an ongoing trend for several decades, strengthened by the acute needs presented by current health topics such as the COVID-19 pandemic, non-communicable diseases, and the mental health crisis. While in many cases technological development has been a conduit for reducing healthcare inequalities, in others it has had the opposite effect. One of the reasons for the suboptimal impact of technology has been the digital divide, i.e., the lack of technological availability and development. This chapter has utilized the methodology of a scoping review to identify the key factors in recent scientific literature that relate to the root causes of the digital divide. Key aspects such as connectivity, digital literacy and accessibility have been firmly mentioned through most of the identified publications. Also, through the scoping review recommendations were identified. This chapter has highlighted the diverse factors affecting the digitization of healthcare in relation to the digital divide, as well as the potential actions that can mitigate this divide based on digital technology availability and development.

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Biobank Digitization in Low-Middle Income Countries (LMICs): Current and Future Technological Developments

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Abstract

Digitization is currently penetrating all fields of modern sciences and has consequently become a critical aspect of modern biobanking operations, as biobanks constitute part of the foundational research infrastructures. Biobanks that specialize in the long-term storage of biological samples, such as tissues, blood, and DNA, have recently been established in several low- and middle- income countries (LMICs) in the Arab region of the Middle East, such as Egypt, Jordan, and Sudan. The current chapter provides an overview of the challenges for digitization of healthcare, current and future technological developments with specific examples from LMICs. Utilizing the experiences from LMICs, and in particular from Egypt, a set of recommendations is also put forward.

Keywords

Digitisation · Low-and middle-income countries (LMIC) · Biobank · LIMS · BIMS · Biological samples

1 Introduction

The global health landscape is evolving rapidly, and digitization is now penetrating almost every aspect of modern society, including biomedical research and healthcare (Jacobs et al. 2018). Healthcare delivery is becoming more technologically advanced with the focus of digital health initiatives shifting towards scalability, integration into the healthcare system and sustainability. In the coming decades, digital health technology will unquestionably play a significant part in assisting healthcare professionals in adopting some of these advances into routine practice. In general, due to the rapid pace of change and digital growth, low and middle-income countries (LMICs) need more resources to be invested in their healthcare development, and those that do exist are unevenly distributed. Therefore, LMICs continue to face considerable difficulties in providing high-quality, affordable, and universally accessible healthcare delivery and research, and in response to these challenges, different types of digital health initiatives have been launched (Labrique et al. 2018).

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Biobanks, whose purpose is the long-term storage and distribution of biological samples, and associated data, have become key actors in the biomedical research fields, by allowing for the analysis of samples long after their collection and by digitally making available information about the sample and its donor. For example, most major biobanks and cohort studies rely on online application procedures for their samples and data through dedicated laboratory information management systems (Jacobs et al. 2018). This allows for a reliable tracking and monitoring of said applications, which improves the efficiency of the use and distribution process. Furthermore, numerous technologies, like electronic health records (EHRs), remote consultations, and mobile health (m-health) applications (apps), are already widely used in several countries in many fields, such as diagnostics, robot-assisted surgery, clinician decision support, and epidemic prediction, however all these remain largely independent activities and not systematically linked (World Health Organization (WHO) 2021).

Many digital initiatives focus on healthcare challenges in LMICs aiming to improve both access to healthcare and the quality of healthcare delivery (Aisyah et al. 2022; Labrique et al. 2018). Egypt highlights the importance of m-health and e-health (Moss et al. 2019) to overcome many long-standing barriers to providing healthcare to the underprivileged in LMICs, particularly barriers like access, quality, time, and resources (Kamel 2021). Moreover, the COVID-19 pandemic has highlighted and amplified the shortcomings of LMICs healthcare systems, especially in terms of health infrastructure. However, one of the positive effects was the growing and accelerated investment in digital health initiatives, such as teleconsultations, which improved access to quality healthcare (Hirko et al. 2020; European Observatory on Health Systems and Policies et al. 2022).

The aim of this chapter is to outline the benefits and challenges associated with the implementation of digital health initiatives in LMICs, as well as to suggest innovative solutions already showing promising results in some LMICs.

2 Digitization and Biobanking

Digitization is currently penetrating all fields of modern sciences and has consequently become a critical aspect of modern biobanking operations, as biobanks constitute part of the foundational research infrastructures. Biobanks that specialize in the long-term storage of biological samples, such as tissues, blood, and DNA, have recently been established in several low- and middle-income countries (LMICs) in the Arab region of the Middle East, such as Egypt, Jordan, and Sudan (Abdelhafiz et al. 2022). According to Abdelhafiz et al. biobank managers in these countries faced similar difficulties for the establishment of their biobanks, for example, lack of trained and skilled staff, limited financial resources, and lack of knowledge about biobanking in the general population and among physicians leading to their reluctance to support these projects. For their training, the staff often has to enroll abroad, at European or USA institutions for instance, however, this training is often quite short, lasting a month/a few months, which might not be enough to gain full knowledge and experience (Abdelhafiz et al. 2022). In that context, digitalization might be part of the solution to this problem, by allowing for some of the training to be undertaken remotely, through virtual conferences and courses, as well as online educational resources.

Prospective biomedical research commonly requires storing tissue and liquid biological samples for long periods. Thus, biobanks have supported several research developments such as mapping the human genome, and the cancer genome atlas project (Abdelhafiz et al. 2022; Coppola et al. 2019) and others, thus are considered as gateways for precision medicine. Biobanks have also gained importance in the last few years due to increased quality requirements for biological samples. Indeed, processing and storage of biological samples with reliable and extensive pre-analytical history plays a key role for reproducibility in scientific research and due to the ever-increasing demand for samples, particular attention must be paid to sample acquisition and preparation in order to guarantee the

highest possible sample quality (Baber and Kiehntopf 2019). Specifically, the time that follows the collection of a given sample and precedes its analysis is called the pre-analytical phase, during which the quality and stability of samples is strongly influenced, making it essential to have accurate information on the sampling time (Lippi et al. 2019). This leads to the role that digital solutions can play, for instance, on the integration of electronic data sources, and with automation of the technical processes, such as the retrieval of samples from storage, and their treatment for analysis.

The automation of biobanks' complete life cycle, from early collection and pre-analytical processing through the storage, freeze-thaw cycles, to its final analysis allows to sharpen their competitive advantage, harmonization and standardization and allow for eventual accreditation (Baber and Kiehntopf 2019). Furthermore, the increasing complexity and amount of data generated by biobanking activities, makes digitalization necessary to manage these resources efficiently. With digital tools, such as virtual databases and software specifically designed for biobanking operations, it becomes easier to manage large amounts of data and to track the movement of samples from the point of collection to their destination after distribution. Digitalization can bring major improvements to the way biobanks manage their activity by allowing for an increase in speed and accuracy of data processing. With digitized information, researchers can quickly search for and access specific samples or data points, speeding up the research process significantly (Arrighi and Hofman 2022). Furthermore, digitization helps reduce the probability of errors and inaccuracies that are inevitable and quite common with manual data entry and handling (Arrighi and Hofman 2022). Another key benefit of digitalization for biobanks is improved data security. With advanced security and access controls, data is less susceptible to be tampered with or handled by unauthorized individuals. Therefore, sensitive data, which could identify a specific or group of donors for instance, can be adequately protected.

Conclusively, digitalization provides numerous potential benefits, including faster and more accurate sample tracking, improved data security, and increased operational efficiency, but can also be of great value for sharing information, networking, and collaboration between biobanks in LMICs. One such project is identified, the Zipline project, which consists in using drones to transport blood from storage units to hospitals. This technology has allowed hospitals in Rwanda to adapt to the lack of transportation infrastructure in rural areas, and minimize transportation time, therefore, addressing the concerns around the pre-analytical phase, which is an essential part of the life cycle of a biospecimen (Ackerman and Strickland 2018). Another example is the DxConnect Virtual Biobank that operates as a collaborative resource. Hosted by FIND, the global alliance for diagnostics, this open-access platform enables researchers across academic, non-profit and industry sectors to view collections- even if not self-identified as biobanks- registered by any institution worldwide, search by disease and other characteristics, and connect with those holding samples of interest (Ongarello et al. 2022). This virtual arrangement is anticipated to bridge the gap between LMICs (where most infectious diseases occur, and samples are collected) and high-income settings (where most samples are analyzed). Having said that, the above initiatives that rely heavily on digitalization of biobanks in LMICs currently constitute the exception rather than the rule.

2.1 Documentation of the Life Cycle of Biological Samples

Perhaps the greatest impact of digitalization in biobanking is on the documenting of the life cycle of biological samples. The life cycle of a biological sample can be divided in three main phases: the pre-analytical, the analytical, and the post-analytical phase. In the context of international clinical studies, an increasing number of biological samples are needed and being collected, which reveals the need for optimal management of these resources, so their quality can be guaranteed to researchers (Betsou 2017). However, health institutions and researchers tend to focus on the performance and efficiency of the analytical and post-analytical phases, during which typically

15–20% of all errors occur. On the other hand, the frequency of pre-analytical errors is generally between 60% and 70%, but despite these results, sampling time information is often missing (Vermeersch et al. 2021; Plebanis 2012). In that context, the problem can be addressed in different ways, including through information technology. Indeed, the ability to follow a biological sample's complete life cycle, from its initial collection and pre-analytical processing through the intermediate storage conditions, including freeze-thaw cycles, to its final scientific usage is made possible by digital information technologies.

Nanni et al. were able to map and track the entire life cycle of stored biological samples using Radio Frequency Identification (RFID) technology. This technology allowed, through communication with radio-waves, to identify samples and their data by reading an electronic tag attached to the samples' container, either manually or through an automated process using special cryotubes and racks. It also allowed us to keep track of every movement of a given sample and the time between each step by recording time stamps (Nanni et al. 2011). The RFID technology showed promising results in high-income settings and allowed for a better management of the technical process of a biobank with better tracking of samples. However, the evidence didn't show a significant improvement on the quality of the samples, while the costs associated with the implementation of this technology are not compatible with the financial challenges and competing financial priorities faced by LMICs.

That being said, a thorough digital history of each biological sample can be created and used in research by combining the collected data within a so-called integrated 'Biomaterial Information and Management System' (BIMS) (Parajuli et al. 2022).

2.2 Biobank Information Management System (BIMS) Interaction with Other Digital Data Sources

Integrating biological sample-derived data (such as '-omics' data) with the broad range of phenotypic data gathered in other specialized research contexts or retrieved from EHRs, or patients themselves could be made significantly easier by digitization. To this end, the Information Management System of a Biobank (BIMS) supervises all the relevant data related to the biobank's activity, including sample movements and exact location, patient data, storage conditions, and governance-related documents.

The BIMS can be connected to multiple software systems and databases, such as the Laboratory Information Management System (LIMS) which handles data related to the life cycle of samples, the hospital information system (HIS) for patient data, and the monitoring system (MS) which keeps track and regulates temperature and liquid nitrogen levels (Fig. 1). BIMS are often a subset of LIMS, repurposed and customized to fit the needs of a biobank, however, customization and staff training as a consequence, can be too costly for LMICs. Therefore, LMICs may need the support of BIMS providers through the development of open access software (Ezzat et al. 2022).

The BIMS allows for a better management of the large amounts of data generated by biobanking and research activities, in addition, it can provide a user interface that does not require programming skills, and the centralization of sensitive and confidential data can create a more secure digital environment in which security breaches can be prevented more easily (Arrighi and Hofman 2022; Olund et al. 2007). Finally, manual handling of data is time-consuming, and errors are likely to appear, but the BIMS can automatically integrate data from different sources and reduce the likelihood of errors to occur (Arrighi and Hofman 2022). Therefore, biomaterial-data sources should be connected to a core BIMS using standard data sharing formats to support and facilitate local biomedical research and enhance networking with more biobanks and research institutions (Pote et al. 2021).

2.2.1 Data Quality

Data is commonly perceived and defined as a set of collected facts, and the International Organization for Standardization (ISO) defines it

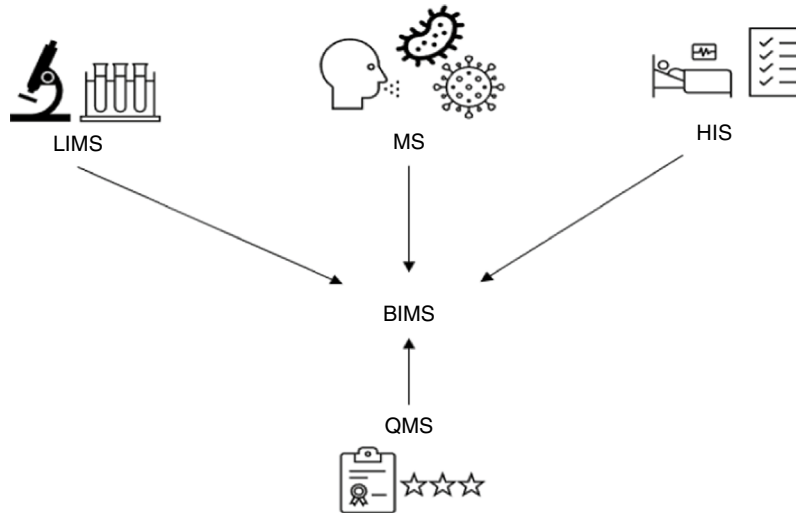

Fig. 1 An illustration of the data input streams for Biobank Information Management Systems. Data streams can be integrated from Laboratory Information Management Systems (LIMS); from Monitoring and Surveillance systems (MS); from Healthcare Information Systems (HIS); as well as Quality Management Systems (QMS)

as "reinterpretable representation of information in a formalized manner suitable for communication, interpretation, or processing." Biobanks store data about patients, samples, analyses and even sometimes drugs. The data quality depends on the degree to which reliable and accurate information can be extracted. Therefore, high-quality data will accurately represent a situation and support interpretations that would be obtained with error free data, as defined by the Institute of Medicine (IOM) (Eder and Shekhovtsov 2021). For that reason, the implementation of a quality management system (QMS) is essential for an organization to be able to monitor the quality of their activities. A QMS is a set of processes and procedures that help coordinate and guide an organization's activities to continually meet quality standards and achieve greater levels of efficiency (Betsou 2017). In that context, to handle biological material, it is crucial for biobanks to develop standard operating procedures (SOP), so a given sample's data can be documented accurately throughout its entire life cycle from collection or reception to distribution. In a low resource setting, the implementation of SOPs can be a challenge, but for example the Golestan Cancer Biobank in northern Iran, was able to develop and put in place SOPs according to internationally accepted standards and protocols with some modifications because of their limited resources (Ghasemi-Kebria et al. 2021).

The quality of a given data point can be appreciated across multiple dimensions, including, accuracy, traceability, reliability, confidentiality, and impartiality. For instance, data accuracy refers to the representation of reality with the highest degree of truthfulness, meaning that it is objectively and measurably correct, as well as precise (Arrighi and Hofman 2022). It is important to consider these different dimensions to determine the relevance and usefulness of a data point, which is a challenge for biobanks in LMICs with limited financial and skilled human resources (Chowdhury and Pick 2019).

3 Challenges in Digital Health in LMICs

Despite the many optimistic views on potential benefits from the digitalization of biobanking in LMICs, severe challenges remain. These many challenges hinder the potential benefits of digitalization in healthcare research, including regulatory and ethical dilemmas and policies, as well as the difficulties associated with integrating digital technology into routine practices, while implementing digital health programs (Al Knawy et al. 2022). The main challenges that need to be addressed in that context are as follows (summarized in Table 1):

Table 1 Summary of main challenges and some potential solutions for digitalization in LMICs

Challenges		Potential Solutions
Technical	Electricity supply	Back-up generators
	Lack of Internet Access	Synergies with existing infrastructures
	Unstable network connections	
	Lack of IT equipment and infrastructure	
Financial and HR	Skilled staff shortage	Financial incentives for investment
	Lack of technical training	Creation of training courses
	Low digital literacy	Staff incentives to train and remain in post
	High maintenance cost	
	Lack of funding	
ELSI	Data privacy and confidentiality	Highlighting gaps and in ELSI-related legislation
	Informed consent	Data protection regulation
	Intellectual property	
	Language barriers	
	Lack of regulatory frameworks	
Geographical	Regional topography	Public infrastructure investment
	Lack of infrastructure	Synergies in logistics with other product types, e.g., vaccines
	Lack of reliable logistics	

1. The most common challenge encountered is a lack of appropriate technical infrastructure, for example basic telecommunications infrastructure, such as reliable internet access, electricity, and mobile networks. In the context of a biobank's operation, high volumes of data are generated, and thus LMICs may lack the necessary IT infrastructure and expertise to effectively handle and analyze them (Parajuli et al. 2022).
2. Limited financial and human resources, making it difficult to invest in staff training, and equipment when digital health programs are implemented. In return, it is difficult to maintain and manage these programs when faced with a lack of skilled staff, such as IT specialists who could provide technical training to health professionals. This can limit the scope and scale of biobank projects, for instance, and make it difficult to sustain them over the long term (Chowdhury and Pick 2019).
3. Data privacy and security, in many LMICs, regulations to protect patient data and ensure privacy and security are limited. Therefore, the trust between patient and healthcare professional, and the trust between patient and digital health services are more difficult to foster. In that context, ethical and legal considerations, related to informed consent, data privacy and intellectual property rights must be considered.
4. The geographical context of a given region can have an impact on the development of digital health programs. Indeed, the geographical distribution and topology, as well as the presence or absence of proper roadways could make transportation operations and infrastructure maintenance more difficult and costly (Parajuli et al. 2022).

3.1 Access to Internet and Electricity

Reliable access to electricity increases services availability, readiness, and quality of care, especially for patients under critical care (Alhadi et al. 2022). On the contrary, a lack of access to electricity is associated with negative health outcomes, for example increased mortality, lower quality of care, and reduced utilization of health services (Irwin et al. 2020). Digital technologies typically rely on having access to the internet and electricity, both of which depend on various fac-

tors, including region, socioeconomic status, and others. The implementation of digital health programs requires a stable and strong internet connection and electricity supply for the equipment to function effectively, however, reliable and affordable access to these resources is a significant challenge for LMICs, affecting equally significantly digital and laboratory aspects of healthcare (Vounba et al. 2022). Furthermore, the cost, which is still considerable in many LMICs, is another prohibitive parameter (Kiehntopf and Krawczak 2011). For that reason, some manufacturers are investing in research around low-cost innovations that could benefit health institutions in low resource settings (Eder and Shekhovtsov 2021).

3.2 Technical Challenges

Biobanks require specialized infrastructure, such as cold storage facilities with −80°C freezers and liquid nitrogen tanks, as well as laboratory equipment and machinery for sample analysis. Basic infrastructure, such as electricity supply and a stable internet connection, necessary for any facility to function properly are also essential for biobanks to be and remain operational. Technical difficulties encountered as network issues, blurry images, poor sound during video consultations owing to a slow internet connection, and service interruptions due to poor network quality are just a few of the technical challenges encountered by healthcare professionals, researchers, patients and users of health services. Indeed, in a study from 2014, Mendy et al. reported that only 55% of biobanks had access to reliable and uninterrupted electricity supply, which is a key component of biobank infrastructure to operate equipment, freezers, and computers. This means that 45% of these facilities face a major challenge in maintaining the quality of their biological samples (Mendy et al. 2014). Therefore, digital health programs and solutions can be technically much more difficult to implement in LMICs. Unfortunately, there is little benchmarking done on this aspect, beyond isolated anecdotal evidence relating to facilities and/or scientific initiatives

3.3 Skill Shortage

LMICs experience severe skilled personnel shortages, and according to the WHO, with current population needs, there is a global shortage of about 7.2 m healthcare workers, which is expected to rise to 12.9 m by 2035 (Chowdhury and Pick 2019). LMICs are particularly affected by this phenomenon, which is amplified by the departure of medical practitioners to more developed nations. Therefore, to combat this issue, it is crucial to offer incentives to physicians for them to remain in their home countries, such as improving their working conditions and recognizing the value of their work, particularly in remote and rural areas (Scheffler et al. 2016). This may require investing in better healthcare facilities and promoting collaboration with healthcare providers operating in rural areas (Chowdhury and Pick 2019). In addition, ongoing training with IT experts will be necessary in a rising digital era, considering the increasing rate of change associated to health technologies, and digital literacy will be a necessary skill for health professionals to acquire for them to be able to address the concerns about technology divide affecting service accessibility (Holland and Davies 2020), between rural and urban areas for example.

3.4 Ethical and Legal Challenges

The ethical issues relevant to using digital technologies include data privacy, confidentiality, transparency, and ownership. The WHO emphasized that digital health interventions must consider individuals' data privacy, security and its appropriate use and ownership (World Health Organization (WHO) 2021). Digital health technologies collect and store sensitive personal health data, which must be protected from unauthorized access or use. For this reason, a trusted and safe environment for health data has to be put in place, for example, with a data access model that enables research in a trusted digital space and doesn't allow sharing data outside this digital space. However, this requires robust protocols to

be established, which can be a challenge in LMICs where there may be limited resources or expertise in this area (Zatloukal et al. 2022).

That being said, patients must be fully informed of the purpose, risks, and benefits of digital health technologies and provide their consent for their data to be collected and used. In LMICs, where the population might not be educated sufficiently or where access to information is limited, this may affect the consenting rates. Another aspect to consider are the cultural barriers and how these can affect the overall approach to digital health. For instance, it may be considered disrespectful, in some cultures, to question or challenge an authority figure, such as a researcher or healthcare professional. Therefore, the necessary steps to ensure that prior informed consent is discussed and obtained, need to be taken, to ensure that samples and data can legally and ethically be used and shared (Vodosin et al. 2021).

Digital health has the potential to revolutionize healthcare delivery and improve health outcomes in LMICs, but also the potential to amplify pre-existing health inequities, for instance, between urban and rural areas in terms of access to the necessary infrastructures to deploy digital technologies (Hirko et al. 2020). Limited internet access and lack of digital education make it difficult to ensure equitable access to these technologies. Finally, on the legal side, there may be unclear or inadequate regulatory frameworks in place to govern the use of digital health technologies in LMICs, particularly in the context of biobanking (Biobank and Population Cohort Building Network (BCNet) 2022). This can lead to concerns around the quality and safety of these technologies, as well as the ethical use of patient data.

3.4.1 Policy and Data Security Challenges

The 2018 WHO resolution on digital health puts an emphasis on the necessity for LMICs to develop frameworks that address concerns around privacy, security, data ownership and consent (World Health Organization 2018). Indeed, a key element of appropriate and secure data management in biobanks should be that clinical data, sample-related data, and identifying data are physically stored in separate databases under different administrative power and using different identifiers, thus reducing the likelihood of a security breach (Scheffler et al. 2016; Zatloukal et al. 2022). However, the BIMS is generally connected to the internet, and data transfer operations are often conducted online which makes biobanks vulnerable to cyberattacks and confidentiality breaches. It is therefore essential for biobanks to be equipped with reliable IT infrastructures closely monitored to prevent data theft (Chowdhury and Pick 2019).

Policy challenges include, keeping pace with evolving digital technologies in healthcare, the establishment of standards for international data sharing (Vodosin et al. 2021). Also, to these challenges can be added, political instability, frequent transfers of skilled health professionals, and a lack of consistent official support (Scheffler et al. 2016). However, according to Vodosin et al. digital health programs have seen some increase in LMICs, as have regulatory frameworks. However, most LMICs still currently lack governance guidance/regulation, thus, long-term leadership and support at a very high level is necessary for them to succeed in this endeavor.

3.5 Funding Challenges

Biobanks in LMICs face several financial, operational, and social challenges in establishing sustainability. These challenges include developing a business plan that relies on dependable funding sources, enhancing operational efficiency, and building trusting governance arrangements with researchers and potential donors (Vaught 2011). Funding challenges in terms of buying costly equipment, high installation charges, and training staff were identified (Abdelhafiz et al. 2022; Van der Stijl and Eijdems 2019). Indeed, costs are an essential part of sustainable biobanking, and are highly variable and specific to the type of biobank, but overall, the initial starting investment at the creation of these structures consists essentially of capital investments in buildings, space and equipment. Across time as a biobank becomes operational, costs associated with sample and data collection, processing, storage and distribu-

tion start to rise (Van der Stijl and Eijdems 2019). During this phase, costs can be divided into different categories, including, human resources, equipment and infrastructure, as well as sample handling and data management (Van der Stijl and Eijdems 2019; Sqalli et al. 2020). Generally, human resources are the biggest source of expenses for biobanks which is a major challenge for LMICs facing skilled staff shortages and difficulties to generate revenue and secure long-term funding (Van der Stijl and Eijdems 2019). Digital health programs depend on funding and volunteers; when funding stops, the whole program gets disturbed and terminated. However, in LMICs the distribution of resources is extremely unequal, and it is widely agreed that funding aligns poorly with global health needs.

For biobanks to achieve longevity, they must be financially sustainable, but the access to secure long-term funding is very difficult. In Egypt, for example, numerous national funding agents are available to fund biobanking and research, Science, Technology Development Fund (STDF) and The Academy of Scientific Research and Technology (ASRT). Furthermore, the Ministry of Higher Education and the Ministry of Planning and Social Development, along with some non-governmental organizations, share in supporting planned research. According to van der Stijl and Eijdems, academic biobanks struggle to get access to enough revenue to sustain their activity, therefore, multiple sources of funding and income need to be considered. This diversification of income streams can include a mix of public funding, such as research grants, commercialization of services, and private funding through collaboration with industry (Van der Stijl and Eijdems 2019).

3.6 Regional Challenges

Accessibility of healthcare refers to the relative ease with which services can be reached from a given location, and one of the difficulties in establishing digital health services is the complex landscape in LMICs. Indeed, uneven geographic distribution and topography such as mountains and hills make the establishment of and access to health facilities difficult (Eder and Shekhovtsov 2021). It is a major barrier that is often underestimated despite its importance since a significant part of the populations in LMICs live in rural areas with no direct access to healthcare facilities but by traveling long distances by foot or public transport (Sqalli et al. 2020). In addition, many LMICs don't have sufficiently developed infrastructure for logistics and transport, which can make it difficult for patients to access health facilities and difficult for health facilities, to move essential equipment and supplies, or in the context of a biobank, to move biological samples and data between different sites.

4 Conclusion

Throughout the world, information and communication technologies are increasingly used in healthcare. Many of the current issues facing health systems in LMICs, such as the non-availability of healthcare professionals in rural areas, the inconsistent quality of care and low patient compliance, may be mitigated through the widespread use of e-health, especially as technologies continue to develop. However, for e-health to spread and deliver its promises, a strong foundation needs to be put in place in LMICs by engaging all stakeholders (physicians, researchers, patients, ethics boards, governments, public and private institutions), and putting in place policies that provide a legal and ethical framework for digital health. Furthermore, investment in technologically advanced infrastructures (reliable electricity supply, stable internet connection, etc.) is essential for biobanks to maintain and develop their operations.

Digitalization offers biobanks a wealth of opportunities to enhance their effectiveness, including the:

1. Better documentation of the quality, life cycle, and scientific application of biological samples
2. Ability to scale-up the use of biological samples from LMICs.
3. Improved interoperability with other sources of donor-related data.

4. Easier and faster access for researchers to biological samples and their associated data, for example, through online applications.
5. Greater link with the automation of the technical processes for the retrieval and analysis of samples.
6. Ability to manage, track, and analyze large volumes of data.

However, for the implementation of digitalization to be effective in LMICs, technical, financial, legal, ethical, and geographical contexts need to be taken into account. These constitute a complex background of competing priorities against which any biobanking operations needs to survive. Thus, while digitalization of biobanking in LMICs is full of potential, the complexities outlined above maintain the high implementation barriers within LMICs.

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Digital Healthcare: Technologies, Technical and Design Challenges

Eduardo Mascarenhas, Anis Abboute, Rachel Wayne, and Zisis Kozlakidis

Abstract

The advancement of digital technologies in healthcare is not a new phenomenon, however it was accelerated by the COVID-19 pandemic when healthcare needs across all settings forced institutions to consider the inclusion of digital health applications in their routine operations. The need for digital healthcare applications to deliver solutions is greatest in LMICs and will continue to be so in the near future. This chapter presents an overview of the technologies driving the digital transformation of healthcare, including Internet of Things, Blockchain, cloud computing and artificial intelligence (AI). The challenges to the implementation of digital healthcare applications are also presented (infrastructure, human capital and data quality), with a particular focus on the design and evaluation aspects.

Keywords

Digitization · Healthcare · Low-and middle-income countries (LMIC) · Technical challenges · Design challenges · Digital transformation

1 Introduction

The COVID-19 pandemic has clearly exposed the discrepancies between countries in terms of prevention, preparedness, and response (PPR) to disease outbreaks, often stretching health systems to their limits. Even though the pandemic demonstrated that all countries need to strengthen their PPR capacity, it is clear that many low- and middle-income countries (LMICs) were heavily affected due to their historical limitations in healthcare provisioning, including: an insufficient number of well-trained professionals; inadequate hospital bed and laboratory capacity; low investment on technology; and, crisis management expertise, including supply chain logistics for equipment and medication (Krubiner et al. 2020).

Furthermore, the pandemic exacerbated the inefficiencies of weaker health systems, affecting not only the prevention and treatment of communicable and non-communicable diseases, but also the delivery of primary health care (PHC) services: health education, prevention and control of infectious diseases, childhood vaccination

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campaigns, prenatal care, etc. (Pillay et al. 2021) In some countries, decisions taken during the pandemic were not science-based, but rather politically biased or based on misinformation about treatments. For example, in Brazil the federal administration recommended drugs that were non-effective for COVID-19 treatment, even after the WHO had denied their effectiveness (World Health Organization 2020). They also refused social isolation and mask usage (World Health Organization 2020; Ferigato et al. 2020; Médecins Sans Frontières 2021).

The pandemic also contributed to a sharp understanding of the PHC mechanics within the healthcare engine, not only as an important interface for basic community service provisioning but also as a surveillance and predictive reporting frontline for the whole healthcare system. Taking the above into account, the digital transformation could be a game changer for healthcare, especially in PHC: the economies of scale associated with a clear picture of end-to-end processes and the latest technologies could result in a state-of-the-art, frictionless, patient-centered care system. In particular, digital transformation could have a revolutionizing impact on PHC provisioning in LMICs (Schwarz et al. 2020). Through leveraging digital opportunities, LMICs could focus on universal accessibility and improved service quality, rather than bureaucratic and, sometimes, erroneous decisions.

It is also important to note that the PHC investment from the public purse has become a mounting priority in the context of introducing Universal Health Coverage in LMICs (Garg et al. 2021; Tilley-Gyado et al. 2016). In the long run this brings additional competitive benefits for the LMICs: the digital transformation could start from the edges (PHC), i.e., closer to the community practice, migrating later to the central and more consolidated secondary and tertiary care facilities.

From a patient perspective, it also makes sense to have access to a more technologically advanced PHC. A recent US report shows that the average cost of patient visits to emergency rooms (ER) was USD 2143 in 2020, up from USD 1704 in 2016. This reflects the increase in healthcare provision for secondary and tertiary care, as emergency functions have been concentrated within fewer, consolidated facilities (Healthcare Cost Institute (HCCI) 2020). ER crowding is also considered a marker of hospital health, indicating a failure to provide adequate PHC (Barish et al. 2012). While these figures are informative and presumed to be reflective of an overall trend observed within healthcare, comparable data from LMICs is missing on a consistent basis.

2 Digital Transformation: The Technologies Behind the Revolution in the Health Sector

Digital transformation brings a common framework that increases efficiency, productivity, and overall user experience (Bitton et al. 2017; Nambiar et al. 2020). In healthcare systems, it streamlines processes and automates routine tasks, resulting in a major reduction in operating costs (OPEX) while in certain cases it can also improve patient outcomes (Bardhan and Thouin 2013). The so-called 'Iron Triangle dilemma in Healthcare' (Callahan 2014), a challenge faced by all health systems around the globe, could be completely transformed in the long run through digital technologies, as accessibility, quality, and affordability (the three cornerstones of the 'Iron Triangle') could all be provided without compromising patient outcomes and well-being. However, an adequate implementation of a digital health system must integrate several digital technologies under the same framework, not as isolated technology silos, but rather as a global puzzle, where ideally every piece counts for solving a local demand, and success relies on the seamless integration of all the constituent pieces.

The key technologies for digital transformation in healthcare systems are the Internet of Things (IoT), Artificial Intelligence (AI), Blockchain, and Cloud. These will be reviewed in the following sections in relation to their implementation within healthcare in LMICs. This is a narrative review, aiming to identify key published information and provide an overview

of the field, rather than a more detailed view on any aspect which should be addressed by a systematic review methodology. Manuscripts were identified for being seminal in their respective technical sections, while additional manuscripts were identified through 'snowballing', i.e., using reverse citation tracking to find articles that cited articles already deemed relevant to the review (Callahan 2014).

2.1 Internet of Things

The Internet of Things (IoT) comprises devices, appliances, and all types of equipment that have built-in sensors, software, and network connectivity (Xia et al. 2012). In healthcare, IoT plays an essential part in digital healthcare systems as it brings the PHC closer to patients with the potential of creating a so-called "Virtual Healthcare space". IoTs are commonly used for monitoring patients' health via wearable devices, collecting data in real time and transmitting the information to the cloud for further processing and analysis. This is particularly relevant for routine monitoring of vital signs in patients, such as heart rate, blood pressure, body temperature, glucose, and blood oxygenation levels. Medical teams could receive real-time alerts from patients that need to be monitored (e.g., post-operatively), considerably improving patient assistance and prioritizing urgent cases as they emerge. For patients, this could mean a reduction in unnecessary visits to tertiary healthcare services such as Emergency Response (ER). A recent European Union report described a patient monitoring solution implemented in Chile that reduced ER visits by 42%, resulting in a 50% saving to insurance companies (Xia et al. 2012). A second study on a targeted implementation, showed a three-fold increase in the risk of acute infection for elderly people after a visit to ER (Andersen 1994).

It is important to note that significant technical challenges remain that could be addressed through further sensor miniaturization and an increase in sensor efficiency, resulting in higher processing power and decreased power consumption (Kim et al. 2019). The resulting wearable devices will be lighter, more precise, and with new functionalities, favoring overall patient experience and treatment outcomes. Additionally, there are infrastructural challenges—especially in LMICs—as the IoT relies on the seamless integration of several technical components all working together. The lack of consistent technical infrastructure to support IoT in LMICs remains a major barrier in introducing these technologies beyond a limited number of centers of excellence. It is also necessary to consider that, for LMICs, different types of infrastructure/infrastructure connections may be necessary to produce the intended results (Dinh et al. 2020).

2.2 Artificial Intelligence

Artificial Intelligence (AI) provides the most disruptive element for a complete transformation in healthcare. AI refers to a field of computer science that accentuates the creation of intelligent machines that mimic human behavior through interconnected algorithms that are designed to analyze and process data, recognize patterns and relationships in the data, and make predictions or decisions based on such data (Dinh et al. 2020). Therefore, AI algorithms rely on long-term knowledge (disease-specific datasets) that create a clear understanding of the disease and minimize the risk of wrong decisions. As such, the positive impact of AI implementations is correlated to the quality and quantity of these datasets, the understanding of existing clinical workflows and intended outcomes, and the representativeness of the target population (de Hond et al. 2022). However, the general goal of AI is not well-defined because there is no consensus on what specifically constitutes 'intelligence'.

From a long-term economic perspective, AI will drive down the costs of high-volume, repetitive tasks in healthcare and is therefore anticipated to have a major impact on healthcare economics at a macroeconomic level. Since AI implementation may also improve the early diagnosis of diseases, treatment could be simpler, less invasive, and potentially, with increased success rates. It therefore makes complete sense to bring

AI to the frontline of PHC. A recent report from the World Bank describes the notable healthcare achievements in China due to increased investments in PHC, including information systems and in response to the intense population pressures. Even though the report does not focus on specific technologies, the improvements are potentially related to an integrated technological framework, including IoT and AI (European Institute of Innovation and Technology 2021).

AI could be applied to clinical notes in PHC Electronic Health Records (EHRs) for predictive analytics. For example, the US National Institute on Aging is funding AI research for detecting early stages of Alzheimer's disease based on the analysis of EHRs of PHC, as some physicians might not be specialized in identifying the potential disease symptoms (Quach et al. 2012). Furthermore, the prediction of adverse neonatal outcomes in newborns based on deep learning models that use EHRs data for different early-life stages, ranging from preconception to a few months after birth, is another relevant use of AI in PHC records (World Bank 2022). Using AI virtual assistants and chatbots brings other possibilities in PHC, especially in LMICs where telemedicine is very relevant due to the acute shortage of health professionals (Naseem et al. 2020). For example, in an ideal scenario, by using a pre-defined questionnaire, it would be possible to understand a patient's symptoms and reach a preliminary diagnosis. Subsequently, the virtual assistant could connect the patient to a human doctor or, depending on the case severity, recommend a hospital nearby. Several implementations of AI virtual assistants have been deployed globally, reducing diagnosis delivery times, and minimizing human errors (European Institute of Innovation and Technology 2021).

A recent report from the World Bank Group regarding PPR addresses the weakness of global disease surveillance networks during the COVID-19 pandemic (Science and Enterprise 2023). AI algorithms could be used for identifying changes in patient disease profiles arriving in the PHC. This would have a major impact on the response of regional authorities, isolating the regional source of disease before it spreads to other regions or globally. This implies that AI for the PHC must be observed both as a global strategy, as well as a country-based decision. Thus, a common global AI framework for PHC should be considered and further discussed as a global public healthcare priority.

Finally, an area with enormous potential to benefit from AI is imaging processing and analysis, such as X-rays and Magnetic Resonance Imaging (MRI). For example, it has been argued that AI can substantially streamline radiologists' work while improving the detection of breast cancer (De Francesco et al. 2023). The approach of using AI on imaging can have a dramatic impact on several diseases that affect the aging population, including cancer, cardiovascular and pulmonary diseases (World Bank 2023). Looking further into the future, if combined with other technologies, AI could further increase its overall impact. For example, CRISPR-Casp9 gene-editing tools (Leibig et al. 2022) which have revolutionized genome editing, could be combined with AI algorithms to automate genomic editing procedures. The gene selection process could also be streamlined, as specifically-designed algorithms could be used to identify diseases in stored patient biological samples (e.g., blood, urine, etc.) kept within biobanks (https://www.arterys.com/clinical-evidence).

2.3 Blockchain

The technology of Blockchain can be described as an immutable record in which data entries are registered in a decentralized manner. This means that users or entities can interact without the presence of a central authority thus allowing more transparency around these interactions (Ledford and Callaway 2020). Cryptocurrencies are a good example of the use of blockchain technology. In this case the blockchain acts as a decentralized database that keeps track of all coin transactions. The continuously increasing number of data entries is then packaged together into blocks of data which are securely maintained within the blockchain by cryptographic protocols and cannot be tampered with (National Institutes of

Health (NIH) 2023). Hence, the data security aspect is ensured, while the added-value argument beyond security remains to be strongly demonstrated.

Healthcare has the potential to benefit from the use of blockchain technology as it is a data- and personnel-intensive domain where the ability to access, edit and have trust in the data emerging from its activities is critical. In that context, blockchain could improve data management by connecting different systems and increasing the accuracy and security of electronic health records (EHRs) (Hasselgren et al. 2020; Hölbl et al. 2018). Moreover, this technology could be used in e-health applications, where patients and healthcare professionals are required to identify themselves, by allowing for an efficient digital identity management which is not possible with current internet protocols that were not originally designed for that purpose (Satybaldy et al. 2022). In the pharmaceutical industry, blockchain can help identify and avoid the dissemination of counterfeit and unapproved drugs, and it is possible to define smart contracts to automate the technical processes, improve supply chain management, and verify the quality of pharmaceutical products (Hölbl et al. 2018).

Blockchain also has the potential to increase transparency and integrity of data in the context of clinical trials by maintaining records of patient consents and clinical data that cannot be modified, therefore ensuring that the trials meet all relevant regulations and that problems of fraudulent results and removal of data by individuals is avoided (Bell et al. 2018). Despite this, blockchain technology is not yet widely used in healthcare in LMICs and the stated benefits remain in the sphere of future achievements or limited to specific users in high-income settings.

2.4 The Example of Non-Fungible Tokens (NFTs)

Health information is highly valued, especially as the implementation of big data and machine learning are increasingly considered in health care. Within this context, non-fungible tokens can help incentivize a more transparent, and efficient system for health information exchanges in which patients can participate in decisions about how and with whom their personal health information is shared, and where data access and control can be automated through smart contracts (Kostick-Quenet et al. 2022).

NFTs are created by uploading digital content on a blockchain and having other computers verify and timestamp the content, location, and owner of the content. NFTs are digital contracts composed of metadata to specify access rights to, and terms of exchange of a given content. They represent the point of access to digital content but are not the content itself, and they allow for its secure storage and sharing, for example medical health records, through the use of pseudonyms that maintain anonymity while ensuring transparency and accountability (Kostick-Quenet et al. 2022). NFTs are used in the entertainment (Regner et al. 2019) and commercial (Ali and Bagui 2021) sectors on platforms that provide collectibles, access keys or event tickets, therefore ensuring the uniqueness of the items exchanged and securing their ownership. However, their use in healthcare is not yet forthcoming, and the case of LMICs remains a distant future potential.

2.5 Cloud Computing

The fast development of the Internet of Things (IoT) technology, commonly used in medical settings to monitor patients' vital signs through a wide range of devices, has greatly improved treatment and health outcomes for patients, but has also led to more stringent requirements for data analysis and data storage (Dang et al. 2019). The increasing amount of clinical, analytical laboratory and '-omics' data due to the integration of IoT technology brings several challenges in terms of data storage, management, and sharing, as well as data confidentiality, security, and high-performance computing (Calabrese and Cannataro 2015). So far, cloud computing technology has been the preferred solution to address these issues by providing the ability for health

professionals, and to a much lesser extent patients, to access shared medical data and other resources at any time and anywhere within a given digital environment, e.g., healthcare providing organizations (Griebel et al. 2015). In addition, with cloud computing, data sharing and storage can be performed at scale in a more structured and organized way with full transparency, thus minimizing the risk of data loss.

This technology provides access to higher computing power and storage capacities at a lower cost than using regular grid technology and so can improve the scalability of healthcare activities and resources (Dang et al. 2019). However, in the case of LMICs, the implementation of cloud computing remains piecemeal and limited only to specific clinical centers of excellence, typically belonging to tertiary healthcare (Clifford 2016). For example, in India, electronic medical record (EMR) systems in tertiary healthcare facilities are linked to a remote health cloud which allows for a direct entry of orders and notes, as well as desktop sharing since EMRs can be accessed from anywhere (Agrawal et al. 2013). In another instance, Zambia was able to set up a local data server that communicates directly with monitoring mobile devices on patients and the cloud. Skin-integrated sensors on patients collect physiological data that are encrypted and transmitted to a local server. The data is then securely transferred to the cloud for broader access and monitoring. Access to this data in the cloud can be granted to authorized individuals through a system of identifiers (Xu et al. 2021).

3 Challenges for the Implementation of Digital Health

The pandemic has demonstrated that even during times of extreme pressure on healthcare systems, it is practically impossible to establish a single global technological solution to a given problem. The acceptability and implementation of digital technologies during the pandemic were driven by context, depending on the different infrastructural, financial, societal, legal and ethical backgrounds of end-users. Digital technologies in healthcare are received and operate in very different ways when implemented in high-, medium-, or low-income countries, or when deployed in 'individualistic' versus 'collectivist' societies (Ferretti et al. 2020). The following paragraphs focus on the technical and design challenges of digital healthcare implementation in LMICs.

4 Technical Challenges

4.1 Infrastructure

The lack of infrastructure for healthcare in LMICs has been highlighted in numerous publications, such as the Lancet Oncology Commission (Ngwa et al. 2022) and many others. The availability of communication networks, electrical networks and equipment has been well documented and remains a major challenge for improving healthcare in resource-restricted settings worldwide. However, from a digital healthcare implementation viewpoint, additional aspects also have an influence. For example, in LMICs healthcare systems are often fragmented, with individual health units providing services that are not integrated into a national network and universal healthcare coverage is unavailable. Furthermore, it is likely that a parallel private system of individual health units exists, that caters for a different portion of the local population, i.e., those with higher income. Thus, there is very high fragmentation, with multiple smaller systems co-existing as in the case in Ecuador (Carlo 2020).

The investment and maintenance costs of the required infrastructures are prohibitive in settings where many critical and competing priorities exist. Suboptimal device use (including digital health applications) is directly linked to incomplete costing and inadequate consideration of connectivity (e.g., data transfer speed), maintenance services (including digital and physical infrastructure) and user training. The accurate estimation of life-cycle cost and careful consideration of device servicing are of crucial impor-

tance, however, there is currently no consensus approach for achieving this within LMIC settings (Diaconu et al. 2017).

4.2 Human Capital

The availability of technical infrastructure, equipment costs and past performance of similar equipment are the primary deciding factors in the procurement of medical devices (including digital technologies) in LMICs (Diaconu et al. 2017). However, maintenance services and user/staff training programs are often limited or even entirely absent in LMICs, leading to equipment under-performing and having a reduced lifespan and in some cases, unsafe device handling practices. It is estimated that 40–70% of medical devices in resource-restricted settings are either broken, unused or unfit for purpose, largely due to the absence of appropriately trained staff and preventive maintenance (Perry and Malkin 2011). This is further compounded in the case of digital healthcare applications, where training schemes for staff are less accessible, the time it takes to become fully trained can be considerable and the availability of expertise and post-training support is often limited (Browning et al. 2020).

4.3 Data Quantity, Quality, Representativeness

Introducing electronic health data systems in LMICs, as a first step towards a wider set of digital health applications, could improve data quality and efficiency in service delivery. A small number of studies have demonstrated that such health information systems can also provide small annual cost savings to the public health system (Krishnan et al. 2010; Fenenga and de Jager 2007). However, the questions on data quantity, quality and representativeness remain addressed only in isolated silos, e.g., for specific clinical trials or within individual tertiary healthcare units, and not as part of a wider healthcare system development. There are however notable exceptions with national or regional healthcare and system-wide investment (including in digital healthcare applications) in countries such as Tanzania (Vasudevan et al. 2020), Egypt (Noby 2022), Rwanda (Ippoliti et al. 2021), Mexico (Uc et al. 2020), Indonesia (Aisyah et al. 2022) and others. The recent G20 meeting in 2020 highlighted the need and value of digital health investment and development in LMICs, as described in the Riyadh Declaration (Knawy et al. 2020; Al Knawy et al. 2022). Therefore, an increase of investment in digital health applications is anticipated, which will eventually result in a better understanding of the data questions mentioned here.

5 Design Challenges

5.1 Design and Evaluation Frameworks for DHI (Digital Health Interventions)

The technical challenges described previously are the more visible aspects of the challenges facing digital health in LMICs. The less visible challenges are those relating to the design. Specifically, the objective of design as defined here, is not about the technology *per se*, but about the overall quality and configuration of service delivery that might result from the comprehensive adoption of a new technology (Holmlid 2007, 2009). Hence, the design challenge is to take a more holistic view, considering the impact of digital health applications as opposed to simply improving existing processes and workflows. Furthermore, a design perspective inherently acknowledges that technologies are not fixed and immutable (Barrett et al. 2015), but subject to cyclical revision and refinement based on emerging insights about their efficiency and effectiveness within the context(s) where they have been introduced (Nambisan 2013; McCool et al. 2020).

Digital health implementations are complex and can alter as the technology matures, often in LMICs in parallel with the healthcare system. One of the most significant issues influencing the effectiveness of such implementations con-

cerns the existing evaluation frameworks. Previous research showed that there is a lack of knowledge related to the development of frameworks for the evaluation of such digital health implementations, which have to be equally as sensitive to the local context, acknowledging diverse technical, social and cultural perspectives and settings (Maar et al. 2017). The lack of evaluation frameworks and the rapid advancement of digital technology make it difficult to compare accessibility and affordability of digitally enabled healthcare across communities, within and between countries, in LMICs. For this reason, published evaluations for digital health implementation tend to be quite heterogeneous and the evidence concerning evaluating frameworks is inconsistent. In response to this need for a common framework a few recent LMIC-centered solutions have been proposed (Kowatsch et al. 2019; Wilkinson et al. 2023; Dodd et al. 2019; Nadhamuni et al. 2021; Marchal et al. 2010), however, these still remain to be extensively tested in the field.

5.2 Implementation Barriers

ROI (return of investment) definition: As a result of the above mentioned barriers to the implementation and sustainability of digital health implementations, there are a limited number of successful case studies that went beyond the pilot or feasibility stage. In some fields, the results are mixed, or the existing studies can only demonstrate impact in the short-term (Marcolino et al. 2018; Aisyah et al. 2020). Thus, understanding the framework by which the tool generates value for the healthcare system is important as a core element in framing the return of investment (ROI) argument. In LMICs, where multiple acutely competing priorities are considered for funding, the ROI is critical. It should be clear which priority digital health applications address, the capital expense as well as the operational expense (the latter incurring costs in perpetuity), as well as staffing requirements, technical support, maintenance, and hosting. Aligning these costs with the evaluation framework and ROI, would provide a transparent and holistic understanding of the costs and requirements of the digital health application and remove any implementation barriers due to hidden costs that such applications or singular initiatives are often associated with (Chen et al. 2023; McCool et al. 2020).

Clinical value demonstration: A few parameters exist for which the value can be demonstrated for digital health applications. In this book, there are specific national examples from Vietnam, Egypt, and Saudi Arabia, demonstrating the plurality of options when measuring value. A meaningful approach to measuring value has been proposed by the Institute for Healthcare Improvement (IHI)'s Quadruple Aim as: (a) improving the health of populations, (b) enhancing the experience of care for individuals, (c) reducing the per-capita cost of health care, and (d) improving the experience of clinicians and staff (Bodenheimer and Sinsky 2014). These are generic enough and fit most contexts, although their respective definitions and evaluations may still differ considerably. Evaluating a digital health application's direct impact on an operational outcome—rather than a higher-level one—may be a better way to capture its value. For example, it may be difficult to measure "total staff time saved," and easier instead to measure any "reduction in number of unnecessary appointments/consultations". A successful digital health application is one that can stratify population groups and/or individuals along specific pathways, and where needed, trigger a human-led intervention. This is a measurable approach and one likely to be able to demonstrate clinical value.

6 Limitations

This narrative review has presented an overview of the different digital healthcare technologies, as well as describing their technical and design challenges, nevertheless it has some inherent limitations. The method of identifying the manuscripts is not exhaustive, and it is likely that some relevant publications have not been considered. For a more detailed view, a systematic review

would need to be performed for each one of the sub-sections above individually. Furthermore, given the rapid pace of technological advancement, some of the anticipated outcomes may materialize earlier than predicted.

7 Conclusion

The advancement of digital technologies in healthcare is not a new phenomenon, however it was accelerated by the COVID-19 pandemic when healthcare needs across all settings forced institutions to consider the inclusion of digital health applications in their routine operations. The need for digital healthcare applications to deliver solutions is greatest in LMICs and will continue to be so in the near future. This chapter has presented an overview of the technologies driving the digital transformation of healthcare, including IoT, NFT, Blockchain, cloud computing and AI. The challenges to the implementation of digital healthcare applications were also presented (infrastructure, human capital and data quality), with a particular focus on the design and evaluation aspects.

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Digitization of Physical Health Data in Low- and Middle-Income Countries

Arpine Muradyan and Karine Sargsyan

"Physical health is defined as the state of the body while considering everything from the absence of diseases to the level of physical fitness."

EUPATI—European Patients Academy on Therapeutic Innovation.

Abstract

Digital technology has the potential to create a wide range of opportunities for motivating physical activity and a healthy lifestyle, implementing programs, and improving health indicators. This chapter presents an overview as to how digitization of physical health data can become the basis of helpful information for implementing and prioritizing physical activity actions in low-and middle-income countries (LMICs). The digitized data can be helpful to policymakers and stakeholders involved in promoting physical activities and physical health at the individual, local, national, regional, and global levels. In addition, digitizing physical health data will be an essential basis for a research program on the economic aspects of physical activity in LMICs. This will be a valuable guide for researchers to plan research in economics and physical health using a reliable methodology focused on the LMICs research needs. In addition, the information obtained from digitalization will help funding agencies allocate and monitor resources efficiently.

Keywords

Digitization · Low-and middle-income countries (LMIC) · Physical health · Physical activity · Armenia

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1 Introduction

Globally, it is widely accepted that the physical health of the young generation is continuously declining, which remains unnoticed in many countries (Fan 2021). The twenties of the twenty-first century are marked by digital transformation. Digital technologies are being actively introduced into all spheres of life and are becoming an indispensable component of business plans. Medicine is not left out. A study from Deloitte showed that 92% of medical institutions consider increased customer satisfaction and engagement as the main result that can be achieved due to digital transformation (Deloitte Center for Health Solutions 2021). In recent years, there have been innovations in physical health tools and health applications designed to manage and promote physical health and fitness among the general population (Sawyer et al. 2023).

Several wearable devices on the market are suitable for monitoring a person's physical health. The growth of technological innovation is rapidly redefining the right to the highest attainable standard of physical health. In a growing number of countries, this has strengthened the ability of governments to protect and fulfill this fundamental human right by ensuring accessibility, acceptability, and good quality of medical facilities, goods, and services. The 2030 Agenda for Sustainable Development emphasizes that spreading information and communication technologies and global connectivity have enormous potential to accelerate human progress, bridge the digital divide and develop (United Nations General Assembly resolution 2015).

Digitalization research is still in its early stages but is expanding. The widespread use of digital technologies in the healthcare sector includes the search for medical knowledge resources, monitoring the quality of patient care, and improving clinical support (Paul et al. 2023). The availability of digital devices with integrated sensors has caused a growing interest in their use in health care systems and sports science (Antunes et al. 2018; Botilias et al. 2020). In addition, digital devices have become a promising tool for improving the regular collection of health data, disease monitoring, and support for public health surveillance (Ravalli et al. 2022).

Digital technologies allow patients and doctors to both inform and control the treatment process. However, this technology complements physical consultation and in no way replaces physical consultation (Haleem et al. 2021). Multicomponent health promotion programs with digital components are increasingly being implemented in the workplace to assess and promote employees' health and reduce the risk of chronic diseases (Thai et al. 2023). Regular physical activity (PA) and good physical health reduce the risk of developing diseases such as heart disease, stroke, and some cancers. Also, it helps to cope with life problems, protecting against fatigue, injury, and illness (National Center for Chronic Disease Prevention and Health Promotion 2023; Booth et al. 2012). Since the positive impact of regular PA on a person's physical health is well known and is an essential prerequisite for healthy aging, digital technologies are also increasingly being used to encourage unstructured and structured forms of PA (Herold et al. 2022). The World Health Organization (WHO) is drafting the 'Global action plan on physical activity (GAPPA) to be implemented from 2018 to 2030 (WHO 2018).

Mobile and wireless technologies, such as mobile phones and wearable devices, have the potential to reach millions of people and can help promote and increase PA and reduce sedentary behaviors. WHO is working with scientific partners and industry to find out what works and scale the reach and impact of applications and programs aimed at helping people of all ages to be more active (World Health Organization 2023). In 2017 the World Confederation for Physical Therapy (WCPT) launched a collaboration to develop initiatives for the global practice and regulations of digital physical therapy practice through a Joint WCPT/INPTRA digital physical therapy Practice Task Force (Task Force). The variety of technologies encompassing digital and physical therapy may include telemonitoring, tele-education, telemedicine, teleassistance, and mobile health, and each field has its subset of technologies and specificities (World confederation for physiotherapy 2017–2019).

2 Focusing on LMICs

Health issues in low- and middle-income countries (LMICs) have been the focus of many digital initiatives to ensure the sustainability of these services. Policymakers should take into account the issues of utility, usability, integration, and infrastructure in order to improve digital health functions (Duggal et al. 2023). Digital technologies can increase the availability of technologically advanced treatment for individuals living in countries where such treatment may be unavailable (Pagliari 2021), e.g., LMICs. Due to recent regulatory changes, the LMICs are just starting to discuss digital practice. Healthcare challenges in LMICs have been the focus of many digital initiatives that have aimed to ensure consistent implementation of these services (Duggal et al. 2023). Digital health can support health care in LMICs by overcoming distance problems, poor infrastructure, and the need to provide community practitioners with specialist support (Hui et al. 2022).

Remote treatment can reduce the need for physical examination and strengthen the human resources of healthcare. Digital medicine can help healthcare systems overcome barriers such as the shortage of healthcare providers in LMICs due to "brain drain" (Human Rights Council Fifty-third session 2023). The COVID-19 pandemic has accelerated the introduction of innovations in the field of digital healthcare due to the availability of various technologies and the urgent need for medical care for treatment and prevention (Abdolkhani et al. 2022). COVID-19 is the first global pandemic of the digital age, and there are numerous examples of how digital health solutions have helped a lot during the pandemic (Aisyah et al. 2022). Perhaps the most notable acceleration in both the United States and other parts of the world has been due to the rapid adoption of telemedicine. In many ways, the response to COVID-19 has led to years of progress in just a few months (Lee et al. 2022).

In just a few weeks in March and April 2020, telemedicine applications and services, health sensors, 3D-printed protective equipment, and laboratory tests at home became part of everyday life (Meskó 2022). For example, in Catalonia, Spain, telemedicine replaced personal visits to primary health care doctors in less than a month. Compared to the beginning of March 2020, telemedicine visits increased by 5.5 times just four weeks later, and personal visits decreased by seven times (Pol et al. 2020).

The COVID-19 crisis considered the possibility of developing telemedicine in several countries. Australia, England, and the USA face several challenges. However, a few years ago, they incorporated digital practice into the healthcare system, and recently their associations have developed recommendations for helping specialists during the COVID-19 outbreak (Dantas et al. 2020).

3 Armenia as a Case Study

Physical inactivity accounts for over three million deaths yearly, mostly from noncommunicable diseases in low-income and middle-income countries (Pratt et al. 2012). An essential component for improving physical health and reducing premature mortality by one-third is an increase in the level of PA. To achieve this goal, research is needed in LMICs to support evidence-based policy development, identify barriers, and motivate people to PA (Liu 2022).Our recent research conducted in Armenia, one of the LMICs, showed the effects of PA on some parameters of physical health. According to the results of studies, the indicators of body composition and stress resistance are on the border between the norm and violation, and the relationship of body composition with stress resistance, endothelial function, and well-being in the population varies depending on the degree of physical activity and gender (Muradyan et al. 2021; Macheiner et al. 2022).

Based on the literature data on practice, we initially hypothesized that regular PA classes would improve stress resistance and wellness indicators. For this purpose, we selected participants according to the method. The change was detected by a comparative analysis of the study's results before and after the inclusion of clients in

the PA program. The study showed significant changes in stress and wellness indicators in the group of supporters of PA two to four times a week. This proves that the regularity of fitness programs is an essential criterion for improving indicators, reducing what leads to stress, and increasing the indicators of health (Muradyan et al. 2022).

We also conducted research before the COVID-19 pandemic (from May 2018 to September 2019) and during the pandemic (November 2020 to December 2021). We evaluated the correlation and infrastructure of some physical health indicators before and during the COVID-19 pandemic in the Armenian population. In conclusion, during COVID-19 pandemic significantly decreased stress resistance, endothelium function, and wellness indicators (Muradyan 2022).

Our current study showed that a high level of PA improves the indicator of body composition and increases stress resistance. We have also identified that the probability of getting infected with COVID-19 was higher among people with low levels of PA. Thus, our research indicates the need to develop and implement health programs, including PA. The application and subsequent analysis of the effectiveness of these programs can be monitored with the help of digital technologies not yet widely used in Armenia.

4 Challenges and Opportunities in PA-Related Research in LMICs

There are many social barriers to encouraging PA in LMICs, including a lack of resources and amenities, which should be the attention of researchers. The most significant barriers are cost and reimbursement, legal liability, and ethical issues such as confidentiality, infrastructure, equipment, Internet, age and level of education of patients, computer literacy, bandwidth range, and internet speed (Pratt et al. 2012; Liu 2022; Kaboré et al. 2022). For example, for pregnant women in South Africa, the lack of prenatal PA can be associated with insufficient relevant information, work commitment, discomfort, lack of time, tiredness and low energy, inadequate or conflicting information about prenatal physical activity, and lack of financial resources (Okafor and Goon 2022). Thus, more profound research and support for introducing digital technologies such as wearables, websites, and mobile applications can help people in LMICs benefit from PA. Moreover, increased access to information technology, even among the most vulnerable people, has led to digital interventions being promoted as a tool to reduce inequalities in health promotion.

Research using mobile devices is gaining popularity. A meta-analysis of electronic databases (PubMed, PsychINFO, SCOPUS) that provided raw data and aimed to influence PA through the distribution or collection of intervention materials using a mobile device suggests that this platform is an effective means of influencing PA behavior, and harnessing the potential of smartphone technology could provide researchers with an effective tool to increase PA (Fanning et al. 2012). Using a systematic search strategy to identify relevant studies from MEDLINE, Embase, PsycINFO, Web of Science, Scopus and The Cochrane Library published between January 1990 and March 2020 suggests that the opposite is true in the context of PA, that is, the people who will benefit most from these interventions are left behind. The authors recommend that in the future when developing digital interventions to improve the PA, more efforts will be made to meet the needs of people with low socioeconomic status (SES) (Western et al. 2021). The review that maps and describes the impact of digital workplace wellness measures in LMICs revealed that digital workplace wellness measures are feasible, cost-effective, and acceptable. However, no long-term and consistent effects were found in this review, and further studies are needed to obtain additional evidence (Thai et al. 2023).

A review of Ovid MEDLINE, EMBASE, CINAHL Plus, PsycINFO, Scopus, and Cochrane Library for peer-reviewed articles, emphasized the advantages of wearable devices for physical activity and also urged people with chronic diseases to maximize the effectiveness of wearable

devices. The authors suggest that wearable devices may develop some special functions in combination with the treatment of chronic diseases. It is necessary to formulate targeted strategies of PA per the specific characteristics of the disease (Yu et al. 2023). A systematic search in PubMed of studies evaluating the impact of the Internet, personal sensors, mobile phone or autonomous computer software on a diet, PA, obesity, tobacco or alcohol use has shown that interventions using the Internet and mobile devices improve important lifestyle habits up to 1 year and supports the effectiveness of Internet and mobile interventions for improving lifestyle and reducing risk factors for non-communicable diseases (NCDs) (Afshin et al. 2016). A systematic review of mobile health and PA was conducted in October 2017 using CINAHL, ERIC, EMBASE, MEDLINE, and PsycINFO databases, and identified two mechanisms by which mobile health use promotes PA: increased motivation and changes in self-awareness and strategizing (Carter et al. 2018). The study was conducted on 46 LMICs; people with chronic diseases and multimorbidity are significantly less physically active (especially the elderly), and it is essential to study the effectiveness and efficacy of PA in treating chronic diseases in LMICs (Vancampfort et al. 2017). Thus, one of the main factors in improving the population's physical health is PA.

5 Conclusion

Considering that digital technology opens up a wide range of opportunities for motivating PA and a healthy lifestyle, implementing programs, and improving health indicators, it is essential to emphasize the use of digital technology in healthcare institutions at LMICs. The digitization of physical health data can become the basis of helpful information for implementing and prioritizing GAPA actions in LMICs. The digitized data will be helpful to policymakers and stakeholders involved in promoting PA and physical health at the individual, local, national, regional, and global levels, with a particular focus on LMICs. In addition, digitizing physical health data will be an essential basis for a research program on the economic aspects of PA in LMICs. This will be a valuable guide for researchers to plan research in economics and physical health using a reliable methodology focused on the LMICs research needs. In addition, the information obtained from digitalization will help funding agencies allocate and monitor resources efficiently.

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Governance and Regulation Specifics

Nicolas Ferry and Paul Hofman

Abstract

Governance defines all the political and administrative aspects of an authority that manage a country's affairs, according to the Committee of Experts on Public Administration (2006). This includes the different institutions, processes and methods used by citizens and groups of individuals to formulate their interests, exercise their legal rights, meet their obligations, and arbitrate their disputes. Thus, science governance usually describes a global organization with a well-defined structure aiming to facilitate a desirable feature set. Many people would probably align on which are the functions that are desirable, and that structure somehow shapes the functions, meaning that this system can be dynamically driven (Lubell 2021).

1 Historic and Definition of Terms

Governance defines all the political and administrative aspects of an authority that manage a country's affairs, according to the Committee of Experts on Public Administration (2006). This includes the different institutions, processes and methods used by citizens and groups of individuals to formulate their interests, exercise their legal rights, meet their obligations, and arbitrate their disputes. Thus, science governance usually describes a global organization with a well-defined structure aiming to facilitate a desirable feature set. Many people would probably align on which are the functions that are desirable, and that structure somehow shapes the functions, meaning that this system can be dynamically driven (Lubell 2021).

Before the late 1960s, the regulations were performed case-by-case depending on the issues encountered at a specific time by the scientists and the general audience. Then a new the era of the prospective rule making was developed. At that period, regulatory agencies started to sharpen policy prescriptions that are called rules and that only differ from laws by the way they are developed. Laws and regulations appeared to be complementary: without a law, the rule would be illegal and not applicable in the courts, without a rule, a law would remain a meaningless declaration (Schmandt 1984). Some episodes in the last century led to precise the regulation concept such as the first In Vitro Fertilization (IVF) in 1978 which divided the thoughts of the public audience bringing morality and religious concerns into the debate. As an example, the first UK regulatory committee, composed of individuals from diverse horizons and not only from the scientific

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community, became responsible of choosing between prohibiting embryo research for moral reasons and allowing it to help science develops. One of the first rules was then to allow live embryo research but only during 14 days after fertilization, this rule also led to the implementation of the Human Fertilization and Embryology Authority (HFEA) that monitors research and clinical procedures. Beyond private morality, those decisions are a strong need for the public and could influence the whole society. From this, standards emerged, trying to balance potential harms and benefits for the community, while avoiding the risk of the individuals' exploitation.

The lessons learned from IVF were applied later to other scientific areas such as embryonic stem-cell research, therapeutic cloning, mixed-species embryo construction, etc. (Warnock 2007).

2 Governance and Regulations in Science Today

Starting with the Nuremberg Code written beside the trials of Nazi "doctors" after the Second World War, and which described ethical principles on human experimentation such as obtaining the signed informed consent from the individuals or the fact that each human experimentation must be preceded by animal ones, international regulations have developed quite fast during the last century. Many noteworthy texts have been prepared like the Helsinki Declaration in 1964, the Animal Welfare Act of 1966 or the National Research Act of 1974, which made institutional reviews mandatory by asking the research centers to establish Institutional Review Boards (IRBs) for conducting research projects within an institution (Silberman and Kahn 2011).

IRBs are meant to review, approve, or disapprove research proposals based on the benefits and risks associated with the projects.

Very specific organizations emerged during these decades like for example the creation, in 1969, of the International Health Regulations aiming at coordinating and linking specific actions in different countries to fight infectious diseases. Those regulations were expanded and reviewed in 2005. IHR requires countries to implement core public health capacities such as legislation, policy and financing, risk communication, surveillance, laboratory, or human resources.

More largely, worldwide institutions such as the World Health Organization (WHO), the Food and Drug Administration (FDA) or the International Standards Organization (ISO) then dictated regulations or implemented standards through the years that are now being used in a large majority of countries and institutions in science and in medical areas.

3 A New Facet of Governance and Regulations: Digitalization in Science and Healthcare

Digital health technologies represent a unique opportunity to enlarge health coverage, strengthen patient care and develop research, using robust and efficient systems. This must be performed under the dome of legal and ethical regulations and policies to keep the healthcare systems and human research fair, trustworthy and accessible to everyone.

Digital innovations are part of the current healthcare system and our daily lives, this raises challenges on building robust frameworks for storing the different types of data (imaging, genetic reports, clinical information, etc.), accessing and sharing data involving many stakeholders, consenting patients, and protecting patients' privacy. Datasets must also be linked together using a common language and an open communication between the different parties to build a trusty relationship and empower the users (Brall et al. 2019).

With the healthcare systems and human research's digitalization, multiple risks exist regarding the patients' privacy, including the access to their identities and medical information, that can jeopardize an individual's accountability or employability. Some of the data can

indeed be traded by data brokers to pharmaceutical companies or insurers, which can severely impact a person's life based on algorithm predictions on their potential sickness or propensity scores to assess if the person will choose a medication or another.

Related to these threats, public organizations such as the Europe's General Data Protection Regulation (GDPR) oversee the treatment of personal data (genetic information, biometric data, and health data) and are constantly establishing and reviewing specific consents for the use of personal data as well as anonymization or de-identification processes to keep the patients protected.

4 Near Future Improvements and Challenges

The governance and regulations landscape today, even if well implemented, accepted, and followed worldwide, remains disparate. Currently, some developing countries are still in need to develop basic health-system functions. Some examples have shown as well that the medical equipment is often worn out or not up to date which leads to data encryption or misconfiguration issues. Artificial intelligence can be used as a benefit but can also become a harm depending on its use and can threaten the digital health systems.

Cybersecurity must then be fully integrated into nowadays research and healthcare but also represents a non-negligible cost for the hospitals and research teams as well as for the governments.

The United Stated of America (as an example of well-developed countries) also faces some challenges like the broadening of regulations in private health care units which is still largely different from one to another. In Europe, research standards, protocols and guidelines are still missing in many places for example regarding reporting and disease notification (Suthar et al. 2018). Concrete examples such as eastern and southern African countries (Juma et al. 2021) have shown that some nations are still in the process of implementing health research legislation like in Botswana or Uganda.

Health research governance is essential to build a robust health research system. However, improving governance in science and health is relatively new compared to the strengthening of health science research capacities.

Some challenges that the countries are facing are usually the fact that only short-term improvements are made because of insufficient fundings for governance missions, discrepancies between research priorities and research fundings or a lack of coordination between the different stakeholders and the health research capacities. In some regions, developing new health research policies takes time and most of the current existing ones are outdated.

The creation or the strengthening of national research authorities is and will be essential in the future for the countries which still need them so far to enhance the sustainability of the operation of the governance system. Legal frameworks and effective resources are also one of the keystones to maintain research improvement.

Through the recent history, governance and regulations in science have shown their efficiency to keep experimentations safe and respectful of the society while helping to move forward the scientific findings. To help continuing this way, national and international authorities will have to keep up with according their rules to the constantly evolving environment and morality.

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Future Developments of Digital Health and Considerations on Sustainability

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Abstract

The transformation of future healthcare capacity through the digitisation of healthcare systems will enable these systems to respond to future emergencies, as well as increased population pressures. The realisation over the last few decades that technologically empowered solutions can be implemented and work well, including within LMICs, was further expanded through the recent pandemic. Current challenges pertain to the scaling up of digital healthcare technologies, and their sustainability post-introduction in the field. Solutions to these challenges have already emerged, such as synthetic data, which allows the use of high-quality datasets without compromising the security of the original datasets. Ultimately, health outcomes can potentially be improved within an active health-data ecosystem, where both patients and healthcare providers are active participants, i.e. both generating and ingesting healthcare data. However, for that to be achieved, the sustainability of digitalization of healthcare in LMICs needs to be considered through the lens of infrastructural, financial, ethical and regulatory concerns.

Keywords

Digital health · Low-and middle-income countries (LMIC) · Sustainability · Synthetic data · Sustainability axes

1 Introduction

The transformation of healthcare is both a necessity and inevitability. A necessity due to the increasing rates of global disease burden and limitations in terms of availability of affordable and trained staff, especially so in Low- and Middle-Income Countries (LMICs) (Ngwa et al. 2022; Kozlakidis et al. 2020); an inevitability because of the rapid technological developments which eventually integrate with and influence all aspects of healthcare (Nadhamuni et al. 2021; Peiris et al. 2014; Ospina-Pinillos et al. 2021; Gurung et al. 2019). For example, the expansion of remote healthcare coverage, already existing before the COVID-19 pandemic (Greenwood

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et al. 2014; Aisyah et al. 2020; De San et al. 2013) and multiplied during its duration (Caetano et al. 2020; Liu et al. 2020; Aisyah et al. 2023), has been a major step in this direction. It is anticipated that many of these remote healthcare coverage services will continue post-pandemic (Jazieh and Kozlakidis 2020), albeit with further context-driven customizations, adapted to the local milieu of patients and professionals (Abusanad 2021).

However, for the sustainability of such transformation in the long-term, a number of parameters would need to be considered, such as the scale-up of existing technologies; the security aspects of big and integrated data; and the personal, social and market acceptability. The transformation is most likely to occur upon the confluence of those factors rather than each one acting separately. This chapter, in the form of a perspective article, presents an overview of current advancements and their likely future impact on the transformation of digital healthcare services, with particular focus on LMIC settings.

2 Scaling Up Digital Health

The speed by which avian influenza (Uyeki 2008), zika virus (Garcia et al. 2016) and SARS-CoV-2 (Koelle et al. 2022) spread -and the potential of other infectious diseases exhibiting a similar, rapid global impact in the future- highlights the need for reliable and agile surveillance systems. Such systems, vertical by necessity as they are initially of a single-disease focus, can be established for surveillance of one disease and then be expanded to incorporate others (Zinsstag et al. 2020; Njuguna et al. 2019). The surveillance of infectious diseases is defined as the aggregate of reported positive results from designated clinical laboratories or laboratory networks for specific microorganisms that constitute a public health threat (Zeng et al. 2011). Thus, the routine use of surveillance data would need to be coupled with the ability to scale up the generation, ingestion and interpretation of such data during times of need (presented in detail in a different Chapter of this book). Moreover, as a preamble to such a scale up during times of emergency, this capacity would need to be tested through the 'exercise' of model crises, i.e., iterated emergency simulations with the aim of identifying and understanding the critical bottlenecks of existing systems. Identifying any such weak points would likely aid their addressing, thus strengthening existing structures over time. Therefore, there is a need for transparent, standards-based assessment of digital health systems that (as a possible solution) will be guided by a formal assessment across the main activity domains in the field, encompassing technical, clinical/operational and financial aspects (Mathews et al. 2019).

As surveillance technologies can now be mobile-enabled, and deployed at scale to monitor and to flag potential healthcare needs as they emerge in individuals and/or populations, one needs to consider that the generation and ingestion of data will be bi-directional. Specifically, the scaling up of digital health will not only be based on healthcare facilities outputting greater volumes of data through high-throughput analytical platforms (e.g., genomics, metabolomics). It would also involve the patients themselves, generating data (e.g., input for remote monitoring applications) and utilising this data (e.g., using clinical details to input into wellness and lifestyle guidance applications) (Moore 2020). Thus, new digital tools are likely to continue being introduced and integrated within public healthcare, supporting our understanding in an increasingly connected and challenging global environment. The ways in which such tools can be adapted and customised to LMIC settings at a population level, and beyond individual cases, is only now starting to emerge (Labrique et al. 2018).

3 Predictive Algorithms and Synthetic Data

The increasing volume of healthcare data underlies an ever-growing need to develop predictive algorithms that can ingest and translate that data.

This will help clinicians treat patients based on their individualised response(s) to care rather than on generalised risk scores. Thus, in order to improve performance of existing algorithms and support the creation of new ones, access to large amounts of diverse and high-quality clinical data is needed. This is especially true for LMIC populations, which are under-represented in existing healthcare data sets, or where collected data can often be of low quality (Curado et al. 2009). Unfortunately, in most settings clinical data is also siloed due to privacy restrictions, and access to them is often limited only to the treating clinician or to clinicians within the same department/institution.

The reasoning behind such stringent data accessibility regulations is based on the premise that algorithms that consume and learn from large amounts of personal data can leak private details pertaining to individuals, which can then be used to discriminate against them specifically. Potential data breaches cannot be entirely prevented with current systems, because of the constant need to access, distribute and utilize information, that provides the opportunity for a deliberate data breach or a spontaneous mistake. According to datalossdb (2015), a platform from the Open Security Foundation (2005–2016), in 2014, approximately 50% of recorded data leakages were in private businesses, ca. 20% in government functions and about 30% in the education and health sectors (Alneyadi et al. 2016). There is the possibility of linking healthcare data to blockchain technology, so as when data actually leaks, it should be fairly straightforward to identify the source of the leak and address it appropriately. However, this technology has not been tested widely (Jayabalan and Jeyanthi 2022). In healthcare this is particularly dangerous, as this data can have irreversible consequences for an individual, or if the data is damaged/deleted, can never be replaced. Thus, a methodology is needed to mitigate the aim to harness data on the one hand, with the requirement to protect patient privacy on the other hand. Possibly, one of the most promising solutions to this need lies in synthetic data.

Synthetic data allows researchers to explore data independently of data protection constraints while maintaining patient privacy, enabling them to potentially share data worldwide. Synthetic data do not contain any of the original data sets (Chen et al. 2021). They have the same format as the original data, and they have identical statistical characteristics as the original individuals/population, across parameters and within subgroups in the population. All of this makes synthetic data similarly suitable for analysis, while at the same time overcoming privacy concerns.

Some of the uses of synthetic data in healthcare are:

- They can simplify the collaborative and regulatory efforts when trying to share raw data.
- Synthetic data platforms can facilitate hypothesis testing and model validation without intermediaries (Foraker et al. 2020)
- Synthetic data can be used to train students and staff on new platforms (prior to using such platforms on real data) and be used to host hackathons and competitions improving existing platforms (Gonzales et al. 2023)
- And finally, synthetic data can liberate data publicly, allowing access for scientists, citizen scientists and clinicians (even from different locations globally) to use those data freely in order to develop better care pathways (Benaim et al. 2020; Foraker et al. 2021)

For example, MDClone, a self-service data analytics environment, has developed a platform for querying and synthesising patient cohorts in a self-service manner. Specifically, a user can query an organisation's data lake while being sequestered from it at all times, and subsequently create synthetic derivatives of the cohort and its corresponding characteristics. This new technology has been used on a great number of recent clinical studies (Masarweh 2019; Inbar and Dann 2019; Hochberg 2018; Meilik et al. 2022; Hod et al. 2023; Masarweh et al. 2021; Isenberg et al. 2022) and has the potential to model/'re-create' LMIC-specific data sets, while maintaining the data security requirements for the real data.

4 A Sustainable Path Forward

As with many other technologies introduced to the healthcare field, the operational advantages for any technology by themselves are unable to guarantee a long-term adoption. Instead, the operational aspects need to be complemented by the social and market acceptability of any new technologies. This definition of sustainability along three axes, the operational, financial, and social, has been successfully applied previously on other large, data-heavy infrastructures, such as biobanking, and can be extrapolated for the digital healthcare data needs, as a useful planning model (Table 1) (Watson et al. 2014; Henderson et al. 2015). For example, in terms of *operational sustainability*, the ever-growing need to produce and consume data, will introduce additional infrastructure requirements in LMICs in terms of data storage and security, staff training and integrations of systems (Kumar and Mostafa 2019; Labrique et al. 2018). Thus, future data infrastructure approaches in healthcare would need to be evaluated so that they align with global healthcare data requirements (to maintain a global connectivity and interaction) (Al Knawy et al. 2020), but also to design new approaches/data architectures that would be more appropriate for local needs/capacities.

Table 1 Summary of the future challenges and developments along three sustainability axes

	Future challenges and developments
Operational sustainability	The increasing volume of data to be produced and consumed requires an infrastructure that demands new approaches to data design and architecture.
Financial sustainability	Investments are needed to maintain infrastructure
	Synthetic data can provide a cost-effective alternative
Social sustainability	Full data anonymization is currently best practice, but a new methodology is needed to improve data interpretation.
	Challenges remain in terms of ethics and the legal framework for handling large amounts of data.
	Future algorithm development should incorporate AI

An example for the successful re-design of data architecture, customised for LMICs, comes from the field of construction (which is also 'data heavy'). In those examples, data flows were adapted to local needs with the aim of reducing costs and infrastructure pressures, while maintaining data output (Raes et al. 2021; Liu et al. 2021). This approach for transforming infrastructure costs was based on the concept of digital twins, i.e., a digital model of a physical entity that results in measurable outputs. The digital twins of existing models were used for example in the re-design of modular construction systems, allowing for a more context-adaptable output, in this particular case a quicker on-site assembly of the construction (Jiang et al. 2022). In terms of healthcare, digital twins can relate both to the physical infrastructure (i.e., a new methodology to enhance the infrastructure creation in LMICs), as well as the digital infrastructure (i.e., allow for the creation of alternative data pathways to identify the optimal one for a particular context).

The *financial sustainability* aspect, inevitably would align to and reflect market-driven needs. The potential structures and needs of financial incentives were presented in detail in chapter "Universal Internet Access Supporting Healthcare Provision: The Example of Indonesia" of this book. While the hard digital infrastructure (i.e., hardware) has reduced in costs considerably over the last two decades, the soft digital infrastructure (i.e., software) follows a different pricing structure, often developed as a Software as a Service (SaaS) model (Berndt et al. 2012; Oh et al. 2015). There have been a few individual SaaS implementations within LMICs (Ogwel et al. 2022; Karthikeyan and Sukanesh 2012), however, a more universal understanding or model has not emerged as yet. As the investment incentives have been discussed in chapter "Universal Internet Access Supporting Healthcare Provision: The Example of Indonesia", a repetition of the information would be avoided here. The only additional aspect that would come into consideration however, in terms of investment, is the necessary investment in trained staff, that is

necessary for all of the described infrastructure to be maintained as operational and impactful (Curioso 2019; Long et al. 2018).

Finally, in terms of *social and market sustainability*, the collection and potential distribution of immense amounts of information regarding individuals (e.g., even if self-reported via social networks) raises ethical concerns, as complete data anonymization is rendered ineffective in concealing the original data source, becoming harded, yet still feasible, to (re)identify individuals via the use of advanced systems and triangulation (Cecaj et al. 2016). However, if systems are entirely designed to use anonymized data, as an effort to protect individuals or population groups, this approach might not work optimally either, as the elements of information accountability and, hence, transparency may be affected. Regarding infectious disease outbreaks the use of anonymous data at source, is considered as current best practice, however, it is not a definitive solution for all situations that might arise within a healthcare ecosystem (Coltart et al. 2018). Therefore, challenges still remain in terms of ethics, as well as in terms of the legal framework for handling large healthcare datasets, including for example "credentialing, licensing, reimbursement, and issues related to technology, security, privacy, safety, and litigations" (Jazieh and Kozlakidis 2020). At this point a distinction would need to be made between public health ethics and clinical ethics: the former prioritizes common good; the latter prioritizes individual autonomy and ways to safeguard it (Chia and Oyeniran 2020). These nuances in ethical views/priorities may come into sharp focus within LMICs, during the implementation of digital healthcare technologies, where the pressures on availability of staff and funding are consistently acute.

Finally, data protection regulations are emerging within LMICs, albeit at a slow pace (Vodosin et al. 2021). The emergence of such frameworks is desirable from a market perspective, as they delineate the extent to which digital health can be implemented, systems integrated and reports provided to competent authorities. A question that is currently often discussed revolves around the regulation of algorithms that evolve (e.g., artificial intelligence (AI)-based applications) (Reddy et al. 2020; Amann et al. 2020). The approach currently proposed, including for LMICs, is that of a 'reasonable explainability' for regulating AI in healthcare, i.e. addressing explainability requirements based on the risks involved and providing explanations based on input, process and output norms (Sharma et al. 2020). Even at this level, the training of experts would be a necessity, in particular of regulatory authorities, as well as users of the AI-based solution (i.e., medical practitioners, nurses) on the limitations of explainability, and the risks that may not be explainable, which need to be communicated with patients. Thus, future developments within LMICs are anticipated to incorporate the development and implementation of healthcare digitization applications.

5 Conclusion

The current SARS-CoV-2 pandemic highlighted limitations and vulnerabilities of health systems and has driven a review of many healthcare systems, so that lessons are learned. The need for an increased capacity of healthcare systems to respond to iterative infectious disease emergencies, as well as systemic pressures, creates a driving force for the transformation of healthcare systems, based on new digital technologies. The examples over the last few decades of new technologies that were introduced, integrated and worked well within healthcare, including within LMICs, constitute the benchmark for an even greater integration of digital technologies. Hopefully this can be achieved as part of routine healthcare services design and procurement.

However, current challenges pertain to the scaling up of digital healthcare technologies, post-introduction in the field, and the use of predictive algorithms. Solutions to these challenges have already emerged, such as synthetic data, which allows the use of high-quality datasets without compromising the security of the original datasets. However, for that to be achieved, the sustainability of digitalization of healthcare in LMICs needs to be considered through the lens

of infrastructural, financial, ethical and regulatory concerns.

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Universal Internet Access Supporting Healthcare Provision: The Example of Indonesia

Dewi Nur Aisyah, Maryan Naman, Wiku Adisasmito, and Zisis Kozlakidis

Abstract

Indonesia formulates a particularly interesting example in terms of internet connectivity, accessibility to healthcare services and diseases surveillance, in relation to digitization of healthcare. As an upper-middle-income country, Indonesia introduced universal health care across the country in 2018, and exhibits a highly developed rate of digitization observed. The recent introduction of digital pandemic surveillance and reporting technologies, represents the single-largest introduction of digital technologies within Indonesian healthcare. Significantly, almost all of those technologies resulted from the collaboration of government bodies with private providers at a national and/or subnational scale, along with higher education institutions and research institutions. Therefore, the experiences from Indonesia provide a tangible example for introducing digital healthcare technologies at a national scale, that can be used as a blueprint for other LMIC settings. Furthermore, the integration of these technologies within healthcare demonstrated the potential benefit for digital technologies to inform public health policy at scale and during health emergencies.

Keywords

Healthcare digitisation · Low-and middle-income countries (LMIC) · Indonesia · Data regulation · Data infrastructure · Multisectoral support

1 Introduction

Health security is a term that has been used on multiple occasions during the COVID-19 pandemic. It is defined by the World Health

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Organization (WHO) as "a set of proactive and reactive activities to minimize the impacts of acute public health events that endanger people's health across geographical regions and international boundaries" (World Health Organization (WHO) 2020). In 2005 the International Health Regulations (IHR) were established, providing a legal instrument for the effective and timely response towards outbreaks and other health emergencies (World Health Organization (WHO) 2008, 2017). Member countries are legally bound to report event with an impact on public health, as well as to establish surveillance and response capacities towards health emergencies, in particular potential infectious diseases outbreaks (World Health Organization (WHO) 2020). Subsequently, in 2014, the Global Health Security Agenda (GHSA), providing a toolkit of policy recommendations, divided into 11 work-packages. Indonesia participates actively in the GHSA and in 2016 became the chair of the Steering Group (World Health Organization (WHO) 2016).

Indonesia formulates a particularly interesting example in terms of internet connectivity, accessibility to healthcare services and diseases surveillance, which this Chapter is going to investigate in some depth in relation to digitization of healthcare. Previous Chapters focused on highly developed economies (e.g., chapter "The Emergence and Growth of Digital Health in Saudi Arabia: A Success Story" focusing on Saudi Arabia), and on transition economies (e.g., chapters "The Digital Divide Based on Development and Availability: The Polish Perspective", "Potential of Digital Health Solutions in Facing Shifting Disease Burden and Double Burden in Low- and Middle-Income Countries", "Health Inequalities and Availability: Needs and Applications", and "Digitalization of Healthcare in LMICs: Digital Health and the Digital Divide Based on Technological Availability and Development", focusing on Poland, Vietnam, Cyprus and China respectively). Indonesia provides the central example of the current Chapter due to the most recent introduction of universal healthcare across the country in 2018 (Agustina et al. 2019), as well as the highly developed rate of digitization observed in relation to healthcare (Lazuardi et al. 2021; Aisyah et al. 2020).

Indonesia within low- and middle-income countries (LMICs), is classified as an upper–middle-income country (World Bank 2019). It is the world's largest archipelagos and has the fourth-largest global population, administered into 34 provinces and 514 districts/cities, with each sub-national government having decentralized authority (Central Bureau of Statistics Republic of Indonesia 2013). From an ethnographic perspective, Indonesia includes 1331 ethnic groups, 2500 local languages and six recognized religions (Naim and Syaputra 2011). All of these aspects are important to understand, as they formulate a highly fragmented background against which any national healthcare campaign would have to overcome a harmonization challenge—especially the deployment of new technologies in relation to healthcare digitization.

Prior to COVID-19, the Indonesian government pursued the strengthening of routine human, animal and wildlife surveillance, for detecting and responding to zoonotic diseases that can potentially cause a public health emergency (President of the Republic of Indonesia 2019). These disease surveillance collaborations were of limited regional scope and timescale, and/or with a narrow focus on a particular disease (Adisasmito et al. 2017; Aisyah et al. 2022a; Budayanti et al. 2020). However, they were considered successful at the local level, as they laid the foundation for intergovernmental collaborations during healthcare emergencies and proved a useful experience during the COVID-19 response (Aisyah et al. 2021a; Azhar et al. 2010; Hartaningsih et al. 2015). The COVID-19 pandemic has acted as a catalyst for further developing Indonesia's laboratory and healthcare capacity, by providing a platform to interconnect these services, but also the opportunity to scale them up. Specifically, the Indonesian government concentrated its efforts in fostering collaborations, thus scaling up testing and increasing laboratory capacity from 1 designated reference laboratory to 685 designated laboratories within the first 12 months of the pandemic (Aisyah

et al. 2021a), and over 1000 as of January 2023. Here we look into some of the aspects that allowed for this positive outcome to materialize, as well as the challenges that still remain.

2 Data Infrastructure

Indonesia has experienced a rapid advancement of telecommunications in the last two decades, predominantly in the most populated areas, e.g., Java Island. The number of Indonesians using the internet has also experienced an exponential growth, increasing from an estimated 8.1m in 2005 to over 57m in 2015, with 80% of the country's internet users located on the islands of Java, Sumatera and Bali (Jurriëns and Tapsell 2017). Thus, behind the increasing connectivity with telecommunications and data infrastructure lies an uneven distribution of these services across the country. The Indonesian government is aware that uneven access to telecommunications has the potential to widen a potential digital divide, hence investment incentives have been provided to companies to ameliorate the costs of developing infrastructure in geographically challenging areas, and so that infrastructure costs do not form the most significant barrier to accessibility. Narrowing the digital divide remains a huge challenge for the Indonesian government and society (Purbo 2017), aiming to harness the potential of digitization of healthcare, and the further development of healthcare services provision as part of the newly introduced universal healthcare coverage.

3 Data Laws and Regulations

The introduction of digital technologies in Indonesia did not occur in a vacuum, but was the result of collaborations between local and international organizations. At the same time, Indonesia developed the legal frameworks for data protection, specifically the regulation No. 20 of 2016 by the Ministry of communication and Information, where personal data protection in national law is stipulated explicitly. Further regulations regarding healthcare data, secondary use of healthcare data, and the regulation of algorithms used in Artificial Intelligence (AI)-driven decision-support systems are also anticipated in the near future.

4 Impact and Example of National Scale Implementation

As described by Aisyah et al., in Indonesia, a digital response and management system specific to public health was built and implemented through the pandemic. It incorporated the following aspects: detection, prevention, treatment, and monitoring (Aisyah et al. 2023). Beyond the main, national-scale deployment of the COVID-19 tracing app (Aisyah et al. 2022b), a total of 36 digital technologies supported more localized healthcare management aspects, such as telemedicine apps providing consultation and local treatment options for individuals exhibiting mild COVID-19 symptoms, as well as information for asymptomatic, infected ones. Of those digital technologies, 11 pre-existed the pandemic, and were expanded during its course. Each of these digital technologies facilitated a mix of remote consultations and prescribed medication delivery services (Aisyah et al. 2023).

Even though there was no precedent for a national-scale rollout of a digital healthcare application prior to the pandemic, there was an aligned thinking in this direction as evidenced by the launch of the Digital Health Transformation blueprint in December 2021. During the pandemic (and almost immediately after the blueprint launch) the health protocol compliance app [Bersatu Lawan COVID-19 (BLC)] became a mainstay of the entire government system, with dashboards showing aggregated, population-level information, the latter customized for the level of access and selection of information relevant to the role and functions of the accessing institution (Aisyah et al. 2021b). For example, the dashboards of the local police department and of the Ministry of Health would contain differently customized dashboards reflecting their different priorities as defined by their functions.

In particular, during COVID-19 pandemic, the Indonesian government developed several innovations using information systems and technology to support the pandemic control programs. For example, the Ministry of Health successfully integrated laboratory test results across more than 1000 laboratories for automatically identified people who were infected to be followed up for contact tracing and treatment (Aisyah et al. 2022c). Another innovation was the development and utilization of Peduli Lindungi as a mobile application used by the community to get information on the COVID-19 cases distribution across regions, automatically linked with laboratory test results, screening of COVID-19 status eligibility to enter public facility, and linked with COVID-19 vaccination records and certificate (Aisyah et al. 2023). The application has been downloaded by more than 100 million people so far. The Indonesian government also has successfully vaccinated more than 200 million people for COVID-19, where the information of COVID-19 vaccination coverage across 34 provinces can be accessed by the public in a designated dashboard (Indonesian Ministry of Health 2023). A public dashboard was also developed showing the COVID-19 situation across 514 districts/cities (number of cases, number of deaths, number of hospital admissions, COVID-19 vaccination coverage, etc). This momentum of digitization was followed-up by the development of the Digital Health Transformation Strategy 2024 Blueprint that laid the foundation for the enterprise architecture of health technology in Indonesia (Indonesian Ministry of Health 2021). It is hoped that the Blueprint will accelerate the government's goal of providing universal, affordable, equitable and quality care nationally, while taking advantage of digital technologies.

There were a number of key elements that drove the success of the national-scale digital healthcare application implementation:

Firstly, there was commitment by the entire political and administrative system, from the office of the Presidency, to the different Ministries, to regional and local administrative units. This was particularly important in the initial adoption of the developed digital tools. *Secondly*, the diffusion of digital technology was facilitated by the standardized protocols regarding data input, and the standardized information display regarding aggregated data. This helped provide a common understanding of the information to the lowest administrative level, and importantly for public servants- who all had access to the app- it allowed for a uniform message and common understanding to be disseminated to the population. *Thirdly*, the technology development was coupled with the efforts for expansion of laboratory capacity. As such, the system was not creating yet another siloed unit, but it was evidently cross-supporting additional initiatives and vice versa. *Fourthly*, the immediacy of information, in near real-time (i.e., with a maximum space of information incorporation of 24h), ensured that the information is relevant even in the face of a fast-paced pandemic.

5 Way Forward

The multisectoral coordination behind the development and implementation of the digital healthcare applications in Indonesia is probably the most pronounced difference to the implementation of digital healthcare applications in other parts of the world, where multidisciplinarity was not achieved to a desired level (Benítez et al. 2020). Furthermore, it highlighted how the micro-level data provided primarily by police officers, military personnel, and community ambassadors (e.g., community/village leaders), can be effectively aggregated at a national scale, applying then big data analytics to analyze these reports on a weekly basis, to provide updates to policy makers and inform government response policies. The massive download of healthcare applications (over 100m downloads), also highlights the necessity for universal internet connectivity, coupled with the rollout of the universal healthcare system.

The way forward would need to include five key elements:

– Continued infrastructure development to improve the reach and performance of this and future digital healthcare applications, in particular in terms of data security.

- Continued stakeholder support for the implementation of digital healthcare applications, even if those need to be more localized and not necessarily at the national scale. Stakeholder support in this instance includes the implementation of and adherence to appropriate ethical and legal frameworks.
- Continued multidisciplinarity, as Indonesia's healthcare needs are complex, and unlikely to be addressed by single vertical initiatives.
- Continued education of the professional workforce to utilize digital healthcare applications as appropriate, laying the foundation for a future generation of technology adopters and users, and
- The transformation of the existing digital healthcare application capacities to expand and incorporate seasonal and/or endemic diseases, so that it can transform into a more systemic healthcare surveillance tool.

6 Conclusion

This Chapter presented a high-level view on the use of digital health technologies in Indonesia, in particular those introduced for COVID-19 detection and response management. This is particularly significant as universal healthcare coverage was introduced within Indonesia in 2018, and such technologies have acted at scale and in addition to greater behavioral and systemic pressures in the healthcare sector. Additionally, it is significant to note the multisectoral coordination among government bodies, higher education institutions, research institutions, and the private sector, that has created a fertile ground for the creation and introduction of such new technologies. Thus, the example of Indonesia is a useful case study for the utilization of digital healthcare technologies within the context of LMIC settings, and in aid of public health decision-making.

This Chapter also acknowledges the many remaining challenges, common amongst LMIC settings, such as absence of a dedicated data privacy framework, technological access disparities, and the ability to support the introduction of such innovations by trained, skilled staff. Thus, any potential benefits of implemented digital healthcare technologies, need to be considered alongside the need of maintaining an active governmental support for the long-term.

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Proliferation, Ingestion, and Interpretation of Health Data in Low-and Middle-Income Countries (LMICS)

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Abstract

Technology will continue to impact the delivery of healthcare across the world. In low- and middle-income countries (LMICs) digitization has the potential to improve current healthcare provision. To date many digital initiatives have been designed addressing healthcare challenges in LMICs, with the eventual aims of improving both access to and quality of healthcare. For those digital initiatives that have managed to move beyond the initial phase of piloting and experimentation, the next steps involve effective scaling, diffusion and integration within healthcare systems. Examples of such digital initiatives include mobile phone applications, feeding into national-level health information systems for infectious diseases surveillance. Other examples include centralized healthcare data information capacities, including the preparation towards supporting national genome projects. Inevitably, the focus regarding these initiatives has been shifting towards scalability and de-escalation, integration within healthcare ecosystems, and long-term sustainability. This chapter considers the aspects of proliferation, ingestion and interpretation of digital health data in LMICs with many specific examples, showcasing the plurality of the approaches that have been implemented in the field so far.

Keywords

Low-and middle-income countries (LMICs) · Digitisation · Healthcare · Data ingestion · Data proliferation · Data interpretation

1 Introduction

Digital health is an umbrella term describing electronically captured data, along with the technical infrastructure and the applications connecting data producers and consumers. Continual technological advances are transforming healthcare delivery, clinical research, and biomedical science, as well as impacting on the design and delivery of the digital tools within those sectors (Abernethy et al. 2022). Specifically, some of

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those advances include cloud computing, remote patient management, artificial intelligence-enabled diagnostics, and consumer-facing mobile health applications (Abernethy et al. 2022). Though most implementations are designed for resource-abundant settings, some examples do exist in low- and middle-income countries (LMICs). In Malawi, for example, VillageReach and the Ministry of Health created and utilize a national health information line, called Chipatala cha pa Foni (CCPF). In less than a decade, CCPF developed from providing Reproductive, Maternal, Newborn, Child Health, and Nutrition (RMNCHN) services locally, to the national level and addresses all health topics, including also COVID-19 relevant information (Mitgang et al. 2021; Viamo 2020). Babyl Rwanda is another such example of an integrated digital health solution, as it delivers virtual triage and primary care services over the phone, and the ability to also provide post-consultation prescription and other downstream services. The latter are referred via a text message and are valid at both public and private designated facilities. These developments promise to transform healthcare delivery, by improving accuracy and/or outcomes, and through a more personalized interaction, increase patient engagement (Abernethy et al. 2022; McGinnis et al. 2021).

The digitization of healthcare represents the foundational precondition for enabling the downstream data analyses for quality of care and operational efficiency and effectiveness. However, the advancement of clinical knowledge and diffusion of digital innovations are integrally linked to establishing and maintaining data standards. For example, understanding the medication lists prescribed to each patient and centralizing this information offers the potential to identify adverse reaction between the offered prescribed medications for each patient (Garfield et al. 2020). However, this knowledge needs to be translated into actionable pathways. Information infrastructure is required to capture such information in detail (e.g., pharmacies must add new drugs as they become available, and new prescriptions to individual patient lists), and digital decision-support systems must be adapted to alert the clinician and/or patient if a pre-defined, unexpected event takes place. For example, if the patient's record does not include entries on potential adverse reactions to particular pharmaceutical susbtances (https://www.measureevaluation.org/resources/publications/wp-18-211/at_download/document). Currently using telemedicine, patients are anticipated to benefit from round-the-clock remote monitoring, in particular for long-term critical illnesses and/or post-operative care. Efforts to enhance communication and information technologies with appropriate health data, are actively being made with high hopes that these can make a significant leap forward toward safer care, although little has been achieved in LMICs. The application of available digital solutions is more likely to be used in the USA, in Europe and other digitally advanced regions for continuous healthcare improvement.

The COVID-19 pandemic has exposed the fragility points of healthcare systems, additional to persistent and deepening inequities (Mitgang et al. 2021). In particular, the limited capacity of LMICs to respond to an evolving pandemic, such as COVID-19, and its impact on the most vulnerable populations presents a marked challenge. Digital health can mitigate some of those challenges, as an alternative communication tool; that is scalable and able to incorporate/combine information service delivery models; thus, empowering healthcare delivery.

2 Methodology

This is a narrative review of publicly accessible information in scientific journals, from the last five years, to identify the opportunities and gaps in the proliferation, ingestion, and interpretation of digital health data in LMICs. To this end, the most highly cited articles identified on the Web of Science and PubMed were used, identified by the keywords: LMIC; ingestion; proliferation; healthcare data; interpretation. The date of search was in the last 5 years (2018–present). Having identified those starting articles, additional manuscripts were identified through 'snowballing', i.e., using reverse citation tracking to find articles

that cited articles already deemed relevant to the review (Callahan 2014). For this topic, a narrative review approach was preferred, as the aim of this chapter was to provide a broad perspective and explore the general debates and developments. By contrast a systematic review focuses on unique and specific queries, using explicit methodology and a typically a narrower perpsective (Rother 2007).

3 The Proliferation of Digital Health Data in LMICs

The proliferation of health is one of the most important developments in the digitalization of health (Chowdhury and Pick 2019). Improving and scaling-up data collection remain fundamental to all these activity domains: process optimization such as digitalization of medical records, training physicians, and improving the quality of care given to patients (Chowdhury and Pick 2019); preclinical research like reducing the time taken for new drugs to reach patients; clinical pathways; including improving access to healthcare information (Aisyah et al. 2021); patient-facing applications like making applications that are user-friendly for patients (Abusanad 2021); including population-level applications (Chowdhury and Pick 2019; Cheong and Wang 2022).

Data-driven research conducted over time and interpreted within a local context can increase the capability to undertake population-level planning. For example, mobile phone data was used to model the spread of cholera in Haiti (2010) and of dengue fever in Pakistan (2013) (Bengtsson et al. 2015; Wesolowski et al. 2015). The Global Health Monitor is another such example: locating and analyzing English-language news stories as a proxy for monitoring infectious diseases outbreaks (https://www.researchgate.net/publication/239813129_Global_Health_Monitor_-_A_Web-based_System_for_Detecting_and_Mapping_Infectious_Diseases). With machine learning techniques there is the potential to identify, map, and track complex diseases quicker. This can reduce response time and attenuate their impact. Another example of data-driven actions is the continuous development of the Global Antimicrobial Resistance and Use Surveillance System (GLASS) by the World Health Organization (WHO), the former launched in 2015 with the main aim "to promote, enhance and harmonize the surveillance of antimicrobial resistance (AMR)" and inform relevant policy decision. Since its launch, GLASS expanded in multiple directions: in its scope, in the data volumes received, and in its global coverage, as over 100 countries and territories worldwide are no enrolled (World Health Organization 2021a). While this is a great proliferation of data producing and sharing, the financial model is entirely based on the WHO funding to promote the scaling-up. A similar model of data generation is followed by the WHO FluNet, originally established in 1952 as the Global Influenza Surveillance Network (GISN) (Monto 2018). In the past two decades it has incorporated genomic data and was transformed into FluNet, a system of over 100 National and international Influenza Centers (NICs), all consistently recording population-level influenza globally (Brammer et al. 2009). The proliferation of data within this platform, where data and Standard Operating Procedures (SOPs) are publicly available, has been significant, and inclusive of many LMIC-generated data.

The availability of healthcare data (at either a global or local level) is anticipated to improve predictions about the changing demands and the effectiveness of any initiatives taken in response (Altmann-Richer 2018). Health inequalities including access to care and life expectancy amongst others can be difficult to resolve at present due to a lack of reliable data on underrepresented populations in research, such as those with low income and educational levels (Chowdhury and Pick 2019). Adding new technologies to such a context, while desirable in terms of providing new data and identifying potential opportunities to resolve existing challenges, can be problematic, as these technologies need to operate consistently within challenging environments. Therefore, evaluation frameworks are needed in LMICs to determine the impact of introducing data-generating

new technologies, such as genomic-based pathways, in these settings both clinically and financially (Roberts et al. 2019). The data from such evaluation frameworks is critical for creating the evidence-base for policymakers and practitioners in LMICs to make better data-based decisions to improve healthcare (https://genomemedicine.biomedcentral.com/articles/10.1186/s13073-021-00911-0). It is also important to note that data-driven systems can mitigate or alternatively entrench inequalities, depending on their implementation (https://www.adalovelaceinstitute.org/report/knotted-pipeline-health-data-inequalities/).

The rapidly expanding quantity of healthcare data poses a significant question in terms of governance of this information across all settings. Information governance presents both risks and opportunities. The weak regulatory frameworks in place in many LMICs are also a challenge (Vodosin et al. 2021) but more than that is the lack of effective governance (Hoxha et al. 2022). The effective governance includes operational aspects of security and safety, as well as the longer-term strategic planning with multiple stakeholders. Inevitably, the latter also requires multi-sectoral coordination, including multiple governmental departments, and a population-level strategy (Chowdhury and Pick 2019).

With the growth of digital health tools and their integration into daily reporting dashboards, data-based decision-making may become the norm. These may confer benefits such as more accurate diagnosis, more efficient resource allocation, and even improved patient outcomes. However, associated risks should also be considered. A potential over-reliance on data-based decision-making may lead to the de-skilling of decision-makers (e.g., clinicians), who may follow algorithms' outputs uncritically (Duran 2021), sometimes unable to explain the automated pathway underpinning them due to the inability of developers to communicate their methodologies in a clear and non-technical manner. Incomplete and/or inaccurate data input may exacerbate these problems further, introducing bias into the decision-making that is difficult to remove. For example, in an article on the 'global measles crisis', the WHO Director-General highlighted the vaccination uncertainty "fueled by the proliferation of confusing and contradictory information online" (Gu et al. 2018; Stahl et al. 2016). Thus, the next focus, following proliferation, is the ingestion of digital health data.

4 Ingestion of Digital Health Data in LMIC

There is a need for digital healthcare information to become findable, interoperable and shareable across organizations, to avoid duplication and magnify the collaborative impact. For example, the Ugandan Ministry of Health in 2012 issued a moratorium on m-Health projects that were unable to share data nor integrated into the health system and were not making lasting contributions to the overall healthcare (World Health Organization 2016). Specialist and secure data warehouses may need to be created to facilitate the ingestion of digital health data on a routine basis (Rudniy 2022). From such silos, data can be used to develop downstream applications, however, the completeness and quality of the collected healthcare data are or paramount importance. If incomplete training data were to be utilized for a downstream artificial intelligence (AI) application and those data do not accurately reflect an entire population across specific parameters (e.g., gender or race), this would result in skewed outcomes for any health application, as recommended treatments may be beneficial only for subsets of the population. In LMICs, healthcare data are often incomplete and of mediocre quality, and these can be ingested into different applications. For example, the real-time generation of evidence in a learning health system (i.e., a system that would integrate the lessons learned at regular intervals), that links datasets, integrates and analyzes those datasets using AI and machine learning remains nascent and limited to a few pilots (Amruthlal et al. 2022; Miguel 2022).

Accurately analyzing the spread of infectious diseases, identifying patient risk factors, and distributing resources effectively necessitate complete and quality data that is currently difficult to obtain in most LMICs through a systemic approach. Having said that, certain parts of the

healthcare ecosystem can develop from the pioneering examples. Specifically, electronic medical records, when interoperable, have the potential to support evidence-based decisions at a system level. For example, a Ghana-based telemedicine initiative supported by the Novartis foundation is frequently highlighted as a positive example of scaling up digital healthcare provision in LMICs, from a single district in 2011 to nation-wide coverage in 2016, incorporating end-user insights, such as front-line community healthcare staff (Novartis Foundation 2010). Another case study is the Open Medical Record System (OpenMRS), created in 2004 as an open-source, electronic health records platform. OpenMRS and one of its better-known implementations was during the Ebola epidemic (2014–2016), when it was deployed successfully in a treatment center in Sierra Leone (Chowdhury and Pick 2019). OpenMRS is currently being used in a number of locations globally (India, Haiti, South Africa, Zimbabwe, etc.), with successful examples reported (Uwamariya 2015; Jawhari 2016), and a third release of the updated product (i.e., OpenMRS 3.0) taking place in 2023. However, it has not become as ubiquitous in its LMIC use as originally anticipated.

The data produced and contained within medical records, beyond their immediate clinical use, can also have a secondary use by researchers and/or commercial parties, for example to create new tools, processes or treatments. This adds a second layer of data ingestion requirements. Hence the need to improve the quality of data collected in LMICs; ensuring that end-users, are trained, digitally literate, and have access to use such information. For example, the use of telemedicine in Indonesian hospitals proved successful, especially during the COVID-19 pandemic (Aisyah et al. 2021; Aisyah et al. 2023).

5 Interpretation of Digital Health Data in LMICs

Data interpretation is defined as "the process of reviewing data and arriving at relevant conclusions using various analytical methods" (Spiggle 1994). It goes beyond the identification of patterns that an analytical process will result to, and highlights the reasons behind those observed patterns. A good data interpretation process typically involves integration which is collecting and merging data from multiple sources to create unified sets of information for downstream applications, resulting to findings, conclusions and/or recommendations. Devices that collect data but do not integrate with other extant databases (e.g., at local or national level) are unlikely to be utilized outside of the program for which the data is collected. However, the interpretation process presumes that a good level of understanding exists throughout this cycle of data collection-analysis-interpretation-recommendation. In LMICs the lack of digital literacy has been highlighted on many healthcare reports, in particular as lack of relevant staff training can lead to misinterpretation. This can be prevented, at least in part, by providing clear, standardized operations to facilitate data utilization. For example, in Nigeria, MEASURE Evaluation provided AIDSRelief with a standardized data checklist, this very tight standardization facilitated the integration of family planning and HIV treatment data, and supported evidence-based decision making at the facility level (Chabikuli et al. 2009).

The relatively low level of digital literacy in LMICs, highlights a need for national governments to adapt their educational systems to be more inclusive of digital applications, to lead in the information and sensitization of people about digital health and the importance of collecting accurate and precise data, while providing successful examples so that there is a direct understanding of the benefits to the individual and to society. The digital tools developed need to be adjusted to best fit the population in which they are to be used, and whenever possible with the input of the local end-user groups (Labrique et al. 2018). The 2018 WHO resolution on digital health and the 'Global Strategy on Digital Health 2020–2025', urge member states to develop, as appropriate, legislation and/or data protection policies (World Health Organization 2018, 2021b). As individuals are both consumers and producers of data, simultaneously at a personal and a community level, the data interpretation

has the potential to affect several facets of their lives. Therefore, developing relevant frameworks for privacy, security, data access and ownership, and consent are essential, if interpretation of digital health data in LMICs is to progress.

6 Discussion: The Way Forward

While technology does not intend to entirely replace human decision-making in healthcare, the vision of precision medicine may become realizable because of the proliferation, ingestion, and interpretation of data. In an ideal scenario, with rich, accessible, high-quality datasets on patient diagnoses, disease treatments, and drug effectiveness, a sustained global growth of personalized treatments could be anticipated, leading to tailored therapies and improved health outcomes (Vogenberg et al. 2010). However, two aspects need to be taken into account. Firstly, precision medicine carries an increased procedural (and perhaps pharmaceutical) cost, as well as the infrastructural burden, and those cost demands could divert funds from elsewhere. The second risk is that precision medicine could become an inequality driver by implementing a barrier to entry for those healthcare systems who cannot afford it.

One initiative addressing the latter risk is the USA-based Digital Square, a partnership between PATH, USAID, the Gates Foundation, and others, that works together with local ministries of health to align digital technologies with local health needs, aiming to improve how healthcare tools are designed, used, and paid for (Novillo-Ortiz et al. 2018). In Europe, the European Open Science Cloud (EOSC) is a European Commission infrastructure providing its users with services for open science practices and digital interoperable environments, including for healthcare research (Budroni et al. 2019). These are high-profile and impactful initiatives but would be slow to produce change in LMICs. Perhaps educational initiatives on core competencies in data analysis, interpretation, synthesis, and presentation would be more applicable for LMICs, especially if staff at all levels of a health system are included in such educational initiatives (https://www.measureevaluation.org/resources/publications/wp-18-211/at_download/document; Amaro et al. 2005; Nutley and Reynolds 2013). Such education activities can be complemented by data quality assessment tools/evaluation framework tools, that are to be used in iterative assessments, including the data quality review (DQR) and the routine data quality assessment (RDQA) (Chen et al. 2014).

The process from data collection and storage to the final interpretation and dissemination to the end-user overgoes different stages, while addressing the need for patients' rights protection through data sharing and access. Successful integration of the plurality of patient related data, from environmental to metadata, and of many digital systems, within national Electronic Data Capture Systems, requires digital ontology engines and protocols for harmonization, standardization, and homogenization of data (Kush et al. 2020). Thus, the investment required in both technology and trained staff is considerable. Data redundancy, as well as legislative and governance issues can be overcome by establishing robust Digital Rights Management (DRMs) systems, enforcing role-based access, manipulation, and control of data (Hu et al. 2014; Alahmar et al. 2022). As the personalized medicine notion, becomes more prevalent, health related data collection systems implemented for interoperability, secure data migration, mining, and interpretation, should have patients as their focal point and be patient-centric. These can include consent status management, predefined data ownership and accredited security options and create a dynamic electronic framework for future uses, without making it obsolete when faced with emerging technologies (Kaye et al. 2015; Ivanova and Katsaounis 2021). Successful interoperability implementation systems will most definitely lead to scalability; thus, regional and national organizations should be established overlooking and synchronizing actions, adoption of technologies and effective non-overlapping adoption and integration (Austin et al. 2021).

Within this need for creating appropriate frameworks, Sensitive information covered by

data privacy and biosecurity must be identified, classified, and protected. There is confidential and exclusive data that can only be accessed by limited individuals (e.g., high-risk pathogen research, and/or personal details). The existence of a reliable infrastructure (e.g., electricity and internet accessibility) is a precondition to the existence of a digital infrastructure and the latter underlies the implementation of diagnosis tools, data analytics, or drug discovery technologies. For example, the internet can lead to greater numbers of trained doctors, nurses, and community health workers, by lowering barriers to access education. Given the low healthcare staff coverage in LMICs, the ability to train healthcare practitioners effectively is vital—and digital solutions can be incorporated within the training courses.

In summary, some recommendations would be closely aligned with those made in the Riyadh Declaration on Digital Health (Al Knawy et al. 2020, 2022).

- Adoption of standards that encourage data harmonization and eventual exchange and interoperability.
- Investment in foundational infrastructures, e.g. electricity, to support digital access.
- Investment in nationwide digital literacy initiatives.
- Development and implementation of clear, national frameworks for data protection, for sensitive and confidential information.
- Establishment of governing bodies to oversee the implementation of digital health strategies.
- Implementation of a digital patient consent

7 Conclusions

In LMICs there is a marked lag in the implementation of digital healthcare applications even though digital healthcare carries the potential to improve overall healthcare provision. Healthcare challenges in LMICs have attracted digital initiatives, which typically are operating siloed, though they all aim to improve access to quality healthcare delivery. Some of these digital initiatives have moved beyond the initial piloting and experimentation phases, and now focus on effective scaling and/or integration with other existing healthcare system operations.

Digital initiatives typically take advantage of existing platforms such as mobile phone networks and devices, combined with health information systems, automated processing and information exchanges. Their focus has been shifting towards data proliferation, ingestion, and interpretation, as critical steps in the development of digitally-enabled healthcare systems. However, digital health interventions are bound by high-quality data, which is not always forthcoming in LMIC settings. Therefore, any investment in infrastructure improvement would need to be complemented by digital literacy training programs, within amenable regulatory frameworks.

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Ubiquitous and Powerful Artificial Intelligence (AI)

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Abstract

The chapter delves into the transformative potential of ubiquitous Artificial Intelligence (AI) for revolutionizing healthcare in low- and middle-income countries (LMICs). It showcases numerous AI-driven benefits, such as enhanced diagnostics, tailored treatment plans, streamlined drug discovery, and overall healthcare improvement in resource-constrained settings. The discussion acknowledges the challenges and limitations of implementing AI in LMICs, including high costs, a dearth of skilled professionals, and data-related hurdles. It proposes viable solutions, such as public-private partnerships, external funding, open-source software, international collaborations, and infrastructure investments. With a focus on ethical considerations, the text underscores the significance of patient data privacy, addressing algorithmic biases and promoting global collaboration to ensure equitable access to AI-powered healthcare solutions. Inspiring real-world examples from Rwanda, Armenia, Pakistan, and India illustrate the profound impact of AI in LMIC healthcare settings. The vision of ubiquitous AI presents a unique opportunity to bridge the healthcare divide between LMICs and high-income countries, enabling proactive and preventive care while tackling global health challenges. This captivating discussion encourages readers to further explore the responsible and ethical utilization of AI's transformative power in healthcare.

Keyword

Ubiquitous AI · Healthcare transformation · Healthcare in low- and middle-income countries · AI-driven benefits · Implementation challenges · Ethical considerations

1 Introduction

As a new chapter unfolds in healthcare, ubiquitous AI shines as a light for low and middle-income countries, turning distant aspirations into achievable outcomes.

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Artificial Intelligence (AI) is a robust developing branch of computer science designed to build machines that can mimic human beings and perform tasks equally or better (Shimizu and Nakayama 2020). The widespread adoption of AI technologies into our daily lives has become ubiquitous, making everyday items and settings, such as cellphones, wearable technology, and homes, smarter and more interactive. Over the past decade, the world has witnessed how AI revolutionized various industries, including healthcare, with machine learning and deep learning techniques enabling the development of medical devices that can aid in diagnosing, screening, predicting, and treating diseases (Esteva et al. 2017). In this era of big data, AI devices can assist researchers and physicians in analyzing large amounts of data and identifying possible connections leading to new insights and discoveries (Obermeyer and Emanuel 2016). In fact, up to 520 marker-cleared AI medical algorithms have already received FDA approval, with more expected to follow (FDA 2022). Developed countries have already begun reaping the benefits of advanced AI techniques in daily clinics. Despite limited access nowadays, this trend into shifting to digital healthcare could be especially noteworthy in low and middle-income countries (LMICs), where traditional healthcare systems often struggle to meet the population's needs.

This chapter will explore the challenges and opportunities of adopting AI in healthcare. We will discuss potential applications of ubiquitous AI in LMICs, including medical imaging, diagnostic decision support, telemedicine, and electronic health records. Despite the challenges ahead, the increasing availability and adoption of AI technology suggest that its impact on the future of healthcare is both exciting and unique.

2 Potential Applications of Ubiquitous AI in LMIC Healthcare

Having limited resources and infrastructure, low- and middle-income countries (LMICs) often struggle to provide their populations with the best available and the most quality-assured healthcare. While challenges exist, the adoption of AI can address the shortage of healthcare professionals by automating routine tasks, enabling early, timely detection and accurate diagnosis of diseases, tailoring treatment plans, and providing real-time monitoring of patients. The future of AI in the digitalization of medicine in LMICs is promising, and its potential must be harnessed.

The potential applications of ubiquitous AI in healthcare in LMICs are vast, ranging from disease diagnosis and personalized treatment plans to drug discovery and development. Improved health outcomes, reduced mortality rates, and enhanced training opportunities for healthcare professionals could be achieved by AI-powered tools with better management and analysis of medical data and increased access to healthcare through telemedicine and remote monitoring. Additionally, AI can improve public health surveillance and disease control while providing increased research opportunities for identifying and addressing healthcare disparities. Finally, the development and application of AI technology can improve resource management, ensuring that medical equipment, supplies, and staff are utilized efficiently and effectively, hence reducing the financial burden, and boosting the economy of LMICs.

One example can be using *deep learning techniques for more accurate diagnoses*. This can provide a more precise diagnosis based on data experience. The histopathologic slice from a country with limited resources and experience can be reviewed and verified within minutes, compatible with those of the experienced center with an expert histopathologist.

Other areas where AI can significantly impact include:

- Medical image analysis.
- Real-time monitoring of patients.
- Predictive analytics for healthcare management.

We can envision this possible application in the example of Armenia. In several border-closed regions of Armenia, there are few specialized

oncology radiologists, and patients must travel to the capital even for a cancer screening. If an AI-based tool were available to identify, for example, suspicious breast masses, a regional radiologist could spare patients without such lesions the need to travel to centralized hospitals for screenings. This would be a cost-effective approach and ensure timely detection and treatment for at-risk people.

Electronic health record (EHR) management and analysis is another area where ubiquitous AI could significantly impact LMICs. AI could automate data analysis and entry, allowing healthcare professionals to enter patient information and obtain relevant data swiftly and simply. This can improve the accuracy and completeness of medical records, serving as a more precise ground for future analyzes. Additionally, AI-powered analytics could identify patterns and trends in EHR data, allowing for more effective disease surveillance, outbreak detection, and targeted interventions. By implementing AI to improve EHR management and analysis, LMICs could significantly improve the quality and accessibility of healthcare services.

Ensuring that medical equipment and supplies are accessible when and where necessary is one of the biggest obstacles in healthcare delivery in LMICs. AI can play a critical role in addressing this challenge by providing advanced *demand forecasting and inventory management tools*. For instance, in Nigeria, the non-profit startup LifeBank has partnered to use AI-powered tools to optimize the supply chain for blood and other critical medical supplies. The demand, transport times, and storage capacity are the main factors to be analyzed by AI to ensure that medical supplies are available when and where they are needed. This has helped reduce waste and improve overall efficiency, enabling healthcare providers to deliver lifesaving care to more patients. By leveraging AI to improve supply chain management, healthcare providers in LMICs can overcome logistical challenges and improve access to essential medical supplies and equipment.

Another example of ubiquitous AI is *wearable technology*, which has great potential to be implemented in LMIC, where doctor visits tend to be infrequent and inconsistent. n such regions, wearables can empower patients to remotely monitor their health and well-being more efficiently, reducing the need for some in-person consultations. For instance, these devices can continuously track blood pressure, heart rate, and blood glucose levels, offering valuable insights for patients with chronic conditions like diabetes and delivering more precise information for physicians (Gao et al. 2016). This remote monitoring allows healthcare professionals to intervene promptly if any issues arise, enabling them to adapt and guide treatment accordingly.

Furthermore, wearables can be employed to monitor physical activity levels, sleep patterns, and other health-related metrics, giving both patients and doctors a holistic view of their health status. Leveraging AI algorithms to analyze the data gathered by these devices, clinicians and healthcare providers can uncover valuable insights into patient health, recognize trends and patterns in health data, and offer more tailored recommendations for patients.

2.1 AI-Driven Drug Development and Clinical Trials

Affecting various fields of healthcare, drug development is another aspect that is highly impacted by the implementation of AI. Particularly in resource-limited settings, these AI tools have the potential to shift the way new therapies are discovered and brought to market (Lecun et al. 2015). One of the most significant advantages of using AI in drug development over human resources is its ability to analyze vast amounts of data, such as genomic, proteomic, and clinical trial data, during a time that would be impossible for researchers. This enables AI algorithms to identify potential drug candidates and therapeutic targets more quickly and efficiently. An example of AI's impact is its application in drug repurposing, where algorithms analyze existing drugs and their interactions with disease pathways to uncover new therapeutic uses (Ahmed et al. 2022). This approach expedites the process of

drug discovery and development, as repurposed drugs have already undergone extensive safety testing and can often bypass early-stage clinical trials.

AI can also improve the efficiency of preclinical drug development, optimizing the design of trials and predicting the likelihood of success for specific drug candidates, ultimately conserving resources, and enabling the development of more affordable treatments for patients in LMICs (Vamathevan et al. 2019). By analyzing large datasets, AI algorithms can help researchers identify the most appropriate patient populations for clinical trials and forecast potential trial outcomes (Weissler et al. 2021). This can lead to more efficient trial designs and increased success rates, ultimately accelerating the development of new therapies. In LMICs, where patient recruitment for clinical trials may be challenging due to limited infrastructure and resources, AI can streamline the process and improve trial outcomes.

From the point of view of LMICs, AI-driven drug development can be particularly valuable in the context of diseases that are prevalent in these regions but may not have been of interest to the industries in higher-income countries to be addressed. For example, AI could identify new therapeutic targets and drug candidates for neglected tropical diseases, which disproportionately affect populations in LMICs. By using AI to develop new treatments for these diseases, researchers can help to reduce health disparities in LMICs. By incorporating AI-driven innovations into the drug development process, researchers can help to address many of the unique challenges faced by LMICs in healthcare and contribute to forming a healthier population.

2.2 AI-Powered Precision Medicine

In the context of LMICs, there is a substantial anticipated benefit for AI-powered precision medicine. Tailored treatment plans based on improved patient stratification can help address unique healthcare challenges in these countries, including limited resources and diverse patient populations facing a high burden of both communicable and non-communicable diseases.

AI algorithms can analyze large amounts of patient data, such as demographic, genetic, and clinical information, and detect meaningful patterns and correlations, which may elude human researchers (Obermeyer and Emanuel 2016). By harnessing this data-driven insight, healthcare providers in LMICs can develop more accurate diagnoses and better understand the factors contributing to specific diseases or conditions, ultimately leading to more targeted and effective treatments.

One example of AI-powered precision medicine in an LMIC context is using AI algorithms to predict the risk of tuberculosis (TB) among patients in high-burden settings. In countries where TB is a significant public health concern, like India, AI can help to identify patients who are most likely to develop active TB. By identifying high-risk patients with the factors such as genetic makeup, environmental exposure, and other health conditions, healthcare providers can target interventions and treatment plans more effectively, ultimately reducing the overall burden of TB in the population (Orjuela-Cañón et al. 2022; Schwalbe and Wahl 2020).

Personalized treatment plans can also help to optimize the use of limited healthcare resources in LMICs. Healthcare professionals can avoid using needless or ineffective tactics by tailoring therapies to each patient's requirements, sparing those who might not benefit from unnecessary procedures. This is particularly important in LMICs, where healthcare budgets may be limited, and the need to allocate resources efficiently is paramount.

Furthermore, AI-driven precision medicine can help to address the unique challenges faced by LMICs in managing both communicable and non-communicable diseases. AI algorithms, for instance, can be used to identify possible interactions between non-communicable illnesses like diabetes and infectious diseases like HIV and create personalized treatment plans that consider these complications. This can lead to better patient outcomes and a more holistic approach to

healthcare in LMICs. The potential for better patient treatment and outcomes in LMICs will only increase as AI is constantly evolving and is more widely integrated into global healthcare.

3 Successful Implementations of Ubiquitous AI in LMICs Healthcare

Besides the potential that can be brought, the benefits of AI tools in LMICs are becoming increasingly evident, with some countries already experiencing successful implementations. One such example is *Rwanda*, where the government is utilizing *AI-powered drones* to deliver medical supplies, including blood units, to remote areas of the country. Advanced sensors on the drones are capable of detecting fluctuations in temperature and humidity, precisely monitoring vaccine and medical supply transportation, to ensure that supplies are kept at the appropriate temperature throughout the delivery process. With 14 drones currently serving 21 hospitals, the program has already delivered over 20,000 blood units, helping to save countless lives (The Guardian 2022). This cutting-edge application of AI in healthcare demonstrates how technology has the power to close gaps in healthcare delivery and allocate resources where needed the most.

Another successful application of AI tools is the use of *telemedicine.* The use of modern communication technologies, such as video consultations and conferencing, to discuss complex patient cases with external experts is referred to as telemedicine. One example of successful telemedicine implementation is in the Pediatric Cancer and Blood Disorders Center of *Armenia*, which established four multidisciplinary working groups to discuss all cases of soft tissue and bone tumours during weekly meetings with an expert from the University Hospital of Münster (UKM) in Germany using VITU (Virtuelles Tumorboard) software. This telemedicine platform is an example of ubiquitous technological application in LMICs, as it provides a unique opportunity for specialists from developing countries to establish effective communication with international experts, increasing educational, practical, and scientific opportunities for local healthcare providers, and improving outcomes of pediatric cancer care (Hovhannisyan et al. 2020).

AI-powered *chatbots* are among the most popular forms of ubiquitous AI. One such chatbot is "Sehat Kahani," which operates in *Pakistan* and aims to help connect patients in remote areas with healthcare providers (Khan 2023). Using natural language processing (NLP), the chatbot understands the patients' symptoms and provides medical advice and referrals to healthcare facilities. Other examples of ubiquitous AI chatbots in healthcare for LMICs include mDiabetes in *India*, which aims to help people with diabetes manage their condition using SMS messaging, Ada in *Ethiopia*, which uses AI to diagnose and treat common illnesses; and SARA in *South Africa*, which helps HIV-positive patients manage their condition by providing personalized information and reminders.

Despite the various areas in which AI tools are implemented, diagnostics remains one of the most prominent. For example, in *India***,** as well as in *Nigeria*, *Ghana* and *South Africa*, researchers are using AI to screen for TB. By analyzing chest X-rays, the AI tool can detect signs of TB and enable healthcare workers to intervene earlier, improving patient outcomes (Khan et al. 2020).

These are just a few examples of successful AI tool implementations in LMICs demonstrating how innovative technologies are revolutionizing healthcare by improving outcomes and delivering healthcare resources to remote areas. With continued advancements in AI, we can expect to see even more exciting innovations in healthcare be approved worldwide.

4 Diabetic Retinopathy Screening in India: A Case Study

India's population of over 1.3 billion people presents a unique challenge for healthcare, with a shortage of doctors being one of the most pressing issues. However, the Indian government has taken steps to integrate AI into the healthcare

system, investing in several initiatives such as the National Institution for Transforming India (NITI) Aayog national program on AI, National Health Stack, and collaborations with companies like IBM Watson Health, Microsoft Healthcare, and GE Healthcare (NITI Aayog 2018). A prime example of successful implementation is the use of AI for diabetic retinopathy (DR) screening (Ting et al. 2016). DR is a complication affecting one in three people with diabetes and can cause blindness if left untreated. India has more than 72 million people with diabetes, and DR prevalence is estimated at around 18% (Brar et al. 2022).

AI has been used to diagnose DR accurately, efficiently, and cost-effectively by analyzing fundus images and extracting clinically relevant information from medical data. AI systems have been implemented by organizations like Aravind Eye Care System (AECS), the Indian Institute of Technology (IIT) Madras, and Sankara Nethralaya (Raman et al. 2019). These systems have achieved accuracy rates of over 85–95% in detecting DR, reducing the workload of ophthalmologists, and making DR screening more accessible and affordable.

The implementation of AI in DR screening has had a significant impact on the Indian healthcare system. Increased accessibility, affordability, and efficiency have led to earlier detection and treatment of DR. Reduced workload for ophthalmologists allows them to focus on more complex cases, and the overall reduction in screening costs makes DR screening more affordable for low-income individuals. However, addressing the ethical, social, economic, and legal consequences of AI applications in DR screening remains an important consideration (Rajalakshmi 2019; Rajalakshmi et al. 2018).

5 Challenges and Opportunities for AI in LMIC Healthcare

Despite potential benefits that could be anticipated, there are a few significant limitations to the implementation of ubiquitous AI in healthcare in LMIC that need to be addressed.

5.1 Challenge 1: Price

One of the biggest challenges is the limited funding available for the procurement and maintenance of AI technology in healthcare facilities. The high cost of purchasing and maintaining AI systems can be prohibitively expensive, limiting its wide adoption. For example, while conventional MRI machine can cost around $500,000 and $1m USD, an MRI with AI-power can be between $1.5m and $3m USD, with additional expenses for installation, maintenance, and staff training. Other AI-enabled healthcare systems, like software for predictive analytics and electronic health data, can also be quite expensive hindering their adoption (Strubell et al. 2019).

These high costs can be especially prohibitive for healthcare facilities in LMIC, where budgets for healthcare are already limited. In comparison to high-income countries, where healthcare budgets can be in the billions of dollars. This means that healthcare facilities in LMIC may have to make difficult choices about where to allocate their limited resources, purchasing an AI-enabled MRI machine or investing in other critical healthcare infrastructure, such as hiring additional healthcare professionals or building new medical facilities (Wilson and Khansa 2018).

In contrast, high-income countries make huge investments, for instance, the government of the United States has allotted billions of dollars in financing for the creation and application of AI technology in healthcare through programs like the Precision Medicine Initiative and the All of Us Research Program of the National Institutes of Health (Sankar and Parker 2017). The financial means to engage in AI technology are also available to private healthcare organizations, some of which have even established their own AI research laboratories to create and test novel AI-enabled healthcare systems.

5.2 Ways to Overcome Challenge 1: Price

To address the issue of limited funding for AI technology in healthcare in LMICs, there have been efforts to develop more affordable and

accessible AI systems. For example, some companies have developed cloud-based AI systems that can be accessed remotely by healthcare facilities, reducing the need for expensive hardware and infrastructure (Mollura et al. 2020). Additionally, there have been calls for increased international funding and collaboration to support the development and implementation of AI technology in healthcare in LMICs.Another solution to overcome the high cost of AI technology in healthcare is through public-private partnerships. In some cases, private companies may be willing to invest in the implementation of AI technology in healthcare facilities in LMICs, for example in exchange for access to medical data. This can provide a mutually beneficial partnership that enables healthcare facilities to adopt AI technology at a lower cost, while also providing private companies with valuable data for research and development. Seeking external funding from international organizations, philanthropic organizations, and other sources could help overcome this challenge. External funding could help ensure that LMICs have access to the necessary resources required to implement and maintain AI systems in the healthcare sector.

Through the use of open-source software, AI technology costs can also be decreased. Open-source software can be accessed and modified by anyone, which can make it a more affordable option for healthcare facilities in LMICs. Together, healthcare workers and software developers can enhance the functionality and usability of AI systems, which can also foster cooperation and invention.

5.3 Challenge 2: Shortage of Professionals

The shortage of trained professionals capable of operating AI models is a challenge that is not unique to LMICs but is a global issue. Healthcare providers need specialized training to understand how to interpret and use the insights generated by AI systems effectively. The healthcare sector has a considerable need for skilled professionals who can effectively collaborate with AI, yet there is a scarcity of such qualified individuals at present (Hee Lee and Yoon 2021; Topol 2019).

There is also a dearth of experts with the skills required to run and manage AI models in healthcare in higher-income nations like the United States. According to a report by Burning Glass Technologies, there were over 7000 job postings for healthcare AI positions in 2019 in the United States alone (Burning Glass Technologies 2019). However, with growing demand, there is relatively limited number of available educational programs for training specialists in healthcare AI.

In LMICs, the shortage of trained professionals is even more pronounced. It may be challenging for healthcare workers in these environments to acquire the specialized skills required to run AI systems because they frequently have restricted access to educational tools and training opportunities. In addition, it is frequently difficult to find tools for ongoing professional growth and training, which can make it challenging to keep up with AI technology advancements. For example, in some LMICs, there may be only a few professionals trained in AI in healthcare in the entire country. This shortage of skilled professionals can limit the widespread adoption of AI technology in healthcare, even in facilities with the financial resources to acquire them.

5.4 Ways to Overcome Challenge 2: Shortage of Professionals

A potential approach to overcoming this challenge involves investing in training programs that help healthcare professionals in LMICs develop their proficiency in AI technology. This could be done in partnership with universities or research institutions that have expertise in AI and healthcare (Bajwa et al. 2021). These programs could include courses on data analytics, machine learning, and AI applications in healthcare.

An alternative solution involves adopting AI models that are easy to use and demand little training for operation. As an illustration, some businesses have created AI-powered software with a user-friendly interface that enables healthcare workers to use the tool with little to no train-

ing (Jacobs et al. 2021). These systems may be particularly beneficial in LMICs, where there is a shortage of skilled personnel to operate more complex AI models.

Furthermore, some initiatives are focused on developing AI tools that are specifically designed for low-resource settings, such as remote and rural healthcare facilities. The purpose of developing these tools is to provide medical professionals with decision support systems, empowering them to diagnose and treat patients effectively even in regions where medical resources are scarce or inadequate. These initiatives aim to make AI more accessible and user-friendly for healthcare professionals in LMICs.

Finally, international collaborations between LMICs and high-income countries can also be valuable for addressing the shortage of trained professionals in LMICs. Such collaborations could involve the exchange of knowledge and expertise, with high-income countries sharing their knowledge of AI and healthcare systems with LMIC. Such collaborations might also encompass partnerships among universities, research institutions, and hospitals from both high-income and LMICs to facilitate training and capacity-building efforts.

In conclusion, tackling the lack of skilled professionals who can operate AI models presents a crucial obstacle to implementing AI in healthcare within LMICs. This could pose a significant challenge for healthcare providers looking to fully utilize the benefits of AI technology.

5.5 Challenge 3: Infrastructure

To develop accurate and reliable AI models for healthcare, a large amount of medical data is required. This is because AI systems use statistical models to recognize patterns in the data they are trained on, and the larger the dataset, the more accurate the model can be. Wu et al. proposed an artificial intelligence (AI) system based on deep convolutional neural networks (DCNN) to classify breast cancer screening exams using mammography. The system was trained and evaluated on over 200,000 exams, which incorporated over 1,000,000 images. This demonstrates an example of AI requiring big data since the large dataset was necessary to train and test the system's accuracy in classifying breast cancer exams accurately. The performance of their network achieved an AUC of 0.895 in predicting whether there is a cancer in the breast, when tested on the screening population and the result was compared to 14 radiologists reading results. The study found that the hybrid model, averaging the probability of malignancy predicted by a radiologist with a prediction of their neural network, is more accurate than either of the two separately. For $\lambda = 0.510$, hybrids between each reader and the model achieved an average AUC of 0.891 (Wu et al. 2020).

The quality of the data, in addition to its amount, is the other key factor of enhancing accuracy of AI algorithms. Incomplete or biased data can lead to inaccurate or misleading results. To gather, store, and handle high-quality medical data for AI applications, it is crucial to have a solid data infrastructure in place. When it comes to obtaining and storing medical data, LMICs may not have enough resources to meet the demand for significant quantities of high-quality data. For instance, it may be challenging to obtain and analyze the data in some areas because usually medical records are on paper. Additionally, there may be cultural or privacy concerns that limit the sharing of medical data, further limiting the amount of data available for AI applications (Bak et al. 2022).

However, there can be issues with data access and accuracy even in high-income nations with well-established healthcare systems. Medical data, for instance, may be kept in various forms by various healthcare systems, making it challenging to aggregate and evaluate. Furthermore, there might be issues with data security and patient privacy that restrict the exchange of medical information between various organizations. Efforts to improve data infrastructure and promote the responsible sharing of medical data will be essential aspects to unlocking the full potential of AI in healthcare.

5.6 Ways to Overcome Challenge 3: Infrastructure

Strengthening infrastructure remains a crucial step towards addressing challenges related to data availability and quality in healthcare AI (Obermeyer and Emanuel 2016). A dependable and well-structured system for collecting, storing, and transmitting medical data is vital to guarantee that substantial volumes of high-quality data are accessible for training AI models (Murdoch and Detsky 2013).

One strategy for achieving this is through the creation of cloud-based systems accessible to healthcare providers from various locations. This approach permits medical data to be securely stored and accessed from a centralized location, simplifying aggregation and analysis. Furthermore, cloud-based systems offer scalability, accommodating increasing amounts of medical data over time (Chassagnon et al. 2020).

High-speed internet connectivity represents another essential aspect of infrastructure investment, enabling the real-time transmission of medical data (Schwamm et al. 2020). This allows healthcare providers to rapidly and effortlessly view and exchange medical data online, regardless of their location. In remote or underdeveloped regions, where medical resources might be limited (Wosik et al. 2020). By enhancing data infrastructure, we can ensure the availability of high-quality medical data for AI applications, resulting in more precise and trustworthy AI models.

5.7 Challenge 4: Ethical Concerns

The deployment of AI in healthcare, particularly in LMICs, presents numerous ethical concerns that require attention. One of the primary issues is privacy, as sensitive patient information needs protection from unauthorized access and usage. Patient data is generally considered confidential, and its disclosure or misuse can result in serious repercussions for individuals, such as discrimination, stigma, and even health risks. In high-income countries, strict regulations like HIPAA in the United States and GDPR in Europe safeguard patient privacy. However, in LMICs, there may be insufficient regulatory frameworks to protect patient data, posing a significant risk to patient privacy (Price and Cohen 2019).

Another ethical concern is bias, as AI models may learn from biased data, leading to discriminatory results. This problem is especially relevant in LMICs, where diverse data for training AI models may be scarce. In high-income countries, efforts to reduce bias in AI models include using diverse data and testing for biases during model development. However, in LMICs, addressing this issue effectively may be hindered by limited resources and expertise (Rajkomar et al. 2018). Accountability is another ethical consideration when employing AI in healthcare. If AI models make incorrect decisions, mechanisms should be in place to hold responsible parties accountable. This is particularly pertinent in LMICs, where AI usage in healthcare may be relatively new, and regulatory frameworks for accountability may be lacking.

Developing ethical guidelines and regulatory frameworks for AI in healthcare is especially crucial in LMICs, where resources for addressing these issues might be limited. In high-income countries, efforts to establish ethical guidelines and regulatory frameworks for AI in healthcare are already underway (Fiske et al. 2019). For example, the European Union's General Data Protection Regulation (GDPR) includes rules for the security of personal data, encompassing medical data. In the United States, regulatory organizations like the Food and Drug Administration (FDA) oversee the use of AI in healthcare.

While effectively addressing these issues in LMICs may be challenging due to limited regulatory frameworks and resources, establishing robust regulatory frameworks and ethical guidelines can help ensure that AI is employed ethically and responsibly to benefit patients and healthcare systems. Careful planning and development of suitable frameworks are vital for responsible and effective AI utilization in healthcare.

5.8 Challenge 5: Accountability and Shifts in Responsibility

The increasing role of AI systems in healthcare raises concerns about how the shift in responsibility affects various stakeholders, including medical professionals, AI developers, and patients. The growing reliance on AI could lead to clinicians becoming overly dependent on these systems, potentially causing a decline in their own skills or personal connections with patients (Shortliffe and Sepúlveda 2018). This shift might also create new obligations for AI developers, who could gain significant influence on healthcare and should be responsible for creating safe, useful AI systems while responsibly shaping public views on health (Price and Cohen 2019).

Moreover, the expansion of AI in healthcare raises concerns about accountability, as it is currently unclear who should be held responsible if a thoroughly clinically validated model makes mistakes (Vayena et al. 2018). Traditionally, doctors are held liable when they deviate from the standard of care, and patient injury occurs. However, as the standard of care evolves to incorporate AI tools, there will be a strong medicolegal incentive for doctors to follow AI recommendations, which can create a dilemma when AI recommendations conflict with standard practice.

5.9 Ways to Overcome Challenge 5: Accountability and Shifts in Responsibility

To overcome this challenge, a human-centered approach is essential. One way to address this issue is to offer patients the option to choose between an AI-based tool or a human practitioner. This allows patients to have a say in their own healthcare while promoting transparency and accountability in the use of AI. By respecting patients' preferences and values, healthcare providers can build trust and improve patient outcomes (Gerke et al. 2020).

Lastly, as people's beliefs may still pose obstacles in trusting AI, it is essential to approach the use of AI systems in healthcare as a continuous learning process. As new challenges and ethical concerns arise, remaining open to feedback and collaboration is crucial to finding effective solutions (Tachkov et al. 2022). By fostering a culture of collaboration and continuous education, healthcare providers, AI developers, and patients can work together to optimize the use of AI systems in healthcare and ensure that accountability and responsibility are shared among all stakeholders.

5.10 Other Challenges and Ways to Overcome These Barriers

Addressing the challenges posed by AI in healthcare for LMICs is vital, as the potential benefits of AI are immense. One of the primary obstacles is the language barrier, which can limit the effectiveness of AI algorithms due to a lack of local language data for training purposes. Cultural beliefs and traditions can also affect patients' willingness to use AI tools. In rural areas, patients may be hesitant to utilize AI tools due to unfamiliarity with technology and a preference for face-to-face interactions with healthcare providers. Overcoming this reluctance is essential to fully realize the benefits of AI in healthcare. To address these issues, it is crucial to create culturally and linguistically relevant AI technologies that cater to the specific needs of LMICs (Meskó et al. 2017). Collaborating with local communities, healthcare providers, and research institutions can aid in developing AI tools that align with cultural beliefs and values. Additionally, establishing large open-source databases in local languages for training AI algorithms can improve the accuracy and applicability of AI models in these regions (Liu et al. 2019). Healthcare providers and institutions can contribute data, while technology companies can provide the necessary expertise and tools to build and maintain these databases. Developing multilingual AI models or models that can adapt to new languages with minimal training data can help ensure that AI models are effective in diverse linguistic contexts (Yang et al. 2022).

The successful implementation of AI in LMICs requires a multi-stakeholder approach that emphasizes collaboration, innovation, and equity. By working together, we can harness the power of AI in healthcare and improve health outcomes for all.

6 Mitigating Risks and Addressing Ethical Concerns in AI-Driven Healthcare

As the future of all-encompassing AI in healthcare offers tremendous potential, we must exercise caution and vigilance to ensure the responsible and ethical harnessing of this transformative capability. As we strive for this promising future, there are several critical considerations to bear in mind to mitigate potential hazards and prevent unintended consequences.

First, the privacy and security of patient data must be a primary concern as we incorporate AI into healthcare systems. Since AI algorithms depend on extensive data, we must establish strong data protection measures to prevent unauthorized access, misuse, or breaches of confidential patient information. This will call for ongoing vigilance and the creation of advanced cybersecurity protocols, particularly in LMICs where existing data infrastructure might be less secure.

Second, we must address the potential for bias in AI algorithms, as they are only as impartial as the data on which they are trained. Ensuring that AI models are trained on diverse and representative datasets is crucial to prevent discriminatory outcomes and the perpetuation of health disparities. This will require continuous monitoring and evaluation of AI-driven healthcare solutions to identify and correct any biases that may emerge.

Furthermore, as AI becomes increasingly integrated into healthcare decision-making, we must not lose sight of the importance of human interaction in medicine. Healthcare professionals must continue to play a central role in patient care, using AI as a tool to augment their expertise rather than supplanting the essential human connection that underpins compassionate care.

Lastly, we must foster global collaboration and the equitable distribution of AI-driven healthcare solutions to ensure that the benefits of this technology are available to everyone, regardless of their location or socioeconomic status. This will necessitate a focused effort to invest in capacity-building, infrastructure development, and local expertise in LMICs, creating an inclusive global healthcare community that embraces the transformative power of AI while addressing its inherent challenges.

By remaining aware of these considerations and working together to tackle potential risks, we can responsibly harness the power of all-encompassing AI in healthcare and create a future where the bright possibilities are realized, and the potential pitfalls are expertly navigated.

7 Future Directions for Ubiquitous AI in Healthcare in LMICs

7.1 Expanding AI in Primary Care Settings

The potential for AI in primary care settings in LMICs offers a valuable opportunity to enhance healthcare access and outcomes in remote and underserved regions. Primary care practitioners are vital in preventive care, early diagnosis, and managing chronic conditions, making them ideal candidates for AI integration.

AI-driven diagnostic tools empower primary care practitioners to deliver accurate and efficient diagnoses, even in regions where healthcare professionals are scarce. For instance, AI-powered mobile apps that use machine learning algorithms to analyze images or symptoms could help diagnose conditions like diabetic retinopathy or skin cancer.

Telemedicine integration can enable primary care practitioners to provide remote consultations and follow-up care to patients living far from healthcare facilities. This technology also allows for collaboration with specialists and other healthcare professionals, improving patient care quality.

Electronic health records (EHRs) play an essential role in AI integration. EHRs store patient data and facilitate AI-powered algorithms to create personalized treatment plans, improving treatment outcomes, reducing adverse event risks, and allowing for more efficient healthcare resource utilization.

7.2 Enhancing Public Health Surveillance and Response

Enhancing public health surveillance and response is another promising future direction for AI in healthcare in LMICs. AI-powered tools can be used to monitor disease patterns, forecast outbreaks, and optimize resource allocation, enabling a more efficient and targeted response to public health emergencies.

For example, during the COVID-19 pandemic, AI algorithms have been used to forecast the spread of the virus, enabling public health officials to allocate resources and plan interventions accordingly. AI-powered surveillance systems can also monitor social media and other online platforms to detect outbreaks in real-time, enabling a more rapid response to public health emergencies.

In addition, AI can be used to develop disease surveillance systems that enable early detection and response to disease outbreaks. AI-powered tools can be used to analyze large amounts of data from various sources, including EHRs, disease registries, and public health databases, to identify patterns and predict the likelihood of outbreaks.

Furthermore, AI can be used to optimize resource allocation during public health emergencies. For example, AI-powered algorithms can be used to predict which healthcare facilities are likely to experience a surge in demand, enabling public health officials to allocate resources more efficiently.

Envisioning the integration of AI-powered public health surveillance and response tools in the future of healthcare in LMICs presents an opportunity to improve the outcomes.

7.3 Strengthening Healthcare Workforce Capacity

AI-driven solutions can enhance healthcare professionals' skills, minimize knowledge disparities, boost diagnostic precision, and ultimately lead to better patient outcomes. AI-facilitated training platforms offer healthcare professionals access to immersive virtual training environments, allowing them to acquire hands-on experience without costly, time-consuming in-person training. AI can further contribute to the development of decision support systems that guide healthcare professionals in making precise diagnoses and treatment choices, thus decreasing error risks, and enhancing patient outcomes (Spatharou et al. 2020).

Furthermore, AI-driven tools can supply healthcare professionals with the latest medical information, ensuring they remain informed about recent medical research and best practices (Davenport and Kalakota 2019). AI solutions can also automate administrative tasks, freeing up healthcare professionals to focus on patient care rather than paperwork.

7.4 Collaborative Research and Development

Collaborative research and development play a crucial role in the future of AI in healthcare for LMICs. Considering the unique challenges and contexts of LMICs, fostering international collaboration among governments, academic institutions, and industry partners is essential for creating AI-based healthcare solutions tailored to LMICs' specific needs.

By joining forces in research and development, stakeholders can capitalize on each other's strengths to create more effective and efficient AI healthcare solutions. Governments can offer funding and establish regulatory frameworks to back AI research and development, while academic institutions can contribute their expertise in AI algorithms and data analysis. Meanwhile, industry partners can supply resources and

know-how in developing and commercializing AI-driven healthcare solutions.

Additionally, international collaborations can address LMICs' challenges related to data availability and quality. Cross-border data sharing enables more comprehensive and accurate health trend analyses, which, in turn, facilitates the development of more efficient AI-driven healthcare solutions (Wirtz et al. 2017; Vayena et al. 2018).

7.5 Long-Term Sustainability and Scalability

Although AI has the potential to revolutionize healthcare in LMICs, a comprehensive approach addressing these settings' unique challenges and opportunities is necessary to ensure long-lasting success.

Sustainable funding remains a key consideration. AI-based healthcare solutions demand significant investments in research, development, maintenance, and support. It is vital to establish funding models that prioritize LMICs' needs, providing continuous, long-term backing for AI-driven healthcare initiatives. Infrastructure development is another crucial factor. To enable widespread AI adoption in LMICs' healthcare systems, investments in infrastructure, such as internet connectivity, computing resources, and data storage, are necessary. Additionally, creating user-friendly interfaces and mobile applications that are easily accessible by healthcare professionals in remote or underserved areas is essential.

Furthermore, continuous education and training play a critical role in the long-term success and scalability of AI-driven healthcare solutions in LMICs. Healthcare professionals require ongoing training and education to effectively incorporate AI technologies into their workflows and fully utilize these solutions' potential. Also, addressing language and cultural barriers through continuous education and training ensures that AI-driven healthcare solutions remain accessible and effective across diverse settings (Topol 2019; Carvalho et al. 2022).

8 Embracing the Future: A Vision of Ubiquitous AI for Universal Healthcare

As we gaze into the future, we imagine a world where AI becomes an integral part of healthcare delivery, transcending geographical boundaries and socioeconomic barriers to create a reality where healthcare is genuinely universal. In this envisioned future, AI-driven innovations will narrow the gap between LMICs and high-income countries, empowering LMICs to overcome traditional developmental challenges and achieve equal access to quality healthcare for everyone.

In this inspiring future, AI will act as a catalyst for proactive, preventive healthcare, benefiting individuals in both LMICs and high-income countries through real-time health monitoring, personalized lifestyle advice, and early interventions. This fundamental change will enable healthcare systems to shift from reactive care to predictive and preventive care, ultimately reducing the burden of disease and enhancing overall well-being.

We imagine healthcare providers worldwide connected via AI-powered telemedicine platforms, working together to deliver expert care and share knowledge across borders. This interconnected healthcare ecosystem will encourage innovation, fuel medical breakthroughs, and enable the rapid spread of best practices, ensuring that state-of-the-art medical advances are accessible to everyone, regardless of their location. In this future, AI will be an indispensable tool in addressing worldwide health crises, such as pandemics and emerging infectious diseases. AI-driven early warning systems will enable prompt identification of disease outbreaks, while AI-powered epidemiological models will guide evidence-based interventions, optimizing resource allocation and enabling a coordinated global response.

Moreover, AI will become a driving force for social change, dismantling barriers to healthcare access and diminishing health disparities in LMICs. AI-driven healthcare solutions will be culturally and linguistically inclusive, respecting local customs and beliefs while adapting to

unique contexts to ensure fair and effective care for diverse populations. This future is not merely aspirational but achievable. By harnessing the power of AI, fostering international collaboration, and investing in the development of human-centered, ethical AI solutions, we can create a world where healthcare is no longer a privilege but a fundamental right for all. Embracing pervasive AI in healthcare will lay the groundwork for a brighter, healthier future, where no one is left behind in the pursuit of well-being and an improved quality of life.

9 Conclusion: Harnessing the Potential of Ubiquitous AI to Transform LMIC Healthcare

In conclusion, this analysis has highlighted the considerable potential of ubiquitous AI in revolutionizing healthcare for LMICs. We have explored how AI integration can dramatically enhance disease diagnosis, personalized treatment, drug development, and overall healthcare delivery, even in resource-limited settings. We have also showcased the transformative impact of AI-driven precision medicine, wearable devices, electronic health records, and imaging techniques that can bring meaningful benefits to LMICs. Success stories from Rwanda, Armenia, Pakistan, and India serve as inspiring examples for other LMICs to follow.

Despite these promising prospects, we have acknowledged the challenges and constraints of implementing AI in healthcare within LMICs, including cost barriers, the scarcity of skilled professionals, and data quality and accessibility issues. To overcome these hurdles, we have proposed solutions such as public-private partnerships, external funding, open-source software, international collaborations, and investments in infrastructure and training.

As we look to the future, we encourage researchers and practitioners to pursue AI applications in primary care, diagnostics, telemedicine, and public health surveillance. These innovative technologies have the potential to extend healthcare access and improve outcomes in remote and underserved areas, optimize resource distribution during public health emergencies, and facilitate more efficient and targeted responses to disease outbreaks.

In conclusion, it is crucial for all stakeholders—governments, academic institutions, and industry partners—to collaborate and invest in the creation and implementation of AI-driven healthcare solutions tailored to the unique needs of LMICs. By focusing on sustainable funding models, infrastructure development, user-friendly interfaces, and continuous education and training, we can unlock the full potential of AI in healthcare.

Together, we can pave the way for a brighter future where the power of AI transforms the lives of millions of individuals in low- and middle-income countries, fostering hope, health, and prosperity for generations to come.

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Non-digital Health Trends in Low- and Middle-Income Countries

Karine Sargsyan

Abstract

Digitization of healthcare has attracted considerable attention globally and has transformed healthcare systems. However, it is essential to recognize that not all low- and middle-income countries (LMICs) have the necessary resources or infrastructure to fully embrace digital technologies. This chapter provides an overview of the non-digital trends that continue to influence healthcare in LMICs, and by extension the implementation of digitisation efforts. These trends span many dimensions, including health policy, workforce development, community engagement, and infrastructure improvements. Understanding these non-digital trends is vital for the successful integration of digital solutions into health systems in LMICs. Thus, highlighting the challenges and opportunities for digitizing medicine in LMICs is essential, to understand the needs of medical support tools in LMICs now and in the future.

Keywords

Low- and middle-income countries (LMICs) · Digitisation · Healthcare · Non-technology trends · Health policy · Capacity building

1 Introduction

While digitization has attracted considerable attention and transformed healthcare systems worldwide, it is essential to recognize that not all low- and middle-income countries (LMICs) have the necessary resources or infrastructure to fully embrace digital technologies. This chapter explores the non-digital trends that continue to shape healthcare in LMICs. These trends span many dimensions, including health policy, workforce development, community engagement, and infrastructure improvements. Understanding these non-digital trends is vital to integrate digital solutions into health systems in LMICs effectively. A broad overview of the current situation and highlighting the challenges and opportunities for digitizing medicine in LMICs is essential, to understand the needs of medical support tools in LMICs.

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2 Health Policy and Regulations

In LMICs, health policies and regulations play an important role in shaping health status. While digitization offers potential benefits, policy frameworks need to be in place to ensure equal access, patient privacy, data security, and interoperability of digital systems. For example, Ghana's National eHealth Policy (2015) emphasizes integrating digital technologies into the healthcare delivery system to increase efficiency and improve patient outcomes (Ministry of Health of Ghana 2015). Similar initiatives have been seen in other countries, such as Rwanda's National eHealth Policy (2018), to use digital technologies to strengthen health systems (Ministry of Health Rwanda 2018). These policies lay the foundation for future digitization efforts while addressing existing challenges and constraints.

3 Workforce Development and Capacity Building

A healthy healthcare workforce is vital to the successful adoption and adoption of digital solutions. LMICs often face a shortage of skilled health workers, exacerbating digitization challenges. Therefore, investment in workforce development and capacity building becomes vital. Educational programs and initiatives focused on digital health literacy, data management, and telemedicine enable healthcare professionals to use digital tools and technologies effectively. For example, Uganda's African Health Innovation Exchange (AHIX) project trained healthcare professionals in digital health solutions, increasing their skills and confidence in using technology for patient care (Mamuye et al. 2022). By strengthening the workforce, LMICs can optimize the benefits of digitalization in healthcare.

4 Community Involvement and Empowerment

In LMICs, community participation and empowerment are critical to successful health interventions. While digital technologies open up new patient engagement and education opportunities, they must be accessible and inclusive. Many LMICs have limited internet connectivity and low levels of digital literacy, especially in rural areas. Thus, non-digital approaches such as community health workers (CHWs) remain essential in health service delivery. CHWs act as trusted intermediaries, providing education, preventive care, and primary treatment to low-income communities (Perry et al. 2014). Integrating digital tools into existing CHW programs can increase their effectiveness and improve data collection for decision-making.

5 Infrastructure Improvement

One of the main problems in LMICs is the inadequacy of the health infrastructure. Limited access to electricity, internet connectivity, and medical equipment hinders the adoption of digital technologies. Improving infrastructure is a prerequisite for successful digitalization. Initiatives such as the Global Digital Health Index (GDHI) assess the readiness of countries' digital health infrastructure and provide insight into areas that need improvement (Global Digital Health Index). In addition, partnerships with international organizations, governments, and the private sector can help fill infrastructure gaps through funding, resource allocation, and technical assistance.

6 Privacy and Security Issues

Digitization in medicine requires strong privacy and security measures to protect sensitive patient data and build trust in the healthcare system. In LMICs, where legal frameworks and data protection infrastructure may be less developed, addressing privacy and security issues becomes even more critical. This subsection discusses vital privacy and security considerations in the context of the digitization of medicine in LMICs.

Protecting patient privacy and providing informed consent are fundamental ethical principles in healthcare. In LMICs it is crucial to establish clear guidelines and rules on data privacy and

agreements to protect the rights of individuals and build trust in digital health systems. Developing comprehensive data protection laws and policies is critical to protecting personal health information. For example, in Malaysia, the Personal Data Protection Act governs personal data collection, storage, and use, including health information (Malaysia Privacy Commission). Similar legislative efforts are needed in other LMICs to ensure the privacy rights are respected in the digitization of healthcare.

7 Data Security and Encryption

Protecting medical data from unauthorized access, hacks, and cyber threats is of paramount importance. LMICs should prioritize investment in robust data security measures, including encryption, firewalls, and secure storage systems. Implementing internationally recognized security standards such as ISO/IEC 27001 can be the basis for building and maintaining secure digital healthcare infrastructures. In addition, establishing incident response mechanisms and regular security reviews can help identify vulnerabilities and effectively mitigate risks.

8 Compatibility and Communication

Interoperability is vital for seamlessly exchanging and integrating medical data across different digital systems. LMICs should strive to develop interoperable standards that enable secure and standardized data exchange between healthcare providers, systems, and organizations. The introduction of technologies such as Health Information Exchange (HIE) can facilitate the secure exchange of patient information while maintaining confidentiality and security standards. Countries such as India have made progress in this area through initiatives like the National Digital Health Mission, which aims to establish a federal health information architecture for secure and functional data sharing (National Health Administration 2020).

9 Cyber Security Capacity Building

Strengthening cybersecurity capabilities is critical to protecting against new threats. LMICs should invest in training and capacity-building programs to develop a skilled workforce capable of addressing cybersecurity challenges in healthcare. Collaboration with international organizations and cooperation with more technologically advanced countries can provide valuable support and knowledge sharing. The World Health Organization (WHO) has recognized the immense weight of cybersecurity in healthcare and offers recommendations and capacity-building initiatives to help countries strengthen their cybersecurity defenses (World Health Organization 2020).

10 Public Awareness and Education

Raising awareness and educating the public about the privacy and security risks associated with digitization is essential. LMICs should invest in public campaigns and educational programs to enable people to make informed decisions about their health data. This includes informing patients about their rights, the necessity of strong passwords, and the risks of sharing sensitive information through insecure channels. Joint efforts involving governments, healthcare providers, and civil society organizations can help spread knowledge and promote the responsible use of digital health technologies.

11 Conclusion

Privacy and security considerations are vital to successfully adopting medical digitization in LMICs. Data privacy and consent, data security and encryption, interoperability and data exchange, cybersecurity capacity building, and public awareness are important areas that require attention. By prioritizing privacy and security, LMICs can build trust, protect patient data, and create an enabling environment for the sustain-

able integration of digital technologies into healthcare.

However, digitization has the potential to revolutionize healthcare in LMICs, but it must be done in the context of existing non-digital trends. Health policy and regulation, workforce development, community engagement, and infrastructure improvements are critical elements in determining the adoption and success of digital solutions. Understanding and addressing these non-digital trends is critical to developing sustainable and inclusive digital health ecosystems in LMICs. By building on existing strengths and addressing challenges, LMICs can pave the way for a fair and efficient digitization of medicine.

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Recommendations for Digitization of Healthcare in LMICs: A Wider Outlook

Zisis Kozlakidis, Mat Clum, and Karine Sargsyan

Abstract

The last two decades have witnessed an explosion of technological developments, such as cloud computing, imaging, mobile-based consultations and others. These developments in turn have brought forward a series of very promising applications for healthcare, which have enjoyed varying degrees of adoption and diffusion within low-and middle-income countries (LMICs). The major themes that emerged within this book as critical in the success (or not) of digitisation of healthcare in LMICs are the data infrastructure, the regulatory frameworks and the education/digital literacy. Additionally, the way forward regarding digitisation in healthcare is going to follow a distinctly different route to the one experienced in high-income countries, specifically it is anticipated to be: context-driven, information asymmetric, culturally sensitive and locally autonomous.

Keywords

Digital health · Low-and middle-income countries (LMIC) · Data infrastructure · Digital literacy · Information asymmetry · Context-driven implementation · Cultural sensitivity · Cultural inclusion · Locally autonomous

1 Introduction: The Promise and Peril of New Technologies

The last two decades have witnessed an explosion of mobile networks, cloud computing and new technologies introduced within the healthcare field. These technologies result to incomprehensibly large volumes of information generated, ingested and translated- which then have to be applied as part of routine practice, both at the individual level, e.g., at a patient-treating physician level, as well as at the population level, e.g., at a public health/governmental level. Furthermore, the handling of this data (from the generation to the end-use) needs to be governed by well-defined ethical and regulatory

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frameworks, to ensure adherence to national and international requirements.

While the above may be achievable within high-income settings, the same cannot be stated for low-and middle-income countries (LMICs), where there are many competing healthcare needs and the continuum of data generation to end-use may not be fully achievable or not present at all. Thus, while there is a clear promise for digital technologies to positively influence healthcare provision, there is a danger that regarding LMICs, such technologies may be over-promising given the local needs and contexts. Indeed, the COVID-19 pandemic has provided ample evidence within LMICs, for introducing digitalization efforts that have performed very well (as described in Chap. "Ubiquitous and Powerful Artificial Intelligence (AI)" for example for Indonesia), and others that have performed less well (as described in Chap. "Long-Term Digital Storage and Usage of Research Data: Data Pooling" for Latin America). Therefore, digitalization in LMICs, needs to follow a careful balancing act, between the promise and peril of new technologies, akin to similar introductions previously in healthcare, e.g., the introduction of radiology in routine healthcare practice.

Reading the chapters of the current book, it becomes clear that the pathway to digitalization in LMICs is highly dependent on the individual contexts and needs of the country. Chapter "The Emergence and Growth of Digital Health in Saudi Arabia: A Success Story" provides the example of a mature digital healthcare ecosystem from Saudi Arabia, with very high interoperability between different healthcare operating units. Chapters "The Digital Divide Based on Development and Availability: The Polish Perspective", "Potential of Digital Health Solutions in Facing Shifting Disease Burden and Double Burden in Low- and Middle-Income Countries", "Health Inequalities and Availability: Needs and Applications", "Long-Term Digital Storage and Usage of Research Data: Data Pooling", "Digitisation in Genetics and Diagnostics Laboratories in Armenia" and "Ubiquitous and Powerful Artificial Intelligence (AI)", captured the experiences of Poland, Vietnam, Cyprus, Latin American countries, Armenia and Indonesia respectively. Thus, this book has managed to provide a balanced, global view of the different digitalization pathways followed, and a comparative read of those chapters will certainly provide insights into similarities and differences. If we consider the national examples as vertical implementations (i.e., for only one specific location), a number of chapters look into the horizontal implementations (i.e., across a particular field of operations). As such Chaps. "Biobank Digitalization in Low-Middle Income Countries (LMICs): Current and Future Technological Developments" and "Digital Healthcare: Technologies, Technical and Design Challenges" investigated the overarching risks and challenges, and the infrastructure risks, needs and opportunities respectively. Furthermore, particular mention should be made for Chaps. "Digitalization of Physical Health Data in Low- and Middle-Income Countries" and "Universal Internet Access Supporting Healthcare Provision: The Example of Indonesia", highlighting technical and design challenges, and investments and incentives respectively. Therefore, taking together the above contributions, thematic units can be identified, forming the core of any future recommendations for digitalization of healthcare in LMICs. These are described below, though the relative prioritization would be context-dependent.

2 Emerging Common Themes in LMIC Healthcare Digitisation

2.1 Data Infrastructure

The availability of data infrastructure is crucial for the success of any digitalization effort in LMICs. The current chapters describe a highly fragmented picture across regions as well as individual countries. There is a high overall need for further data infrastructure development across LMICs, including the provision of financial incentives and/or direct public health investment for the expansion of existing infrastructures (Al

Knawy et al. 2020; Zhang et al. 2022). However, as with digital health itself, the data infrastructure does not need to copy blindly what was implemented in high-income settings, but develop methodologies and data architectures that are LMIC-friendly and suitably tropicalized in terms of their performance and maintenance needs (Muinga et al. 2020).

2.2 Data Laws and Regulations

In most of the LMICs that have been mentioned in the different chapters of this book, it is evident that there don't exist specific laws and regulations designed and implemented with digitalization of healthcare in mind. This does not mean that legal frameworks do not exist. Though the case differs between different countries, data protection legislation has been extant for clinical trials, teleconsultations, collection of biological samples and associated clinical data for research, etc. (Camacho-Leon et al. 2022; Vodosin et al. 2021; Purtova et al. 2015). It is the case that most of these regulations have expanded their remit and interpretation to include the introduction of digital applications in healthcare. Perhaps this is a sufficient course of action given the relatively restricted digital healthcare applications in LMICs and the many other competing interests. However, if digitalization is to reach its full potential, it would need to have clearly defined laws and regulations on the collection of data, regulation of access, sharing (nationally/internationally) and use, reporting of data analyses, and secondary use of collected data.

2.3 Education, Education, Education

Finally, and almost universally mentioned, the lack of education has been identified as a major barrier for digitalization of healthcare in LMICs. It should be noted though, that the term education is used as a blanket term, addressing a number of different aspects and needs (El Benny et al. 2021). The medical students and young healthcare professionals report higher levels of digital literacy than other sections of healthcare, and as such the education is more likely to be task-specific deepening already existing skills (Kuek and Hakkennes 2020). However, educational needs also address entire populations, especially in the case of COVID-19 pandemic where surveillance systems are thought to have underperformed due to the limited reach of the internet, and reduced digital literacy of the general population (Hennis et al. 2021). It has to be noted, that education is not an instantaneous activity, but would require persistence and structural incorporation of existing activities if it is to be effective in the longer-term. This is particularly true for LMICs, where in many cases the levels of digital literacy still remain at low levels, e.g., beyond 25% of the population.

3 Way Forward Is Context-Driven, Asymmetric, Culturally Sensitive and Locally Autonomous

During the COVID-19 pandemic a number of high-level discussions took place, looking into the post-pandemic landscape, and have been summarized in relevant publications (Kozlakidis et al. 2020; AlKnawy et al. 2023; Jazieh and Kozlakidis 2020). However, a second look is now warranted for these early viewpoints, as the implementation experiences from the field can inform and enrich the 'building back better' propositions (Adisasmito et al. 2023). Given the intense discussions that took place during the creation of this book, the following key factors are emerging as critical:

Context-driven: The digitalization of healthcare in LMICs cannot follow a single common blueprint. Different countries find themselves at different stages of financial and infrastructural development, facing different combinations of healthcare and socioeconomic pressures. Being unaware of the context can potentially create unintended consequences such as biases, discrimination, errors or unexpected results, and an overall lack of transparency with regard to how

outcomes are achieved (Stahl and Coeckelbergh 2016). The consideration of context is not only important within national boundaries, but also at the regional level, and can influence the possibilities and reach of data access and sharing.

Asymmetric: Information asymmetry is one of the key features separating healthcare away from a traditional market economy definition which assumes that all parties have access to perfect information in terms of their decision making and negotiating power (Major 2019). In healthcare, patients typically lack the medical knowledge that healthcare professionals possess, and this causes information asymmetry. Digitalization of healthcare in LMICs has the power to reduce this information asymmetry (e.g., by involving the patient in the information translation and democratizing the decision-making process), or to further increase the existing information asymmetry by enlarging the digital divide and thus, enlarging the information availability only for the one party. In particular for a market that is in its initial growth stages, enlarging information asymmetry can have a detrimental impact on the rate of market growth and quality of services rendered.

Locally autonomous: The many different challenges within LMICs, necessitate that challenges would be most effectively addressed within a local context. This also impacts the digitalization model in LMICs, where applications may be preferably locally customized, and operating autonomously, while bearing the capacity of supporting federated data access, allowing for national and international data analyses (Loftus et al. 2022). As an inherent part of being locally autonomous, digitalization would also need to be dynamic (i.e., capturing temporal changes in physiologic signals and clinical events), precise (using high-resolution, multimodal data, interoperable and complex architecture), and finally in the case of machine learning algorithms able to learn with minimal supervision and execute without human input. Thus, autonomy transcends both the technical and hierarchical aspects of healthcare provision.

Culturally sensitive and inclusive: While digitizing healthcare generates large amounts of data, that data is only valuable when it's accessible. The success of any application will be contingent on delivering data in a form the end-user, whether patient or care-giver, can easily understand and comfortably engage with. This requires focusing data-extraction on information relevant to the end-user local environment. In LMICs where education may be limited and newer technologies unfamiliar, special attention must also be paid to identifying alternate modes of communication that can more effectively reach the end-user. These may need to go beyond language-specific models and appeal to other traditions and modalities, e.g., audio and visual-only applications or culturally-responsive implementations. Combining finely-tuned datasets with local knowledge in readily accessible formats improves uptake and expands the application's scope to reach a wider proportion of the population, including, crucially, marginalized communities.

4 Conclusion

This Chapter serves as the epilogue of a very rewarding process, addressing an existing knowledge gap for LMICs. The digitalization of healthcare in LMICs is a continuing trend that has accelerated by the COVID-19 pandemic. However, as with any new technologies introduced into routine practice, promises and perils entail. The optimal digitalization of healthcare in LMICs would need to address three major challenges: the data infrastructure (including financial support for widening digital access), the creation of relevant legal and regulatory frameworks (including implementation evaluation frameworks), and the education to be made available to multiple audiences. Finally, the way forward for the digitalization of healthcare in LMICs is anticipated to be: context-driven, asymmetric, culturally sensitive, and locally autonomous.

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