Health Informatics

Homero Rivas
Thomas Boillat *Editors*

Digital Health

From Assumptions to Implementations

Second Edition

Springer

Health Informatics

This series is directed to healthcare professionals leading the transformation of healthcare by using information and knowledge. For over 20 years, Health Informatics has offered a broad range of titles: some address specific professions such as nursing, medicine, and health administration; others cover special areas of practice such as trauma and radiology; still other books in the series focus on interdisciplinary issues, such as the computer based patient record, electronic health records, and networked healthcare systems. Editors and authors, eminent experts in their fields, offer their accounts of innovations in health informatics. Increasingly, these accounts go beyond hardware and software to address the role of information in influencing the transformation of healthcare delivery systems around the world. The series also increasingly focuses on the users of the information and systems: the organizational, behavioral, and societal changes that accompany the diffusion of information technology in health services environments.

Developments in healthcare delivery are constant; in recent years, bioinformatics has emerged as a new field in health informatics to support emerging and ongoing developments in molecular biology. At the same time, further evolution of the field of health informatics is reflected in the introduction of concepts at the macro or health systems delivery level with major national initiatives related to electronic health records (EHR), data standards, and public health informatics.

These changes will continue to shape health services in the twenty-first century. By making full and creative use of the technology to tame data and to transform information, Health Informatics will foster the development and use of new knowledge in healthcare.

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Homero Rivas
Mohammed Bin Rashid University of Medicine and Health Sciences, Design Lab
Dubai, United Arab Emirates

Thomas Boillat
Mohammed Bin Rashid University of Medicine and Health Sciences, Design Lab
Dubai, United Arab Emirates

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Chapter 1
An Introduction to Digital Health: Current and Future Trends

Homero Rivas and Thomas Boillat

Abstract Over the last 25 years, life as we know it has changed considerably. Starting from generation Z (born after 1996), the young generations are true citizens of a digital world. Ever since their birth, information and communication technologies (ICTs) have been very pervasive in all aspects of their lives. On the other hand, older generations, including all adults, represent a group of digital immigrants that grew up without such technology. Only a few years ago, digital health was not a common term in our lexicon much less something well understood by patients and most care providers. Since the beginning of the COVID-19 pandemic, circumstances have changed globally and the ecosystem has become fertile for the rapid expansion of digital health. Most if not all large healthcare systems, pharmaceutical companies, medical device companies, etc. have groups dedicated solely to digital health. Visionary medical schools are implementing an increasing number of digital health courses in their curriculums or at least in their informal courses. Entrepreneurs have identified great opportunities to innovate and create ingenious, cost effective, and sustainable value propositions in digital health. Venture Capital (VC) investment has exponentially increased over the last few years on a scale not seen for a very long time, either in healthcare or even in other industries. This chapter highlights this unique growth and transformation being experienced by digital health and healthcare in general.

Keywords Digital Health · Wearables · Telemedicine · Artificial intelligence Virtual reality · Augmented reality · Mobile health

H. Rivas · T. Boillat (✉)
Design Lab, Mohammed Bin Rashid University of Medicine and Health Sciences, Dubai, United Arab Emirates
e-mail: Homero.Rivas@mbru.ac.ae; Thomas.Boillat@mbru.ac.ae

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1.1 Introduction

In our first book, "Digital Health – Scaling Healthcare to the World" (Rivas and Wac 2018), we described the opportunity offered by Digital Health Technologies (DHT) to improve the delivery and quality of care and wellbeing, and to reduce healthcare costs. In this regard, we explained the role of mobile health and wearable technologies in tracking quality of life, the use of augmented and virtual realities to treat mental diseases, the implementation of 3D printing in medical education and clinics, and the use of drones to deliver care to areas that are difficult to access. The book also includes discussions on existing challenges in the healthcare system and initiatives that use DHT to redesign it. When the book was written, the Apple Watch celebrated its first anniversary. To date, more than 100 million units have been sold (Rogerson 2021); moreover, few years back, the smartwatch demonstrated its ability to detect atrial fibrillation in one of the largest clinical trials, involving almost half a million participants (Perez et al. 2019). Similarly, in the U.S. between 2019 and 2020 alone, amid COVID-19, the volume of telehealth delivery increased by 38 times, allowing medical professionals to maintain a relationship with their patients by delivering care remotely (Bestsennyy et al. 2021). When it comes to artificial intelligence, 80% of the algorithms used for health-related applications were approved by the U.S. Food and Drug Administration (FDA) between 2018 and 2021 (The Medical Futurist 2021). The creation of the Digital Health Center of Excellence by the FDA in 2020 also marked the increasing development and role that digital health plays in the healthcare system (Health C for D and R 2021).

Defined by the World Health Organization (WHO) as "the use of information and communications technology in support of health and health-related fields" (WHO 2017), DHT encompass a wide range of technologies from electronic medical records to telehealth, mobile health, wearables, augmented and virtual realities, and also paradigms such as blockchain and artificial intelligence. To understand the adoption and impact of DHT compared to traditional health innovation such as X-ray, Magnetic Resonance Imaging (MRI), or ultrasound, it is important to look at the origins and types of the aforementioned technologies. On one hand, technologies such X-ray, MRI, and ultrasound were designed specifically for healthcare based on thoroughly analyzed needs, and sold and installed by specially trained personnel. On the other hand, DHT such as mobile health, wearables, or virtual reality, were designed for serving multiple industries with unclear needs and expectations. These differences are also highlighted by the way some researchers and practitioners compare the evolution of health technologies with those of the four industrial revolutions (Li and Carayon 2021). In this vision, healthcare 1.0 includes traditional patient encounter, diagnosis, and treatment; healthcare 2.0 relies on medical equipment, such as ultrasound, CT scans, and surgical and life support equipment including ventilators as well as monitoring devices such as continuous EKG

and pulse oximeter among many others. Healthcare 3.0 encompasses the use of electronic medical records, patient portals, telemedicine, and virtual visits. Finally, healthcare 4.0 utilizes the Internet of Things (IoT), wearables, cloud computing. and artificial intelligence to deliver personalized medicine. When comparing healthcare with industrial revolutions, it is clear that from revolutions 3.0 upwards, the technologies used become increasingly less specific to the industry. For companies and hospitals in particular, this means that additional work is required to understand how the identified needs can be addressed by a technology, a task that is not required by specific devices used in revolutions 1.0 and 2.0. In addition, though hospitals and clinics had the pressure from other institutions to acquire medical equipment, with healthcare 4.0 the demand comes from patients and medical professionals. Before healthcare 4.0, hospitals and clinics were the innovation-driven forces, with equipment and know-how to which only a few people had access. To describe changes in industry forces, researchers and practitioners use the term "consumerization" or "bottom-up innovation" whereby customers are pushing industry to adopt a new technology (Moschella et al. 2014). Nowadays, many patients use mobile applications to track their food or wear activity trackers to measure their number of steps or amount of sleep, thereby collecting health-related information that hospitals do not have access to and do not know how to trust or use (Ho et al. 2017).

1.2 Current Trends

DHT are increasingly used in healthcare by different stakeholders from clinicians to administrative staff and patients. To contextualize the impacts DHT have on the health system, in this section we present the latest technologies alongside the "Quadruple Aim" for healthcare optimization. This framework was initially developed for the delivery of high-value care (i.e., Triple Aim) and then revisited as the Quadruple Aim in 2014 (Berwick et al. 2008; Bodenheimer and Sinsky 2014). The Quadruple Aim framework suggests four dimensions for the delivery of high-value care (Bodenheimer and Sinsky 2014): (1) improving the individual experience of care; (2) improving the health of populations; (3) reducing per capital cost of healthcare; and the newly added d) improving the experience of providing care. The latter dimension not only includes work recognition but also dignity and respect with which the medical staff is (should be) treated as well as the requirements addressed in terms of education, training, tools, financial support, and encouragement. The Quadruple Aim framework is often represented as a circle to highlight the continuous required improvement of each dimension and their relationship with one another as shown in Fig. 1.1.

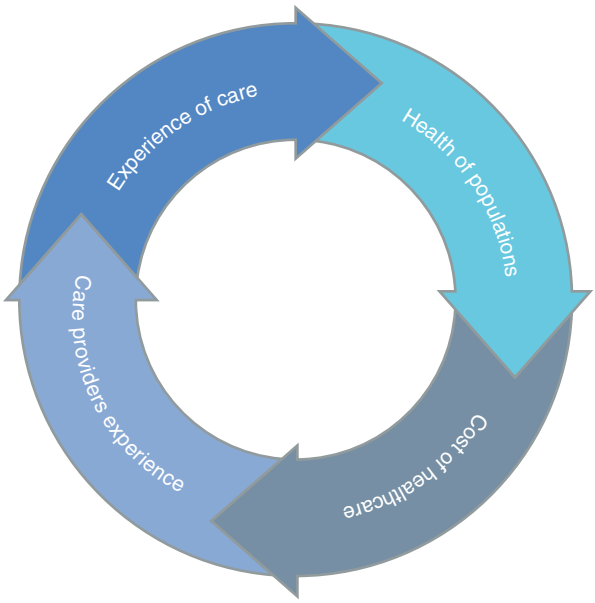

Fig. 1.1 Quadruple Aim framework

1.2.1 Improving the Health of Populations

The first step in improving the health of populations lies with connecting with people. With social media platforms, information has no temporal or geographical barriers unlike traditional media such as radio, newspapers, or TV. Take Mikhail "Mike" Varshavski, a family medicine doctor practicing in New Jersey (USA). Dr. Mike publishes short videos on YouTube and Instagram mostly to demystify medicine and simplify medical concepts. Since 2016, his videos have been viewed more than 1.2 billion times on YouTube (Varshavski 2021) alone. While many find his work controversial and more medical entertainment than true medical education, he has been successful in effectively communicating to the masses through a video digital platform. Not only do social media platforms empower the voice of their content creators, but they also create a communication channel with their viewers by means of comments that viewers can post. During the first months of the COVID-19 pandemic, an important number of physicians relied on social media platforms to fight against misinformation, relying on scientific evidence to provide a neutral analysis of the situation (Topf and Williams 2021). Another technology that has been increasingly leveraged for digital health purposes is the smartphone. Smartphones, also called mobile devices, are used by more than 6 billion people around the world (Statista 2021), offering them opportunities to better understand their behavior and health, or toward changing "bad" habits. Additionally, data collected from mobile device users open new avenues for medical professionals to connect and gain understanding of people's lifestyle, behaviors, and conditions

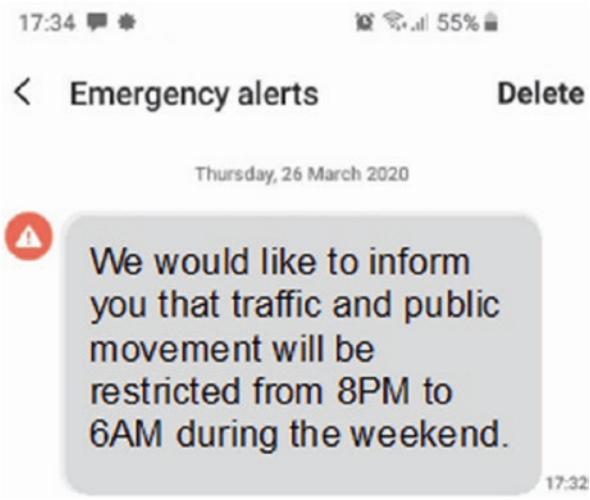

Fig. 1.2 Example of an alert message sent by the police to all citizens' mobile devices during COVID-19

(Bradway et al. 2017). The combination of mobile devices and health is defined as mHealth and described by the World Health Organization as "medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices" (WHO 2011). Definitely, COVID-19 helped people understand the value of mHealth with the use of apps to inform the population of new decisions and restrictions (Fig. 1.2), and to trace people with whom a COVID-positive person was in contact and forecast areas that will be most prevalent to see clusters emerging based on the number of close contacts, people's movement, and density of living (Kamalov et al. 2021).

Looking at the last years, the number of mHealth apps has not increased much, with 318,000 in 2017 (IQVIA 2017) against 350,000 in 2020 (Olsen 2021) in both Android and Apple stores. There are, however, more interesting facts to discuss. In 2019 alone, 100,000 new mHealth apps were published, demonstrating an important turnover and potential market saturation. In addition, the nature of mHealth apps is evolving from apps covering general needs such as tracking exercises, fitness activities, and eating diets to apps that support specific diseases such as mental health, diabetes, hypertension, or women's health (IQVIA 2017). Second, over the last 5–10 years, mHealth apps have become more active in the way they support their users. Not only do they collect and monitor data, but they also suggest interventions in order to help the user change his or her behavior. For instance, a group of researchers demonstrated that sending customized text messages was efficient to help patients suffering from coronary heart disease change their behavior when it comes to reducing the amount of smoking and increasing physical activities (Chow et al. 2015). Over the last 5 years, an increasing number of mHealth apps have leveraged machine learning algorithms to provide a higher level of data analysis, thus offering new opportunities. For instance, a small Swiss startup developed a mobile

app that can measure blood pressure from data collected from a mobile device's camera (Schoettker et al. 2020). With so many available apps, the bigger challenge for users lies in finding the most appropriate ones. The growth in health apps is poorly aligned with the capacity of evaluation of such apps. A few years back, the FDA had approved much less than 1% of those apps for clinical use. Most innovators and entrepreneurs of health apps purposely target the "wellness market" in order to bypass the legal challenges and strict regulation processes required for FDA-regulated apps or digital devices. Moreover, customer reviews may in theory represent some helpful feedback to prospective app customers although very often their content is superficial and of no real value. One might think that it would be of some benefit if the application stores would categorize mHealth apps that have undergone systematic evaluation, even when there is only a paucity of apps. In a 2017 study, out of the 3296 mHealth apps analyzed, only 11 had been analyzed for their effectiveness (Buechi et al. 2017).

Another technology that has been shown to have a big impact on improving the health of populations is wearable and comprises all devices whose embedded sensors and analytic algorithms can track, analyze, and guide the wearers' behavior (Schüll 2016). Activity trackers and smartwatches are most probably the most common and known wearable technology. In one of the largest clinical trials ever conducted, involving 400,000 participants and published in the New England Journal of Medicine, a group of researchers demonstrated the ability of the Apple Watch to detect atrial fibrillation (Perez et al. 2019). With an increasing number of embedded sensors, such as oxygen saturation, electrocardiogram, and blood pressure monitoring, wearables have shown great potential in remotely monitoring mildly symptomatic patients during COVID-19 and will most probably continue to do so beyond the pandemic (Islam et al. 2020). Wearables have been shown to help children suffering with autism recognize the emotions of other children. The researchers used the affordances of a pair of smart glasses (i.e., Google Glass) to analyze the facial expressions of children in the field of view of the child suffering from autism and then display in his or her screen whether the children are smiling and being happy, sad, or angry to name of few (Daniels et al. 2018).

1.2.2 Reducing the Cost of Healthcare

Chronic diseases such as obesity, cancer, and diabetes account for a majority of healthcare costs of developing countries along with lifestyle choices (e.g., alcohol, tobacco, food). Lately, researchers and governments have been leveraging machine learning algorithms and data science in general to predict early obesity using data collected during medical visits (Triantafyllidis et al. 2020). These predictions have allowed governments to create targeted interventions such as awareness campaigns as well as changes in policies. When it comes to cancer prevention, the combination of mHealth and machine learning has allowed for the screening of skin cancer. From a picture taken with a mobile device, a machine learning algorithm is able to

identify whether the mole is malignant or benign. Already used by millions of people, not only can these mHealth apps save people's life, but they also reduce treatment costs by identifying skin cancer at an early stage (SkinVision 2021).

1.2.3 Improving the Experience of Care

When broken down, experience of care often includes elements of scheduling (e.g., how and when can a specialist be booked), accessing the medical facility, registration, waiting, reception of the care by medical professionals, discharge, and reception of medication. Until recently, this traditional model of care delivery requiring a patient to visit a physician in a clinical setting had been prevalent in the majority of the world. It did not change due to new technological advancements, but mostly due to the restriction of movement caused by the COVID-19 pandemic. Within a very short amount of time, governments and hospitals chose telemedicine to permit mildly ill patients to get the supportive care they need while minimizing their exposure to other acutely ill patients (Portnoy et al. 2020). The pre-identified barriers that prevented a larger scale adoption of such technology, including a breakdown in the relationship between the patient and the physician, had a much lower impact than expected (Hollander and Carr 2020). An increasing number of hospitals have integrated telemedicine as part of their portal, allowing patients to search and find a specialist, book an appointment based on their preferences, run a telemedicine consultation from their personal computer or mobile device, receive an electronic prescription, and access their discharged report from the comfort on their home.

1.2.4 Improve Care Provider Experience

Though to date digital health has primarily targeted patients, some technologies have had indirect and direct impacts on the care provider experience. These impacts can be at the same time positive and negative. Electronic Medical Records (EMR) is most probably the technology that has been researched and discussed the most. On one hand, many concerns have been raised with regard to the impact of EMR on medical professionals' wellbeing due to their lack of usability (Shanafelt et al. 2016); on the other hand, they have allowed care providers to access, trace, share, and analyze data of multiple patients with limited effort, leading to better care (Khalifa 2017; Rathert et al. 2019). Telemedicine is a technology that has had more direct impact by allowing physicians and other medical professionals to save time by more efficiently sorting patients and redirecting them to specialists (Mahtta et al. 2021). For physicians practicing home visits or living in rural areas, this allows them to consult more patients while reducing risks linked to driving (Mahtta et al. 2021). As described above, telemedicine has been key to delivering care but also to protect care providers from infection (Hoffman 2020). During the COVID-19

pandemic, several DHT were used in several studies to better understand the amount of stress on care providers and to preventively identify people at risk of burnout or mental and physical breakdowns (Goodday et al. 2021). Several techniques were used to collect objective and subjective data from surveys, mobile applications, activity trackers, smart rings, and video calls with specialists.

1.3 Future Trends

Aligned with the title of this book, "Digital Health: From assumptions to implementations," the trends presented below leverage existing DHT and are foreseen to be implemented within 3 years (Fig. 1.3). With the increasing adoption of DHT by the population, patients will play a bigger role in the health system, first through the amount and variety of data that patients will be collecting but most importantly by sharing that data with medical professionals. Though to date many people already use activity trackers to collect physical activity level, sleep, and heart rate, future activity trackers will be able to collect blood glucose levels, detect toxins, vitamins, or micronutrients, and perform molecular diagnostics through biosensors among others (Parkhey and Mohan 2019). In addition, we foresee an increasing use of home testing triggered in most countries by different types of COVID tests. By monitoring diagnostic test results sent from devices worn by patients at home, the clinic or general practitioner will decrease the cost and risk of cross infection while improving the comfort of the patient. All data collected by the patient will be either automatically or manually transferred into his or her Personal Medical Records (PMR). PMR or PHR (Personal Health Records) capture health data entered by individuals and provide centralized and easy-to-access information related to the care of those individuals (Tang et al. 2006). Until recently, maintaining a PMR mostly meant copying information from one or more Electronic Medical Record (EMR). However, with the increasing amount of data collected by patients, there is now an incentive for hospitals and clinics, in addition to software vendors, to centralize that data and share it. Big players, such as Amazon and Microsoft, have developed such centralized PMR that can be shared with hospitals and clinics in some countries only. In the meantime, researchers look into more decentralized and traceable solutions by leveraging blockchain (Chen et al. 2019). From a medical professional perspective, an increasing number of tests will be performed in local clinics or health hubs located in malls, train stations, or in high-density living areas. Tests requiring more advanced technologies and skills will be performed by regional hospitals. On-demand, data will be integrated in a national EMR and synchronized with the patient's PMR. Both will be connected to a data analysis layer that will use deidentified health data to provide recommendations to the patients and the medical professionals. Such service is, for instance, being offered by Microsoft and Amazon but at a local (hospital) level only. By using PMR and EMR data at a national level, the recommendations will gain in relevance and efficiency. Such recommendations will promote preventive routines and quality of life through personalized and

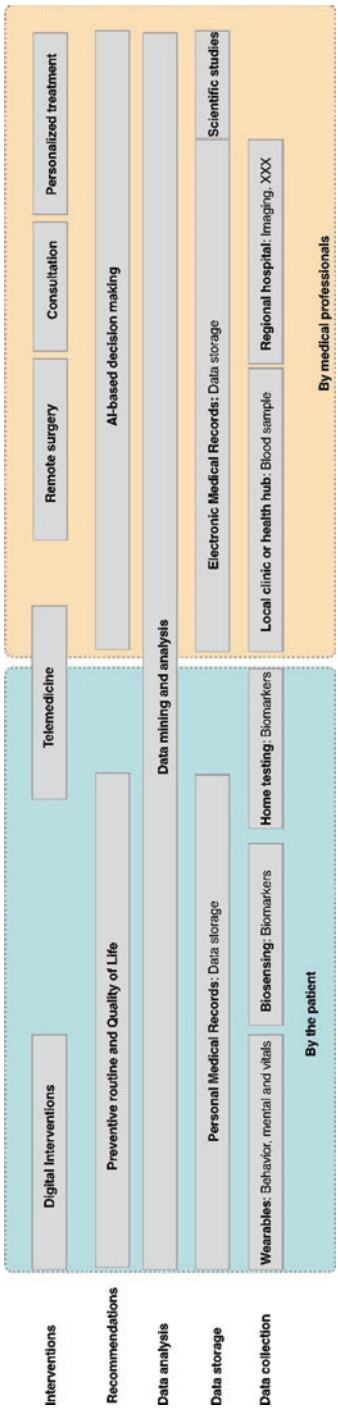

Fig. 1.3 Digital Health Technologies—patient and medical professional perspectives

action-based digital interventions. The data analysis layer will support medical professionals' interventions by leveraging artificial intelligent-based decision making. Medical professionals' decisions will, therefore, be seconded for safer and more accurate medicine. Remote interventions, such as telemedicine and surgery, will be leveraged to ensure that the patient is treated under the best conditions. The use of 3D-printed drugs will be more common to deliver personalized treatment. With the recent commercialization and certification (e.g., FDA for the U.S.) of non-proprietary 3D printers dedicated to drugs such as the FabRx M3DIMAKER, one might expect a high use of such techniques for very specialized treatments.

Deliberately, we did not mention some key advancements such as precision medicine or precision nutrition, which are without doubt shaping predictive, preventive, personalized, and participatory medicine (Moore 2020). We argue, however, that precision medicine does not really fall under the DHT category although some services such as 23andMe leverage mobile health as a communication channel between the customers and the company.

Ultimately the adoption of DHT will depend on the ability of the medical sector, the government, and the technology companies to understand the needs of patients and of each other. Tech companies now have chief medical officers to identify clinical needs and constraints. Governments are pushing hospitals to adopt and integrate their EMR while the average U.S. hospital has 16 different EMR (Sullivan and Why 2018). Digital Health Technologies are, without doubt, disrupting medicine—but the journey is only at its beginning.

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Chapter 2
How Mobile Technologies Are Changing the Life of Physicians and Patients in Hospitals

Frederic Ehrler and Katherine Blondon

Abstract The growing adoption of mHealth technology in hospitals by both patients and care-providers has the potential to modify in-depth the patient-provider relationship and to improve the quality as well as efficiency of care. However, this transformation must be accompanied by a clear strategy by the healthcare institutions to avoid the fragmentation of the initiatives that could lead not only to a sub-optimal experience for the patients but also to possible safety risks. Besides requiring to solve all the technical, regulatory and organizational problems, entering this new era will deeply transform the role and engagement of the patients in their journey as we progress towards a more collaborative vision of care. In this chapter, we present the main challenges associated with the deployment of a mHealth strategy at the institutional level, as well as from a care-provider and patient perspectives.

Keywords mHealth · Patient Generated Health Data · Empowerment · EHR Chronic diseases · Cybersecurity

2.1 Introduction

Since the emergence of the first mobile devices in the form of personal digital assistants (PDAs), people involved in healthcare have been interested in using mobile devices to improve healthcare processes, quality and efficiency. Dealing with one's health is a time- and energy-consuming task, which occupies one's attention continuously (MacGregor and Wathen 2014). This is especially true for patients with

F. Ehrler (✉)
IT Department, University Hospitals of Geneva, Geneva, Switzerland
e-mail: Frederic.Ehrler@hcuge.ch

K. Blondon
Medical Directorate, University Hospitals of Geneva, Geneva, Switzerland

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chronic conditions, who can spend up to 2 hours each day dealing with health issues (Jowsey et al. 2012). Mobile devices, which are kept within reach throughout the day, offer a privileged channel to reach people at any times (Vo et al. 2019). It also offers new opportunities to reach individuals of lower socio-economic status, who have more prevalent chronic diseases (Lowry et al. 1996). The healthcare sector has witnessed the rapid emergence of many new tools involving mobile technologies to support health care professionals with many important tasks (Ventola 2014a; Mosa et al. 2012), such as: information and time management; health record access and updates; communication and consulting; information gathering and researching references. Mobile tools have also demonstrated the potential to support patients' self-management for many chronic diseases such as hypertension, diabetes and cancer (Lalloo et al. 2017). New medical apps are created and launched daily and contribute in many ways to transform the way patients and providers deal with the healthcare continuum (Smahel et al. 2019). The World Health Organization global observatory of eHealth defines mobile health (mHealth) as "medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, Personal Digital Assistants (PDAs), and other wireless devices". MHealth includes different subcategories such as telemedicine that has become well-established amid COVID-19 restrictions and defined as "the communication or consultation between health professionals about patients using the voice, text, data, imaging, or video functions of a mobile device. But it can be applied to other situations; the management of chronic diseases of patients living at home is one example".

In hospital settings, mobile technologies offer numerous opportunities for change: they can modify the way clinicians work and practice medicine (Ventola 2014b), empower patients, and improve patient-provider communication (Lu et al. 2018; Krohn 2015). This evolution started with the digitalization of the clinical documentation process that was initially supported by paper records. These records were initially designed to fulfill billing and legal requirements. The evolution toward the first electronic medical records systems often kept the same approach rather than being designed to facilitate and optimize clinician workflows (Evans 2016). As a result, the clinicians were forced to adapt their workflow to the electronic tools rather than having the tools adapted to their needs (Sieck et al. 2020). With the advent of mobile technologies and the rise of user-centered approach, the paradigm is slowly changing in the attempt to provide personalized tools adapted to the real need of the providers, rather than being considered as a support for administrative processes (Saparamadu et al. 2021; Molina-Recio et al. 2020; Bruce et al. 2020). These new tools provide ways for health professionals to more easily access their patients' data, as well as to explore larger databases to access the latest practice guidelines. Furthermore, mobile technology has deeply changed the role of patients in the care process and its relationship with healthcare professionals. It bolsters patient empowerment by enabling patients to be informed about their diseases, guided, prompted and reminded about self-management tasks, and helps keep track of their health. The evolution of this trend has led to the rise of several channels of communication between patients and providers, such as patient portals, emails or texting, all of which are more readily accessible with mobile technologies.

Even if mHealth is full of promises, the deployment of a sound mobile ecosystem improving providers and patients' collaboration at the level of a healthcare institution is not as simple as it seems. Allowing the introduction of these tools in the hospital without a proper strategy can led to a fragmented landscape and engenders problematic situations. For instance, providers may need to carry several devices, use unreliable apps, jeopardize data security or adopt heterogeneous practices. It could also lead care provider to develop the feeling of being overwhelmed by patient-generated data as well as losing control of the patient trajectory. To avoid these drawbacks, the challenges of mHealth implementation must be anticipated from the provider's and patients' perspectives to fully benefit from its potential.

2.2 At An Institutional Level

2.2.1 Enabling the Use of Hospital Health Data

To construct a rich ecosystem of apps for care-providers and patients, a clinical information system (CIS) must meet several requirements. CIS must support the deployment of multiple client applications without jeopardizing the integrity of the data. An important ingredient of success is to choose a software architecture that enables the easy creation of multiple apps that can be used to support specific user experiences, while limiting redundancies and facilitating reutilization (Fig. 2.1). An adapted architecture should favor the exposure of numerous and product-agnostic application programming interfaces (API) that allow an app to easily combine different functionalities. Optimally, these interfaces must comply with the data models proposed by existing standards such as Fast Healthcare Interoperability Resources (FHIR) or Integrating the Healthcare Enterprise (IHE) profiles to ensure the compatibility with other systems in the care network (Bent et al. 2021). Another recommendation is to minimize the amount of business logic contained in the front-end to

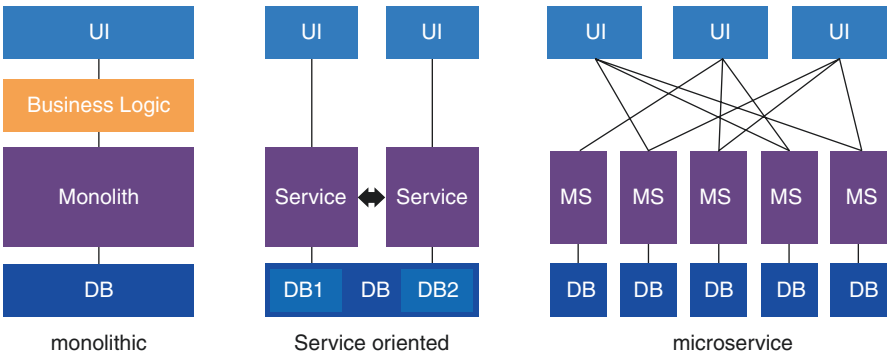

Fig. 2.1 Schematic diagram of clinical informations system architecture

ensure coherent behavior in each application using the back-end services. Finally, relying on numerous small-sized, loosely coupled business services should be privileged, as it is a good way to ensure a smooth lifecycle of the whole system. It allows the modification of a component with limited impact on the rest of the system, and therefore increases the system's agility.

Unfortunately, many of the actual CIS architectures are often monolithic or rely on an enterprise service bus and are maladapted to provide the required flexibility to support a rich application ecosystem leading to additional challenges for the deployment of mobile apps for care-providers.

2.2.2 Security, Trust and Legal Aspects

Apps are subject to many regulations constraining to ensure privacy, confidentiality, and security of the collected data (Martínez-Pérez et al. 2015). Mobile technologies can collect a lot of data unobtrusively, which is a blessing if it can avoid having to transcribe data in the app (e.g., syncing blood glucose results rather than having to enter them one by one manually). This ease of data collection also triggers several privacy concerns, however. Some of these data may lead to considerable unexpected consequences, such as when the Internet service Strava allowed its users' geolocalization data to be publicly available, causing havoc when app users from the military revealed patrol routes and bases. Although users should be attentive to how their data is used, this example also illustrates how many do not consider this point when choosing which app to use.

Concerns about trust and security issues can be a barrier for using mobile technologies, especially among older patients (Wilson et al. 2021). Some patients are very sensitive about their privacy and are reluctant to let private companies use their health data, even sometimes with public authorities (Trinidad et al. 2020; van Haasteren et al. 2019). This tendency was observed during the COVID pandemic, where people were very suspicious about symptom-tracking apps as well as contact-tracing apps (Dowthwaite et al. 2021; Simon and Rieder 2021). For apps recommended by or developed within a health institution, all the guarantees must be given to ensure the trust of the patient, because it reflects the trust the patient is placing in the institution (van Haasteren et al. 2019). It implies defining a clear disclaimer, which specifies who has access to the data, and for which duration. Ensuring a secured storage of the patient data usually prevents the use of a cloud solution if the storage is not done on the same country as the service provider.

Also, a strong guarantee must be given regarding access to the data. An account must be created for each patient to ensure that they will be the only one to have access to their personal data. Connecting to these accounts rely usually on dual-factor identification such as a password and an SMS challenge and must be created through a process that validates the patient's identity. Managing these accounts is a heavy responsibility for the healthcare institution and requires having dedicated human resources that can deal with the enrollment process and offer support when required.

Authentication is an additional challenge when designing mobile applications for healthcare. Whereas desktops or mobile computers that access sensitive data are physical machine that are generally dedicated for clinical use, mobile devices are portable, and can be easily stolen, lost or left in a public area (Martínez-Pérez et al. 2015; Medical and Bromwich 2016). The problem is not so much what happens to the device itself, but the concern about potential access to patient data that the institution needs to keep confidential. Costly (though not yet foolproof) strategies had to be put into place when deploying tablets for patients in our institution, to avoid theft and "misplaced" accessories. Although mobile devices in hospital settings may be shared in a care team to reduce cost, exploitation costs are even lower with a "bring your own device" (BYOD) strategy, which is increasingly favored currently (Wani et al. 2020). A BYOD strategy reduces the cost of maintenance of device as well as the need for the clinicians to carry multiple devices. Owners of a device will also take better care of the device and its accessories (charger and cable, for example), than if it is considered an institutional device. The constraint of this BYOD strategy is the necessity to ensure sufficiently strong security (Al Ayubi et al. 2016). If institutional devices can be easily enrolled on a mobile device management system (MDM) that will control the access and limit its connection to a private and secure network, a BYOD, on the other hand, is, by definition, completely open and connected to public networks. It is therefore necessary to put several safeguards into place. First, an appropriate authentication strategy must be implemented to ensure a secure connection. However, if the connection process is too cumbersome, or is required repeatedly throughout the day with short time-outs, user adoption will be low. Also, institutional liabilities imply that no sensitive data can be stored on the device, in case the device is stolen. Finally, since apps are accessible from an external network, all security breaches must be corrected. For this purpose, an external audit by cybersecurity specialists must be performed.

2.3 At the Provider's Level

2.3.1 Transforming the Way to Deal with EHR

Patient records have undergone a transformation from paper to virtual files stored in large clinical information systems. In the beginning, these digital systems barely contained numeric versions of paper documents; rapidly, however, the collection of information has become structured, allowing a better use of the data. New technologies for imaging and wider access to patient information over a patient's lifetime, rather than being limited to the last hospital stay, have led to huge increases in the amount of data available for each patient. Modern medicine seeks to manage these large amounts of data with continuous information flow: providers need easily available tools with decision support capabilities, analytics and visualization of these data, as well as communication channels to exchange information about these data between healthcare professionals.

Unfortunately, despite the numerous advantages of EHR digitalization, one of the drawbacks of this transformation was the loss of mobility that previously existed with paper as well as an increased time spent on documentation (Ammenwerth and Spötl 2009). Indeed, whereas clinicians could carry their paper files with them, consulting electronic medical records requires a computer. Requirements for documentation have increased considerably, and has become a time-consuming process with suboptimal tools (e.g. dispersed data to review, difficulty of documenting in real time or at the point of care), that can sometimes lead to provider exhaustion or even burn out (Tajirian et al. 2020). Obviously, accessibility was improved with the apparition of laptops and computers on wheels, but remained limited in some situations, such as for protective isolation rooms for immunocompromised patients, where such equipment is prohibited (Jen et al. 2016).

Mobile devices provide a ubiquitous access to electronic medical records and can be useful to support bedside documentation. Instead of jotting notes down on a piece of paper, bedside documentation on a mobile device can help avoid transcription errors, additional delays in entering clinical data such as vital signs, and decrease the number of interruptions in clinical documentation, which can also lead to errors (Sowan et al. 2019).

Besides improving the documentation process, mobile devices provide a new opportunity to combine the benefits of accessibility and digital capabilities, such as quick searches for just-in-time information, checking emails, and text messaging.

2.3.2 From Standardized to Personalized System

Operating the transition from system running on desktop computer toward mobility is not only a question of having an adapted system architecture. Indeed, clinical information system (CIS) interfaces are designed to be run on computer screens and cannot be visualized without change on a mobile screen (Alnanih and Ormandjieva 2016; Huang 2009). In traditional CIS interfaces, it is not uncommon that a lot of information is displayed on the screen often leading to some problems (Nijor et al. 2020). These problems are further emphasized on the small size of mobile screens limiting the amount of information presented. The design of smartphone interface requires careful consideration of what information to focus on for a user in each context. Therefore, traditional CIS interfaces can apply a one-system-for-all system on computers, whereas mobile device designs need to tailor the interface for each type of user. Another difference between desktop computer and mobile device is the way one interacts with the device. With desktop computers, users interact through a keyboard and mouse, whereas mobile devices rely on a tactile gesture. Consequently, the interface must be redesigned, given this constraint. It is much more time consuming and complex to enter free text on a mobile device, and therefore predefined

options must be favored. A study by Ehrler et al. compared data entry of vital signs with different interfaces, and found differences in precision and efficiency. Various types of errors occurred, which ranged from 0.7% for the most reliable design to 18.5% for the least reliable one (Ehrler et al. 2015). Choosing an inappropriate interaction widget not only reduces the capacity of care-providers to interact efficiently with the system, it also increases the risk of error. User-centered design with close collaboration with the various types of care-provider users is a key process in understanding and supporting the different needs and workflows for mobile devices (Johnson et al. 2005). For example, doctors need to *see* the vital signs in a patient's chart, whereas the nurses need to have a reliable way to *enter* these types of data. Likewise, doctors need to be able prescribe tests and treatments, while nurses need to document what medications are administered, and so on. Addressing the needs in a way that is specific to each type of user is a key process for better usability and satisfaction, while keeping the tool simple and efficient. Users need to understand that the *mobile* CIS is not meant to address all a user's needs but should rather be *complementary* to the desktop CIS.

For example, the "Bedside" app in our institution (Fig. 2.2) was designed for nurses to document short, structured data such as vital signs at the bedside, whereas they preferred to type the longer daily progress notes at a desktop in the nurses' office (Ehrler et al. 2018a). This demonstrates the high importance of designing application with user at the center to ensure adoption and to focus on features adapted for mobile context. If the users develop the need for writing longer progress notes away from their computer, we will then need to consider the right type of device (computer on wheels vs smartphone vs tablet), the right sensor (typing vs voice recognition) and type of support (suggested nursing targets, based on vitals, labs or physician-entered medical problems).

Switching from a computer screen to a mobile device not only enables better mobility but also unleashes new capabilities with the use of sensors that are integrated in mobile device. One of the most useful sensors is the camera: for example, scanning the patient bracelets to open a chart ensures that a user is accessing the right chart. Besides reducing the risk of selecting the wrong chart, these sensors can help improve care-provider efficiency. Using the camera also facilitates documentation and data entry. Documenting the follow-up of wounds (Biagioni et al. 2021) become more convenient when the camera is in one's pocket, for instance, especially if the picture taken is directly imported in the patient's chart. However, integrating sensor's data in healthcare process must be done with particular care. Indeed, relying on devices' sensors often open security breaches (Kumar and Lee 2011). Data is often transferred through cloud solutions that have their own policies regarding data management. Therefore, it is important to verify and guarantee that the software chosen to support the care workflow does not send data outside of the desired secured channel.

Fig. 2.2 Screenshot of the Bedside mobility app. The screens shows all the tasks to be done by a nurses during her shift

2.3.3 Communication and Notification

Besides all the functionalities offered by mobile devices, its core purpose is to be used as a communication channel. Care-providers have long been equipped with pagers and feature phones, which require almost synchronous connections. Information exchange is of high importance in healthcare teams, and texting and chats have become common nowadays (Vermeir et al. 2015; Pourmand et al. 2018). This channel of communication has been demonstrated to be especially useful in the context of emergency department where clinicians loose often precious time to find

their colleague to exchange information (Nittas et al. 2019). Again, security constraints need to be considered for these types of communication, which is why many companies have appeared with secure channels for healthcare (Nikolic et al. 2018). Direct access between the chat system and the electronic chart is recommended, as clinicians often send images of a scan or ECG to their colleagues for a second opinion. E-mails are also widely used, but can also easily lead to overload, since alert systems may also use this channel. Several papers have reported how excessive emails from EHRs and patients can contribute to provider burnout (Gardner et al. 2019; Armstrong 2017).

Besides benefits in communication, mobile devices can also help care-providers be more aware of data arriving in the electronic medical system. Smartphones allow alerts to be directed to one or two individuals, rather than a pop-up for all who access a given patient's chart. For example, a highly abnormal lab results may go unnoticed unless an alert is triggered in the medical chart (Kuperman et al. 1999; Slovis et al. 2017). Notifications and alerts have much greater potential with smartphones, with a lower risk of alert fatigue. Alert fatigue is a well described phenomenon where the user becomes less responsive to alerts when alerts are too numerous or overwhelming (Backman et al. 2017). Mobile devices allow alerts to be targeted to an individual, therefore decreasing the risk of alert fatigue. For example. Designing alert systems require careful consideration of user needs, especially for the choice of thresholds that trigger alerts. For example, oncologists will have many patients with very low white blood cell count due to chemotherapies, and may therefore not want to have that alert, whereas this same result in a patient elsewhere in the hospital may lead to many new considerations for her care.

2.4 At the Patient's Level

2.4.1 Patient Empowerment

Digital technologies, and especially mobile devices, have revolutionized the way patients get involved in their care (Marcolino et al. 2018). Many digital interventions empower the patient both through better access to information (Crondahl and Eklund 2016) and by the ability to act during the care trajectory. Apps can provide information about a disease, helping users to understand practical aspects in daily management (Anshari et al. 2021). For example, after a recent diagnosis of diabetes, a patient will need help to interpret the blood glucose results, or to decide how much insulin is needed (Gómez-Velasco et al. 2019). An app can provide guidance about food choices, or about what parameters should be tracked. It can help record data, and provide reminders for medications or stimulate the user to exercise with motivational messages. The patient is empowered for better self-management. The latter improve patients' autonomy and freedom of choice, for instance by allowing them to make their appointments themselves, to choose their menus during

hospitalization and to monitor certain parameters, including reporting the results directly to the providers. Finally, digital technologies enable better communication between patients and their healthcare team. Mobile apps provide a ubiquitous tool to support patients all along their journey, helping them to learn about their disease, to understand different aspects for management, to suggesting what, when and how to collect relevant data, with reminders and prompts for medication and other health-related tasks.

Patient empowerment has been associated with improved health outcomes and lower adverse events (Powers and Bendall 2003; Hibbard and Greene 2013). Patients can participate in their care during a hospital stay in many ways: they can keep track of their daily progress (vitals, lab results, etc.), discuss daily goals with the care team, or be aware of the planned activities of the day. Knowing what medications have been prescribed and why can help them monitor the drugs they receive (Graffigna et al. 2017) (Fig. 2.3).

They can play a role in detecting possible side effects, adverse events and may even prevent medication, shared daily goals and higher awareness of scheduled events each day allow patients to organize their day around these (family visits, walks, etc.)

The ever-growing number of mHealth applications available on the market makes the choice difficult for patients. As mentioned above, patients often receive little guidance about apps from their care-providers and do not have the time to keep up with the rapidly changing app market. Patients find themselves in front of a huge choice of applications, not knowing what criteria to use to find a "good" app: how do they judge the quality of medical information, and can they tell whether their personal data will be used for a commercial purpose by the app company?

Despite the wide selection of apps, a gap may remain for patients with chronic diseases. Indeed, many health problems require a multi-pronged approach for self-management. For example, individuals with coronary heart disease need to improve their medication adherence, eat more healthily, exercise regularly and for smokers, to quit smoking. There are many medication management apps (Pérez-Jover et al. 2019; Park et al. 2019), as well as many diet and exercise apps. Yet how many address all these issues in a single app? Habit changing apps are starting to integrate goal setting to help individualize the functionalities for each user. Other approaches such as gamification have also increasingly applied for health and self-management goals (Ehrler et al. 2018b) (Fig. 2.4).

There are several main challenges that result from having to use several apps to manage one's health. If a patient must use one app for medications, another to track his blood pressure, and a third to exercise regularly, the dispersed information makes it difficult for the user to get an overall picture of their health and self-management status.

Furthermore, all these applications often possess their own authentication system and do not communicate easily with each other. So, one app may need the same data as another, and the user can either enter it twice, or else not be able to benefit fully from the second app with missing data. These data in silos are also barriers to sharing data with the user's healthcare team. All these interoperability issues also

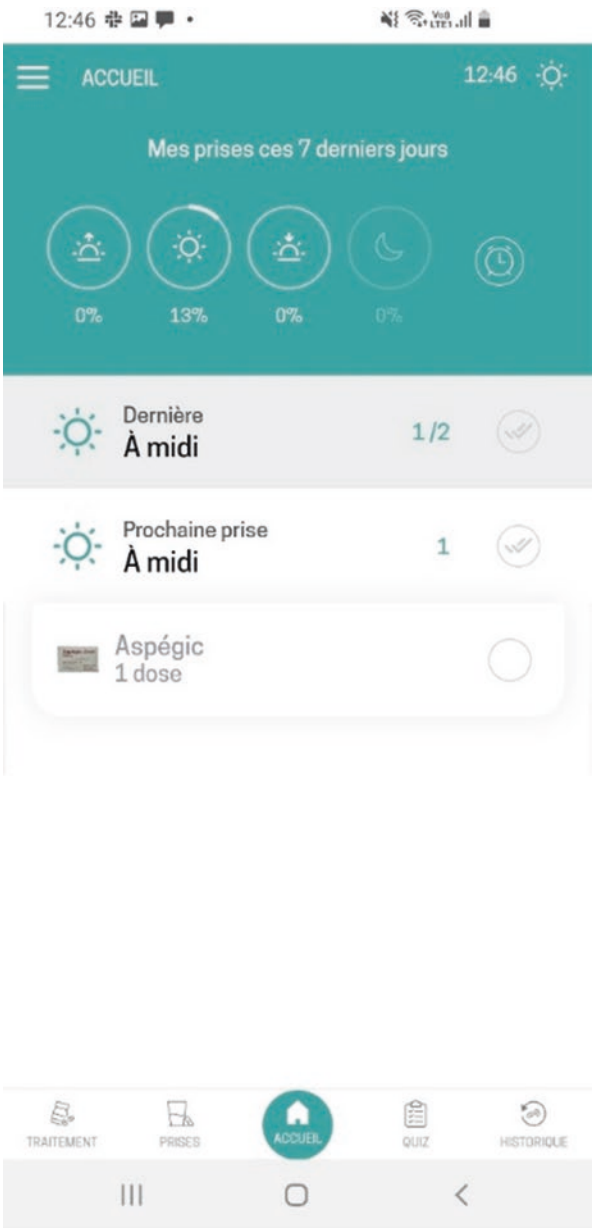

Fig. 2.3 Screenshot of the swiss-Meds homescreen allowing the patients to validate her intake

lead to limitations in implementing artificial intelligence tools to help guide the user, either analyzing whether results are normal, or predicting future actions that need to be taken.

Finally, apps are generally not adapted to help individuals with more than one chronic disease, when there are multiple self-management needs. Besides

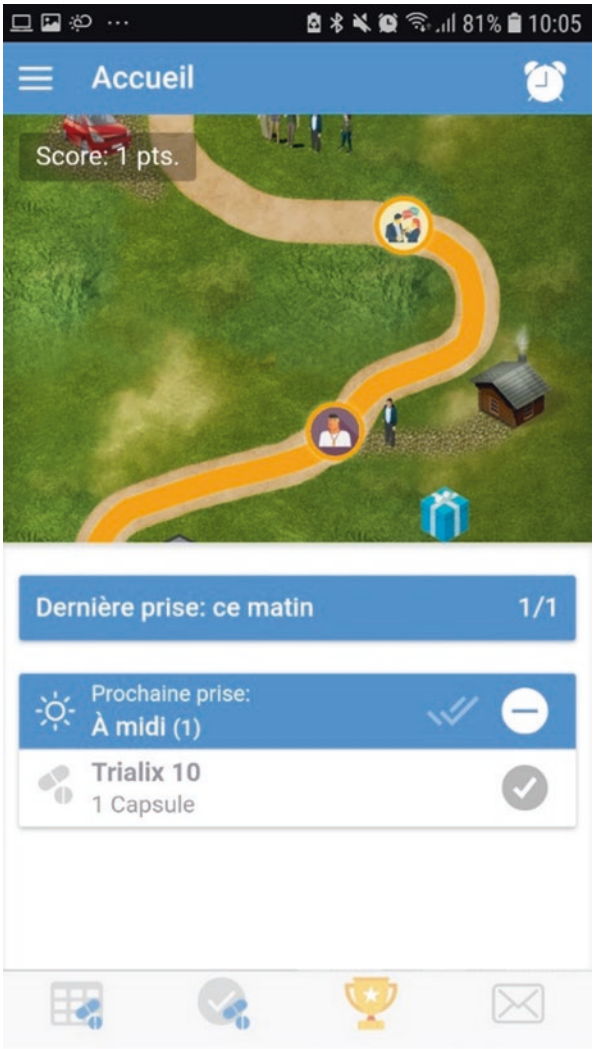

Fig. 2.4 Home screen of the gamified Swiss-Meds apps. The screen present a path were the user progresses each time she report accurately her medication intake

potentially needing several apps to help manage coronary heart disease (for medication, diet, exercise, blood pressure monitoring, etc.) the patient may also have other diseases such as diabetes, renal failure and so on. Each app will address one or two health issues, and may do it very well, but not in coordination with the rest of the patient's health concerns. Ideally, an interoperable and coordinated app in an ecosystem would be able to avoid having to enter data twice, as well as prevent potential contradictory recommendations from different apps. For example, the exercise app may recommend that the patient stay hydrated, while his kidney disease app may suggest a water restriction strategy. Complex health issues and multiple chronic diseases are unfortunately not uncommon: although improving interoperability

issues between health apps will address some aspects, it is only a fully integrated system (or ecosystem) that will allow the patient to receive personalized, contextualized and safe care.

2.4.2 Challenges of Long-term Engagement with Health Technologies

After receiving a diagnosis of a chronic disease like diabetes, patients seek support, and need to learn how to manage their disease. They may test websites and apps, and if they like a tool and find it helpful, will use it for a while. When data entry is tedious, or the decision aids are no longer useful because the patient now know more about the disease, these tools are no longer used (Middleton et al. 2016). In other words, the perceived effort outweighs the perceived benefit of the tool. This relationship has been clearly demonstrated through the technology acceptance model that shows clearly the link between intention to use and perceived usefulness and ease of use (Holden and Karsh 2010). And this is the challenge in designing support tools for the long-term: patients' needs for support change over time. Rather than simply not using a tool any longer, we should start examining how the patient's needs change over time to provide an adaptive tool. It should be able to have reminders when it isn't used but should also be able to "move to the next level of use" and stop providing the "basic" information that the patient no longer needs, and move to more subtle adjustments of self-management, that are adapted to the user's context. For example, a patient with experience in diabetes self-management will have mastered how her body responds to physical activity and travel and can adapt her insulin doses. She does not need further help to calculate insulin doses and may in fact not even be documenting all the ingested foods and glucose values. But the day she decides to hike in the Himalayas or go deep sea diving, the app should detect a change in a new parameter (altitude) and pop back into action, with explanations of how this context will affect her metabolism.

2.4.3 Communicating in Both Way

Patient portals have become widespread to help provide support for patients, both during hospital stays and for out-patients (Baldwin et al. 2017). Portals allow patients to communicate with their providers through emails or texts. They can easily be accessed through smartphones and websites (Fig. 2.5).

Electronic patient records, which are records that belong to the patient, and that can be shared with whomever they choose, are also being implemented in Switzerland for instance. They provide a way for patients to access their medical reports and prescriptions, and in some cases, will allow inter-professional care

Fig. 2.5 Home screen of the Concerto app, the patient portal of the University Hospitals of Geneva, allowing to interact directly with the clinical information system

teams to document shared progress notes (e.g., between a doctor and the home nurse team). All these shared records help to agree on care objectives: for example, which parameters should be monitored for M. Smith (e.g., weight)? What is his normal weight range (e.g. 65 ±2 kg) and what action needs to be undertaken outside

of that range? Since M. Smith controls the access to his chart, he can also give his wife and daughter access, allowing them to be involved in his care.

Designing portals and electronic patient records for patients on their smartphones lead to the same challenges as for care-providers for considerations about screen size, or usability of smartphone for data entry, for example. Additional considerations are health literacy and numeracy, as well as readability (e.g. font size), and the digital divide. Some individuals may not have access to mobile devices or may not have data plans; others may find apps too difficult to see or may not understand how to use it easily. Yet interestingly, access to portals from smartphones is allowing minorities to be connected and more involved in their own care. Chat may also facilitates asynchronous communication through text messages. And finally, for healthcare use, some individuals may be worried about how their data may be misused by companies or insurances, for example.

The deployment of patient portals along with the widespread adoption of smartphones, tracking devices and connected devices enable the capability for the patients to collect vast amounts of data about their health. PGHD include several types of data. Some require patient inputs such as clinical parameters (e.g., blood pressure or glucose measurements), or patient-reported outcomes (typically surveys or questionnaires). In fact, the definition of patient-generated health data by the Office of the National Coordinator for Health Information Technology (ONC) (Shapiro et al. 2012) also includes health data collected from family members or other caregivers. Healthcare providers may encourage their patients to collect and share their health data to help manage a medical issue. They may send questionnaires before or after a medical visit or may want to help patients with their self-management (Nittas et al. 2019).

Since PGHD can potentially generate vast amounts of data, providers worry about receiving too much data from their patients, and not having time to process or manage these data (Lavallee et al. 2020). This leads to concerns about subsequent liability for abnormal findings that may be missed. One approach to address this concern is to implement analytical tools for PGHD that can support health professionals' work by for instance creating alerts if anomalies are detected. Integration of PGHD in electronic health records or in larger databases requires addressing interoperability issues from the various sources of data (Tiase et al. 2019). One approach to help detect abnormal findings would then be to use artificial intelligence analyses of these large dataset. Although the interest in using the information from PGHD to improve healthcare is growing rapidly, we will not discuss this further as it is beyond the scope of this chapter.

2.4.4 Assessing Apps for Quality and Safety: Use Case

Mobile app markets for patients have grown exponentially over the past decade, yet it is still difficult for patients to know whether an app is trustworthy in terms of medical advice, whether the decision support aids are sound and up to date, and

how their data is stored or used by the app company. In fact, mobile apps are appearing so fast, that patients sometimes know more about available apps than their care-providers do (Klasnja et al. 2015). Providers do not have the time nor the expertise to be able to provide a thorough assessments of apps. Several initiatives to assess apps for quality and safety of use in healthcare, because these are not evaluated by the app stores (Agarwal et al. 2021; Boudreaux et al. 2014). These initiatives are difficult to maintain over time. Furthermore, legal aspects and other criteria may differ from one country to another, so the analyses only have a local value.

In 2019, our institution created a mHealth/consumer health committee with representatives of physicians, nurses, patients, legal services, cybersecurity specialist and informatics. The aim of this committee is to evaluate apps and connected devices (blood pressure device with app and/or website to visualize data for example) for patients and providers, according to usability, confidentiality, quality and safety criteria. This committee also provides guidance and support for apps that are developed within our institution. With the rapidly changing landscape of apps, all assessments are limited to a year, or until the next major change of an app. Legal constraints also change rapidly in this field, and therefore require a yearly revision of the assessment criteria. Regular, yearly reassessments of previously approved apps are also needed to ensure the validity of the results.

Community-based healthcare also needs to have this type of expertise available for patients and private practices. While sharing the results of our institution's committee can partially address this need, creating a larger structure to handle regional needs or even a country's needs, leads to other difficulties. Country boundaries are imposed with the legal criteria for mobile apps that differ from one country to another. Other issues to consider are sources of funding (e.g., should it be institutional, governmental or by the app developers), ensuring reassessments of all the apps to ensure that new versions of the app remain compatible with the assessment criteria. Several different models have been tested internationally (e.g. Appscript), with several lists of criteria used for assessment e.g., (examples available at the European Hub).

2.5 Conclusion

There is no doubt that mobile technologies are changing the way patients manage their health and the way providers take care of their patients. In this currently increasingly large market of apps for health, we underline the importance for health institutions to consider not only the potential benefits but also to anticipate some of the challenges with the implementation of mHealth. Mobile apps provide clinicians with easy, ubiquitous access to patient data and to resources to guide patient management; it can also play a role for patient safety with targeted alerts and improve

patient care through facilitated documentation. Yet implementing such solutions in an institution need prior considerations of cybersecurity, legal constraints, development capabilities and cost.

While patients have much to gain with mHealth, individuals with chronic diseases, especially multiple disease, may not yet find the perfect support tools: despite advances with sensors, and connected devices, several apps may be needed to address the various self-management tasks, leading to fragmented data in different systems with low interoperability. This makes it difficult for the user to have an overview of their health and limits the possibility of using artificial intelligence tools for now. The vast amount of data generated and gathered by patients provides an opportunity to improve healthcare but raises concerns about accountability and liability for the institution that integrates these large data. Current approaches include pattern recognition and screening tools with artificial intelligence-based analysis methods.

Both patients and providers need guidance about which apps are reliable, trustworthy, and respect privacy and legal constraints. Some institutions and international structures have arisen to provide this service, using different assessment criteria. Although country laws limit the extent of this collaboration, shared findings can help improve the effectiveness of these app reviews.

Besides all the organizational, regulatory and technological aspects, one of the most important challenges ahead is certainly the way mHealth will transform the relationship between the patient and the care-provider. By offering an unprecedented access to information, a monitoring and decision-support tool, mHealth allows the patient to become the main actor in his own care trajectory, hopefully leading to a collaborative approach with more optimal patient activation.

The future of mHealth is bright and lively and emphasizes the importance of considering both patient and provider's needs. Reviewing prior findings and recommendations to propose amendments and modified solutions is needed to be more effective in moving forward; the speed of change in all areas (app markets, legal constraints, analytics, etc.) prohibits us from starting from scratch. We should also seek to improving collaborative efforts in our research to optimize the efficiency of the work in this field.

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Chapter 3
The Future of Telemedicine After Covid-19

Homero Rivas

Abstract The American Telemedicine Association defines telemedicine as the remote delivery of healthcare services and clinical information using telecommunications technology. This includes a wide array of clinical services using internet, wireless satellite, and telephone media. Telemedicine itself, as part of digital health, leverages on information and communication technologies to expand access to healthcare by the masses. It is not quite certain when telemedicine first started but during the last one hundred years, several different levels and types of telemedicine have been implemented in clinical practice. Those would include telegraphic transmission of clinical information, transmission of electrocardiograms sent electronically, phone calls from patients to care providers to communicate their symptoms or outcomes after treatment, electronic transfer of diagnostic imaging, the National Aeronautics and Space Administration (NASA) utilizing telemedicine to monitor the health of astronauts in space, and the recent COVID-19 pandemic and global efforts to expand access to healthcare by means of telemedicine.

Although information and communication technologies have dramatically advanced over the last 20 years, with greatly improved telemedicine platforms, a myriad of health-related devices in the market, innovation in neural networks, and artificial intelligence among others, the implementation of telemedicine in daily clinical practice before the COVID-19 pandemic has been very limited at best. This is likely due to multiple factors including reimbursement challenges, obsolete legislation and state or board license limitations, lack of awareness among stakeholders, and fear of privacy and security of medical information, among others.

H. Rivas (✉)
Design Lab, Mohammed Bin Rashid University of Medicine and Health Sciences, Dubai, United Arab Emirates
e-mail: Homero.Rivas@mbru.ac.ae

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Historically, the most prevalent barrier for adoption of innovative technologies has been the fixed mindset of care practitioners and their risk aversion towards innovation.

During the surge of the COVID-19 pandemic, there was a true crisis and need for expanded access to healthcare, which rendered telemedicine as an ideal way to extend care to the masses with literally no risk of infectious contagion. Suddenly, many of those previously described bureaucratic challenges were relaxed globally as reactive emergency measures were implemented to expand care. This included the immediate universal adoption of virtual care practices during the acute phase of the COVID-19 pandemic. This chapter evaluates the landscape of telemedicine before, during, and after the COVID-19 pandemic.

Keywords Telemedicine · Virtual care · Licensing · COVID-19 pandemic · Healthcare systems · Digital health

3.1 The Calm Before the Storm

For years, telemedicine has been implemented in all different medical specialties. It is estimated that up to 78% of doctors' visits can be handled safely and effectively using some form of telemedicine, from a simple phone call to more sophisticated technology. The same is true for up to 40% of emergency room visits (American Telemedicine Association n.d.; Rivas 2018; Beck 2016; NHS 2018). Undoubtedly, there are some medical specialties that better lend themselves to the use of telemedicine than others. Medical specialties such as psychiatry, endocrinology, rheumatology, gastroenterology, and some others can be very suitable for virtual care provider–patient encounters, whereas others, such as any surgical specialties, have inherent challenges to the implementation of telemedicine practices (Cordina et al. 2021). However, until recently, the adoption of telemedicine in most healthcare systems around the world, especially those in developed countries, has been limited despite all its promising benefits. In places like the U.S., legislation, licensure barriers, insurance, and reimbursement challenges have been probably the most pervasive reasons to explain telemedicine's limited adoption. On the other hand, during the last 10 years, there has been great technological innovation in all different realms of digital health including wearables, improved telecommunications, blockchain, internet of things, mobile networks in addition to the implementation of artificial intelligence and neural networks (Rivas 2018; Beck 2016; NHS 2018; Cordina et al. 2021). Stakeholders of the telemedicine market have been a bit ambivalent as patients have always pushed the envelope and have been very welcoming of innovation including telemedicine. On the other hand, care providers, third-party payers, and regulators have always been very risk-averse and not full proponents of the

universal adoption of telemedicine (Rivas 2018; Blumenthal 2020; Zenooz 2020). Even then, the global telemedicine market before the COVID-19 pandemic was estimated to be almost 50 billion U.S. dollars (Cordina et al. 2021; Krasniansky et al. 2021; Bestsennyy et al. 2021).

3.2 The Perfect Storm and Its Surge

At the end of 2019, the world witnessed an epidemic that changed the way we live our daily lives. A true global health crisis challenged even the most prepared healthcare systems to the extreme. Due to the highly infectious nature of this epidemic and the inherent need for isolation practices, many patients in need had no adequate access to immediate health care. As telemedicine can overcome most of the physical barriers that resulted from the pandemic, it became immediately instrumental in the delivery of daily clinical practice (Cordina et al. 2021; Krasniansky et al. 2021; Bestsennyy et al. 2021; Chwistek 2020; Hamza et al. 2020; Hollander and Carr 2020; Houchens and Tipirneni 2020; Keesara et al. 2020; Macedo 2020; Mehrotra et al. 2021; Werner and Glied 2021). Different stakeholders responded very well to this situation. Regulators immediately removed many of the restrictions that had been present for many years, allowing temporarily care providers to expand their access to care across states or even borders where otherwise their medical license would not be allowed (Keesara et al. 2020; Mehrotra et al. 2021; Werner and Glied 2021). Insurance plans and reimbursement fee schemes adjusted to compensate for virtual evaluation of patients through telemedicine platforms. A clear example of these temporary reforms in the U.S. is the Centers for Medicare & Medicaid Services' expansion of reimbursable telehealth codes for the 2021 physician fee schedule. All different medical specialty societies around the world immediately endorsed telemedicine practices and encouraged most of their associates to adopt them in their daily clinical practice; most importantly, they promoted research in telemedicine delivery and education on telemedicine. Care providers in general responded well by adopting telemedicine practices as much as possible. Healthcare systems and hospitals implemented into their electronic medical record systems platforms that would allow for virtual care provider–patient engagements. Innovators around the world invested great efforts in designing novel ways to improve current telemedicine platforms and to leverage in multiple other digital health technologies to be used in tandem. Entrepreneurs have continued to implement innovative business models to promote telemedicine practices. Medical educators adopted telepresence teaching for all their core courses, but also identified the need to include telemedicine as part of their medical school curriculum. Lastly, investment in digital health and telemedicine has skyrocketed to record the highest levels since the pandemic, with a growth of at least three times the level seen in 2017.

3.3 The Quiet After the Storm

A recent McKinsey and Company report estimated that the use of telemedicine in the U.S. during the early peak of the COVID-19 pandemic in April 2020 was 78 times that in the pre-pandemic period (Bestsennyy et al. 2021). Since then, the initial spike in telemedicine use has subsided and has been maintained at around 38% among all medical specialties. This represents an overall 32% of office and outpatient visits occurring via telehealth in April 2020 and utilization levels that have largely stabilized, ranging from 13% to 17% across all specialties. Consumer willingness to use telemedicine services has increased accordingly from 11% pre-pandemic to up to 76% after the pandemic despite some general concerns regarding information and technology security (Cordina et al. 2021; Bestsennyy et al. 2021).

Pre-pandemic clinical case mix use of telemedicine involved urgent but low-complexity issues, e.g., colds, sore throats, urinary tract infections, rashes, etc. On the other hand, post-pandemic virtual care aims to include a much broader spectrum from preventive health, wellness programs, integrated management of chronic diseases along with ongoing behavioral health therapy and others; therefore, the burden of travel and opportunity costs from presential doctors' visits could be reduced to a minimum. Wearable technologies—many of which were initially catered directly to consumers as mere instruments of wellness promotion—have morphed into true remote patient monitoring technologies. Their adoption continues to rise and, more importantly, many of them have adapted interoperability with some telemedicine software systems. There is still only a paucity of FDA-approved health-related devices/wearables specific for clinical use although a myriad exists in the wellness market. Today, one-third of consumers are more likely to choose care providers that allow them to share data from a wearable, which in theory promotes more positive outcomes. However, currently, there is very little type I evidence that wearable devices would improve clinical outcomes.

During post-pandemic times, many governments and regulating bodies around the world relaxed quite dramatically many of the historically imposed restrictions on telemedicine (Mehrotra et al. 2021; Werner and Glied 2021). In the U.S. alone, state licensing limitations were temporarily removed, allowing licensed physicians in a single state to virtually care for patients in all U.S. states and territories. In addition, in-person, direct supervision of physician extenders was relaxed so their supervision by physician leaders could be done remotely through videoconference platforms (Mehrotra et al. 2021; Werner and Glied 2021). Many additional clinical problems were deemed adequate to be evaluated and managed via virtual care and reimbursed by either Medicare of by third-party payers. While most of these emergency changes took place during the pandemic, only a few of them may be permanently adopted and severe limitations, such as state licensing barriers, will prevail as in the pre-pandemic era. Nevertheless, such emergency measures have fueled and jump-started extensive adoption of telemedicine by multiple stakeholders; without the pandemic, this would likely not have happened.

Investment in digital health and virtual care continues to accelerate. The total venture capital investment into the digital health space in the first half of 2021 was nearly USD 15 billion, which is more than the investment in 2020 ($14.6 billion) and nearly twice the investment in 2019 ($7.7 billion) (Krasniansky et al. 2021; Bestsennyy et al. 2021). This investment was expected to double by the end of 2021. Since the pandemic, government and non-government organizations (NGOs) around the world have also invested significant resources in funding research related to telemedicine and digital health. Additionally, government, industry, and academia continuously promote innovators from different walks of life to create innovative businesses, revenue streams, and clinical models that are adaptable to the nature of telemedicine and digital health. This has strengthened a global ecosystem for the widespread introduction of telemedicine and digital health technologies.

3.4 The Future of Telemedicine and Final Thoughts

We are still far from the end of the pandemic; even with improved vaccinations, therapies, and preventive health strategies, and perhaps more than ever, healthcare systems will rely greatly on digital health and virtual care practices going forward. Patient-centered strategies should be designed by multi-disciplinary teams that include not only stakeholders in healthcare but also others such as engineers, designers, computer scientists, entrepreneurs, investors, regulators, and payers among others. The epidemic has leveled the world and even many powerful nations have struggled enormously. Some countries, big and small, which have proved to be nimble and agile, have adopted telemedicine and virtual care-friendly practices, and are being more successful in prevailing over the pandemic challenges. Even for them, they would have hardly ever considered adopting those practices only a few years ago.

In many ways, we design our future, and it has become clear to most healthcare leaders that telemedicine is a core pillar of any future healthcare system; hence, strategies must be crafted to support virtual care practices. Only innovations that make economic sense will have universal adoption and become self-sustainable (Rivas 2018; Rivas 2020). Therefore, only if achievable reimbursement strategies are implemented can telemedicine and digital health innovations be maintained. Unfortunately, many seem to forget this lesson as in the case of preventive care not being funded, resulting in suboptimal preventive care. We hope that virtual care will be reimbursed universally as well as in-presence clinical care. Only then will widespread adoption become a reality.

All insurance care plans, even basic ones, will include virtual care and digital health coverage, and even some incentives for telemedicine visitations as opposed to in-presence ones. These schemes would also offer lower premiums but, most importantly, greater patient convenience. Those programs will also include a much

bigger virtual care provider network compared to existing ones as consultations will be done across geographical or even international boundaries. Synchronous and asynchronous consultations will take place among patients and care providers, and access to personal electronic health records will be universal. Blockchain will maintain security and privacy of all personal health information. Technologically, better multi-system integration should take place, allowing diverse platforms to smoothly interoperate with each other, especially with personal medical record systems.

Telemedicine represents a one-quarter trillion-dollar economic opportunity that will only become a reality if healthcare systems, including their leaders and stakeholders, follow this roadmap collectively, and with a common vision in mind. Many challenges will remain prevalent, but many have been greatly lessened by the reactive response to the COVID-19 pandemic.

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Chapter 4
Introducing Computer Vision into Healthcare Workflows

Candelaria Mosquera, María Agustina Ricci Lara, Facundo Nahuel Díaz, Fernando Binder, and Sonia Elizabeth Benitez

Abstract A wide range of methods and algorithms elaborated over decades by scientists from diverse fields—such as artificial intelligence, statistical learning, and computer vision—led to the development of automated systems that are able to mimic or assist health specialists in both routine and complex tasks related to medical images, such as identifying a pathological finding on a chest X-ray or contouring a tumor on an magnetic resonance image.

Although the high performance of these systems has been reported in an ever-increasing number of scientific studies, their introduction into daily clinical workflows is still challenging. A careful design of the implementation pathway is imperative to achieve a successful impact for healthcare actors (physicians, patients, or healthcare providers, among others). This implementation takes place at the intersection of machine-learning engineering and medicine, which makes the deployment of these systems into real clinical settings an inherently multidisciplinary task.

In this chapter, we explore the current context by describing the main definitions, chief challenges, and existing solutions of each step involved in the process. Firstly, we illustrate how quality image datasets are key to obtaining robust models in algorithm development. We then describe the role of validation studies: the evaluation of the ethical and legal aspects of artificial intelligence in the medical imaging field is

C. Mosquera (✉) · M. A. R. Lara
School of Engineering, Universidad Tecnológica Nacional, Buenos Aires, Argentina

Health Informatics Department, Hospital Italiano de Buenos Aires, Buenos Aires, Argentina
e-mail: candelaria.mosquera@hospitalitaliano.org.ar

F. N. Díaz
Radiology Department, Hospital Italiano de Buenos Aires, Buenos Aires, Argentina

F. Binder · S. E. Benitez
Health Informatics Department, Hospital Italiano de Buenos Aires, Buenos Aires, Argentina

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even more incipient than the technologies themselves. This assessment is key to devising appropriate regulatory frameworks adapted to the particular characteristics of these technologies in order to adequately audit the processes involved. Then, we discuss the integration into health informatics systems focusing on how and what approaches exist to walk this last mile of the introduction of computer vision into healthcare workflows. Finally, we summarize the current state of development and application of these tools and then point out some of the future directions in this area.

Keywords Computer vision · Medical imaging · Artificial intelligence · Clinical implementation

4.1 Introduction

Medical imaging is a fundamental tool in most current diagnostic processes, as it provides anatomical and physiological information of the different regions of the human body by means of minimally invasive techniques for the patient. Although these techniques have existed since the experimental research on X-rays by Wilhelm Roentgen and Nikola Tesla towards the end of the XIX century, the technological and computer advances that followed gave rise to a large number of acquisition techniques, which generate diagnostic images in greater quantity and of higher quality and complexity.

In turn, recent trends in precision medicine, which aims to delineate patient subtypes according to their disease mechanisms and their particular response to therapies, demand greater diagnostic precision in the analysis of medical images.

These factors lead to an increased workload on physicians interpreting and analyzing the images, who are increasingly overburdened by these tasks. This problem is one of the driving forces behind the application of computer vision (CV) using artificial intelligence (AI) in the field of medical imaging, with the ultimate goal of generating tools to assist and support clinical decision-making.

This chapter describes the intersection of CV and medicine, focusing on the deployment of CV systems into real clinical settings: we will describe the current context in the steps involved to achieve implementation into clinical practice, depicted in Fig. 4.1 (i.e., algorithm development, validation studies, and integration to health information systems), including the main definitions, chief challenges, and possible solutions.[1] Finally, we explore the current situation worldwide by evaluating CV systems that are already being used at health centers in their daily workflow.

[1] The analysis of these subjects is based on the book "*Inteligencia artificial en imágenes médicas*" (Mosquera et al. 2021), written by the authors in Spanish, which provides a more detailed description of this chapter's content.

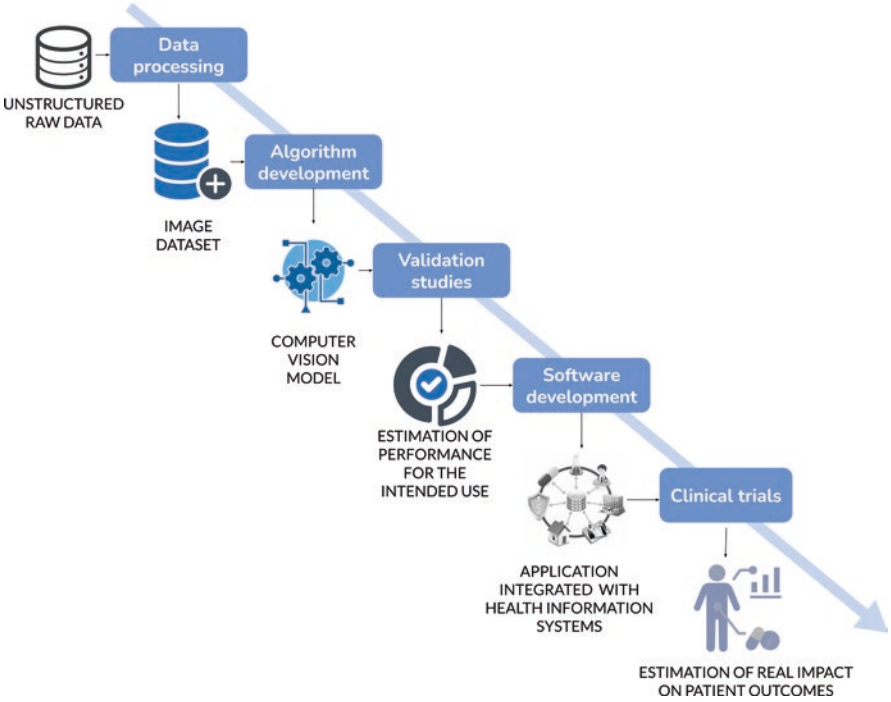

Fig. 4.1 The process of introducing computer vision into healthcare workflows

4.2 Computer Vision

CV is a set of methods and algorithms that attempt to acquire, process, analyze and understand images of the real world, seeking to simulate human visual perception and understanding. CV is employed in a large number of applications, which can be categorized according to the type of task to be performed. The main tasks of computer vision include:

1. **Image classification**: assigning a single label to an image. For example, classifying whether a chest X-ray has pathological findings or whether a skin lesion is a malignant melanoma or a benign nevus.
2. **Object detection**: locating and classifying objects in an image, considering that the same image may contain multiple objects of multiple classes. In other words, the image is not given a unique label. An example in medical images is the detection of cells in histological images or detecting findings that may have multiple locations in the same image (e.g. multiple rib fractures in a chest X-ray).
3. **Segmentation**: assigning a class to each pixel in the image. Possible classes include the categories of objects to be detected and, generally, also a class corresponding to the background. In medical images, for example, the aim is to

segment different anatomical structures or lesions, separating them from the background. There are two types of segmentation: semantic segmentation, where a label is assigned to each pixel of the image corresponding to one of the classes under consideration; and instance segmentation, where objects are detected individually and a class label is assigned to each object.

4. **Others**: image-generation, super-resolution, image retrieval, image reconstruction, image registration, among others.

Deep Learning (DL) took a firm foothold in CV when convolutional networks outperformed other methods in benchmark competitions of image-analysis. In 2012, in the famous ImageNet competition (ILSVRC, ImageNet Large Scale Visual Recognition Challenge (Krizhevsky et al. 2012)), a convolutional network obtained an error metric on the image classification task that far surpassed previous performances. Deep learning enabled CV to advance at an unprecedented speed, solving pattern recognition tasks that had previously failed to be automated (Esteva et al. 2021).

4.3 Algorithm Development: a Relation Between Useful Datasets and Robust Models

Algorithm development in the context of CV for medical imaging can be understood as the creation of an informatics tool that can process a medical image and generate a result of interest. The building of these tools involves many stages, starting with the identification of a problem to solve, the construction of image datasets, the use of this dataset to train AI models, and the evaluation of their performance. Finally, if the intention is to deploy the algorithm into clinical practice, validation studies that assess AI performance in a context closer to the real world should be performed, as well as integration into healthcare workflows. These later steps are covered in the following sections.

The first step when starting an AI project should be an extensive analysis of the current state of the art on the topic, to guide the definition of the project's scope and objectives, focusing on clinically relevant applications by identifying bottlenecks and promising methodologies to define the scope and final application of the development. The feasibility of a project depends largely on the availability of a useful image dataset.

4.3.1 Preparing Image Datasets

Before medical images can be used for the development of an AI algorithm, certain steps need to be taken. An initial requirement is typically the approval from the local ethical committee and the design of data collection strategies that address

deidentification to comply with data privacy regulations. Most health care systems are not adequately prepared to collect large amounts of medical images, as medical data is often stored in disparate silos (Esteva et al. 2021).

Furthermore, adequate curation, analysis, and labeling of images are critical to achieving high-impact robust algorithms. Adequate clinical image data for the training and testing of algorithms implies both a sufficient number and an acceptable quality of images and annotations, and this is considered a chief obstacle. Although methods that can take advantage of limited data are now being explored by the research community (i.e., semi-supervised or weakly-supervised techniques), the widely adopted fully supervised AI methods still require images to be associated with a ground-truth diagnosis (Willemink et al. 2020). This ground-truth can be annotated through automatic methods (such as parsing of radiology reports) or expert review, and it is task-dependent: it ranges from assigning a class or category for the whole image (classification) to delimiting a bounding box (localization or object detection) or performing a manual delineation on the region of interest (segmentation). In the context of radiological screening, these three tasks can usually be different solutions for the same problem, differing in the level of visual interpretability obtained and the annotation effort implied in building a dataset. In particular, the detection of a pathological finding can be learned through examples with weak labels, as a classification problem; or through examples with stronger labels, such as bounding boxes or masks. With these stronger labels, explicit information of disease localization is provided to the model, so similar screening performance could be achieved with a smaller dataset size for training. However, the annotation effort per image involved in the preparation of a dataset also increases as the label strength increases. A usual challenge for health AI teams when addressing the automated detection of radiological findings is dealing with the trade-off between label quality and feasibility considerations (as better labels require more resources), to determine an optimal dataset size. In the medical context, the need for specialized healthcare professionals for data curation and the implications of using sensitive and confidential information in terms of security and privacy are primary obstacles in dataset building.

To reduce the costs associated with collecting and labeling data, developers can apply transfer learning—in which an algorithm is first trained on a large and unrelated dataset (e.g., ImageNet) and then fine-tuned on a dataset of interest (e.g. medical)—, or techniques to generate synthetic data, such as data augmentation and generative adversarial networks (GANs). Recently, methodological alternatives have been explored by the research community, such as weakly-supervised learning —in which soft labels are used to train more complex tasks—, self-supervised learning —in which implicit labels are extracted from data—, or vision transformers, a recent technique whose novelty is not using the widely adopted convolutional neural networks (Matsoukas et al. 2021).

The construction of large, high-quality, heterogeneous and reliable datasets is crucial for the development of robust DL models.

4.3.2 Training Robust Models

An important challenge when working with image data is the need for **large computation power**. Images are high-dimensional data, as they are essentially arrays of hundreds to millions of coefficients called pixels (2D) or voxels (3D), which poses obstacles in their transmission and storage. The size of a medical image dataset is often between hundreds of gigabytes to terabytes, depending on the number of samples in the dataset as well as its dimensions (height, width, depth) and modality (2D or 3D, color or gray scales). Modern technologies for storing and accessing this data include cloud solutions and parallel processing. Moreover, implementing DL methods for image processing requires the computation of a large number of mathematical operations during the training phase, which is the most demanding stage in terms of computational resources. Many strategies have been adopted by CV researchers to address these issues, such as mini-batch optimization and image preprocessing. The use of graphics processing units (GPUs) becomes crucial to train algorithms in reasonable time spans. This technology—a specialized processor with dedicated memory—allows parallel processing of operations, making the development of AI models faster and more efficient.

Another challenge to consider when training models that are to be deployed in real scenarios is their generalizability: the degree to which the algorithm gives consistent outputs for inputs of different distributions. The robustness of an algorithm is determined by assessing whether its performance level is maintained in new samples that were not used during its training. Two important phenomena could compromise model robustness: domain shift and bias.

Domain shift refers to a variation in the target domain (i.e., real-world data) relative to the source domain (i.e., the data employed to train the model) (Choudhary et al. 2020; Subbaswamy and Saria 2019). This usually results in a decrease in performance, because machine learning algorithms trained with supervised learning assume that training samples are independent and identically distributed to the target samples. Domain shift often occurs when the two sets of data are not extracted from the same image population, for example when models are trained with public datasets but evaluated with local institutional images, as this might have different image acquisition equipment or protocols or a shift in patient demographic and epidemiological characteristics. A simple example would be a model trained for detecting skin cancer with public datasets, which are composed mostly of patients with fair skin tones, that is evaluated in a population with intermediate to dark skin tones. In general, training any CV model requires that the training data be representative of the data that the model will encounter in the final application.

Habitual medical behavior and the actions of humans usually have biases, often systematic. An algorithm that "learns" from such behaviors or decisions could reproduce and even amplify these biases: this is known as algorithmic bias. As previously mentioned, a model trained only with samples from Caucasian people is expected to perform worse in non-Caucasians, increasing existing social disparities. In the context of healthcare, the discrimination of models against certain individuals

or groups of individuals due to underdiagnosis, overdiagnosis, or disparate allocation of resources could have undesirable consequences for patients.

In the last few years, these ethical and legal concerns have been actively addressed by the scientific community, for example with domain adaptation techniques and fairness assessment methods. A research direction of particular interest is **federated learning**, which aims to learn a common, robust algorithmic model through distributed computing and model aggregation strategies so that no data are transferred outside a hospital or an imaging lab, alleviating issues related to data privacy, data security, and data access rights (Rajpurkar et al. 2022). In medical imaging, federated learning has been applied for brain segmentation (Li et al. 2019; Sheller et al. 2018) and discovery of disease-related biomarkers (Li et al. 2020), reporting a trade-off between model performance and privacy protection.

4.4 Validation Studies: The Path from Diagnostic Performance to Clinical Effectiveness

Despite the growth in published works about deep learning applied to medical imaging diagnosis, substantial implementation challenges have hindered the translation of these models into clinical practice and limited the potential of these advancements (He et al. 2019).

This may be due to the gap that exists between the "algorithm development lab" and the final application domain: healthcare processes. Several obstacles hinder the implementation of AI models in real healthcare processes, including, for example, the domain shift between the data used for training the models and the real images of the healthcare setting. As explained in the previous section, if the training samples have very different data distributions from the real scenario, the generalizability of the model will be lower than expected. The images often used in research and model development -high quality, preselected and reviewed images- contrast with those of health care processes -heterogeneous, sometimes messy, and unstructured.

Another obstacle to the implementation of CV models is the potential discrepancies between the goals that guided the model development and its **intended use** in the medical field. The intended use is the objective intention determined by the team responsible for the tool in clinical practice, which may use it for diagnosis, screening, staging, monitoring, prediction, or prognosis. In the in silico world, concrete, quantitative goals are often pursued, such as error minimization and accuracy. In the *on-site* clinical world, on the other hand, the objectives also have a qualitative component or include clinical parameters, such as the occurrence of medical events of interest. The flexibility and interpretability of the systems, for example, might be more valuable for specialists than their accuracy or classification error.

There is also a problem of adoption and adherence to behaviors, ubiquitous in medicine: knowing an accurate prediction or diagnosis does not necessarily imply that appropriate actions will be taken with that information. Thus, an algorithm may

correctly detect a medical finding of interest, but if the notification of this finding does not modify medical or patient behavior, its clinical impact could be null, despite its adequate diagnostic performance. Behavioral changes in physicians and patients are complex; the difficulties of moving from medical evidence to care practice predate AI and continue to be a huge challenge today (Emanuel and Wachter 2019).

Conceptually, the process of evaluating CV algorithms for medical imaging can be schematized as a continuum from technical laboratory evaluation, which focuses on the diagnostic performance of the algorithm in conditions similar to those in which it was trained, to routine implementation in a medical setting, which considers its utility and clinical impact. In this sense, some authors have proposed analogies with the evaluation process of drugs or other health technologies: the evaluation instances go through a process of progressive and controlled exit from the laboratory until they reach routine clinical practice. At each stage of this process, different domains or constructs are evaluated: the initial evaluation of the technical soundness of the algorithm gives way in later stages to epidemiological considerations on the clinical usefulness of the tool (Park and Han 2018).

4.4.1 Ethics

Ethical considerations play a critical role in the development and implementation of AI algorithms in imaging; implementing intelligent, automated algorithms into radiology practice carries risks of systematic errors and of amplifying complex social problems (Raymond Geis et al. 2019). Possibly, the most important challenge is that our understanding of the ethical challenges of AI in health and our responses to them are constantly changing.

Some of the most important specific ethical challenges in this field include (Char et al. 2018; Pesapane et al. 2018):

- Concern that algorithms reflect human biases in making diagnoses, predictions, and/or suggesting behaviors; for example, because of biases in the data with which they were developed.
- Concerns about the goals for which algorithms are trained. Algorithms can be trained to avoid sanctions or regulations. There is more experience with this problem in non-medical areas: for example, algorithms that assist in driving vehicles "learn" to circumvent speed controls or technical/environmental regulations. In the medical field, algorithms can be trained to pursue the economic interests of specific stakeholders: for example, recommending tests or referrals according to cost or profitability criteria, leaving patient care criteria in the background. An institution's Clinical Decision Support System (CDSS) could serve economic interests over care priorities.

- Accountability. For example, changes in the notion of personal responsibility, in the patient-physician vs. patient-health system relationship. One of the ethical issues under constant review is the new definition of responsibility. If an algorithm's recommendation results in harm to a patient, is the developing company liable? In a classic model, the medical staff has the "last word" and therefore bears the responsibility. That paradigm may need to be revised as the use of AI models in healthcare increases.
- Confidentiality and cybersecurity. Confidentiality has been in check since the emergence of electronic medical records (to the point that, to preserve patient confidentiality, physicians in some cases refrain from recording certain sensitive information in them (Char et al. 2018)). AI algorithms raise new confidentiality challenges because they require large amounts of data to be developed, often gathered from multiple sources and/or shared among multiple actors. Unlike other fields of AI development (as in AI-generated product recommendations), the development and validation of these tools for medical imaging requires research protocols approved by an Institutional Review Board to ensure that patient integrity, autonomy, and privacy are respected throughout the process.

These ethical considerations have regulatory implications, depending on the notion of medical device and its definition in the regulatory framework of each country. This chapter does not address regulatory issues directly; teams working on AI for medical imaging must familiarize themselves with local regulations for developing, testing, and deploying these tools. Today, there is a gray area in determining accountability for algorithm-driven decision-making. The authorization of AI systems by regulatory agencies such as the American Food and Drug Administration (FDA) has increased in recent years, although without the requirements usually demanded by these agencies before coming to the market. Unlike medical devices and drugs, AI systems often undergo modifications once implemented, so their dynamic nature limits the issuance of full approvals (Rajpurkar et al. 2022; Myers 2020). The challenge then lies in defining new frameworks that take into account the differences between these products, as well as considering data security and confidentiality in light of emerging proposals for simultaneous and shared development between institutions.

In an attempt to address these vast and complex ethical challenges, initiatives have emerged to include these notions in the development, validation, and evaluation processes of AI models (Spiegelhalter 2020), such as the FATML (fairness, accountability and transparency in machine learning) initiative and the FUTURE-AI (fairness, universality, traceability, usability, robustness, and explainability in artificial intelligence) recommendations (Lekadir et al. 2021). In particular, for CV systems the Radiological Society of North America (RSNA) published a Checklist for Artificial Intelligence in Medical Imaging (CLAIM) to outline good practices for researchers and developers (Mongan et al. 2020).

4.4.2 Interpretability and Transparency

The **interpretability** of AI models is defined as the ease with which a person understands the relation between the variables or features extracted by a model and its predictions (definition adapted from (Reyes et al. 2020)). An interpretable model, then, is one in which a human being can understand this relation. The concept of interpretability is not new and became more relevant with the development of more complex models: as DL models have hidden layers, it is difficult for a human being to understand how they reach their conclusions or predictions; a problem sometimes described as a "black box". Some authors point to the challenge of increasing the interpretability of DL models without losing predictive accuracy/diagnostic performance, arguing that there is possibly an inverse —albeit nonlinear— relationship between interpretability and predictive performance (Defense Advanced Research Projects Agency (DARPA) 2016).

Interpretability methods —strategies to increase the interpretability of an AI model— are on the rise and their use is considered necessary in many fields of AI application. Some methods to address this issue are designed to be present from the model development stages. Other interpretability methods operate directly at the model input or output (model-agnostic) level. These methods are usually easier to implement in practice (Reyes et al. 2020) and include some visualization strategies that mark or flag image elements that were important for the prediction, for example by making use of class activation maps overlapped on a medical image. In later stages of evaluation, interpretability is linked to the usability of the tool, acceptance, and adoption by users, and ultimately to its clinical utility.

The term **transparency** in AI models refers to two concepts. On the one hand, in a broad scientific sense, transparency refers to the model development/training process being accessible or auditable (Spiegelhalter 2020). A model trained with erroneously labeled data results in erroneous predictions or diagnoses. In this sense, communication about the data and methods used to train a model helps to ensure that its quality is controlled and possible errors are detected.

On the other hand, the term transparency refers to the degree of access to the model's "internal" information, as opposed to the "black box" model, in which the internal procedures are not accessible to the user. It is possible that a transparent model may be more interpretable, but this is not always the case: in very complex models, providing extensive information or even their programming code may not solve the interpretability problem (Spiegelhalter 2020). Moreover, transparency is not a prerequisite for interpretability, as we pointed out earlier for "model-agnostic" methods.

4.4.3 Clinical Trials

Medicine is a field of knowledge that prioritizes empirical evidence, and randomized controlled clinical trials are considered the gold standard method for evaluating the benefit of an intervention. Randomization (the random assignment of an

intervention among study participants) implies that groups of patients exposed or not exposed to the intervention of interest are "interchangeable" (Hernán and Robins 2019) at the time of study initiation and, broadly speaking, differences in clinical events between groups can be interpreted as an "effect" of the intervention. Like other medical interventions, AI tools for imaging should be tested by randomized clinical trials to generate higher-quality evidence for or against their implementation in practice. Conducting prospective validation studies and randomized controlled trials that account for the efficacy of CV tools is essential to support their adoption (Rajpurkar et al. 2022).

It is still unclear how human performance varies when assisted by intelligent systems, so new study designs and evaluation metrics should be built to assess human-computer interactions and the impact of AI in real clinical scenarios. It is true that many classical diagnostic tests were historically introduced into clinical practice without randomized trials of their clinical impact. However, many AI tools do not only offer data to be judged or critically interpreted by health professionals —like classic diagnostic tests—, but also add elements of clinical judgment or even suggestions for specific behaviors. Thus, AI algorithms could affect medical decisions more substantially than classic diagnostic tests (Angus 2020), further justifying their rigorous evaluation by randomized trials.

Examples in the literature of randomized clinical trials of AI are scarce at the time of writing this chapter. Their execution faces both the challenges inherent to the implementation of AI in healthcare (development of algorithms, software to acquire data —sometimes in real-time— and integration into health information systems, training of professionals, etc.), as well as general challenges of clinical trials (organizational, human resources and materials). In addition, there are challenges specific to the field of AI in health:

- As in the rest of AI research studies in health, it is difficult to choose and measure relevant events to compare patients exposed and not exposed to AI: many times, it is a challenge to transcend intermediate or process events and measure clinical events (outcomes) focused on the patient or overall safety (Angus 2020). For example, in AI used for intraoperative blood pressure monitoring (Wijnberge et al. 2020) it is often easier to measure intermediate events such as the number of times anesthesia specialists take active action on an algorithm alert than to measure the medium- or long-term deleterious effects of operative hypotension and elucidate whether the tool reduces them.
- So far, research study designs have focused on algorithms with fixed parameters (invariant, locked algorithms) already trained, and not on algorithms that actively learn during the development of the study. In this second case, methodological difficulties are added: assessing the potential impact of a tool that may have different effects throughout the study (as it "learns") brings additional statistical and methodological challenges.

Despite these challenges, the field of randomized clinical trials of AI deserves to be explored; its contributions to the implementation of AI tools in healthcare are likely to continue growing in the coming years. In this regard, two guidelines for designing and reporting interventions using artificial intelligence algorithms were

published: SPIRIT-AI (Cruz Rivera et al. 2020) and CONSORT-AI (Liu et al. n.d.). These guidelines were developed by international multidisciplinary groups and validated by consensus using the Delphi method with volunteers from the scientific community. Adherence to them is not mandatory, but highly recommended, both for newcomers to the field and for advanced researchers.

4.5 Integration to Health Information Systems: What and How

AI in medical imaging is not new. It has been particularly explored in data-driven disciplines, such as radiology, pathology, and ophthalmology, among others. In applications where images may contain clinically meaningful information sometimes imperceptible for human eyes (Rajpurkar et al. 2022; Syed and Zoga 2018), pattern recognition and pixel-level analysis carried out by AI models can help by raising alerts and capturing the attention in difficult cases for the user. Ultimately, it may help to deliver a better standard of care and improve cost-effectiveness (Helm et al. 2020). This research field has been widely explored, and even though there is still a long way to go before the implementation of CV systems becomes a reality for healthcare centers all over the world (Rajpurkar et al. 2022), there are currently some systems that have already been introduced into healthcare workflows. Technical and human-centered challenges still lie ahead. An implementable system implies much more than a trained and validated algorithm. In this section, we describe the possible applications in healthcare scenarios (what) and the steps to accomplish a successful implementation (how).

4.5.1 What

Clinical AI is intended to collaborate in one (or several) of the tasks performed by health personnel. In the interpretation of medical images, this occurs fundamentally within the category of CDSS (Kohli et al. 2019). A CDSS analyzes the information and collaborates with the health team, but does not make the final decision.

Based on intended use, CDSS in images are divided into computer-aided detection (**CADe**), computer-aided diagnosis (**CADx**) and computer-aided triage and notification software [**CADt**] (Food and Drug Administration 2012; Firmino et al. 2016). Nevertheless, this division is not restrictive as a tool can perform one or more of the above, provided that this is made explicit in the intended use.

CDSS represent a paradigm shift in current medical care. These tools are designed to help sift through vast amounts of digital data and suggest next steps for treatments, alert providers to available information they may not have seen, or spot potential problems such as dangerous drug interactions; often integrated into the

electronic medical record to streamline workflows and leverage existing data sets, useful in creating intuitive, easy-to-use, and effective protocols for alarms, alerts, and decision pathways (Sutton et al. 2020).

The acronym CAD, for computer-aided diagnosis/detection, was initially used to refer to computer-aided detection or diagnosis interchangeably. With the advent of recent advances in AI it became necessary to distinguish between CADe, CADx and CADt.

Basic research and early development for traditional CAD dates back to the 1960s, culminating in FDA approval of a CAD for mammography in 1998 (Fujita 2020). In 2016, this CAD was applied to 92% of screening mammograms in the United States (Gao et al. 2019). The traditional CAD showed a series of disadvantages throughout its implementation, including high development cost, high rate of false positives (with its consequent increase in the rate of unnecessary biopsies), not always being effective in clinical evaluation, difficulties in workflow and cost-effectiveness, and limitation to specific injuries (Land Jr et al. 2006).

The initial results in the evolution of traditional CAD, framed in the so-called "third wave of AI", show promising improvements in the above-mentioned issues, because they use deep learning techniques (Fujita 2020). This evolution entails a diversification of the intended use (CADe, CADx, CADt) and poses a final unsupervised step (unsupervised computer-aided detection/diagnosis [uCAD]).

A CADe is used for the detection of possible anomalies or pathologies in the images. The system can mark specific areas of the image to attract the attention of the operator/reader, but do not delve into the analysis of the etiology. This information is received by the doctor who must analyze the study as a preliminary reading, who may or may not agree with the CADe report. An example of CADe is a tool for the detection of pulmonary nodules on chest radiographs.

A CADx adds to the detection of possible anomalies the evaluation of said finding, suggesting a specific diagnosis or a series of differential diagnoses, collaborating in its characterization. Therefore, in most cases, a CADx includes the instance of a CADe. Following the previous example, a CADx can offer the prediction about the probability of malignancy in the pulmonary nodule detected by CADe. The association of the two tools is recorded as CADe/x.

Computer-assisted triage and reporting refers to tools intended for the selection and classification of patients to prioritize reading or attention, optimizing the use of available resources. A CADt will select those cases with potential abnormalities (Food and Drug Administration 2012). An example of CADt is a tool that performs an analysis of chest radiographs and prioritizes in the worklist those in which it detects potential findings.

4.5.2 How

The real impact of medical image analysis through AI lies in the possibility of assisting in the resolution of unmet clinical needs. In this sense, **multidisciplinary work** is essential (Cosgriff et al. 2020): the professionals who assist patients,

together with specialists in Diagnostic Imaging, know the difficulties in the diagnostic process and the traditional analysis of images; whereas the technical team of biomedical engineers, bioengineers, systems engineers, developers, and data scientists know the capabilities and limitations of available technologies; and specialists in Health Informatics can supervise the development process with a clinical vision while focusing on the implementation and the end-user experience.

The integration of AI models for the analysis of medical images into healthcare workflows requires the involvement of several components of the health information systems (HIS). The current software development paradigm of microservices determines that communication between software components is done through web application programming interfaces (APIs). An important step for the deployment of CV algorithms is their integration into an API framework. The machine learning community works mainly with Python as programming language and the best-supported packages for deep learning and data science are Python-written libraries, such as Tensorflow (by Google) (Tensorflow 2022), Pytorch (by Facebook) (PyTorch 2022), or Scikit Learn (Scikit-learn 2022). The translation of the finished algorithms to an API component is simplified by using Python API frameworks, such as Django (Django 2022) and Flask (Flask 2022).

To access medical images in an automated, secure, and protocolized way, software architecture should include a connection to the Picture Archiving and Communication System (PACS). Some applications might need real-time access to images: for example, a CV tool for analysis of chest x-rays should guarantee that its outputs are available within minutes, because this imaging study is usually evaluated by the physician in charge of emergency or hospitalized patients soon after it is acquired. On the contrary, the radiological report of other imaging studies such as mammographies or magnetic resonance studies is performed on a daily basis, where studies are evaluated by imaging specialists on subsequent days after acquisition. A CV algorithm that assists in the interpretation of such images can process studies in a scheduled batch at a specific hour of the day.

Several preprocessing steps should be considered for a CV algorithm to work as expected in a real clinical scenario. Rule-based logic must be applied before extracting images from the PACS, to select studies of adequate modality (for example "FRONTAL AND LATERAL CHEST RADIOGRAPHY", "CONTRAST-ENHANCED ABDOMINAL COMPUTED TOMOGRAPHY", etc.) and setting (i.e.: emergency, out-patient, or hospitalized patients). Other preprocessing steps characteristic of computer vision pipelines include image resizing, rescaling, or cropping.

An important decision is whether to deploy systems onsite in local servers, on cloud platforms, or use a combination of both. Health centers should perform cost analyses considering the volume of images that will be evaluated periodically to choose the best option.

To achieve successful adoption of a new CV tool by physicians, the user interface should be integrated into the applications they use regularly, such as the electronic health records, the patient's personal health record, or the radiological information systems. Interface design should be user-centered and involve the final users in the

entire design process: from initial surveys and usability tests to auditing and monitoring stages of the final product (Rajpurkar et al. 2022). In this way, users get to know from the beginning what the system is expected to do, how it will do it, which of these activities may suffer changes or will be impacted by the incorporation of these tools, and what is expected from them in the interaction with it. The users' feedback can help improve the performance of the system and is crucial to guarantee its use and adoption.

Acceptance remains one of the biggest barriers to AI adoption, and users' involvement in the development process is key to overcoming this obstacle. Despite the fact that AI intervenes in our day-to-day lives through numerous applications and content recommendation systems, there is still a generalized lack of trust, mainly due to the "black box" nature of algorithms (Helm et al. 2020; Morales et al. 2021). Specialists can be afraid of being replaced when these tools are trained to solve some task in their professional environment, so concrete actions should be considered to encourage their engagement with these technologies, such as assertive communication, dedicated training, and change management. A good starting point is to promote a collaborative human-AI approach — in which technology "enhances and empowers" humans (Shneiderman and Human-centered 2021)— rather than the futuristic AI paradigm where computers outperform humans in certain tasks (Rajpurkar et al. 2022; Syed and Zoga 2018). Although it is not expected that AI will be able to replace experts in the near future, it is believed that those specialists who are not willing to adopt AI will be replaced by those who do. The incorporation of AI is not only aimed at reducing medical error and improving the time to diagnosis, but also at reducing the burden on the professional with the ultimate goal of bringing him or her closer to the patient (Myers 2020).

All in all, introducing CV into healthcare workflows goes far beyond algorithm training. Fundamental disciplines that should be involved include software development, health informatics, user experience analysis, interoperability, infrastructure, and coaching, as well as monitoring of task performance and user engagement.

4.6 Current State: Where Are We Standing?

4.6.1 The Scientific Community

The speed at which this discipline has moved forward is closely linked to the academic work of a scientific community that is constantly growing. Mainly, this area is nourished by methodological contributions made in sister fields such as computer vision and machine learning, which are then transferred to the application in medical imaging. In these fields, we can mention important conferences such as CVPR, ICCV, NeurIPS, or ICML. On the other hand, the intersection is also with the medical radiology community, with major conferences organized by large institutions such as the Radiological Society of North America (RSNA), the European Congress

of Radiology (ECR), or the Society for Imaging Informatics in Medicine (SIIM), among others. The integration of experts from both fields allowed the emergence of a new scientific community dedicated to the application of machine learning in medical imaging, with its own conferences such as MICCAI.

Another strategy that has encouraged more professionals to become interested in this discipline is the organization of online competitions, which generate a competitive environment through the awarding of prizes and rankings for winners and participants. The best known are the annual MICCAI competitions or those that take place on open platforms such as Kaggle. However, the number of teams participating in medical imaging competitions is significantly lower than in typical CV competitions. This could be due to the medical terminology adopted in the organization of such competitions. An adaptation to more common terms among the CV and machine learning community could help to popularize medical images competitions among these experts.

4.6.2 Commercially Available Products

Although the number of AI products that analyze medical images has rapidly expanded over the past 2 years, clinical implementation remains limited. In the Medical Imaging field, many radiologists seem willing to engage with AI tools and adopt them in their daily practice. van Leeuwen et al. (2021) have published a detailed review of commercially available products for radiology, with a search that resulted in 100 AI solutions with CE mark that are approved for clinical use in Europe. Their results show that there is a large number of products, and more than 65% were introduced to the market between January 2018 and April 2020, suggesting that this market is still in its infancy. This is seen in the fact that deployment and pricing strategies have not yet converged to a preferred standard. Some vendors offer multiple options (22/100), with subscription or license models being more prevalent than pay-per-use pricing strategies (56/100 and 28/100 respectively).

Scientific works on the impact of these tools in patient outcomes are also still scarce. Only 36 out of the 100 CE-marked products surveyed by van Leeuwen et al. have peer-reviewed works showing evidence for their efficacy. Moreover, they noted that in many cases similar products have been certified under different classes (for example, systems for large vessel occlusion detection, chest X-ray abnormality detection, or brain region quantification). A class I mark is obtained through self-certification, whereas a class II mark involves an external audit by a notified body.

Another interesting observation of their review is that most products perform a specific task. Only in the area of stroke and oncology, there are “suites” that aim to cover the whole diagnostic path. Radiology departments are thus forced to interact with multiple vendors in order to supply their whole AI needs, implying an

overhead of sales and contracts and requiring several procedures of training and technology integration. This is mitigated when the solutions are integrated into previously existing products by scanner manufacturers, PACS companies, or hospitals' Health Informatics Departments.

4.7 Future Directions

In the immediate future, efforts will be focused on the implementation of more policies to solve the controversies that emerged in the past few years, such as the misrepresentation of minorities in the datasets and the unintended errors in datasets' labeling (for example, as a consequence of the use of natural language processing systems for mining radiological reports). Although centralization and federated learning can help address these situations, new methods and techniques need to be developed to ensure fairness and domain adaptation. In addition, the lack of quality-labeled datasets is already being addressed through alternative learning paradigms, such as weak supervised and unsupervised learning.

The utility of AI for medical image analysis will increase as CV systems incorporate the fusion of different modalities of data (Morales et al. 2021) and work with a wider spectrum of semiologic findings and medical specialties. New challenges will emerge related to the management of massive amounts of heterogeneous data, but this will bring the AI-assisted decision-making process closer to the knowledge paradigm used by health professionals, who integrate knowledge from several sources of information (Rajpurkar et al. 2022).

Even though the focus has been set on interpretative applications, an increase in non-interpretative CV solutions is expected, including report worklist management, image correction, and synthesis, among others. Additionally, the use of intelligent systems through telemedicine will allow its use in remote areas that lack specialists, empower patients and encourage their self-care (Myers 2020).

Computer vision has the potential to transform healthcare delivery by reshaping image processing workflows, but its adoption on a worldwide scale depends on prior fundamental aspects such as the digitization of health information systems, especially in the case of less developed countries. The differential value of health institutions will lie in the constitution of transdisciplinary teams capable of making the most of their own resources —especially data— to advance in strategic lines of innovation, research, and development. The possibility of AI growth in medical imaging will also be linked to the institutionalization of formal education programs that foster academic and practical development in the field. The real importance lies not in creating AI products, but in ensuring that people have access to them (Myers 2020).

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Chapter 5
Technology-driven Solutions in Mental Health and Physical Well-being

Reem AlGurg, Faisal A. Nawaz, and Ammar Albanna

Abstract Mental disorders are increasing worldwide in terms of their prevalence and burden. Current healthcare systems are struggling to respond to the mental health needs of their communities, resulting in difficulties such as accessing healthcare services. Therefore, innovative mental health approaches are desperately needed to bridge this gap and enhance mental health. This chapter reviews the role of digital health innovations in mental health and well-being, including the role of technology in mental health screening, and predicting mental disorders. Furthermore, case studies of specific mental disorders such as the role of digital health in early autism diagnosis and anxiety disorders interventions are provided. Given the important connection between mental and physical well-being, this chapter also reviews the role of digital health in overall physical well-being. We also provide suggestions on how to move forward. Digital health augments well-being at the critical intersection of environmental, social, and personal factors that motivate healthy behaviors and cultivate sustained behavioral change. The goal is to foster confidence to better understand the relationships among physical activity including sleep and nutrition, and other health behaviors analyzed with the promise of this digital health revolution. This chapter also looks at different digital health applications; chatbots as well as Nutritional Tracking/Monitoring. The number of digital health solutions is on the rise in the post-pandemic era; this needs to be centered in the heart of healthcare delivery in order to lower the burden of disease screening and treatment.

R. AlGurg (✉)
College of Medicine, Mohammed Bin Rashid University of Medicine and Health Sciences, Dubai, United Arab Emirates
e-mail: reem.algurg@mbru.ac.ae

F. A. Nawaz
Department of Psychiatry, Al Amal Psychiatric Hospital, Dubai, United Arab Emirates
e-mail: Faisal.Nawaz@ehs.gov.ae

A. Albanna
College of Medicine, Mohammed Bin Rashid University of Medicine and Health Sciences, Dubai, United Arab Emirates

Mental Health Centre of Excellence, Al Jalila Children's Speciality Hospital, Dubai, United Arab Emirates
e-mail: AAlbanna@ajch.ae

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5.1 Introduction

The global burden of mental disorders is estimated at approximately $16 trillion by 2030 (Patel et al. 2018). Despite the advancements in prevention, diagnosis, and treatment, there remains a wide gap in awareness, funding, and accessibility to mental healthcare. Consecutively, the lack of mental health resources negatively impacts mental health outcomes and physical well-being. The role of important parameters to physical well-being such as sleep and nutrition have added to this syndemic health crisis. At this juncture, we are witnessing a rise in technology-enhanced solutions to various global health challenges. As the digital health industry grows in size with over $57.2 billion invested worldwide (The digital health sector set new records in 2021 for global deals 2022), the potential for scalable impact is revolutionary. The promising diversity in digital health technologies ranging from software-based to hands-on products is a boom for the health consumers' needs. This chapter dwells deeper into the current challenges, implications, and updates surrounding the mental health and physical well-being landscape through digital health innovations.

5.2 Challenges in Mental Healthcare

Mental disorders impact a large proportion of patients worldwide and pose significant challenges to healthcare systems (Rehm and Shield 2019). Furthermore, COVID-19 had a significant impact on the mental well-being of children, adolescents, and families, and brought mental health to the forefront of healthcare. Moreover, there is scarcity of trained mental health professionals worldwide creating a significant challenge in delivering mental healthcare services. Indeed, studies show that less than half of adolescents with mental disorders receive treatment (Costello et al. 2014) and more than half of youth with depression do not receive any intervention (The State of Mental Health in America n.d.). This problem is not limited to low income countries, as, for example, the USA requires to train many more professionals in order to meet its mental health needs (United States n.d.). The World Health Organization (WHO) has highlighted that lack of funding and services constitutes an important barrier in addressing the mental health gap (Keynejad et al. 2018). Henceforth, there is a need for innovative approaches that bridge the mental health gap. It is, therefore, not surprising that digital innovations have been implemented across different domains of mental health care. This section will focus on a few examples of how technological advances helped improve mental health, including early identification and treatment using different innovative methods.

5.3 Role of Digital Mental Healthcare

5.3.1 Mental Health Screening

Screening for mental disorders in primary care offers an important gateway to mental health services, and time constraints are among important barriers. Using technology may very well support primary care physicians as several studies showed that enhancing screening at Primary Health Centers with applications is feasible and may reduce time and increase accessibility across different countries (Diez-Canseco et al. 2018).

One of the important areas of clinical care is being able to predict which children will develop mental health symptoms later in life, as this will open the doors for early intervention and prevent future severe negative outcomes. Using a comprehensive Swedish data registry, Tate et al. explored the possibility of predicting mental health problems among adolescents using machine learning techniques, rather than the traditional statistical methods (Tate et al. 2020). They reported that although model performance varied, their results indicated non-significant superiority for the random forest model (AUC = 0.739, 95% CI 0.708–0.769), and support vector machines (AUC = 0.735, 95% CI 0.707–0.764). Although their models were not suitable for clinical use, it serves as a model for future studies to predict general mental health outcomes.

5.3.2 Digital Health for Mental Disorders

Autism Spectrum Disorder (ASD) is a heterogeneous developmental disorder, and innovative approaches such as artificial intelligence (AI) and machine learning in particular have been applied in ASD (Anagnostopoulou et al. 2020). One challenging aspect in ASD is that the diagnostic process is time-consuming and labor-intensive, and therefore many studies focus on either reducing the diagnostic time or substituting it with different phenotypic approaches. As an example, Chen et al., using resting-state functional MRI (rs-fMRI) scans from the Autism Brain Imaging Data Exchange (ABIDE), comparing matched samples of children with ASD (n = 126) with typically developing participants (n = 126). They reported high accuracy utilizing different machine learning methods (Chen et al. 2015). In view of reducing diagnostic time, a different study that analyzed data from a widely used structured ASD assessment, the Autism Diagnostic Observation Schedules (ADOS), machine learning was used to study if algorithms can classify people using abbreviated characteristics of the ADOS to identify children as ASD or not (Kosmicki et al. 2015). Authors reported around 98% of accuracy and concluded that with machine learning, a smaller number of behaviors can achieve high validity for ASD diagnosis. Mobile applications utilizing AI have been studied in ASD. For instance, Shahamiri et al. studied a mobile application that captures data from a questionnaire and

interfaces with a Convolutional Neural Network (CNN) trained with a database and previous ASD cases, and reported higher accuracy, sensitivity, and specificity when compared with usual methods of ASD screening (Shahamiri and Thabtah 2020). Again, the goal was to improve screening and diagnostic ability in a shorter period, given time constraints of clinicians. Despite these examples, it is important to acknowledge that this area of research is in its infancy and further studies are needed in order to assure that the tools provide acceptable psychometric properties and are applicable in real life. Indeed, Da-Yea Song et al. highlighted this point in a literature review of the use of artificial intelligence for ASD screening, emphasizing that despite that studies show high psychometric properties, the feasibility and real-world applicability is faced with challenges that needs to be addressed before AI can be implemented in ASD care (Song et al. 2019).

ASD is not the only area, as novel approaches have been implemented across a wide range of mental health conditions. Anxiety disorders are amongst the most prevalent mental disorders. In a recent review, Silk et al. showed that mobile technologies, including apps, have an important role in augmenting treatment or providing stand-alone treatment for anxiety disorders (Silk et al. 2011). As an example, Anxiety Coach is an empirically supported application developed by Mayo Clinic that provides assessments and educational material related treatment (Carper 2017). Another area in anxiety disorders is Virtual Reality (VR), as VR can simulate anxiety-provoking situations and aid as a treatment modality. These VR situations have been shown to be very comparable, based on biological data such as heart rate variability and saliva cholesterol, to real life situations (Kothgassner et al. 2016). Studies have reported lower refusal rate with VR exposure, compared to in vivo exposure, suggesting VR may be used to increase access to mental health interventions such as exposure-based treatments (Garcia-Palacios et al. 2007).

5.3.3 Pandemic-driven Digital Mental Health Services

There is worldwide appreciation of the mental health impact of COVID-19 pandemic, that correlates with many factors including the fear of infection, losing loved ones, as well as related to the public health measures such as keeping physical distance from others, staying home and school closures. These same factors supported an expansion of digital mental health services (States' Actions to Expand Telemedicine 2021). This was partly due to the transition to tele-health, in light of the interruption of face-to-face interactions in many areas of the world (Shah et al. 2020). Indeed, the pandemic led to a rapid increase in mental health services within a few weeks of the onset of the pandemic (Sharma et al. 2020). The current pandemic also provided new possibilities for web-based and app-based digital mental health interventions such as, for example, an individually tailored web-based cognitive behavioral therapy program that demonstrated preliminary evidence of effectiveness at reducing stress, and anxiety symptoms (Aminoff et al. 2021).

5.4 Physical Well-being

Understanding the implications of poor mental health will be incomplete without exploring the role of physical health as co-dependent synergists. Up to 50% of cancer patients suffer from a mental illness. Moreover, treating symptoms of depression in cancer patients has been shown to improve survival time. Similarly, the risk of having a heart attack is more than twice in patients with depression as compared to the general population; further, depression increases the risk of death in patients with cardiac disease (Rosenstein 2011).

In a population-based cohort study of more than two million New Zealand citizens who were followed up across 3 decades, mental disorders were associated with the subsequent onset of physical disease, the accumulation of physical disease diagnoses and associated health care use and costs, and early mortality (Richmond-Rakerd et al. 2021). This impact of mental health on physical health and vice versa is a vicious cycle that worsens the existing burden of diseases. The emphasis on prevention is vital to leveraging the goals of sustainable development in healthcare. Awareness of risk factors that increase the likelihood of developing illness is crucial. This brings us to the need for focusing on well-being as a protective factor for a healthy life. It also requires a holistic approach of incorporating both physical and mental well-being as complementary aspects of our daily routine.

5.4.1 The Key Areas of Population Well-being: Sleep and Nutrition

The WHO constitution states: "Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity." The essence of well-being comes from integrating activities within our lifestyle in the form of health-conscious behaviors. This establishes the connection of well-being with health and brings a continuum of care. There are various evidence-based practices to ensure mental and physical well-being of the population as a whole. For instance, mindfulness training has been associated with improved mental health in several high-stress career populations, while meditation-based well-being interventions have also been shown to have a positive impact on population health (Badger et al. 2008). Interestingly, there is growing evidence of changes associated with endocrine function after meditation with improvements in mental health outcomes (Pascoe et al. 2020). The same applies to physical well-being practices being key to improved health outcomes. This includes regular exercise, adequate sleep, and following health-conscious eating as driving forces to optimize longevity and quality of life (Loef and Walach 2012). While prevention is better than cure, we are yet to fully embrace well-being as an active part of our lifestyle due to various hidden challenges. For instance, lack of education surrounding well-being practices and the health implications of not following such interventions are potential reasons for these challenges. The pandemic has

further exacerbated the mental and physical demands during unprecedented times, which inevitably impacted the basic necessities to healthy lifestyle. This is burdened by isolation, increased social media use, sleep dysregulation, financial loss, and health disparities that have collectively submerged the state of healthcare today. Needless to say, the availability of resources to tackle this global challenge is direly insufficient to meet the needs of population well-being. However, the environment built around negative lifestyle did not originate from the pandemic or in recent years. We have been plagued by chronic well being and sleep-deprived habits for far longer. With the main social determinants of population well-being, sleep and nutrition, it is key to focus on this area of need.

5.4.2 Impact of Sleep on Health

Poor sleep is known to impact a number of psychiatric conditions. Recent studies suggest that sleep can affect both the development and maintenance of different mental health problems ranging from poor cognitive performance to mental disorders including depression and generalized anxiety disorder (Scott et al. 2017). Lack of sleep is also associated with pathologies of heart disease and type 2 diabetes. According to the Centers for Disease Control and Prevention (CDC), a third of adults in the U.S. report that they get less than the recommended amount of sleep each night. The reasons for lack of sleep vary according to age groups. Younger people tend to lose sleep due to lifestyle and social factors. Other factors include eveningness in adolescence, electronics usage before bed, caffeine consumption, and poor sleep hygiene (Owens et al. 2014; Hershner and Chervin 2014). While the long term impact of sleep on physical and mental well-being has been documented over the years, the paradigm shift of environments, lifestyle, and lockdown measures during the COVID-19 pandemic have further worsened the sleep deprivation challenge. Sleep problems appear to have been common during the COVID-19 pandemic. This is noted by one in every three individuals reported to having sleep problems (Alimoradi et al. 2021). This poses an unimaginable risk to the future of well-being as the world rushes to gather more data to study its consequences to healthcare. Moreover, sleep hygiene may play an even bigger role in the COVID-19 disease burden due to the strong association of sleep deprivation with dysregulation of the immune system (Garbarino et al. 2021). All in all, this calls for a stronger need for understanding current sleep trends as a core mediator of well-being.

5.4.3 Impact of Nutritional Demands on Health

We are in the midst of a growing disparity in unhealthy lifestyles and consecutively impacting the prevalence of nutritional diseases. This is also affected by the lack of awareness around diet patterns with changing times. It has led to an obesity

pandemic through the known relationship between excess weight and comorbid conditions such as diabetes, increased cancer risk, heart disease, stroke, osteoarthritis, sleep apnea, liver, and pulmonary disease. Unfortunately, the impact of nutritional diseases negatively affects health systems on a bigger level, particularly in the lower and middle income countries. Multifactorial reasons are responsible for the complex interplay of genetic, physiologic, environmental, psychological, social, economic, and political domains. The rise in sedentary behavior is a major contributor to obesity. The sedentary lifestyle prevalent in modern society contributes significantly to the prevalence of obesity worldwide (Robinson 1999; Levine et al. 2000). Lower socioeconomic status also affects the needs of the population. This in turn increases food insecurities and prevalence of mental health conditions, either due to nutritional deficiencies or other environmental stressors. Among low-socioeconomic status families, controlling for income variation, food insecurity co-occurred with maternal depression (Melchior et al. 2009). With the main modifiable social determinants of population well-being as sleep and nutrition, it is key to focus at this intersection of healthcare.

5.4.4 Nutrition and Sleep Syndemic

Understanding the syndemic burden of sleep and nutrition on well-being is vital to devising practical solutions for monitoring, diagnosing, and treating preventable health conditions. The rising epidemic of obesity is closely followed by increased trends in sleep deprivation. Various studies have observed an association of short sleep duration and poor sleep quality as risk factors for obesity (Beccuti & Pannain 2011). Research has also shown that sleep deprivation also causes an increase in food consumption without a parallel increase in energy expenditure (Grandner et al. 2014). Furthermore, sleep deprivation also creates a tendency to prefer high-calorie foods with poor nutritional advantage and increased risk of weight gain (Greer et al. 2013). Sleep loss occurs not only as a result of conscious behavioral habits, but also due to medical conditions such as obstructive sleep apnea (OSA). There is sufficient evidence that indicates the importance of adequate nutrient consumption for sleep. This is seen in one study where lack of key nutrients, such as calcium, magnesium, and vitamins A, C, D, E, and K was associated with sleep problems (Ikonte et al. 2019).

5.4.5 Role of Technology in Physical Well-being

This well-established relationship between sleep and nutrition as part of well-being holds the potential for positive change just as much as its negative implications. Technology plays a pivotal role in shaping this balance and is often represented as the culprit more than a solution. While there is no doubt that technology has strongly

influenced these biopsychosocial factors to well-being through increased screen time amongst children and adults, increase in sedentary lifestyle, and lack of motivation to improve physical well-being, there is an untapped paradigm of promising potential with the same. This double-edged sword where the same technology with adequate innovation can help bring back well-being in society. We are on the forefront of this current wave of technology as various advances continue to arise in the digital health market with the synergy of sleep and nutrition at the core of health and well-being. Enhancing synergy of sleep and nutrition in order to enhance the core of well-being are the core functions of apps; examples of which include types of apps such as mood trackers; food trackers; sleep trackers and more recently specific disease management apps are increasing in number (Olsen 2021).

The gamification aspect of the apps along with connectivity to a database of like minded peers work as one of many incentives that are embedded within the apps, other examples of incentives that are used in health and wellness apps can be related to workplace; this would also work on opening up dialog with employers, as employees progress towards fitness goals can be provided to administrators through dashboard and reports that measure employees engagement on such platforms. Individuals use of app; organizational use of apps are all catered towards the same goal is to bring back health to society.

Current health technology allows for accurate measurements of heart rate, exercise time, distance, and estimated caloric expenditure, which is both accessible and user-friendly for the general population. This mode of health awareness is well-integrated in our daily lifestyle and serves as a medium for well-being checkups. It is therefore essential to create guidelines that target precise and quantifiable health parameters which in turn promotes individualized health optimization (Algieri 2022). Understanding the unpredictable nature of sleep patterns, diet, and other health behaviors over the past century have become a rising challenge worldwide (Hicks et al. 2019). The potential impact of digital health on physical well-being is hampered by various non-technical barriers. This is seen by the lack of transparency in the development of such technology which creates further insecurities related to privacy amongst the general public. The need for a common bridge of understanding is essential for collaboration between consumers, developers, and business stakeholders. This gap in digital literacy drives the motivation towards explainable technologies on a larger scale. It also brings forth the opportunity to harness the surge of health-centered data for sleep and nutritional interventions using digital technologies to advance healthcare delivery. This is made possible through a diverse range of innovations from wearables, biosensors, and mobile applications to name a few. Digital health augments well-being at the critical intersection of environmental, social, and personal factors that motivate healthy behaviors and cultivate sustained behavioral change. Our goal is to foster confidence to better understand the relationships among physical activity including sleep and nutrition, and other health behaviors analyzed with the promise of this digital health revolution.

5.4.6 Mobile Apps

With the advancement of technologies in size and process power, it has become possible to integrate various sensors and technologies to accessible consumer grade wearables. It has always been a challenge for health professionals to induce change in behavior of people and societies. The data acquired from wearable technologies can provide great insight into detailed behavior, social and personal factors that promote better living and lifestyle (Mustafa et al. 2022).

Although there has been a great amount of spread of use of these technologies accompanied with a very massive amount of data captured, yet their analysis and depth insight are not what the industry and professionals desire. The nature of this challenge is that it requires both data analysts and health scientists. Another challenge is the factor of trust of consumers, as the sharing of personal data is a very huge concern for many.

There is a surplus of health applications available to be used on most smart mobiles. These applications have attracted mostly younger populations even though they're targeted for adults, which can be reasoned to the extensive use of younger populations of social media and adaptation of new technologies such as Fitbit's and Nike fuel band. These devices provide data relating to heart rate, sleep and even water intake.

There has been a variety of wearable technologies that work hand in hand with health oriented applications. A study looked at the behaviors and factors that influence users of such technologies. Several points and factors were observed: First, for any change in behavior, a person must use it over a long period of time. Users go through periods of use followed by disengagement with this technology. It was realized by looking at the Azumio dataset that people when reengaging with a health application after not using them for a while, usually start from the stage they were at the beginning rather than continuing where they left off. Another observation is that those who use these technologies for long periods of time tend to be surrounded by fitness oriented people and are less active on social media in regards to showcasing these kinds of activities. It has also been shown that people that use smart scales often tend to have greater weight loss.

5.4.7 Wearable Technologies

Wearable technologies can extend their benefits of what is expected of them. Wearable technologies have encouraged self monitoring of sleep and physical activity levels without intervention of medical practitioners. Virtual assistants and virtual societies created in these areas act as support groups and methods of checking in on the elderly or disabled. The application of wearable technologies in healthcare is

fascinating. The Sunrise system, a coin-sized device attached by the sleep technician to the chin of the patient, is developed to be used for ambulatory diagnosis of OSA outside of a sleep center setting (Pépin et al. 2020). This technology allows for automatic identification of obstructive and mixed apneas and hypopneas or respiratory effort–related arousals by analyzing mandibular movement patterns. The portability and cost-effectiveness of this innovation can be a game changer for diagnosis in impoverished regions. In summary, wearable technologies have shown huge promise and results for self monitored behavioral improvements. The amount of data produced over a long time will open new doors to further research and observations never witnessed before at this scale and further details.

5.4.8 Nutritional Tracking/Monitoring

Widespread usage of wearable technologies, multiple sensors, large data sets of multiple types requires strong and deep analysis of the data to make meaningful observations. Recent evolution of AI algorithms and processing power and technologies have assisted in reaching better conclusions and sophisticated applications in medicine and nutrition. Although the latest technologies have lagged in their application in the field of nutrition, yet there are disruptive innovations that are close to becoming fruitful.

5.4.9 Chatbots

The final circle of technology based nutritional and well-being care is chatbots. Bots provide the interaction part that wearable technologies and health oriented apps need with the consumer. Chatbots are essentially a “conversational agent”, which means a program built to support and engage with humans by means of sound-related or text techniques. It supports systematic and documented knowledge dissemination and sharing. It can also provide consumer support and aid with mental and physical well-being. The fundamental design of chatbotchat bots are often centered around mimicking human-to-human text messaging interactions. By simulating a human-chat experience, chatbotchat bots can help build seamless conversations on the topic of need. The level of advancement in chatbotchat bot services can add-on to provide automated responses, internet-derived suggestions to user problems, including image-detection features in some cases. An interesting example of mental well-being innovation is called ESTORE (El Kamali et al. 2020). It utilizes a chatbotchat bot functionality in the form of text-messaging and voice assistant to provide mental health support to older adults. In this process and interaction, chatbotchat bots will also be a tool to collect nutritional care and complaints to help further enhance and research in the field. A food diary coaching chatbot called “Rupert” is

an app-based platform centered around offering personalized dietary support. It aims to regularly engage with users by maintaining a food diary and encouraging a dietary lifestyle that aims to reduce meat consumption for ecological reasons, and increase fruits and vegetables consumption for nutritional reasons. The study further concluded that 82% of the app users reported that Rupert allowed them to think and be aware of their consumption (Casas et al. 2018).

There is further work needed in understanding the personalized nature of chatbots and motivational factors surrounding user compliance. In conclusion, these solutions are ideal in a world where medical units and organizations are spread thin in times of crisis similar to the recent COVID-19 pandemic.

5.5 Conclusion and Path Forward

As the healthcare landscape continues to evolve in diverse ways, the trends in mental health and physical well-being have drastically changed over time. This has created an unprecedented gap in accessibility and monitoring of big data for vital health parameters. Technology has the potential to redefine the current challenges and support the transition to a digital health-optimized world. This can be made possible by focusing on patient-centered innovations that utilize the existing advancements for the existing mental health and physical well-being ecosystem. This calls for increased collaborations in digital health investment, research, and awareness amongst stakeholders along with the general community. The path forward with the acceptance of digital health can in turn lower the burden of disease screening, treatments, and the continuum of care. By keeping digital health solutions at the center of healthcare delivery, the future of pandemic-driven care fosters novel possibilities for fast-paced innovation.

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Chapter 6
Present Capabilities of Artificial Intelligence in Surgical Oncology

Raja R. Narayan

Abstract With many institutions incorporating algorithms and devices leveraging artificial intelligence into clinical practice, it is increasingly necessary for clinicians to become proficient in interpreting these resources to steward their integration. Oncologists have a great opportunity to benefit from integrating these resources to assist with better patient selection for targeted therapies and sequencing of treatment strategies. The development of large oncologic datasets has ushered in the opportunity to leverage big data to address these research questions as well, however, many clinicians may not understand how artificial intelligence platforms are developed or tested for their accuracy. In this chapter, a review of the most common branches of artificial intelligence are discussed including examples of how these platforms are developed or deployed in the oncologic setting. Finally, a caution is given on how the lack of regulation or the over-reliance on artificial intelligence platforms can be problematic.

Keywords Surgical oncology · Cancer research · Artificial intelligence · Machine learning · Deep learning · Neural networks

6.1 Introduction

Since the term *artificial intelligence* was coined in 1956, (Merriam-Webster 2022) rapid adoption of this growing discipline has created opportunities to enhance a variety of fields. With the relatively recent advent of big data and multi-center collaboration to create consortia of medical institutions, data-driven guidance for clinical decision making is readily becoming a reality. Surgical oncology is thus a field readily positioned for innovation with these tools to improve our understanding of

R. R. Narayan (✉)
Section of Surgical Oncology, Department of Surgery, Stanford University School of Medicine, Stanford, CA, USA
e-mail: narayanr@stanford.edu

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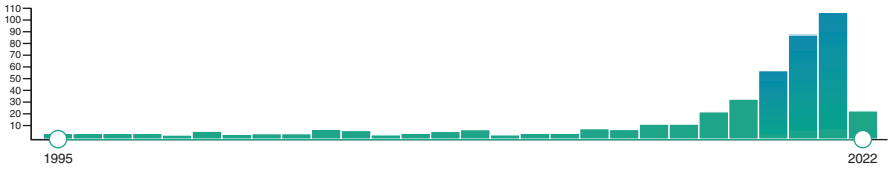

Fig. 6.1 Volume of Surgical Oncology clinical studies published incorporating "Artificial Intelligence" or "Machine Learning" indexed in PubMed from inception to April 1, 2022

patient selection and sequencing for the variety of therapies available to the modern oncologist. From the inception of PubMed in 1996 to April 1, 2022, over 300 articles have been published utilizing some fashion of artificial intelligence to investigate a clinical question pertaining to surgical oncology with an upswing seen in recent years (Fig. 6.1). With this trend expected to continue and even accelerate, it is essential that providers understand the various modalities of artificial intelligence, how they can be leveraged for oncologic research, and the limitations of its use. In this chapter, descriptions for the broad field of artificial intelligence and its subcategories are first defined, then a review of recent implementations in the field of surgical oncology are discussed, and finally limitations and cautions to the application of artificial intelligence in surgical oncology are noted.

6.2 The Use of AI in Surgical Oncology

6.2.1 Machine Learning

Artificial intelligence (AI) refers to any platform that can simulate human thought or behavior including problem-solving, recognizing images or words, or making conclusions based on patterns of data (Hashimoto et al. 2020). Machine learning is often conflated with AI but instead represents a major sub-category of programs that build their own knowledgebase from increasing amounts of data to create more precise conclusions about an output of interest. A machine learning program can thus learn from and respond to data in three separate ways. Supervised machine learning develops an algorithm from a training and testing dataset to predict an output of interest (Hashimoto et al. 2020). A training set is necessary for the program to identify an association between the input and output of interest whereas the testing set allows the program to gauge its performance on unseen data. Generally, a larger proportion of a dataset in a study utilizing supervised machine learning will go into the training set and the remainder in the testing set (e.g., 90% vs 10%). The testing set or validation set may also be further classified as an internal validation set (e.g., subjects included from the same dataset) or an external validation set (e.g., subjects included from a new dataset not used to train the algorithm). Unsupervised machine learning, however, represents algorithms that identify patterns within a

dataset. For example, a dataset of patients can be clustered into distinct subgroups that represent quartiles with respect to an outcome of interest. Finally, reinforcement machine learning describes the development of an algorithm that makes iterations to the performance of a pre-specified task as more data is introduced (e.g., text autocorrect, automated driving) effectively learning from successes and mistakes. The choice of using supervised, unsupervised, or reinforcement learning is thus dependent on the type of dataset to be utilized and the design of the question at hand.

Several techniques can additionally be employed using the above machine learning strategies. Classic machine learning utilizes features describing the dataset to perform a task or predict an outcome of interest, like independent variables predicting an outcome through regression analysis (Hashimoto et al. 2020). Laukhtina et al. utilized classic machine learning with least absolute shrinkage and selection operator (LASSO) regression (a modality that selects features predictive of an outcome of interest) to develop a nomogram predictive of cancer-specific survival for patients with metastatic renal cell carcinoma under consideration for cytoreductive nephrectomy (Laukhtina et al. 2022). Of 613 included patients, 65% were allocated to the training set to develop the nomogram and the remaining 35% served as the testing set or internal validation for the nomogram yielding a c-index = 0.644. Of note, this study reported the median cancer-specific survival to be 17 months where 99% of patients passed due to their metastatic disease underlining the importance of designing a study with a common outcome event to train an algorithm with. For rarer malignancies (e.g., pancreatic cancer) with even rarer subtypes (e.g., resectable pancreatic cancer), this may pose a challenge highlighting the need for multi-institutional collaboration. Random forest plots are a subset of classic machine learning that take a supervised approach to create a decision tree incorporating features to arrive at an endpoint or outcome of interest by determining the cumulative probability of that outcome (Fig. 6.2) (Kashyap 2019). This decision tree can either be constructed to perform classification and/or regression tasks. Rahman and

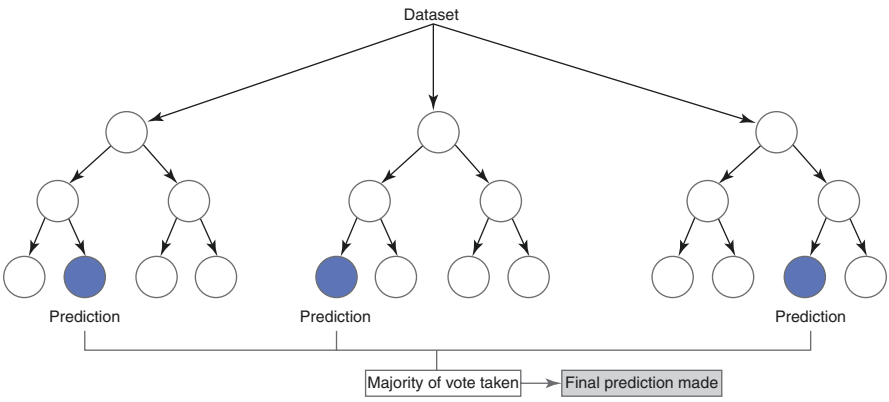

Fig. 6.2 Random Forest Decision Tree schematic illustrating nodes for classification or regression analysis leading to an average endpoint or outcome of interest

colleagues utilized random forest plotting to predict 5-year survival among 2931 patients with gastric adenocarcinoma undergoing curative gastrectomy from a multi-national audit dataset spanning England and Wales (Rahman et al. 2021). With a 5-year survival of 53%, the time-dependent area under the curve (AUC) for this period was 0.80 with a c-index of 0.76 based on a model incorporating 10 out of 29 evaluated clinical and pathologic variables. Moreover, other types of AI modeling can be included at various steps along the way for this decision tree.

For example, a k-clustering algorithm is a supervised learning technique that evaluates training data geometrically to categorize additional testing data in relation by plotting the Euclidean distance from the testing example to related training data. Depending on the number of groups or clusters of data to be attained, this could be targeted in comparison to a single point—1-nearest neighbor—or balanced on the weight of several points—k-nearest neighbors (Hastie et al. 2016). Yin et al. employed k-clustering when studying 14,134 cancer patients across five Chinese institutions to categorize nutritional status based on 17 core nutritional features (Yin et al. 2021). Herein, 75% were allocated for the training set and the remaining 25% for internal validation yielding four clusters based on nutrition status with a model AUC of 0.941. Similarly, support vector machines represent another type of supervised learning where classification and regression are utilized to cluster training data in space relative to hyperplanes (Fig. 6.3). Testing data incorporated thereafter are thus clustered in space based on their similarities or differences to the hyperplane (Toledo-Pérez et al. 2019).

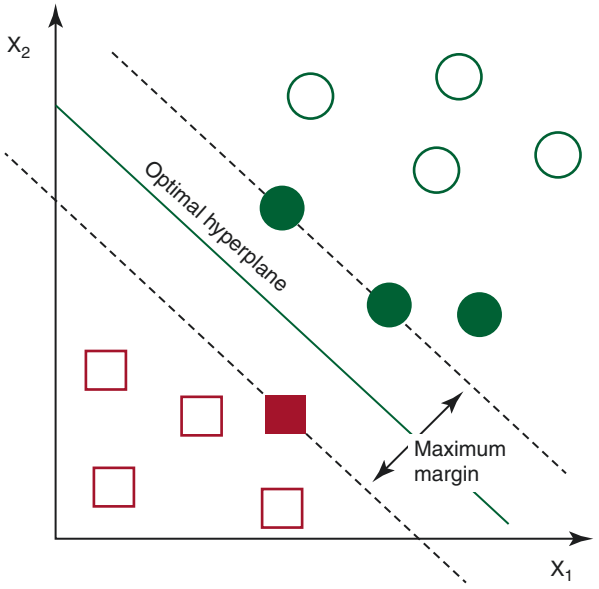

Fig. 6.3 Support Vector Machine classifying data in relation to the optimal hyperplane (solid black line), planes through support vectors (dotted lines), as well as support vectors themselves (colored in circles and square). The maximum margin between the support vectors is also shown (Toledo-Pérez et al. 2019)

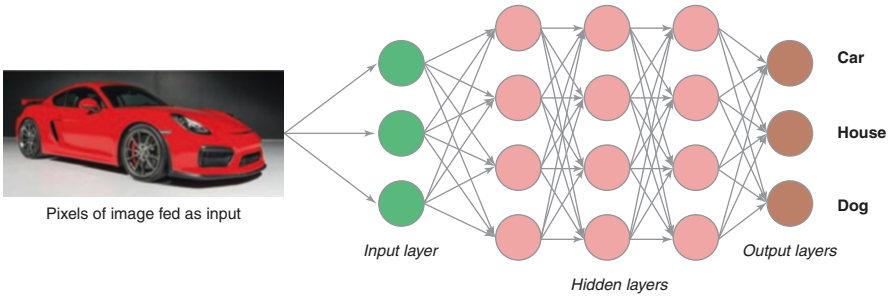

Fig. 6.4 Schematic of neural networks processing several features of an image in the input layer to generate a constellation of findings in the output layer to yield an outcome of interest. Multiple hidden layers in between perform mathematical transformations of features included in the input layer to generate the results of the output layer

6.2.2 Deep Learning

Neural networks and deep learning refer to platforms where machine learning techniques are modeled after the human nervous system (Hashimoto et al. 2020). This consists of at least one input layer incorporating data, one output layer yielding an outcome of interest, and a hidden layer in between that will conduct certain mathematical transformations on the input layer to yield the output layer (Fig. 6.4). Rather than representing a specific type of machine learning technique, neural networks are more of a framework through which multiple machine learning techniques can be incorporated to process an input layer to yield an output layer of interest. More complex networks can be constructed as convolutional neural networks that bear many arrays or recurrent neural networks (Manav 2001). Liu and colleagues utilized a 16-layer convolutional neural network to develop an internally and externally validated nomogram to predict the likelihood a solitary pulmonary nodule would be malignant based on epidemiologic and radiologic features (Liu et al. 2021). With 70% allocated to the training set and the remaining 30% for the validation sets, an ultimate AUC of 0.916 was established. Additionally, other modalities of AI can be utilized in these networks to augment the processing capabilities of the larger platform.

6.2.3 Computer Vision

With the increasing volume of image-based datasets and archives of pathology slides, computer vision is another modality of AI that uniquely performs analysis of images or videos to identify patterns related to an outcome of interest. Several elements can be identified including color, texture, shape, contour, and focus.

Empirically, computer vision platforms convert visual data into categorical or numerical format that may then be tested for its association with an outcome of interest. Similar processing is performed when an autonomous vehicle is trained to respond to cues on the road. A subset of computer vision, called radiomics, identifies texture features on images often imperceptible to the human eyes to identify associations with an outcome of interest. These features can be quantified following color extraction into components of red, green, and blue (RGB) as well as statistical measures including mean, standard deviation or variance, skewness (a measure of symmetry or asymmetry), kurtosis (a measure of the complexity of the image), entropy (a measure of the randomness of the image), energy (a measure of the distribution of signal portrayed by an image), contrast, homogeneity, and correlation (Fayaz et al. 2021). One study by Creasy and colleagues from the Memorial Sloan Kettering Cancer Center utilized radiomics to predict volumetric response to neoadjuvant chemotherapy from segmented pre-treatment imaging of 157 colorectal liver metastasis patients (Creasy et al. 2018). After a regression model was trained from 70% of the cohort and 30% left for internal validation, a mean absolute prediction error (or the difference between the actual and predicted response to chemotherapy) was reported to be 21.5%.

6.2.4 Natural Language Processing

Natural language processing (NLP) is an artificial intelligence technique that seeks associations between the syntax and semantics of words (e.g. documents or data in the electronic medical record) and outcomes of interest (Nadkarni et al. 2011). Although many fields in the electronic medical record are becoming boxes to check or items to select on a synoptic list, NLP pertains to the use of free text and the context of words used therein as they apply to a particular outcome. A study from Patel et al. out of the University of Chicago used an established NLP platform to harvest information from reports of 10,196 average-risk colonoscopic exams to identify a relationship between proximal serrated polyp detection rate and median withdrawal time (Patel et al. 2018). Another report by Yang and colleagues described the development of an NLP platform to identify patients with bladder cancer invading into the muscle from the computerized patient record system (CPRS) from several Veterans Affairs health systems including 600 patients that underwent trans-urethral resection of bladder tumor (TURBT) (Yang et al. 2022). The NLP platform was trained on 83% of the dataset and internally validated on the remaining 17% to give an accuracy of 94% to predict muscle-invasive bladder cancer. Use of this technique is relatively new to clinical research but with the availability of standardized radiologic, operative, and pathology reports, there is great potential for its incorporation to enhance the quality of the electronic health record and possibly streamlining its annotation as well.

6.3 Limitations on Artificial Intelligence in Surgical Oncology Research

For the few published models that are accessible for open-source use, such as a machine learning model constructed by Paredes and colleagues from the Ohio State University for the prediction of recurrence after resection of colorectal liver metastases, (Paredes et al. 2020) the lack of internal validation for its use at new institutions may limit its generalizability. In addition, it is not uncommon to find mislabeled images in publicly available dataset used for training purposes. For instance, Northcutt et al. found an average error rate of 3.3% across the 10 most commonly-used computer vision datasets (Northcutt et al. 2021). In another dataset of mammogram images used to train an algorithm, more than 15% of the images were mislabeled (Kay et al. 2021). As a consequence, models may be unable to account for nuances in practice patterns related to differences in resources available at the institution to care for the same population of patients. Additionally, as standards of practice are updated over time, the need to update these AI models is inherently essential to maintain their relevance to clinical use. The rapid change in applicable systemic regimens (e.g., emerging indications for immunotherapy) necessitate frequent updates that may not be feasible on a multi-institutional level without a supervising consortium. This concept of *time drift* has been highlighted in the failure of established models to keep up practice changes as obvious as updates from the International Classification of diseases (ICD) 9 to ICD10 coding as well as more specialized changes such as the concept of damage associated molecular patterns (DAMP) following operations clouding the suspicion for sepsis from automated sepsis protocols embedded in the electronic health record (Ross 2022).

6.4 Conclusion

Despite the variety of resources available to employ or develop AI platforms, it is extremely necessary to remain cautious of unchecked incorporation of these models into clinical practice. Current models function best as a supplement to clinical decision making to guide radiologists, pathologists, and oncologists in patient care rather than a tool for cutting corners when it comes to making a diagnosis or prognosis. Although many recently developed models have both been published, none of the aforementioned publications give public access to these tools.

Ultimately, it is critical for clinicians to be the driving force for incorporating and supervising the use the AI models in clinical practice. Without due clinical oversight, unnecessary alarms may be raised or with over-reliance on these models, windows for intervention may be missed if warning signs are not recognized. The multitude of available AI tools provide a great opportunity to advance the care of oncology patients, but clinicians must be the stewards for this growth in order for this field to be incorporated with impact and sustained.

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Chapter 7
Machine Learning for Decision Support Systems: Prediction of Clinical Deterioration

Farah E. Shamout

Abstract In-hospital clinical deterioration could lead to unfavorable adverse events, such as mortality, cardiac arrest, or unplanned admission to the intensive care unit. Early detection of deterioration allows clinical staff to respond in a timely manner in order to avoid such events. Advancements in data digitization and computational power enable the development of new algorithms for the prediction of clinical deterioration. Such algorithms, traditionally based on simple aggregate-based Early Warning Score (EWS) systems, seek to drive the *inference engine* of clinical decision support systems. They geared even more attention since the coronavirus disease 2019 pandemic to support the prognosis of in-hospital patients. The purpose of this chapter is to provide a brief overview of classical EWS systems as well as systems based on state-of-the-art machine learning and deep learning. We also compare their strengths and limitations, summarize current findings on the clinical impact of EWS systems in practice, and provide a future outlook on early warning clinical decision support systems based on current needs.

Keywords clinical deterioration · decision support · early warning scores machine learning · deep learning · artificial intelligence

7.1 Introduction

Dating back to the 1970s, Clinical Decision Support Systems (CDSS) intend to inform the decision-making of medical practitioners in patient care settings (Mould et al. 2016), such as for tasks pertaining to patient diagnosis, prognosis, or treatment. Although CDSS were limited in their early days due to time inefficiency and integration challenges with existing information technology (Sutton et al. 2020),

F. E. Shamout (✉)
Engineering Division, NYU Abu Dhabi, Abu Dhabi, United Arab Emirates
e-mail: farah.shamout@nyu.edu

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their value was later recognized in improving patient safety and minimizing medical errors in the early 2000s (Donaldson et al. 2000). With the adoption of Electronic Health Record (EHR) systems, CDSS can directly access digitized medical information or personalized patient data, including historical data from previous hospital encounters or data collected in real-time during hospitalization (Menachemi and Collum 2011).

CDSS are generally categorized as knowledge-based or non-knowledge-based systems (Berner 2007), though other classifications exist. Both types of systems share the notion of an *inference engine*, which performs a reasoning task. As implied by the name, knowledge-based systems reason based on information extracted from a knowledge base, which is compiled based on expert medical knowledge (Sutton et al. 2020). The reasoning component applies rule-based logic based on the patient's clinical data and existing literature, such as IF-THEN statements (Berner 2007). Since such systems rely on the information stored within the knowledge base, the knowledge base must be constantly maintained and expanded, which is highly costly.

Non-knowledge-based systems rely on pattern recognition approaches within the Artificial Intelligence (AI) domain, such as machine learning and deep learning (Sutton et al. 2020). While they do not require a knowledge base, such systems require extensive model development using large datasets (Sutton et al. 2020). Model development is also coined as model training in technical terminology, since the model learns to reason by recognizing patterns within an existing dataset (Jordan and Mitchell 2015). Once optimized, these models also require retrospective and prospective validation prior to clinical deployment to ensure a robust performance. Information processed by either a knowledge-based or non-knowledge-based system is communicated with the end-user via a dashboard or a graphical interface to support a variety of decisions (Berner 2007), such as to alert clinicians for unfavorable events.

Early warning CDSS, in particular, play a crucial role in the context of patient monitoring (Bonnici et al. 2013). Hospitalized patients may suffer from unexpected life-threatening complications due to the delayed detection of deterioration (Hodgetts et al. 2002; Hillman et al. 2001). Clinical deterioration refers to the worsening of a patient's condition on hospital wards (Jones et al. 2013). It is often defined based on the occurrence of an adverse event, which is an unintended injury or complication, which results in disability, death or prolongation of hospital stay. The delayed recognition of deterioration has been shown to be associated with human-related monitoring failures (Van Galen et al. 2016). This motivated the development and use of Early Warning Score (EWS) systems that seek to assist clinicians in recognizing deterioration signs prior to adverse events, in order to ensure that the deterioration is managed in a timely manner (Fu et al. 2020). The goal of such systems is to predict whether an adverse event is likely to occur within a future time-window of N hours from the time of assessment, e.g., 24 h. In this chapter, we provide an overview of classical EWS systems (Sect. 7.2), some of which were originally built on the basis of expert-based knowledge, as well as state-of-the-art AI-based solutions (Sect. 7.3), and present a future outlook on the new generation of EWS systems, or inference engines of prognostic CDSS (Sect. 7.4).

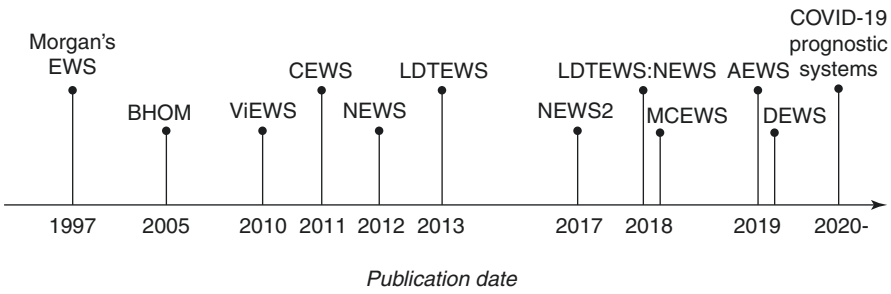

Fig. 7.1 Timeline illustrating the publication date of EWS systems mentioned in this chapter. For additional readings on other EWS systems, we refer readers to related reviews (Gerry et al. 2017; Downey et al. 2017; Gao et al. 2007; Kamio et al. 2017; Smith et al. 2014)

7.2 Classical Early Warning Score Systems

Classical EWS systems, also known as 'track-and-trigger' systems, aim to assess patients for clinical deterioration by assigning scores to simple measurements of physiological variables, such as heart rate, respiratory rate, temperature, blood pressure, and oxygen saturation (Fu et al. 2020). The first physiological EWS system was introduced in 1997 (Morgan et al. 1997), and subsequent modifications were developed and adopted across different hospitals largely based on clinical expertise and intuition (Prytherch et al. 2010), as shown in Fig. 7.1. EWS systems perform continuous assessment during a patient admission, whenever a set of vital-sign measurements is recorded. Most of them are simple to use and can be easily calculated with pen and paper.

Alerting scores within an EWS system are computed based on predetermined normality ranges for the input variables. For example, the heart rate variable is assigned a score of 3 if the measurement exceeds 130 beats/min (Royal College of Physicians, 2012). The aggregate score, which is usually a sum of individual scores assigned to all physiological variables, alerts clinicians for signs of deterioration that usually precede adverse events (Royal College of Physicians, 2012). The total score may also prompt a rapid response team to act accordingly, especially if it exceeds a critical threshold (Ludikhuize et al. 2014). The pre-determined normality ranges are developed in various ways and early work relied on heuristic means and clinical expertise (Smith et al. 2006). Here, we describe how such ranges were determined in two examples: the VitalPAC EWS (Prytherch et al. 2010) and the Age-based EWS (Shamout et al. 2019a).

7.2.1 VitalPAC Early Warning Score

In an effort to standardize EWS systems, the VitalPAC Early Warning Score (ViEWS) was introduced in 2010 (Prytherch et al. 2010). ViEWS assigns scores to measurements of heart rate, temperature, respiratory rate, and systolic blood

pressure, the patient's level of consciousness (indicated via the Alert-Verbal-Painful-Unresponsive Score or the Glasgow Coma Score (Raman et al. 2011)), and whether the patient is being provided supplemental oxygen. The authors developed a database of the clinical variables collected from adult patients between 2006 and 2008 at a hospital in Dartmouth, UK, using the VitalPAC software (Smith et al. 2006). They then determined the normality ranges of ViEWS based on their expert clinical knowledge, the existing literature and their previous experience with other EWS systems. Specifically, they varied the ranges in a trial-and-error process and investigated its impact on the diagnostic accuracy of the total score in predicting mortality at hospital discharge within 24 h. They used the Area Under the Receiver Operating Characteristic curve (AUROC) as the primary performance metric. The final alerting ranges of ViEWS were made freely available and the score can be calculated on paper. This was an intentional objective of the authors in order to enable accessibility to ViEWS especially for hospitals that do not use digital charting systems. The authors also explored the idea of incorporating age as an additional parameter, by increasing the total score by one point if the patient is 65 years or older. However, this did not result with any significant improvements in the AUROC. Two years following its initial publication, ViEWS served as a template for the National Early Warning Score (NEWS) in the United Kingdom (UK) (Royal College of Physicians, 2012), and its updated version NEWS2 (Royal College of Physicians 2017) shown in Table 7.1. Although the development of ViEWS is mostly based on heuristics and clinical judgment, it brought attention to the importance of data-driven analysis.

Table 7.1 Normality ranges of the updated NEWS2 (Royal College of Physicians 2017) that was introduced in 2017. In this version, the level of consciousness score includes the traditional Alert, Voice, Pain, Unresponsive score, as well as a new parameter "C" to represent a new-onset of confusion (i.e., ACVPU). There are also two oxygen saturation scales, where the second one is dedicated to patients with hypercapnic respiratory failure

Vital sign	Score						
	3	2	1	0	1	2	3
Heart rate (*beats per minute*)	≤30		41–50	51–90	91–110	111–130	≥131
Systolic blood pressure (*mmHg*)	≤90	91–100	101–110	111–219			≥220
Temperature (*Celsius*)	≤35.0		35.1–36.0	36.1–38.0	38.1–39.0	≥39.1	
Respiratory rate (*breaths per minute*)	≤8		9–11	12–20		21–24	≥25
Oxygen saturation	≤91	92–93	94–95	≥96			
Scale 1 (%)							
Oxygen saturation	≤83	84–85	86–87	88–92	93–94	95–96	≥97
Scale 2 (%)				(air)	(oxygen)	(oxygen)	(oxygen)
ACVPU score				Alert			CVPU
Supplementary oxygen		Yes		No			

7.2.2 Age-Based Early Warning Score

Motivated by clinical evidence pertaining to physiological changes associated with age, we investigated the impact of age on EWS systems and proposed an Age-based Early Warning Score (AEWS) in our previous work in 2019 (Shamout et al. 2019a). Using large datasets of vital-sign observations collected at the Oxford University Hospitals and the Portsmouth Hospitals National Health Services (NHS) Trust, we determined age-specific alerting ranges based on statistical distributions of the input variables for the composite outcome of mortality, cardiac arrest, and unplanned admission to the intensive care unit within 24 h of assessment time. To determine the ranges, we adopted a simple statistical approach presented by the Centile-based Early Warning Score (CEWS) and its modified version (Tarassenko et al. 2011; Watkinson et al. 2018). In particular, we computed the cumulative distribution function for each variable at each age, and used a grid-based approach to select the centiles that represent the normality ranges. The performance results indicated that AEWS has performance benefits specifically in younger patients. Similar to ViEWS, AEWS can also be calculated on paper but it requires the patient's age and access to the age-specific alerting ranges. It can also be easily adapted to new patient cohorts, since the ranges are computed in a data-driven manner rather than having to rely on clinical expertise and heuristics as in ViEWS and other scores. Overall, the improvements in performance highlight the value of accounting for patient-specific information in EWS systems, such as age.

7.2.3 Strengths and Limitations

The main strength of classical EWS systems, such as ViEWS and AEWS, is the simplicity of their application. They are easy to use and implement. The total score can be calculated manually using pen and paper, pending the real-time acquisition of physiological variables. Due to their simplicity, such scores are considered to be highly interpretable, as a clinician can easily infer which variable is most indicative of patient deterioration based on the highest individual score assigned. Additionally, the aggregate scores of approved clinical EWS systems, such as NEWS2, are associated with a specific clinical response and a series of recommendations for ongoing care. This supports staff in knowing how to respond based on the patient's total score.

Despite their strengths, the scoring systems also have their limitations. Since the scores tend to consider a single set of measurements, they discard a lot of information that could aid the assessment, such as physiological changes over time or patient-specific information like sex or comorbidities. This is partially the fault of the simple inference engine, which generally is in the form of a weighted sum. Another limitation is that the normality ranges cannot be easily maintained or updated, especially in EWS systems whereby the ranges rely on human judgment and heuristics. While some EWS are even recommended to be standardized across

different hospitals and patient sub-populations (Royal College of Physicians 2017), many are developed using data from a single-center and hence should first be extensively validated across the target cohort, which is not always feasible. To highlight the importance of external validation, two EWS systems were evaluated as part of a study across a target patient cohort in Malawi (Wheeler et al. 2013). Both EWS systems showed a drop in performance, highlighting that disease and population differences can significantly influence the performance of EWS systems.

7.3 Modern Computational Approaches for Early Warning

Recent advances in AI research in healthcare offer many opportunities towards improving patient care (Buch et al. 2018). This includes applications pertaining to disease diagnosis (Shen et al. 2021), patient phenotyping (Overby et al. 2013), prescribing medication (Dilsizian and Siegel 2014), as well as deterioration prediction (Shamout et al. 2019b). With the recent surge in the quality and quantity of digitized medical data, various AI-based CDSS have emerged to support clinical decision-making (Jiang et al. 2017). These advances are also largely supported by substantial developments in high-performance computational resources.

Machine learning, a sub-field of AI, is the scientific study of optimizing mathematical models using data (Bishop 2006). Those models are closely related to foundational statistical approaches and are generally categorized under three basic learning paradigms: supervised learning, unsupervised learning, and reinforcement learning. Supervised learning aims to map a given input sample to one or more outputs by approximating the underlying function (Cunningham et al. 2008). During training, we refer to those outputs as *ground-truth labels*, since they are collected based on verifiable observations. Unsupervised learning aims to discover patterns in the data and does not use any labels (Ghahramani 2003). Reinforcement learning pertains to teaching intelligent agents how to take actions in an environment in order to maximize a reward (Wiering and Van Otterlo 2012). In the context of predicting patient deterioration, we study the task under the supervised learning paradigm. Given a set of clinical observations, the goal is to predict whether the patient will deteriorate or not (yes/no, i.e., a binary classification task).

There are several popular machine learning models that are used for binary classification tasks, such as support vector machines, decision trees, random forests, k-nearest neighbor, boosting models and artificial neural networks. Neural networks fall under a wider field of study called deep learning (LeCun et al. 2015). Deep neural networks consist of multiple layers of artificial neurons that learn abstract representations of the input data. The *architecture* of a neural network describes how the layers, neurons, and functions are organized. Some neural network architectures have already achieved tremendous success in computer vision applications, such as convolutional neural networks, as well as in natural language processing. In the next sections, we present a few examples that used machine learning for the purpose of predicting clinical deterioration.

7.3.1 Laboratory Decision Tree Early Warning Score

For a long time, EWS systems mainly relied on assessing the patient's status based on changes in vital signs (Kyriacos et al. 2011) as described in Sect. 7.2. This was motivated by clinical literature highlighting the correlation between vital signs and deterioration, and the fact that vital signs are collected more frequently than other types of clinical data. Considering the information captured by laboratory tests, one study proposed a new EWS system using a binary logistic regression classifier and seven commonly collected laboratory tests in 2005 to predict in-hospital mortality: hemoglobin, white cell count, urea, albumin, creatinine, sodium, and potassium (Prytherch et al. 2005).

Despite the simplicity of logistic regression compared to other types of machine learning models, one limitation is that the calculation cannot be easily computed on paper. Hence, a later study proposed a Laboratory Decision Tree Early Warning Score (LDTEWS) in 2013 (Jarvis et al. 2013). The authors developed LDTEWS using a decision tree analysis for females and males separately, with data collected from adult patients in the Portsmouth Hospitals NHS Trust and the end-outcome of mortality. They then assigned weightings to the decision tree branches, in order to tabularize LDTEWS and allow ease of implementation on paper in a similar fashion to classical EWS systems.

The LDTEWS:NEWS risk index was later introduced in 2018, consisting of a weighted sum of LDTEWS (laboratory test results) and NEWS (vital-sign measurements) at a given time (Redfern et al. 2018). The weighting also considered the time difference between the two scores using a linear decay weight, since the vital signs are collected more frequently. LDTEWS would not be considered as part of the calculation if it was computed more than 5 days prior to NEWS. The LDTEWS:NEWS index performed better than NEWS, highlighting the benefit of considering the information in both types of data.

7.3.2 Deep Interpretable Early Warning System

As discussed in Sect. 7.2.3, one limitation of classical EWS systems is that they do not consider any temporal information in the vital-sign measurements, and rather assume that they are independent and identically distributed random variables. On the other hand, while certain deep neural network architectures are able to capture sequential information, they are usually treated as *black-box* models since they lack interpretability. In our recent work, we proposed the Deep interpretable Early Warning System (DEWS) (Shamout et al. 2019c) based on an attention-based recurrent deep neural network. Recurrent neural networks are a type of deep neural networks that are able to capture sequential information, such as within textual or time-series data. We considered the composite outcome of in-hospital mortality, cardiac arrest, or unplanned admission to the intensive unit

within 24 h from assessment time. Since vital-sign sequences are sparse, our system first samples the posterior mean and variance at regular intervals from the raw sequences using Gaussian process regression (Rasmussen and Williams 2006). For interpretability, we implement an attention layer in the classification network that assigns an importance score, between 0 and 1, to each timestep within a vital-sign sequence. The importance scores hence represent how the network pays attention to information at different timesteps. The attention-based network finally processes the regularly sampled sequences to compute a prediction, and its attention scores are assessed for interpretability. DEWS outperforms existing baselines in terms of discriminative ability and in decreasing the trigger rate at a fixed level of sensitivity.

Our subsequent work compared the effect of data interpolation of time-series vital-sign data using Gaussian process regression and generative neural networks, i.e. neural processes (Sharma et al. 2021). Although deep neural networks and other types of machine learning models cannot be implemented manually using pen and paper, they offer performance gains compared to classical EWS systems.

7.3.3 Advances during the Coronavirus Pandemic

The coronavirus 2019 (COVID-19) pandemic led to strained hospital resources and staff burn-out worldwide. Due to the urgency, significant efforts focused on the development of algorithms for CDSS for patients with COVID-19 (Wynants et al. 2020), with the majority focusing on the diagnosis of the disease rather than prognosis. The latter is of utmost importance in the context of this chapter, since hospitalized patients with COVID-19 may suffer from a variety of adverse events, including the need for extensive respiratory support, transfer to the intensive care unit, or mortality.

In our recent work, we identified an imminent need for deterioration prediction algorithms that can inform patient triage in the emergency department. Chest X-ray imaging was considered a first-line triage tool for COVID-19 patients. Compared to other imaging technologies such as computed tomography or magnetic resonance imaging, it is less costly and minimizes the risk of contamination due to portable technology. We proposed a prognostic system that predicts the composite outcome of mortality, intubation, or admission to the intensive care unit in the emergency department using data collected at NYU Langone Health (Shamout et al. 2021). Specifically, the system first processes chest X-ray images using a convolutional network (globally aware multiple instance classifier (Shen et al. 2019)), and then fuses the imaging predictions with those of routine clinical data, computed using a gradient boosting model, via weighted averaging. The network is *multi-task* since it predicts the risk of deterioration within each of 24, 48, 72, and 96 h time windows. The system also computes saliency maps that indicate important regions in the image using weakly supervised learning. The findings of our study highlight the significance of chest radiographs in the context of deterioration prediction and the complementary nature of imaging and non-imaging clinical data. While the results

are promising, such systems largely diverge from the classical EWS systems. They only go as far as providing an overall risk prediction score, rather than a scoring system with multiple levels to prompt action accordingly.

Although classical EWS systems were originally developed for pre-pandemic hospitalized patients, they were still being used in hospitals during the pandemic. Hence, in another project based at the University of Oxford, we also evaluated the performance of such scoring systems, including NEWS, AEWS, LDTEWS, and LDTEWS:NEWS for the prediction of respiratory deterioration among patients admitted to the Oxford University Hospitals (Youssef et al. 2021). All systems significantly underperformed in the COVID-19 cohort compared to previously reported results. Such work emphasizes the lack of generalizability of EWS systems when transferred to different adverse events or patient cohorts, and illustrates the benefits of machine learning algorithms compared to traditional scoring systems that are currently used in practice.

7.3.4 Strengths and Limitations

Early warning systems based on machine learning and deep learning models also have their unique strengths and limitations. Since the models learn from large and diverse datasets, they are likely to perform better than classical EWS systems. Additionally, they can be easily modified, or *fine-tuned*, for a specific patient cohort of interest, compared to classical systems where alerting ranges need to be adjusted heuristically or based on clinical expertise. This can help reduce the performance gap when the models are adapted to patient populations that were not seen during model training. Their input space is also scalable, since the models are not limited to a specific number of input variables as in classical systems, where the inputs are carefully curated based on clinical expertise.

On the other hand, training accurate machine learning models, especially deep neural networks, requires a large amount of labeled data. In practice, we encounter two main challenges: a limited amount of labeled data, or if the data is available, then it may be noisy due to the inherent nature of data collection in healthcare systems. The collection of data is not a trivial task, and may not always be viable, especially in low-resource settings where digitized electronic health systems are not even available. Furthermore, the models are prone to learn different kinds of biases, such as dataset bias, leading to biased models in practice. Model fairness is indeed a growing area of research in AI in healthcare. Another related limitation is that machine learning models can only be developed and applied using computerized systems, since they cannot be easily implemented using pen and paper due to the complexity of the calculation. Hence, many models are viewed as black-box models as their reasoning process lacks interpretability. Finally, most of the early warning systems that are based on machine learning are designed to output an overall risk score, which can be binarized on the basis of a clinically appropriate level of sensitivity or specificity. Thus, such systems still lack an appropriate clinical response plan compared to the classical EWS systems.

7.4 Future Outlook

7.4.1 Evidence of Clinical Impact

Despite recent advancements, the value of EWS systems in real-world clinical settings has been strongly debated, which directly limits their proliferation. This is largely attributed to the fact that the quantity of retrospective studies, especially in machine learning, largely exceeds the number of prospective validation studies. Prospective validation studies offer the opportunity to implement and deploy a proposed algorithm, in order to understand its performance in a real-world environment. For example, one systematic review evaluated the reported impact of EWS systems on specific patient outcomes, such as in-hospital mortality, length of hospital stay, and cardiac arrest (Alam et al. 2014). While only seven studies met the review's inclusion criteria, the findings were mixed: only two studies showed a significant reduction in mortality, while the rest reported positive trends with no significant findings. Two of the studies included in the review interestingly reported that the deployment of the EWS system led to an increased collection of vital-sign measurements. This highlights that algorithm deployment can have a positive effect on data collection practices, eventually leading to even better algorithms.

Another systematic scoping review investigated the impact of machine learning-based EWS systems for clinical deterioration (Muralitharan et al. 2021). While 24 studies fit the inclusion criteria, 23 were retrospective and only one was prospective. The latter investigated the impact of deploying a random forest classifier in a prospective cohort with 178 patients. The model resulted with a significant improvement in performance in detecting early signs of deterioration, however the study provided no further insights on the clinical effect of the system (Olsen et al. 2018). In the context of COVID-19, most studies were also retrospective with only a few highlighting good performance in prospective studies (Wynants et al. 2020; Schöning et al. 2021; Tang et al. 2021). A careful systematic review is needed to understand the findings of studies that performed prospective validation of EWS systems for clinical deterioration of patients with COVID-19. Although prospective validation is rather expensive, since it requires deployment and involvement of clinical staff, we emphasize the need for more prospective studies to leverage a positive clinical impact of early warning systems upon implementation.

7.4.2 Learning From Diverse and Heterogeneous Data Modalities

With the proliferation of digital devices and systems, medical data is vast and heterogeneous. Multi-modal machine learning pertains to building models that can process information from different modalities (Baltrušaitis et al. 2018), where a *modality* refers to a single source of information. Existing work on multi-modal

learning has mainly focused on language, vision, or speech modalities for various applications, such as audio-visual speech recognition. In the context of clinical deterioration, most approaches focus on learning from uni-modal data, except for a few recent studies (Shamout et al. 2021). We argue that the next generation of algorithms for EWS systems should focus on processing different types of information available in the patient record and not just vital signs such as imaging data like chest X-rays, data collected from wearables, genomic data, or the patient's family history. This could lead to more accurate models considering the diversity of information captured by each modality.

7.4.3 Towards a General Decision Support System

There are numerous algorithms within the existing literature that aim to support clinical decision-making by predicting deterioration. Unfortunately, many of those models seek to compete with one another or are developed in silo for a particular patient cohort or clinical outcome, yielding models that fall under the narrow AI domain, i.e. they focus on one narrow task. In the pursuit of Artificial General Intelligence (AGI), where a single system is theoretically expected to perform all human tasks, there needs to be focused efforts that aim to standardize clinical models towards a *general* CDSS. This could include standardizing definitions of clinical outcomes and performance metrics, and democratizing access to data to encourage multi-center trials with larger and more diverse patient cohorts (Alam et al. 2014). Such efforts need inter- and multi-disciplinary collaborations in order to build better algorithms with the common goal of improving patient outcomes.

7.5 Conclusion

In summary, we provide the readers with an overview of recent advances in computational approaches for EWS systems as a form of CDSS. We mainly focus on the *inference engine* of CDSS in the context of predicting clinical deterioration, but there is also important work related to human factors research and how to best communicate the predictions with clinical staff. We note that the predictive models have significantly evolved in the last decade, based on the increased availability of clinical data and computing resources. To meet the potential of such systems in practice, we are now in need of a new generation of multi-modal EWS systems that can integrate complex data modalities, as well as centralized learning capabilities to reach the goal of a general CDSS. To ensure robust performance in practice, we also need to shift some efforts towards evaluation research.

We only cover a handful of EWS systems to illustrate advancements in model development over time within the scope of this chapter. For further readings on EWS systems, we refer the readers to extensive reviews published on the topic

(Gerry et al. 2017; Downey et al. 2017; Gao et al. 2007; Kamio et al. 2017; Smith et al. 2014). We also refer readers to the doctoral work that proposed AEWS and DEWS, titled *Machine Learning for the Detection of Clinical Deterioration on Hospital Wards* (Shamout et al. 2020). Finally, while this chapter focuses on clinical deterioration, we would also like to refer the readers to our review on *Machine Learning for Clinical Outcome Prediction* (Shamout et al. 2020) for a more extensive review on machine learning applications beyond the prediction of clinical deterioration.

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Chapter 8
Mixed and Augmented Reality in Healthcare: When Will It Deliver Its Promises?

Natalia Wrzesińska

Abstract Medical innovations mean improvement to patients' safety and outcome. Sometimes modern technologies that are not designed for medicine turn out to have applications in medical practice. Augmented or mixed reality is a great example and countless applications in various medical fields have proved its usefulness. So, when will mixed reality be used routinely in medical practice and what is keeping this technology from becoming part of modern medicine? This chapter will highlight possible benefits and some challenges concerning the use of mixed reality in medical practice and education.

Keywords Mixed reality · Augmented reality · Hologram · Head-mounted display Smart glasses · Image-guided surgery

8.1 Introduction

The world around us is changing rapidly as we increasingly rely on technology. New generations cannot even imagine the world without it. The technology to support mixed, augmented, and virtual reality has already become a part of our world. Nowadays, medicine is changing rapidly compared to past centuries when none of these digital health technologies were available.

Mixed Reality (MR) brings together the real and virtual worlds. In mixed reality, physical and digital objects interact in real time but have no specific place in a virtual or real world. One can say it is a mix of augmented reality and virtual reality in either two or three dimensions (meaning adding virtual objects to the real environment). In 1994, Paul Migram described mixed reality as a scale of reality—a virtual continuum where mixed reality covers every state between the real and virtual worlds (Milgram et al. 1994).

N. Wrzesińska (✉)
Department of General, Endocrine and Vascular Surgery, Medical University of Warsaw, Warsaw, Poland

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Although mixed reality is still mainly associated with entertainment, various other industries have implemented it for different purposes. So far, it has been already used with success in education, military training, remote working, architecture, interior design, and product content management, among many others. In the case of medicine and its wide range of possible applications, the use of mixed reality stands out as a very promising tool in healthcare as well.

In practicality, to accomplish a mixed reality environment, there is myriad of digital tools from mobile devices or wearable technology to entire rooms designed for it. The usefulness of smart glasses in medicine has been especially evaluated and proven to be of benefit in many studies even when, in many cases, the evaluated devices were not medical devices and were not designed for medical purposes. Analytics from Market Data Forecast predict the market compound annual growth rate of global mixed reality to be 47.9% during 2020–2025 and the medical holography market to grow from only USD 500 million in 2021 to over USD 2 billion in 2026. This growth will be driven by improvement in technology and by access to it. This chapter will highlight potential benefits, opportunities, and some challenges to the application of mixed reality in medical practice and medical education.

8.2 Possible Use of Mixed Reality in Medicine

Mixed reality devices often come in the form of headsets or smart glasses. Smart glasses are usually web-connected wearable computing devices that allow the transmission and projection of various types of data in the field of vision. Early models could perform basic tasks and display some pictures and figures in the field of vision. Such visualization could be useful in everyday medical practice. However, with technological progress, other devices have rapidly appeared that are capable of displaying three-dimensional objects with which users can interact in real time. These devices use special mobile applications dedicated for specific tasks.

In general, smart glasses can display all kinds of information: patient data, test results, imaging studies reconstructions etc. Almost a decade ago, Google Glass™ was one of the first models of smart glasses to be used in medicine. These efforts were not only popularized in the media, but also were described in numerous investigational studies and reports. Using a wireless platform, smart glasses present practically no obstruction to human interactions and movements. The other advantage is the short learning curve and the fact that smart glasses can run on the well-known android system. Other early smart glasses had low wearability, a longer learning curve, and were obstructive to human-to-human interactions. O. J. Muensterer is a pediatric surgeon and a Glass explorer. He wore Google Glass in LMU Munich Children's Hospital for 4 consecutive weeks, each in different clinical situations, and kept a diary of his experience. He focused on how well the device is tolerated by the user, checking features like wearability, battery life, and audiovisual quality. Patients' and their families' responses to the device were also assessed (Muensterer et al. 2014).

Google Glass allows the projection of various data. This concept was used by Jeroudi et al. to investigate the accuracy of electrocardiogram interpretation by Google Glass. Each of 10 compared electrocardiograms was visualized in four formats: as viewed by Google Glass; picture taken by Google Glass; paper version; and a picture taken by the camera. The researchers then compared differences in the interpretations of the electrocardiograms. Although users were not satisfied with the images compared to the paper version, this study among others is an example of using such a device in telemedicine (Jeroudi et al. 2015).

Smart glasses also allow the sharing of information among specialists, whether as a consultation from within the hospital or from anywhere in the world. Authors from Yale University attempted to show the application of Google Glass for teleconferencing in emergency medicine. In their project, a team of paramedics performing triage during mass accidents consulted with an emergency medicine specialist. The results revealed some obstacles but overall performance was not decreased; however, it took the users more time to perform their tasks. This study showed that with some technical improvements, smart glasses could be used in medical emergencies (Cicero et al. 2015).

There are few mixed reality head-mounted displays available; the most commonly used platform for mixed reality currently is Microsoft HoloLens (Redmond, WA, USA). This system projects holographic three-dimensional images in the user's field of vision and runs on Windows operating system, which is familiar to users worldwide, making it extremely easy to navigate. It contains an internal battery and features Wi-Fi and Bluetooth connectivity.

This head-mounted mixed reality device is light (566 grams) and comfortable to wear, with an adjustable headband and fits over eyeglasses, which is another advantage.

Many companies and start-ups from around the world are developing specific applications for Microsoft HoloLens, some for medical use. Some applications provide access to medical data, remote patient care tools, life streaming, educational tools and, of course, 3D reconstructions for surgical planning and assistance.

Almost every field of medicine from anatomic pathology (viewing 3D specimens, navigation through specimen slices, telepathology) (Hanna et al. 2018), primary care physicians, oncology, and radiotherapy (mixed reality-guided patient positioning systems) (Li et al. 2022) among others can take advantage of MR.

With the global COVID-19 pandemic, another advantage of using MR devices has emerged. The pandemic led to acceleration in the implementation of digital tools and telemedicine solutions in many countries. The main goal was to provide safety for patients and medical staff when accessing medical professional diagnosis and treatment.

A pilot study was conducted at Imperial College London Hospitals using mixed reality during COVID-19 patients' consultations. In that study, a single senior staff member entered the COVID-19 ward for rounds and patient care wearing a Microsoft HoloLens2 while other practitioners joined the rounds and took part in the process virtually. This reduced the risk of coronavirus transmission by minimizing physical interaction between hospital staff and infected patients. Total reduction of exposure

time in all participating teams was 222.98 h/week. In addition, a significant reduction in the use of personal protective equipment (PPE) was noticed (approximately 3100 fewer items of PPE used per week). When staff members were questioned about their experience using the mixed reality device and its impact on their work, 75% said it was easy to navigate and more than 70% noted that it is comfortable to wear. HoloLens facilitated the work, the rounds were less time-consuming, and teamwork was improved (Martin et al. 2020).

A similar study conducted by Jeremy B Levy et al., also in London, reported similar results. In this study, COVID-19 patients were asked about their views on the use of the mixed reality headset during medical rounds. No patient claimed that the device disturbed their medical care or their interaction with medical staff (Levy et al. 2021).

In another implementation of mixed reality concerning COVID-19 patients, 3D holograms with mixed reality techniques were used to assess pulmonary lesions in COVID patients. The study showed that compared to standard CT scans, mixed reality 3D holographic images can be helpful to evaluate pulmonary lesions especially by less experienced doctors (Liu et al. 2021).

8.3 AR and MR in Surgery

Smart glasses react to simple voice commands, eye movements, or gestures. The hands-free system is particularly helpful in surgical practice and other fields of medicine that require practitioners to work manually, sometimes in sterile field. Numerous proofs of concept for smart glasses in surgery have been proposed.

The concept of projecting test images in the field of vision has been studied widely. For example, Wu et al. used Google Glass to facilitate ultrasound-guided central venous access. In this study, the Google Glass user had fewer additional head movements (Wu et al. 2014).

Three-dimensional pictures are routinely applied in the preoperative evaluation of surgical patients. This is usually a simple 3D reconstruction of images viewed by the surgeon on a plane screen. However, in some complex cases this is not adequate. Spatial understanding is crucial to achieve surgical precision and avoid complications. There is growing interest of 3D printing in preoperative planning, which would allow the surgeon to see and touch the printed organ and even practice the surgical procedure beforehand. This permits a better understanding of a patient's anatomy, thereby improving safety and accuracy. Using augmented reality and 3D reconstruction, for example, holographic images could be as useful but cheaper and faster than 3D printing. Additionally, with mixed reality, the surgeon can interact with the anatomical reconstructions in real time during the procedure and remain sterile in the surgical field. The holograms can be rotated, sliced, or scaled freely by the surgeon and can be placed anywhere in the visual field. The user can even "step inside" the target organ virtually, an experience never before possible. Most applications created to display holographic reconstructions of a patient's anatomy work

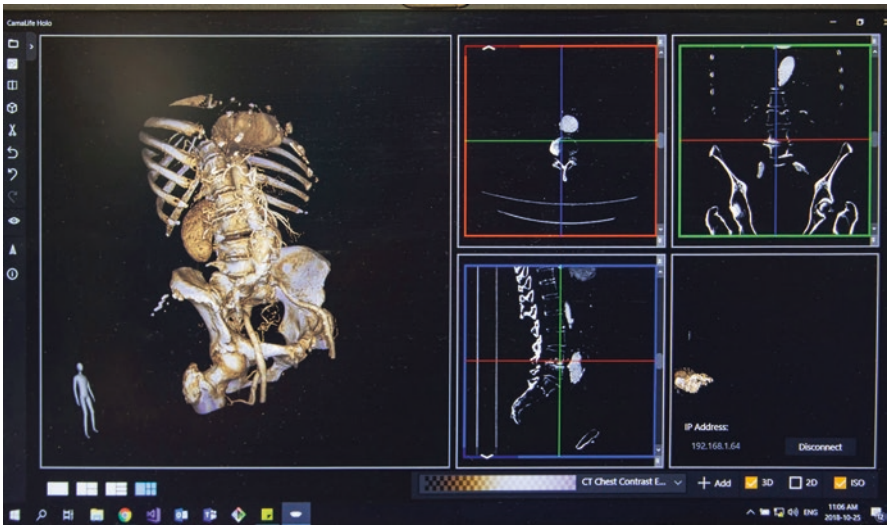

Fig. 8.1 Process of rendering CT scans to hologram. Photo: Tomasz Jędrzejewski, Medical University of Warsaw press office

with different imaging techniques recorded in the DICOM standard (Digital Imaging and Communications in Medicine) such as computed tomography (CT), magnetic resonance imaging (MRI), angiography, or 3D ultrasonography, and some have the capability to connect directly to imaging devices, for example, echocardiography devices, to visualize the images in real time (Fig. 8.1).

The application of Microsoft HoloLens has been described in various surgical fields, e.g., orthopedic surgery, plastic surgery, neurosurgery, oncological surgery, and many others. Practitioners from all fields of medicine see the prospects of mixed reality in their everyday work and are trying to explore its possibilities in their practice.

Mixed reality tools in preoperative planning might be of great benefit in cases where the patient's anatomy differs such as congenital diseases or in complicated oncological cases. Brun et al. described one of the first examples of preoperative planning using mixed reality in congenital heart disease. The suggestions for the surgical repair were made based on 3D mixed reality reconstructions. The holograms were easy to interpret and helped the surgeons solve challenging tasks intuitively and were rated highly by all users (Brun et al. 2019). Some of the applications for HoloLens provide specific tools for surgical planning (Kumar et al. 2020).

Research relating to the use of mixed reality in the spatial understanding of liver anatomy showed that it decreases the time to correctly identify lesions in the liver and, in some localizations, also increases accuracy (Pelanis 2020).

Dimitrios Chytas and Vasileios S Nikolaou in their literature review outlined the state of the use of mixed reality in orthopedic surgery (Chytas and Nikolaou 2021). They described numerous implementations found in the literature. For example, reverse shoulder arthroplasty performed with the aid of an MR headset to better

visualize the anatomy (Gregory et al. 2018), cervical spine complex fracture procedure where MR was used for preoperative planning and perioperatively (Wu et al. 2018), and total hip arthroplasty with the use of both mixed reality and 3D printing. These are only a few examples of countless proof–of-concept studies conducted in many areas of surgery (Lei et al. 2019).

MR is a tool that can help personalize treatment and could help in the implementation of new methods with better visualization and accurate planning. An example is a study conducted in Cracow where patients with unresectable pancreatic or liver tumors had irreversible electroporation or microwave ablation treatment with the assistance of Microsoft HoloLens 2. MR was used preoperatively for planning and during the procedures to support the decision-making process. Additionally, the researchers assessed the remote connection with a team of specialists (Wierzbicki et al. 2022).

3D reconstructions for surgical planning with the use of MR can potentially increase the surgeon's precision, help with the expertise, and increase the safety of the procedure. Having the opportunity to see the organ in 3D and to interact with it proved to be the most advantageous for trainees and less-experienced doctors in particular.

Another step toward the future will be totally augmented or mixed reality-guided surgery, where anatomical reconstructions would not help plan the procedure and understand the anatomy, but the surgery would be navigated by a mixed reality platform.

One of the best examples of augmented reality image-guided surgery is spine surgery (pedicle screw insertions) with Augmedics Xvision Spine system, a wireless surgical navigation platform that allows visualization of a patient's spine anatomy through the skin and tissue using a minimally invasive percutaneous procedure. The system helps in navigating implants while looking at the surgical field with no need to look on the other monitors for imaging study results. The platform consists of a transparent near-eye-display headset; otherwise, it is similar to currently used traditional navigation systems. Researchers on a cadaveric proof-of-concept study determined its accuracy. Additionally, with no need to look at separate screens it eliminates attention shift (Molina et al. 2019).

The advantage of using smart glasses during surgery also lies in the possibility for the surgeon to consult and interact with other specialists, and to ask them for advice. For example, while performing reverse shoulder arthroplasty with the aid of a mixed reality HoloLens, Gregory et al. shared the procedure video in real time with four other specialists for expertise (Gregory et al. 2018).

Another interesting implementation of augmented reality in the operating room is using it for following the surgical safety checklist developed by the World Health Organization. Because many medical errors happen in the operating room, the surgical safety checklist can be lifesaving. Many surgeons read the checklist from a list hanging on a wall or do it from memory, which can lead to skipping some important steps. Thomas Boilat and Homero Rivas developed the Digital Checklist Box

(DCB), which can be projected directly onto the draped patient and completed and verified before starting the surgical procedure, preventing the surgeon from missing steps (Boilat and Rivas 2021).

8.4 MR in Endovascular Procedures: One of the Greatest Examples of Its Usefulness

Endovascular surgery, interventional radiology, and interventional cardiology are notable examples of medical fields that could benefit most from these MR technologies.

One of the major challenges of endovascular procedures is working with two-dimensional images of a three-dimensional anatomy. Oftentimes, vascular anatomy is complex, requiring the surgeon to use their spatial imagination; nevertheless, sometimes many angiographic images have to be taken in order to insert catheters or wires in the right position, which raises concerns about radiation exposure for both patient and surgeon, and the use of iodine contrast.

One of the first implementations of the HoloLens on larger scale was made by interventional cardiologists. Opolski et al. performed 15 percutaneous coronary interventions for chronic total occlusions with the assist of MR and showed lower contrast exposure compared to procedures without MR assist (Opolski et al. 2017).

The author of this chapter had the opportunity to use Microsoft HoloLens during endovascular aortic aneurysms repairs (EVAR). We thought that using 3D holograms of a patient's anatomy could make orientation within the vascular anatomy easier.

The EVAR procedure involves radiation exposure and iodine contrast agent, which can cause acute kidney injury. Dealing with more complex aneurysms using fenestrated or branched stent-grafts also involves increased radiation, more contrast use, and a prolonged procedure. In those cases, mixed reality could be most useful.

We used the Carna Life Holo application created by Polish company, MedApp. Holograms of the patient's anatomy are created from preoperative standard cross-sectional DICOM computer tomography images that are segmented and processed. The stent-graft implantations were successful, and we observed no adverse events during follow-up. Seeing the patient's vascular anatomy reconstructions precisely in three dimensions certainly helped us navigate the vascular tree (Fig. 8.2). To our knowledge, this was one of the first implementations of holographic visualization during an EVAR procedure in the world (Fig. 8.3) (Wrzesińska n.d.).

To see the anatomy and position of the catheters and stents in real time would revolutionize the field of endovascular interventions. Authors from Germany proposed a mixed reality guidance system for the EVAR procedure with the use of a HoloLens display. They used a special artificial human torso with an aortic aneurysm phantom to assess the electromagnetic tracking system (sensors were attached

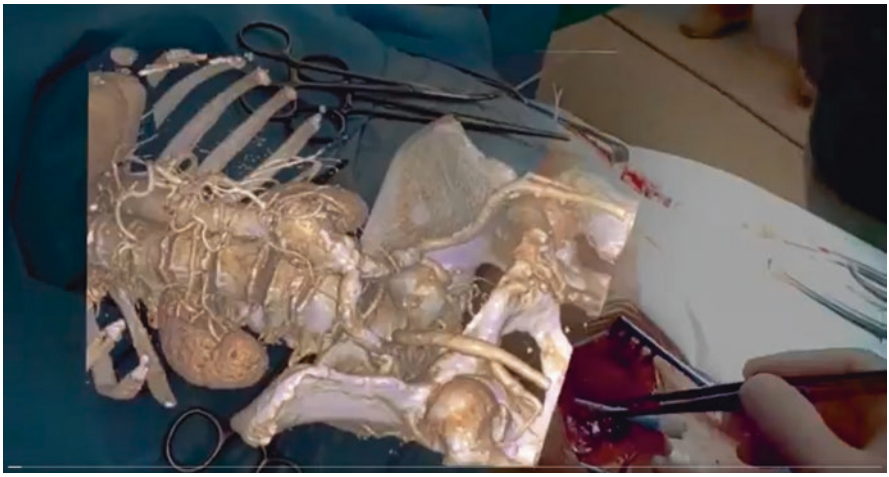

Fig. 8.2 Holographic visualization of vascular tree projected on a surgical field

Fig. 8.3 Visualization during mixed reality-assisted EVAR procedure. Photo: Tomasz Jędrzejewski, Medical University of Warsaw press office

on the catheters' tips and navigated by ultrasound), and display this information on the HoloLens in real time (García-Vázquez et al. 2018). Those techniques with technological improvements might result in shorter procedure time and a decrease of radiation and contrast use in the future.

One way to obtain visual data in real time is by using 3D ultrasonography. Currently, this is easier to apply in cardiac procedures as many applications allow the creation of holograms directly from echocardiography.

An example of a system that creates holographic images in real time is RealView Imaging, an Israeli company. According to the manufacturer, this is the first medical holographic system in the world. It was initially targeted to support interventional cardiology procedures. This system provides 3D holographic images projected with the use of special patented Digital Light Shaping™ technology. There is no need for smart glasses or other wearable devices as images are projected in the air. The system has FDA clearance for clinical use.

Researchers from Israel conducted a feasibility study using this holographic system during cardiac catheterization procedures. The system uses intraprocedural data from live 3D transesophageal echocardiography and 3D rotational angiography to make real-time holographic reconstructions. Eight patients were enrolled in the study. All anatomical landmarks during the procedures were identified successfully with no adverse events (Bruckheimer 2016).

8.5 MR in Education

Given its interactive features, mixed reality has an enormous potential in medical education.

One of the first and most spectacular examples of bringing mixed reality to teaching is a program conducted by Case Western Reserve University. In their project, medical students study anatomy via MR with the use of Microsoft HoloLens. The device enables students not only to see the anatomical structures in 3D but also to interact with holographic images and even whole-body holographic mannequins. This teaching method was compared with traditional anatomy classes on cadavers. Upon examination, there was no statistical difference between the scores of students taught using MR and those taught learning on cadavers (Stojanovska et al. 2019).

Another prospective study of anatomy students compared anatomy course study time and effectiveness between two groups: those using an MR learning platform and those using traditional methods (cadaveric dissection). The results indicated that while learning time was shortened using MR, there was no difference in the groups' examination score (Ruthberg et al. 2020).

One more example of using MR in anatomy training was described for plastic surgeons. Researchers used a mixed reality HoloLens platform and virtual face models reconstructed from pictures taken from different angles. The device was able to project individual layers of the face anatomy (Kumar et al. 2021). These and other research studies prove that mixed reality can be successfully implemented in teaching anatomy.

With the use of smart glasses that have potential to bring demonstrations, recording, and live-streaming videos at any given location globally, education becomes

not only easier but also more attractive. This attribute of mixed and augmented reality is particularly exploitable in surgical training. Traditionally, when performing surgical procedures there are some limitations on the number of persons that can participate in or watch. Those physical limitations end when the procedure can be transmitted, recorded, and explained. Harnessing mixed reality in the medical education process allows students and trainees to interact with the content they are studying, which by all means is more effective than just observing. Using mixed reality methods, the teaching surgeon can reach many trainees all over the world at the same time, whereas traditional methods limit the number of trainees.

Telementoring is another interesting application for augmented or mixed reality, allowing students or residents to perform some procedures on a patient by themselves while being constantly monitored and controlled by a supervising person. This can be done regardless of distance between trainee and supervisor as they can work, for example, in different hospitals (Mitsuno et al. 2019). Residents and more experienced surgeons learning new techniques could also benefit (Guraya 2019). Telementoring can help in potential guidance for a complex procedure not performed by a surgeon on a daily basis or when the patient is in a critical condition and cannot be transported to a specialized surgical center.

MR can also be used to simulate scenarios of potential clinical situations. This is a particularly popular way of teaching procedural and technical skills. Simulation-based training has been confirmed to be safe and effective, and to reduce the rate of complications. Trainees using MR simulations learn tasks mimicking relevant clinical situations. Assorted studies have shown that the results of such training are similar to traditional one but that the lower cost and improvement of patient safety are a benefit of MR simulations (Barsom et al. 2016; Huang et al. 2018).

As mentioned earlier, the global COVID-19 pandemic not only had an impact on providing healthcare but also on education, making it necessary to implement remote access in many places in the world. Likewise, medical education, which is based on interactions with patients, had to change dramatically during lockdowns. Again, augmented, or mixed reality in such a case presented a fine solution (Kassutto et al. 2021).

8.6 Patients Also Can Use MR

Not only healthcare practitioners can benefit from using mixed reality in their work but patients can also directly benefit from it. Using MR can empower patients in the sense of interaction between them and their physicians, telemedicine, simplifying hospital or outpatient visits, and patient's education before surgery among many other functions. Companies make applications for patient use in pain management, rehabilitation, or to plan pharmacological treatment. Mixed reality can help patients with chronic diseases like Parkinson's disease or with chronic pain (Wrzesińska 2015).

8.7 Challenges

With all those possible implementations, MR seems like a solution to many problems by the facilitation and betterment of existing solutions (Table 8.1). So, when will it deliver its promises and why does it take so long? Though medicine is becoming more technology-dependent, innovations in medicine take longer than in other areas. Because medicine has strict rules and restrictions, the speed of technological progress is limited. Every new method and device has to proceed along a path from its inception to its implementation in medical practice; indeed, questions arise about the use of mixed reality in medicine.

The first and most important limitation that may hinder the use of mixed reality in medicine is the law because most of the augmented/mixed reality devices are not medical devices. Although the devices do not need to be certified for medical use, the medical applications of them oftentimes do. The legislation process in medicine takes a long time, especially if the innovation is something completely new, and the slow FDA approval process is not flexible for a prompt digital revolution.

We have to address also issues of data protection before using MR tools as this could be the main inhibitory factor in implementing these technologies in everyday clinical use. Of course, all medical software applications for MR systems must deal with the issue of confidentiality and adapt to local regulations.

For now, research is dominating the medical holography market according to a Market Data Forecast report. Geographically, the North American region is holding the largest market share in medical holography. This might be attributed to better support in medical research and better funding as well as good accessibility to and acceptance of innovative technologies (Market Data Forecast 2021).

Various technical aspects may inhibit MR implementation in healthcare. If the technology is to be used in everyday practice, then it has to be not only safe and

Table 8.1 Current applications of mixed reality smart glasses in healthcare

Area of application	Examples
Reading data, interacting with data	Vital signs, test results, 3D anatomical reconstructions
Communication	Consultations, teleconferences
Video recording	Life streaming of procedure, teleconferences, video records for digital documentation
Workflow, documentation	Digital patient history, remote consultations, emergencies, drug delivery tracking, procedure recordings
Patients' empowerment	Used in chronic diseases, telemedicine, patient connection, rehabilitation, pain management
Education	Telementoring, trainees' evaluation, self-evaluation
Safety and efficiency	Safety checklists, surgical navigation/guidance, anesthesia and intensive care treatment monitoring, infectious diseases treatment safety

effective but also ergonomic and not obstructive. Even though most devices can operate wirelessly, poor battery life is reported in many studies. For example, Google Glass has a reported battery life of 40 min (Muensterer et al. 2014; Chimenti and Mitten 2015). With Microsoft HoloLens, the battery life is longer (up to 5.5 h according to some studies), with around 3 h of active use and up to 2 weeks of standby time according to the manufacturer, and the device is fully functional when the battery is charging (Gregory et al. 2018).

Hence, because those devices were not designed for medical purposes, some technical limitations are not a surprise. Tao Zhan et al. addressed some technical issues like brightness, panel resolution, or vergence–accommodation conflict in existing MR and VR systems (Zhan et al. 2020).

With HoloLens, the user can control the amount of information in order to make the cognitive load tolerable. The quality and stability of the image do not cause motion sickness, and the voice and gesture commands are easy to use. In many studies, users were questioned about the comfort and ergonomics of mixed reality platforms (Gregory et al. 2018; Léger et al. 2017).

The gap between research and clinical work is caused to a significant extent by costs. Hopefully, this will change over time as these devices become more popular and, therefore, more affordable. However, when compared to 3D printing, mixed and augmented reality applications cost less.

It seems that the younger generation of practitioners is more willing to try new technologies than older doctors. There is also a problem of mindset of medical practitioners who are taught to be risk-averse and to use only proven methods; hence, they are oftentimes reticent to try new things. What has to be changed to move an innovation into practice is the mindset among clinicians.

In conclusion, it will take some time before we witness the use of MR in healthcare on a daily basis, but it is inevitable. It represents a phenomenal opportunity to adapt new technologies in medicine in order to improve patients' outcome and safety. Despite some challenges that for now delay its wider use, I am sure that mixed reality will become a part of future medical and surgical practice as it is already a part of our everyday life.

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Chapter 9
Why Healthcare Needs Blockchain

Stewart Southey and Mehran Zarrebini

Abstract As Healthcare evolves into a more patient-centric and digitised experience, we need a foundational technology layer that enables trust. Data exchange is at the heart of how health systems succeed or fail. Trust in how this data currency is transferred is critical to patient care, administrative efficiency, commercial relationships, and the advancement of medical science in general. The fundamental value proposition of blockchain is that it enables disparate, potentially competing entities to transact peer-to-peer via a shared foundational infrastructure that brokers the trust between them. It manages the rules and builds the roads upon which a trusted data economy can exist. Our current healthcare systems are broken - precisely because the flow of critical information cannot occur without clinical or commercial risk. Blockchain is transforming the financial services industry through disintermediation and friction reduction with blockchain. Healthcare must similarly be transformed. This chapter explores this claim, examines the reality of what has been developed thus far and offers a vision for how we might achieve a better future for healthcare. There will most certainly be barriers, but we believe that these are worth overcoming. This is what drives us forward. It is, we believe, essential for good healthcare.

Keywords Patient Centric · Data Economy · Blockchain · Trusted Data Exchange

S. Southey
Anaesthesiologist at Doctor's Hospital Cayman, George Town, Cayman Islands
e-mail: stewart@catena.mba

M. Zarrebini (✉)
CEO PFE International Inc., London, UK
e-mail: mehran@catena.mba

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9.1 Part 1: The Promise of Blockchain for Healthcare

The introduction of bitcoin to the world in 2008 sparked a revolution in how value is exchanged across the globe. It seems quite a leap to go from Peer-to-Peer Digital Cash (Nakamoto 2008) to where we are today, and the connection to healthcare may not seem immediately apparent. We examine the issues by considering the evolution of healthcare systems and the problems the technology aims to solve. A detailed explanation of the underlying technology is beyond the scope of this chapter. However, by exploring a few use cases in action, we aim to illustrate the value proposition and provide insights into how we anticipate a better vision for healthcare than the one we experience today.

While some of the start-ups that launched in the last 10 years or thereabouts are no longer operational, there are many that have found success. Blockchain technology is evolving at a blistering pace, and the agile companies with strong teams have managed to adapt or pivot into commercially viable entities. Below, we analyse and present some of these successes, explore the potential reasons that others perhaps have failed and deliver insights for how the future may play out.

9.1.1 The Technology: A Primer

Without delving too deeply into the technical jargon, it is imperative we explain the value proposition that this technology promises to deliver. Most readers will know about Bitcoin and digital currencies but perhaps not entirely understand just why they appear to have any value. Though the use of blockchain (the technology upon which these currencies are based) does not necessitate a 'coin', some foundational knowledge of how a crypto-economy functions will aid the discussion as we explore the use cases in this chapter.

9.1.2 Blockchains

At its most basic level, a blockchain is a shared read-and-write database within which an object of value can be exchanged and recorded between two or more parties. This database acts as an independent network or ecosystem in which members can interact and has embedded within it an agreed set of rules by which participants abide. The rules of interaction in the network are defined by the members, and the underlying protocol therefore acts as a governance structure underpinning the value exchanges for which it is designed. Each blockchain thus acts as a 'Mini-Economy' within which disparate entities who may not necessarily know or trust one another can trade objects of value directly with each other without relying on a trusted intermediary or central authority. Instead, by agreeing to the protocol of 'trading rules'

defined, members place their trust in the underlying code to execute agreements faithfully. Members can contribute and vote on the governance rules of the system, and any changes to these rules generally requires a majority vote to amend the protocol.

The objects of value being traded can either exist as native assets on the blockchain (e.g., like bitcoin) or can be digital 'tokens' which represent an asset off-chain. Each 'digital asset' is housed permanently on the blockchain at a specific address (think of a cell on an excel spreadsheet) and the holder of the private key (think pin number) which proves ownership is required to transfer the asset to an address owned by another participant.

The 'state' of the blockchain (i.e., who owns what right now) provides a snapshot in time of the 'state' of the mini-economy. Every time an exchange of value is agreed as valid by the network and therefore permitted to occur, the new 'state' is finalised. With each new 'state' cryptographically linked to the previous state (all the way back to the very beginning of the network), the blockchain acts secondarily as an unalterable record of all previous value exchange events. An 'append-only' structure, it functions as an ever growing 'chain of states', documenting the events which lead to the current version of the 'economy'.

Of critical importance, the confirmation of a new state can only be achieved through consensus in the network—"It is only true if we all say it is true". The way this is achieved depends on the design of the particular blockchain in use as we shall see below.

The blockchain 'Trilemma' (Ledger n.d.) presented by Vitalik Buterin, CEO of Ethereum, argues that there is a trade-off between decentralisation, security and scalability, and numerous variations on the 'blockchain' theme exist to balance these conflicting elements. Security is best achieved with high levels of decentralisation, but with a consequent reduction in scalability. With private, permissioned blockchains, a semi-trusted consortium of actors maintains the integrity of the ledger through consensus mechanisms that generally do not utilise crypto-economic incentives. These systems prioritise scalability but limit decentralisation and security.

Permissionless blockchains on the other hand, have much larger networks with many more unknown and untrusted entities participating. These systems usually utilise consensus mechanisms which issue cryptocurrencies as rewards for maintaining the ledger integrity.

Built into this game-theory approach is the crypto-economic disincentive of trying to alter the record. With Bitcoin, for example, the cost of computing required to control the contents of the ledger is far greater than the reward for acting honestly. Miners are thus incentivised to ensure only valid transactions are accepted onto the blockchain.

Deciding the need for a native 'coin' depends on the functionality of the blockchain in use and perhaps whether crypto-incentivisation is required for ledger consensus. Whether being used as a cryptocurrency (as a payment mechanism or store of value), a crypto-commodity (such as the Ethereum 'gas' fees used to fuel the execution of smart contracts), crypto-tokens with a particular economic purpose in

a closed economy (Tapscott 2020) (such as used in gaming) or as security tokens that represent ownership of a real-world asset (e.g., real-estate), the use of virtual assets can be fairly broadly defined. As previously mentioned, however, a private 'permissioned' blockchain with a limited number of semi-trusted members can achieve ledger integrity to an acceptable degree with consensus mechanisms that do not require crypto-incentivisation. We explore the utility of deploying crypto-tokens later in the chapter when discussing use cases in healthcare. What is essential to understand, however, is that although cryptocurrency as it was envisioned for Bitcoin is a necessity for blockchain according to purist 'Bitcoin Maximalists', the industry has evolved and this is no longer considered the case.

What we take from all of this is that by using blockchains, it is possible for two or more parties to exchange objects of value peer-to-peer within a database, the integrity of which is maintained by the participants on the network. Recipients of these data objects can SELF-VERIFY the author and content of the data being transferred, knowing that it has not been altered en-route, as attested to by the network consensus. Assets on-chain (such as a native currency) or digital representation of assets off chain must be differentiated. In both cases, however, the record of the value exchange is immortalised on the blockchain, which displays the state of data asset ownership as well as the event log of when and by whom the transfer was permitted. It is important to mention here that the data being transferred between parties does not necessarily need to exist on the blockchain. Small amounts of data such as the details of a cryptocurrency can exist on-chain without too much concern. Transferring large volumes of data would, however, be inefficient. Instead, by representing the data being transferred with a unique digital hash (which changes if the underlying data is altered), we can record the data transfer event as a transaction on the connected blockchain layer. This provides us with a shared, unalterable, and fully auditable log of the information exchanges that have occurred.

To understand the implications for healthcare we need to examine the types of data being exchanged, the trust required to do so and the value that is derived by each party from that process.

9.1.3 Healthcare Data

With a single patient generating nearly 80 megabytes of data each year in imaging and Electronic Medical Records (EMR) data, according to 2017 estimates, RBC Capital Market projects that "by 2025, the compound annual growth rate of data for healthcare will reach 36%." This growth rate is notably faster than what's projected for many other massive industries, including manufacturing, financial services and media and entertainment. While accounting for a rapidly multiplying amount of data—and data that is highly sensitive in nature—healthcare is uniquely ill-equipped to protect it. Today, approximately 30% of the world's data volume is being generated by the healthcare industry (Capital Markets n.d.). An International Data

Corporation report sponsored by Seagate Technology delivered this blunt assessment: "IT investment in healthcare is among the lowest of all industries (Culbertson n.d.). The value derived from this data in use is immense. A 2019 report by EY (Digital Health n.d.) estimated the value of the U.K. NHS data alone to be worth £9.6Bn per year. Globally, the figure for Big Data in Healthcare is estimated to reach $78.03 Bn by 2027 (Emergen Research n.d.).

To understand the value in greater detail, we need to examine the environment in which this data is being generated and utilised. To do this, we must explore the nature of healthcare systems, the multitude of players involved, and the risks associated with misuse of this data. Healthcare systems are inherently complex and have a myriad of stakeholders whose interests are not always necessarily aligned. Industry competition aside, it is evident that any sort of data sharing in healthcare brings not only unimaginable benefits but also clinical and commercial risk. The relationships between payors, providers, patients, suppliers, regulators, big tech firms and industry R&D are by no means simple. While many entities exist in silos, all cohabit a fragmented yet inherently connected ecosystem, each influencing the dynamic either directly or indirectly. These complex networks themselves exist within a wider socio-political context and differ in their design across the globe. The way individual systems are architected varies from country to country, with each working to satisfy the needs of individuals and society. Policymakers are tasked with balancing these sometimes-conflicting demands with varying resource constraints. It is safe to say that no single system is perfect, and that taxpayer funded structures and those that are privately run each have their own challenges and benefits. Regardless, some commonalities exist across each.

We are increasingly seeing a more patient-centric approach to healthcare. This trend is changing the power dynamic in the ecosystem, resulting in new technological and economic models for how care is delivered. In their prescient 1997 book The Sovereign Individual, Lord Rees-Mogg et al. (Rees-Mogg and Davidson 1997) predicted the rise of the sovereign individual, a movement which appears to be growing across the globe in many spheres of life. More empowered patients are driving the "Amazonification" or health consumerism paradigm, with globalisation and technological advancements further enabling choice for patients. As Doctors, therapeutics, and care experiences become more commoditised, we observe a centralisation of these services. In fact, only this week (article dating from 1997) Amazon launched their telemedicine services nationwide in the USA (Rees-Mogg and Davidson 1997), further demonstrating this notion.

Healthcare generally lags other industries where technology adoption is concerned. This fact is of possible relevance when considering the future of blockchain. Given that there is an increasing appetite for self-sovereignty and patient-owned data, it is curious that the healthcare industry appears to be centralising this data even further in the hands of multinationals. The success and longevity of this process will ultimately rest on the trust of patients being earned by these oligopolistic tech giants seeking to dominate. We propose that in certain circumstances (at least initially) this may be successful and perhaps even more feasible and desirable than

the nascent blockchain solutions emerging. That said, we believe there are certain circumstances in which a leapfrog to decentralisation makes more sense, and we will explore these use-cases later in the chapter.

At the heart of any healthcare system, the primary currency fuelling the success or failure of care delivery is data. We will examine the different types of data, the value attached to it, and the barriers current systems place in exchange of that data, and by doing so, we will be able to understand more clearly the value proposition that a blockchain based value exchange mechanism might bring. Before this, however, we ask the reader to indulge us as we contextualise these issues in a perhaps flippant but relevant case study.

The story that follows will gradually become increasingly complex as we explore the movement of this data currency within a healthcare system. The examples are generic and may cut across several divergent healthcare-system models but are indicative of the complexity and value derived from health data by various stakeholders.

9.1.4 Case Study: The Currency and Value of Healthcare Data

Mrs. Mary Smith is a 79-year-old lady with a multitude of medical complaints. She lives alone in a rural part of the U.K. and although she predominantly makes use of the state-funded National Health Service (NHS), she also pays for private health insurance to be able to access care more conveniently when required. Her General Practitioner (Primary Care Physician) in the village is generally her first point of contact for medical care but Mrs. Smith, being a progressive technophile with a fierce sense of independence has also adopted numerous health technologies (devices and mobile apps) which she uses to monitor, maintain, and improve her health. Although she lives alone, she has a supportive family and social group who play active roles in her health and wellbeing. Some of Mary's conditions necessitate specialist care. Whilst her GP (Dr. Jones) generally initiates referrals to the local hospital, many of her medical interactions occur at the tertiary centre.

More recently, being in lockdown during the COVID-19 pandemic, Mary has had telemedicine consultation follow-ups, with medications delivered from her local pharmacy via an international courier company. Some of her medication is not accessible via the NHS, and Mary has elected to see a private physician to obtain these via her private insurance policy. The independent physician sources the specialist medication from two competing pharmaceutical suppliers—one in the U.K and the second in China to ensure availability and maximise profitability. Mrs. Smith suffers with a chronic condition that results in significant pain. She is on maximal therapy for this but has recently heard that an experimental drug not yet approved by her insurance, or the NHS may help alleviate some of her symptoms. While the reports on the Internet appear promising for this novel CBD related

treatment, Mary is concerned that many of the online vendors are not necessarily ensuring the quality of their products. She worries that any purchases she might make may contain impurities or inaccurate drug content or concentrations.

Though her GP does prescribe opioids for her pain, he is reluctant to increase the dose she is on. Mary has on occasion visited a private GP to secure additional opioids. For these prescriptions she usually visits a pharmacy in the neighbouring village and pays cash rather than using her insurance plan to pay for it. Dr. Simon Jones is one of three partners in an NHS Surgery. The practice earns revenues based on the number of patients on their list. This is recorded in a database held by NHS Digital on behalf of NHS England. In addition to this revenue, the GPs are paid for their performance under the Quality Outcomes Framework (QOF). Each Doctor is tasked with capturing his/her activities and meeting the targets on the framework to ensure this revenue. NHS Digital also utilises this QOF data to run reporting collections throughout the year. The Care Quality Commission (CQC) additionally runs independent inspections and collects data to ensure practises are meeting quality standards.

Simon runs a dispensing service from his Surgery but also has links with the local pharmacies for certain medications and appliances which he is unable to source. An ambitious and tech-savvy Doctor, he has also signed a licence agreement with a data analytics company which (after obtaining patient consent) aggregates and analyses the data and provides insights to several multinational pharmaceutical companies conducting research. When Dr. Jones is away, the Surgery usually employs locum GPs via a medical recruitment agency. Whilst this has worked well in the past, Dr. Jones recently had a patient complain that his stand-in didn't seem to know very much and had prescribed an inappropriate drug which luckily caused no harm.

9.1.5 Private Insurance Company

As mentioned previously, Mary utilises a variety of gadgets to manage her health. She regularly connects her smart scale, blood pressure machine, wearable devices, and glucometer to her phone, uploading the results to a remote patient monitoring platform to which she subscribes. Her family is able to see these results and can be alerted when there are deteriorations from her normal baseline. Dr. Jones is also able to access these records and has on occasion been alerted unnecessarily because Mary's nephew wore her smart watch for a day and used it to measure his heart rate when he went running. Mrs. Smith's insurer had provided her with the watch, and they too have a platform to which her data is uploaded. Mary receives discounts for the local health food shop when she demonstrates positive healthy behaviours. Mary has also recently had her genome tested—mostly out of curiosity for her ancestry data. She was, however, concerned to learn that she is a carrier of a cancer-inducing

mutation which prompted her to tell her daughter in case she might develop cancer. Having recently learned that her data might be sold to a pharmaceutical company, Mary was pleased to learn she might be able to positively contribute to science. That said, she did have some reservations, thinking that her insurance company might use the data to her disadvantage. It also occurred to her that her DNA record might be used by other more nefarious actors should they be able to access it.

Last month, Mary felt that her blood sugars were poorly controlled. Her symptoms were familiar to her as she had experienced this in the past. Despite this, her glucometer kept delivering normal test results. Mary wondered whether there may be a problem with the test strips or device. Always community-minded, she felt it necessary to report this to the manufacturer. When she went online, she discovered a 16-page feedback form and an address to which she could post her concerns. Still worried, Mary ordered a different brand of glucometer to confirm her suspicions but wondered how many other diabetics might be clinically compromised by the faulty test kit. She found this particular incident quite interesting as in her pre-retirement life Mary had owned a medical device distribution business and knew all too well the impact this sort of feedback could have on sales.

Dr. Jones, now back from his vacation, was reviewing the financial accounts of the practice. The process of reconciling activities and payments was always burdensome and error prone, never mind trying to keep track of pharmacy supplies, insurance payments for his private patients and performing payroll activities for his staff. He was also painfully aware that he needed to complete his annual appraisal for revalidation with the medical council and had to collate proof of his continuing medical education from multiple sources.

Table 9.1 below captures some of the important elements illustrated in the above use case.

Table 9.1 Healthcare Ecosystem Data Utility

Data example	Data type	Data owner/user	Data value/utility
Medical Records, Prescription Data	Clinical	Patient/ Healthcare Provider	Patient Care, Research, AI/ML training, Public Health, Payors, Supply Chain, Pharma
Wearable Data	Clinical	Patient, Provider, Insurer, Tech Company	Patient Care, Data Science, Research, Payors, Device Manufacturers
Clinical Activities Data; Clinical Quality Data	Clinical, Financial	Provider, Payor	Payments, Public Health, Operational Service Planning
Diagnostic Devices	Clinical	Patient, Provider, Manufacturer	Supply Chain, Quality Assurance, Clinical Safety, Economic Intermediaries
Administrative Data, Activity Data	Financial, Operational	Provider, Payor	Operational Efficiency, Cost Reduction. Payors, Public Health
Educational, Clinical Outcome Data	Regulatory	Provider, Regulators	Public Safety, Revalidation

Blockchains are not ideal for high volume data storage. Where electronic health record sharing is concerned, the usefulness of blockchain is not in having these records on chain, but rather in having the access to these records stored in servers (either in situ or in the cloud). Directory servers may be used to maintain the inventory of user data, mapped to the actual storage location and allowing data sharing sessions. A blockchain server can then be used to verify data integrity and log access for later audit.

9.1.6 Discussion

The narrative we have presented illustrates just a glimpse of the data complexities within a healthcare system. Whilst we have focused on an individual patient and her interactions with the system, the reader will appreciate that these examples are the tip of the iceberg when discussing data exchange between various healthcare stakeholders. Identifying the sources of these data is only the first step in understanding their value as currency. It is the utility that data provides which drives the incentives for either withholding or sharing it. We will return to the case study later, but in the interim, it is useful to discuss the conditions for a data economy and the value it provides to various stakeholders.

9.1.7 Healthcare Data Economy

There are many participants in a data ecosystem, each deriving different types of value and managing risks that are pertinent to them. A Framework published in August 2021 by the World Economic Forum (WEF) (WEF n.d.) discusses the key components required to build a data economy. Although we will not explore this in full detail here, it is important to note that core principles include managing the functional architecture of a data exchange, the governance of that exchange as well as the incentivisation of data sharing. The model discusses enablers for creating a data-exchange ecosystem with availability, usability, and trust via a multistakeholder approach being essential. There are many stakeholders to consider, with data owners, data users, analytics companies, venture capital and researchers being just a few examples. Value is derived from acquiring and combining data, from having low latency access to high quality, high integrity data and then from extracting insights to deliver meaningful outcomes. The many data types (structured, unstructured, multilingual, machine or sensor generated, static or real-time etc.) and legal risks associated with it (from how to define ownership, data in use, data protection, privacy, security, liability, intellectual property rights and vulnerability to cybercrime) suggest that having a framework in place is critical to a successful data economy. The WEF framework (WEF n.d.) defines the roles of various stakeholders in a Data Exchange Ecosystem, and it is pertinent to our discussion.

Creating frameworks for the production and sharing of quality data is important. Equally relevant is quantifying the value and risks for doing so. Understanding the *qualitative* value of data to various entities is of course only part of the discussion. EY (Digital Health n.d.) examined the factors *quantifying* the value of data and as mentioned previously estimated the NHS Health data to be worth a staggering £9.6 Billion per year. Their paper outlines just how they arrived at this figure, and it is certainly worth a read. We will not delve into it here, only to say that being able to provide data that is accessible, accurate, private, and protected where necessary are just some of these determinants observed.

Incentives for sharing, therefore, must incorporate the value and risk of data exchange that stakeholders perceive. The framework proposes some examples, and these include policy and regulatory frameworks as well as monetary and non-monetary incentives (reciprocity, opportunity to innovate and data credits) (PWC n.d.-a) - the fundamental message being that some form of incentivisation is generally desired.

Broadly speaking, the benefits of data exchange in healthcare include:

- Improved care delivery
- Reduction in unnecessary duplication
- Fewer silos with a more holistic view of patients
- Efficiencies in resource and budget allocations
- Faster and more efficient research
- Unlocking innovation through data aggregation, combination, and analytics

For patients:

- An up to date and available medical record resulting in more efficient, higher quality, safer and more personalised/coordinated care
- A longitudinal view of one's own health over time—empowering and enabling action
- Faster scientific discoveries leading to new treatments

For Healthcare Systems:

- Easier identification of risk and quicker diagnoses
- Identification of disease transmission pathways and subsequently faster prevention
- Outcome predictive analytics improving treatment effectiveness and disease prevention
- Improved quality assurance and safer treatments
- Knowledge dissemination—both administrative and clinical
- Enhanced public health strategies

Healthcare Providers:

- Redesign better care pathways
- Improved patient experience and care

- Insights for strategic planning and operational improvements
- Improved resource management
- Ability to participate in clinical research

Research and Development:

- Data aids new discoveries in Pharmaceuticals, Devices, Machine Learning Algorithms, AI diagnostics

The findings published to date from Big Data validate these claims and include:

- Validation of >200 novel biomarkers predicting cardiovascular risk
- Investigating variation of 174,000 observed national prescribing patterns to national guidelines for COPD
- Comparing ~8000 treatment outcomes for leukaemia by age: uncovering a major unmet treatment need
- >700 million records mined to develop new cancer risk-stratification algorithms (Data Saves Lives n.d.).

9.1.8 Analysing the Case Study

If we return to our case study, we can identify several themes which illustrate the issues more generally:

- Mrs. Smith has multiple Medical Records across a range of healthcare systems including her NHS General Practitioner, the local NHS hospitals, her private physician, the remote patient monitoring platform that collects her wearable data, the genomics platform, and the insurance platform which collects some of her smart watch data. Each user has operational, financial, and quality control reasons for utilising this information notwithstanding the clinical benefits Mrs. Smith might derive from its availability.
- Some of her prescription data originates with Dr. Jones and is occasionally shared with the local pharmacies, but Mrs. Smith also obtains private prescriptions which are not visible to her GP nor her usual dispensing pharmacist. There is a disconnect between the needs and desires of the patient and the duty of care to protect her from harm. Better visibility across these systems may prompt more open discussions about her pain management and potentially avoid an accidental overdose or addiction risk. Worldwide, about 500,000 deaths are attributable to drug use. More than 70% of these deaths are related to opioids, with more than 30% of those deaths caused by overdose (WHO n.d.).
- The use of wearable devices has the potential to greatly improve the ability to care for patients—reducing the workload of doctors, enabling patients to be more empowered with greater longitudinal visibility of their health trends. The data collected has value for Mrs. Smith, her physicians, her health insurance

company and potentially researchers or pharmaceutical companies. But who verifies the data is hers and not her nephew's? Is it fair that these entities profit from it financially and Mrs. Smith does not?

- Telemedicine can be another great enabler for improved care delivery. But who verifies the identity of the doctor or the patient? How is the health record accessed and shared? The issue of identity extends further when considering the locum GP. Credential management and medical licensure relies on multiple attesting parties and the collation of appraisal and revalidation documents. A PwC report (PWC n.d.-b) suggests that U.S. payers alone spend more than $2 billion a year maintaining provider databases with most credentialing processes taking more than 120 days to complete (NAMSS n.d.).
- Mrs. Smith's private physician works with two competing pharmaceutical distributors to be able to provide her specialist medications. Having supply chain visibility is essential for the doctor, as is his desire to keep the commercial arrangements of each contract confidential. Similarly, Mrs. Smith is eager to be able to procure experimental treatments but would like more confidence in the provenance of the products she plans to use. There is an estimated loss of $200 million globally through counterfeit medications (Siwicki n.d.) as well as the potential for significant clinical harm (Blackstone et al. 2014). A Penn Medicine Study concluded that nearly 70% of CBD Extracts sold online are mislabelled (Penn Medicine News n.d.). A similar study published in the Journal of the American Medical Association (JAMA) found that 40% of CBD products online have a drug concentration that is different from that on the label. In 26% of products, the concentration was higher than advertised, and some had THC in sufficient quantities that would cause consumers to fail a drug test (Bonn-Millerv et al. 2017). There is a clear need for enhanced supply chains in the pharmaceutical industry.
- A similar concern exists with medical devices. One needs to look no further than the plethora of fake Covid-19 test kits on the market today.
- Administration in a physician practice can be burdensome and prone to error. Extrapolation to the global arena illustrates just how significant a problem this can be. BIS Research has revealed estimated reports that the immediate application and integration of blockchain in healthcare could save more than $100 billion per year in costs related to IT, operations, support functions, personnel, and health data breaches by 2025 (HIT Infrastructure n.d.).
- Patient recruitment for clinical trials is known to be a challenging aspect of clinical research. There are multiple competing concerns from the sponsor, patient and principal investigator's perspectives resulting in most clinical trials not meeting recruitment requirements on time. Conducting under-enrolled clinical trials affects the power of conclusive results or causes premature trial termination. There is evidence that utilising blockchain can provide significant benefits in recruitment as well as enhance data provenance and security (Zhuang et al. 2019).

What our meandering story of a patient and her interactions with healthcare serves to illustrate is that even a superficial glance under the hood reveals a tangled

web of disparate, non-trusting parties who rely on highly valuable data for their clinical, commercial, and academic endeavours. This 'currency' fuels the business of healthcare, and its veracity and accessibility are vital to success in the industry. As we strive toward a more robust data economy, one of the tools available to us that is demonstrating value is the use of blockchains. Though by no means a panacea, we believe that blockchains (at least as a foundational layer, perhaps combined with artificial intelligence, IoT and other emerging technologies) can play a part in helping us to build the data ecosystems which we so desperately need.

In the next section, we continue to elaborate on the details of this case study to highlight some of the companies developing solutions to the problems identified. Though not all have succeeded, there are some that have found commercial success. Our discussion will explore the reasons for this and perhaps shed some light on what is required for future adoption and triumph.

9.2 Part 2: The Current Landscape of Blockchain in Healthcare: A Brief Analysis

We recently conducted a review to understand the progress that has been made by companies deploying blockchain technology in healthcare. A selection of our findings is summarised below, followed by a discussion of the results. Whilst we admit that perhaps there are companies which we did not identify, it is our opinion that it represents a fair reflection of the current state of the industry.

9.2.1 A Selection of our Results

Our research identified 75 companies (Fig. 9.1) claiming a blockchain as part of their healthcare solution. 75% of these were established in 2016/2017 which perhaps correlates with the ICO (Initial Coin Offering) craze, and significant funding

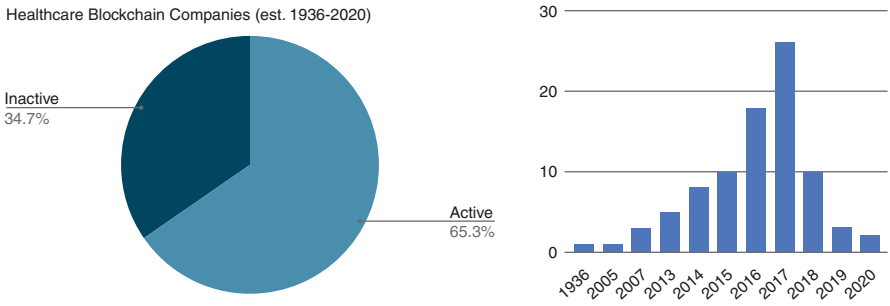

Fig. 9.1 Number of companies actively involved in Blockchain implementation/development

was raised in the last decade. Roughly two thirds of the companies identified are still active. It is possible that a small percentage of these failures relate to crypto scams, but it is more likely that there were fundamental flaws in the teams, business models or technology choices that lead to their demise. The Covid-19 pandemic may equally have had a significant impact on some of these entities, and further examination of the reasons for failure is required to tease this out. The apparent drop off in funding after 2017 is likely due to the reputation of ICOs in general. Whilst there were many scams, and most companies raised funds without having anything but a white paper, there is a significant percentage of companies that have used those funds to build substantial products. Though difficult to predict, it is our view that when the legitimate products come to market, there is likely to be an increase in further funding.

9.2.1.1 List of Active Companies and Focus Areas

Table 9.2 below lists the companies that are still actively building solutions. It remains to be seen which of these will become commercially successful. We anticipate further failures and perhaps some mergers or acquisitions to occur.

Table 9.2 List of Active Blockchain Healthcare Companies (Catena.MBA, 2022)

Company name	Focus area
Synaptic Health Alliance	Provider, Patient and Payor Directories linked to reduce friction in administration.
Chronicled	Blockchain, MediLedger, Pharmaceutical Supply Chain, Contracts & Chargebacks, Product Verification, Roster Management
Medicalchain	EHR, Blockchain
Guardtime	Blockchain- Vaccine Guard, HSX,
HealthVerity	EHR, Clinical Trials, Blockchain
BurstIQ	Security, Blockchain
Axuall, Inc.	Credentialing, Blockchain
PharmaLedger	Blockchain- Healthcare, Pharmaceutical Supply Chain, Clinical Trials
MediShares	Insurance, Blockchain
Skyflow	Blockchain- Security, Healthcare, Financial
Fortanix	Security, Healthcare, Financial, Manufacturing, Public Sector
Gem	Crypto- Payments API
Nebula Genomics	DNA Testing, Blockchain
KitChain	Pharmaceutical Supply Chain, Blockchain
Hashed Health	Blockchain- Healthcare, Credentialing, Clinical Data Sharing, Marketplace, Digital Signatures
Mosio	Clinical Trial Recruiting, SMS, Blockchain
ClinTex	Clinical Trials, Blockchain
dHealth Foundation	EHR, Blockchain, Network
EncrypGen	Blockchain- Healthcare, DNA
FarmaTrust	Blockchain, Pharmaceutical Supply Chain

Table 9.2 (continued)

Company name	Focus area
Genomes.io	DNA, Blockchain
MediBloc	EHR, Blockchain
OncoPower	Cancer, Physician Network, Telemedicine
Patientory	Blockchain- Healthcare, Clinical Trials, Health Monitoring, Pandemic Reporting, OpenEHR
Solve.Care	Engagement, Blockchain
Avaneer Health	Patient Retention, Blockchain
BlockTEST	Blockchain- Healthcare, Drug Tracing, Financing
Bowhead Health	Blockchain, Health Tracker
ConsilX	Clinical Trials, Engagement, Telemedicine, Blockchain
EHR Data	EHR, Engagement, Blockchain
Humanscape	Clinical Trial Recruiting, Blockchain
LedgerDomain	Blockchain- Pharmaceutical Supply Chain
LifeFilez	EHR, Blockchain
MAPay	Payments, Blockchain
MediLedger	Blockchain- Network, Healthcare, Pharmaceutical Supply Chain, Contracts & Chargebacks, Product Verification, Roster Management
Murrieta Genomics	Biotech- Genomics
Radiologex	Radiology, Blockchain
SoluLab	Blockchain- Enterprise, Healthcare, Logistics, Oil and Gas, Education, Retail, Transportation, Wellness and Fitness, Cannabis, IoT
Stem Cell Coin	Biotech- Regenerative Medicine
Unicsoft	Blockchain- Healthcare, Supply Chain, Fintech, Manufacturing, Automotive, Retail & E-commerce, Marketing & Media
Veridat	Supply Chain, Pharmaceuticals, Blockchain
Well	EHR, Wearable, Blockchain
Doc.AI	Analytics, Mental Health, Blockchain
Embleema	Pharmaceutical Supply Chain, Blockchain
Open Health Network	EHR, Blockchain
Longenesis	Data Management
ProCredEx	EHR, Credentialing, Blockchain
Datavant	Analytics, EHR, Tokenization, Blockchain

A similar review was performed in January 2021 on all projects in the CoinMarketCap database by Hao Sen Andrew Fang and published in BHTY (Blockchain in Healthcare Today) looking at commercially successful blockchain healthcare projects. Though the authors acknowledge that their review is limited to projects listed in a single database and only those utilising cryptocurrencies, they conclude that it is likely that there will be increasing interest and further commercial success for blockchain companies in healthcare as the market matures.

Table 9.3 Distribution of the types of healthcare projects among those reviewed (Fang 2021, p. 166)

Field	Number of companies
Data exchange and interoperability	1
Citizen based reporting	1
Health financing	1
Telemedicine	1
Supply chain management	1
Personal health tracking	4
Data collection, management and use	1

The paper highlights 10 companies (Table 9.3), the majority of which have projects in the personal health tracking space (Fang 2021).

The approach we took in our research was to look at all companies claiming to utilise both private and public blockchains in their solution. The paper above restricted their research to those that deployed crypto-tokens and listed on exchanges.

The question of whether a blockchain (in general or in healthcare) requires the use of a cryptocurrency is not a simple one to answer. We alluded to the topic earlier in the chapter when discussing the types of blockchains and consensus mechanisms deployed. Certainly, it is not a binary key success factor if a crypto-token is used. What is key, is how the token functionality is defined. Holding native tokens which enable utility in an ecosystem is distinctly different from tokens that allow voting rights in a governance model or those that represent ownership of an underlying security such as the rights to future dividends.

Additionally, while the ICO craze helped fund many of these companies, the Securities and Exchange Commission (SEC) has since deemed many of the 'utility tokens' to be securities. The craze was, in part, fuelled by speculative investors who were simply seeking to profit from the launches of these coins. As a result, some 'utility tokens' have seen their value on exchanges drop to almost zero. Understanding tokenomic models is critical to the long-term success of these projects.

As we witness the rise of a more patient-centric healthcare system, with self-sovereignty at its core, many of these projects have tried to incorporate crypto-related game theory and behavioural economics into their models. Whether a blockchain token can incentivise healthy behaviours or data sharing remains to be seen, but there is clearly a shift towards this ideology, though it might require some tweaking and learning before it finds purchase.

The industry (particularly where crypto incentives are concerned) is still in its infancy, and there are several obstacles to overcome. Fundamentally, however, we still believe that there is much to gain. In the final section of this chapter, we explore some of these barriers and offer some thoughts on what is required to achieve the potential that blockchains have for healthcare.

9.3 Part 3: A Future Vision for Healthcare Blockchains

We have alluded to numerous challenges facing healthcare in the coming decade. Many of these point to the need for a more robust data economy as discussed previously. A selection of these issues is listed below:

- The amount of knowledge a healthcare professional needs to remain up to date is rising exponentially (Illingworth and Chelvanayagam 2017), and there is increased need for multidisciplinary cross-collaboration (Keys et al. 2017).
- This complexity renders systems more prone to errors (Braithwaite et al. 2017) and we therefore require better knowledge sharing mechanisms.
- Healthcare organisations tend to be slow in adopting new technologies. Adoption is influenced by assessments of feasibility, cost-effectiveness, profitability, and potential success (Tal et al. 2019). Technology evaluations involve a complex, multi-disciplinary approach that reflects organisational politics, as well as the organisation's values (Tal et al. 2019).
- The shift towards patient sovereignty and patient-centred care relies on patient engagement with technologies. For this, they need to be empowered (Tobiano et al. 2021) and have sufficient access to and literacy with technology. Patients also need to be able to trust virtual care services which has been shown to be reduced when compared with traditional environments (Hasselgren et al. 2020).
- The transparency of the knowledge and data stored in these systems is often siloed (Nelson and Staggers 2016), and organisations seek secure methods of aggregating and utilising data for healthcare research, operations, and quality control (Porsdam Mann et al. 2021).
- Current health technologies struggle with interoperability and perceived usability remains a challenge (Son et al. 2021).

Adoption of any new technology is generally slow and requires overcoming barriers which we will explore below. There appears to be growing interest in the use of blockchain for healthcare with significant percentages of health executives and data users admitting that they see immense value in the technology.

The EU Blockchain Observatory Forum (EU Blockchain Observatory and Forum n.d.) conducted a survey and asked respondents to identify blockchain use cases of highest value. Their answers follow below:

- Data transparency (91.1%)
- Medical and pharmaceutical supply chains (88.2%)
- Data immutability (85.3%)
- Collaboration between manufacturers, suppliers, retailers, and end consumers (85.3%)
- Medical records sharing (79.4%)
- Secure payment transactions (76.5%)

- Record accuracy (73.5%)
- Data interoperability (70.6%)
- Identity management (70.6%)
- The use of smart contracts for insurance purposes (67.7%)
- Data management (61.7%).

These findings corroborate our own observations and are reflected in the use cases that have been produced. A more topical and perhaps controversial use for blockchain that has been explored is that of pandemic response and some solutions are already on the market.

The topic introduces several ethical and legal questions which are perhaps beyond the scope of this discussion. We take the view, however, that these dilemmas aside, blockchain technology has great potential in the management of any future pandemic, provided the balance of personal liberties and public good can be managed. "It should make extensive use of its encryption characteristics combined with decentralised peer-to-peer engagement so as to improve security, regulatory compliance, durability, consensus, selective privacy and timing" (Kritikos 2020). The use of Federated Learning (Li et al. 2021) may bring us closer to being able to share datasets in a more privacy-preserving manner.

Some of the barriers to widespread blockchain adoption in healthcare thus concern issues of data accuracy and integrity, regulatory and privacy concerns and ethical considerations - "health data quality is still subject to the consideration of "garbage in, garbage out" (EU Blockchain Observatory and Forum n.d.), and any inaccuracies would be carried forward in a blockchain (Wong et al. 2019). While the goal is for a blockchain to serve as a source of trusted data, LaPointe and Fishbane (LaPointe and Fishbane 2019) point out that we have not achieved "trusted data" by adding inaccurate data to a blockchain (EU Blockchain Observatory and Forum n.d.).

Regulatory frameworks such as The General Data Protection Regulation (GDPR) have also created concerns for the use of immutable ledgers in healthcare. Whilst this chapter does not delve into the intricacies of this potential barrier, we are aware that there are GDPR compliant blockchain solutions for healthcare (Hasselgren et al. 2020), and that expertise utilising proper blockchain architecture in deployment will be critical to ensure regulatory compliance.

The question of ethics-by-design is a far more nuanced one. Allen et al. (2020) recommend the development of scenario-based ethical dilemmas across blockchain uses in various healthcare to ensure that the right questions are considered for decision making. Understanding the complexities will require a multidisciplinary approach involving legal and healthcare experts working in conjunction with developers. Work has already started with the development of regulatory sandboxes and adopters are advised to work within these evolving frameworks to ensure compliance.

Much has been written about the interaction of blockchain and other emerging technologies. Though this deserves a chapter in its own right, we believe that blockchains can be part of a solution that provides the high quality, trusted data that

artificial intelligence and machine learning algorithms require to provide meaningful insights. The use of Internet of Things (IoT) and oracles further add to the veracity of the data that can be used, and the intersection of these technologies is going to be critical for complete solutions.

Though there remain challenges to the widespread adoption of blockchain, particularly in healthcare where the complexities and regulatory hurdles are perhaps greater than in other industries, we believe that their use, at least in part (or combined with complementary technologies) has a significant role to play in helping achieve a better future for healthcare.

Digitisation of healthcare is an inevitability and securing high quality data and a robust trusted data economy will be critical to realising the value from its creation.

We encourage healthcare executives to engage with the opportunities presented. No doubt there are challenges and risks associated with adoption of novel technologies, however, there is, we believe, an even greater risk in the longer term for not engaging with them.

As consultants, we constantly advise clients on Blue Ocean Strategies for their organisations. Blockchains represent a new paradigm in business. A more coopetitive model, it relies on stakeholders seeing greater benefit in sharing a common infrastructure for mutual gain. Blockchain is a governance technology and building the rules of engagement in the network is just as important as the technology choices deployed. Technology aside, we see much of the hesitancy in adoption coming from a mistrust in this very different way of working.

An African proverb "If you want to go fast, go alone; but if you want to go far, go together" captures the benefits succinctly. Healthcare is an enormous industry and there is opportunity for entrepreneurs to find commercial success at many levels. However, it is perhaps unique in its importance when compared with non-essential services. Balancing profit with individual care and public utility is a tightrope which many other businesses do not need to walk. We believe that collaboration has far greater value than individual success, and that these are not mutually exclusive. This belief drives our passion for helping companies build solutions in this industry.

We offer a brief suggested template for executives wanting to realise the potential opportunities of joining the data economy. This approach is founded on evidence from the Blockchain Research Institute in Canada and has been demonstrably proven to be a useful approach. We suggest the principles needing to be applied below:

- Think "We" vs "I": What are the shared problems across the 'trade' network?
- Evangelise the new perspective - Demonstrate the potential of a new solution.
- Identify the Minimally Viable Ecosystem/Network (including legal and regulatory bodies).
- Define Governance Structures.
- Define Technology Committee.
- Define Voting Structure and Executive Committee.

When starting:

- Identify the highest impact use case needing innovation.
- Define Governance Model (JV/Consortium/Statutory Body) and agree a funding structure.
- Perform Stakeholder Analysis to identify and create measurable value for all partners
- Define Metrics of Success.
- Define the Technological Minimally Viable Product.
- Examine legacy infrastructure and establish integration options.

For many organisations, blockchain does not need to replace any existing infrastructure. It can, rather, be a technology layer above what already exists. What is evident is that technology change is 75% cultural and 25% technical. We need to build a new culture in healthcare data value exchange if we want to provide better care for patients, better work environments for clinical and administrative staff. In doing so, we will be able to realise the enormous potential of 30% of the world's data that is currently locked away in silos preventing treatment innovations and better health outcomes. We hope you join us on this incredibly important journey.

In the words of futurist Jim Carroll: **Think Big, Start Small, Scale Fast.**

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Chapter 10
Nudging to Change, the Role of Digital Health

Aditya Kumar Purohit, Sofia Schöbel, Olivier Bill, and Adrian Holzer

Abstract The use of nudges, i.e., design changes in the way choices are presented to steer users towards predetermined choices, has dramatically increased over the last few years. These interventions have moved online to become digital and are present across many fields from politics to healthcare. As the use of these mechanisms in healthcare has grown exponentially recently, it is crucial to understand the opportunities they offer and the risks they pose. However, at this stage, such an analysis is lacking. This chapter specifically addresses this issue by (1) analyzing how digital nudges can be applied in the continuum of care and (2) mapping the current empirical research landscape on the topic. To do so, this chapter presents a scoping review of the literature by searching relevant research in the electronic database of JMIR (Journal of Medical Internet Research). The search yielded 150 unique articles, of which 19 articles satisfied the criteria for inclusion in this study. The results indicate that feedback and reminders are the most commonly used digital nudges for behavior change in digital health. Moreover, the results show that most digital nudges research focuses on prevention and the post-acute phase of the continuum of care, with none of the studies investigating nudges for the acute phase. Finally, the results indicate that current empirical research on digital nudging in healthcare rarely discusses ethical considerations.

Keywords Digital Health · Digital Nudging · Nudging · Continuum of care Ethics of nudging · Scoping review

A. K. Purohit
Radboud University, Nijmegen, Netherlands
e-mail: aditya.purohit@ru.nl

S. Schöbel
University of Osnabrück, Osnabrück, Germany
e-mail: sofia.schoebel@uni-osnabrueck.de

O. Bill
Lausanne University Hospital and University of Lausanne, Lausanne, Switzerland
e-mail: Olivier.bill@chuv.ch

A. Holzer (✉)
University of Neuchâtel, Neuchâtel, Switzerland
e-mail: adrian.holzer@unine.ch

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10.1 Introduction

Most diseases can be prevented by assisting people to change their habitual risky behaviors (Kelly 2000). A variety of risky behaviors are negatively associated with health, including being sedentary (Bakker et al. 2021), smoking (Wang et al. 2021), eating unhealthy foods (Marucci et al. 2021), and binge-drinking (Åberg et al. 2017). If people change their health risk behavior, they can reduce their risk of developing diseases that cause premature sickness and death, like cancer and heart disease (Kelly 2000). A case in point would be that millions of premature deaths are preventable if individuals stop smoking cigarettes, which not only cause lung cancer (Sasco et al. 2004) but also increase the risk of pulmonary and cardiovascular diseases (Stallones 2015).

Historically, interventions to change risky health behaviors were offered in service settings or within communities, but today, this is no longer the only way to do so. Through the IT infrastructure that has been developed with data from patients and service providers (Shah and Adusumalli 2020), research and practice in digital health have become more relevant to clinical needs. Through continuous, real-time, and objective measurements of physiological parameters and motion activity, it has become possible to change risky behaviors through digital interventions. However, this is a challenging task as it requires combining evidence-based approaches with trust in technology while respecting patient autonomy and consent.

A potential behavioral theory that could be leveraged to address this issue is nudge theory (Sunstein and Thaler 2008). Behavioral economists have proposed the idea of nudging, which uses human cognitive processes to direct people towards the desired behavior without restricting user choice (Sunstein and Thaler 2008). This theory is gaining traction in the digital health context as researchers have started to apply it to different contexts such as mental health (Okeke et al. 2018), smoking cessation (Free et al. 2011), weight management (Valle et al. 2020), medicine adherence (Angellotti et al. 2019), and digital well-being (Purohit and Holzer 2021) to name a few. Despite these examples, there is currently no unified picture of how digital nudges are used in healthcare and where the state of research stands. In this chapter, we address this issue by mapping the landscape of digital nudging for healthcare. In particular, the chapter will summarize which specific health behaviors are targeted, which nudging techniques have been employed for behavior change and how these strategies have been delivered including their ethical implications. In an examination of the nudging landscape in digital health, two main research questions will be addressed:

- RQ1: What kind of digital nudge strategies can be leveraged to improve health?
- RQ2: How can digital nudge strategies be used to support behaviour change on the continuum of care?

The remainder of this chapter is structured as follows. First, the background provides a definition of “nudging” and “digital nudging” in the context of behavior

change. Second, existing digital nudging strategies are detailed and their employment in continuum of care is illustrated. Third, the current state of the literature is discussed through a scoping review of the JMIR electronic database. Finally, the chapter wraps up with a conclusion.

10.2 Background

Originally, Sunstein and Thaler (2008) suggested that policymakers can design nudges to promote change in behavior among citizens. They defined a nudge as "any aspect of the architecture of choice that changes people's behavior in a way predictable without prohibiting all options or significantly changing their incentives" (Sunstein and Thaler 2008). To modify behavior, nudges change how we see things and make people more receptive to one option (Levy 2017). A typical example is the way products are displayed in cafeteria, the more prominent, the greater the chance a customer will select them (Sunstein and Thaler 2008). Meanwhile, researchers and practitioners have taken the nudging concept online, resulting in so-called digital nudges. The term digital nudges refer to nudges that are provided through digital technology and employ user-interface design elements to influence people's decisions and behaviors (Weinmann et al. 2016), again without restricting choice (Jesse and Jannach 2021). For instance, intuitively reminding individuals by giving them feedback about their Instagram use while they are mindlessly scrolling through their Instagram news feed can help them reduce their consumption (Purohit and Holzer 2021). Especially, digital nudges delivered via mobile devices are becoming increasingly common. As a result of recent technological advancements, mobile phones have acquired new and distinctive characteristics that make them a compelling behaviour change support system. These characteristics include (1) their ability to gather contextual and bio-metric data from users, such as location, movement, or heart rate, (2) their ability to be reached by users at anytime as they carry their phones around almost 24/7, and (3) their ability to potentially reach their users any time through notifications.

These characteristics imply that delivery of digital nudges can be much more fine tuned than traditional nudges to fit optimal timing (Purohit and Holzer 2019). More precisely, through adequate identification of user context, nudges can take advantage of so-called *teachable moments* (Purohit and Holzer 2019) i.e., "naturally occurring health events thought to motivate individuals to adopt risk-reducing health behaviours spontaneously." For example, a woman might benefit from a smoking cessation intervention during the perinatal period (Ockene et al. 2002). In an attempt to motivate incremental dietary behaviour change, Intille et al. (2003) suggested that information should be provided on a PDA (personal digital assistant) at the time of purchase (the nudge moment). Another study examined how weight loss could be achieved by altering eating behavior in obese adolescents (Ford et al.

2010). The study indicated that real-time feedback was given to the participants during meals (the nudge moment) to help them eat more slowly. It should be noted that despite these examples, of "just-in-time" technology, most other studies do not address digital nudges explicitly with timing.

10.3 Digital Nudging Strategies

This section outlines different strategies of digital nudging used to influence human behavior exemplified in the context of digital health. The digital nudges outlined here have been adopted from Caraban et al. (2019), they are: defaults, reminders, feedback, social, framing, suggesting alternatives, and positioning. Several nudges such as hiding, scarcity, and deceptive visualisations and many others are not included as they do not fall within the scope of healthcare.

In addition to different digital nudging strategies and examples from healthcare research, we also present scenarios that illustrate how clinicians and designers might apply digital nudges in healthcare. Consider James. He is overweight and sedentary. Through the app store, James has downloaded an application called *Fitness* to his smartwatch that will help him increase physical activity and manage his weight.

10.3.1 Default Nudge

A default nudge occurs whenever there is a predefined option chosen by a system designer. A prime example of default is the initial organ donation status of a person in a country, i.e., their default status. In some countries, people are organ donors by default and they have to actively opt out, whereas in other countries, people are not organ donors by default and they have to actively opt in. The status quo bias of human psychology is such that people will tend not to change default settings. As a result, the number of people on the organ donor list increased by 60% in the countries where it is the default option compared to the national average of 38% (Thaler et al. 2014) in the countries where it is not. On top of the status quo bias, defaults produce such large effects because individuals do not have explicit preferences for every possible good or service offered (Van Dalen and Henkens 2014). For instance, If individuals are assigned permanent appointments by default, assuming they have consented beforehand, they are more likely to have a flu vaccine appointment, thus increasing the possibility of being vaccinated (Lehmann et al. 2016). Figure 10.1 illustrates a default nudge.

10.3.2 Reminder Nudge

A reminder nudge is a nudge that brings a choice to the user's attention. With the ubiquity of mobile phones, this nudge can typically be delivered through a visual, sound, or haptic cue to a user (e.g., a push notification). Most of the time, people have a lot on their minds, and they may forget to start an activity (Karlsen and Andersen 2019), become preoccupied, or simply put it off. A reminder can act as a helpful digital nudge to help them follow through with a certain behavior. For instance, text messages sent by the clinician to remind or alert patients to read relevant health resources or to perform an activity. Figure 10.2 illustrates a reminder nudge.

Fig. 10.1 Default nudge on the Fitness app. The app's log in page requires users to agree with the terms and conditions, but they are free to choose to subscribe to the newsletter or not. However, as James logs into the application, the subscription option is ticked by default in order to steer his behaviour towards simply leaving it as is and subscribing to the newsletter

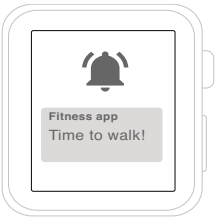

Fig. 10.2 Reminder nudge on the Fitness app. The sensors in the watch recognize that James is sitting idle for some time. While James sits on the couch watching TV, a notification is sent to his watch to make it vibrate and displays a message to steer him towards doing some physical activity

10.3.3 Feedback Nudge

Feedback nudges aim to inform users about their performance on some task in order to raise their awareness and potentially rectify a misconception a user has about their problematic behavior by presenting evidence that their behavior is inconsistent with what is actually deemed acceptable (Clayton Neighbors et al. 2015). For instance, to motivate an individual, a feedback nudge can be utilized to provide feedback on goals achieved by the end of the day, or the total number of steps taken during a certain period. Moreover, a feedback nudge can be tailored/personalized to an individual to solve the problem of heterogeneity, i.e., individuals' behaviors differ despite being nudged in the same way. Figure 10.3 illustrates a feedback nudge.

10.3.4 Social Nudge

A social nudge is a nudge that informs individuals about what other people are doing. This is also known as a peer comparison nudge. Nudges of this type aim to establish social norms that users will be motivated to follow (Arigo and Suls 2018). For instance, a user could receive the following message on their app "Approximately half of your co-workers walk at least 10,000 steps per day. And you?" Figure 10.4 illustrates a social nudge.

10.3.5 Framing Nudge

The way information is presented affects the way people make decisions (Tversky and Kahneman 1985), and framing is the deliberate phrasing to encourage the target behaviour. A good example is the fact that people respond differently to information presented as a loss or a gain. Consider the following framing example: "If skin cancer is detected early, it can be treated before it becomes life-threatening" stresses

Fig. 10.3 Feedback nudge on the Fitness app. The sensors in the watch record James' physical activity using the accelerometer and GPS. James' steps are recorded whenever he moves. To further motivate James, the health application provides James with feedback on his weekly move goal. The presentation of the feedback makes it easier for James to track his performance

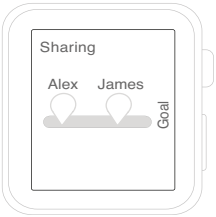

Fig. 10.4 Social nudge on the Fitness app. The app provides a peer comparison feature. James can invite his friends and compete against them. Whenever James exercises, the watch records the activity via its sensors. It then informs him about how well or poor he is doing in comparison to his friend Alex to motivate him to follow through on his exercise goals

Fig. 10.5 Framing nudge on the Fitness app. The app features a Q&A section that answers question related to health. When James visits the Q&A section within the app, he is presented with various questions and related answers that are framed as a loss or a gain. To encourage James to increase his physical activity the answer to why walking is important is framed positively

more on benefits while "if skin cancer is not detected early, it cannot be possibly treated before it becomes life-threatening" stresses more on costs. Figure 10.5 illustrates a framing nudge.

10.3.6 Suggesting Alternatives Nudge

This nudging strategy aims at providing individuals, about to make a decision, with alternatives that they might not have considered at this point (Forwood et al. 2015). For instance, to reduce the antibiotic over prescription, patients/clinicians could be suggested alternatives to antibiotics medication at the time decision is to be taken. Likewise, an individual who is mindlessly switching between social media apps could be given alternative tasks to complete: Take a walk. Figure 10.6 illustrates a suggesting alternatives nudge.

Fig. 10.6 Suggesting alternatives nudge on the Fitness app. As a means to motivate James and support him in his decision-making, the health app offers James a variety of activities to improve his health each morning that he may not have thought of before. Moreover, the options have been ordered to favor the first three options visible on the screen (example of a positioning nudge)

10.3.7 Positioning Nudge

Positioning nudges tap into the status-quo bias by changing the way the options are presented visually (Caraban et al. 2019). Intuitively, options that are more salient, will be chosen more often than options that are less salient. In the extreme, system designer can hide certain options to make users less likely to select them. For instance, re-positioning the food choices to make nutritious food more prominent in a physical setting can increase their sales (Ensaff et al. 2015). In the digital context, Wyse et al. positioned nutritious food at the top of the list on the food ordering web-platform, resulting in an increased selection of nutritious food (Wyse et al. 2021a). Figure 10.6 also illustrates how positioning of physical activity options can assist James in being more active.

10.4 Digital Nudges in the Continuum of Care

In medicine, continuum of care is the provision of health care over time. The term refers to all the phases of a patient's illness, from before the diagnosis to the end of life. The continuum of care can be split in five general phases: prevention, pre-acute, acute, post-acute and chronic home-care (Cohen et al. 2020; Spring et al. 2020). Below, readers are provided with an overview of what it means for digital nudges to be used in digital health and how they can be leveraged to address each aspect of the health care continuum (Fig. 10.7).

10.4.1 Prevention

In the prevention phase the goal is to employ digital nudge interventions before the onset of a disorder and discourage risky health behaviours and prevent individual risk factors for a certain medical condition. The following study presents a case in

Fig. 10.7 Continuum of care

point, Milkman et al. employed text-based nudges delivered on a phone that used a framing nudge to boost vaccine adoption, i.e., to prevent influenza (Milkman et al. 2021). The application of framing led to increase in influenza vaccination rate by 5% when individuals were reminded twice to get their flu shot and were also informed that their vaccination appointment was already booked. Within the prevention phase of patient care, digital nudges are generally used to target individuals toward increasing behavior such as physical activity, food intake.

10.4.2 Pre-Acute Care

The pre-acute phase encompasses the time when a patient starts to experience a deteriorating health condition and starts self-monitoring. Patients with a progressing health condition following the prevention phase receive pre-acute care that often includes services such as health screening, lifestyle behavioural modification (healthy living) and disease risk reduction. One among many case in point for pre-acute care are digital interventions such as feedback and reminders to improve dietary intake and physical activity behaviour. To illustrate, Xu et al. employed feedback nudges to improve dietary behaviour and increase physical activity for the patients who were at high risk for type 2 diabetes (Xu et al. 2020).

10.4.3 Acute Care

The acute phase starts with medical diagnostic by medical professional and treatment. Following the prevention phase, patients with potentially unstable health condition then receive acute care that often includes services such as the provision of urgent, targeted, primary care or hospital-based care. An example of the area where acute care and chronic care is crucial for recovery is motor training for individuals affected by stroke (Krakauer and Cortés 2018). The game-based digital therapy supports user motivation. The goal of gamification is to use game mechanics such as competition, awards, and timely feedback to motivate and reward players. These elements of the game such as feedback, rewards and social comparison are in fact digital nudges integrated into the game mechanics. For instance, Perez-Marcos et al. employed gamification-based games for functional training of upper limb after brain damage (Perez-Marcos et al. 2017). Also, it has been proposed that immersive

VR therapy based on gamification can be beneficial in treating balance problems associated with chronic ischemic stroke (Cortés-Pérez et al. 2020). Moreover, digital nudges are also employed for clinicians in acute phase. One classic example is by Boillat et al. to prevent the human error-related complications in operating rooms. They proposed smart glasses to overcome the challenge where surgeons in an operating room have to rely on a poster or paper to complete a time-out checklist that takes place before the surgery (Boillat et al. 2019). There was a 100% completion rate with an 18% decrease in the average checklist duration, demonstrating the efficacy of reminders digital nudge in reducing patient complications from surgery.

10.4.4 Post-Acute Care

Patients with stabilized conditions following acute hospitalization receive later care services such as nursing care, monitoring, drug administration, rehabilitation, health education and residential care (Wang et al. 2019). The employment of various digital nudges in post-acute care phase has shown some promise. For instance, elderly patients who recently suffered a heart attack were significantly motivated to become more physically active with loss-framed incentives and personalized goals using a wearable device (Chokshi et al. 2018). In context of residential care, medicine adherence is one of many self-management behaviors in which digital nudges are being employed. In a recent clinical study, Horne et al. identified the medicine adherence barriers using proprietary recursive machine learning algorithms (Horne et al. 2022). Based on augmented intelligence, digital nudges were formulated on the content, frequency, timing, delivery method, and feedback metric. These digital nudges were distributed via computer-generated emails, SMS messages, and interactive voice response phone calls. A 12-month randomized controlled trial indicated that the participants in the nudge group adhered to their medicine significantly more than the participants in the control group.

10.4.5 Ethical Considerations

As illustrated above, digital nudging in the health context seems to have promising applications, as it could potentially steer behaviour in a very cost-effective fashion. However, one important aspect to note is that most digital nudges such as feedback, social comparison, or reminders require a multitude of data. Therefore, it is important to put some attention on the ethics of digital nudging and how existing studies are taking care of it. As to ethics, Thaler proposed a set of design guidelines that should be used to design what he called nudges for good (Thaler 2018). Nudges should be (1) transparent, (2) easy to opt-out, and (3) designed with the wellbeing of the user in mind (Gold et al. 2020; Sunstein and Thaler 2008). Transparency can be understood both as the goal of the nudge, which should not be deceitful or

obfuscated, but also as the mechanism of the nudge by which it operates (Purohit and Holzer 2021). This second aspect involves transparency about data usage and privacy. Opting out easily means that users should have the autonomy to follow the nudge or to decide not to follow it. However, individuals being nudged are often unaware of the nudge or the psychological mechanisms employed by the choice architect (Stuart Mills 2020; Reijula and Hertwig 2022). Lastly, the well-being of users should be the central focus for nudging and not the well-being of the designer (Purohit and Holzer 2021); however, even with the noblest intentions, who is to decide what is in the user's best interest? An ethical analysis of nudges is particularly important to mitigate potentially undesirable or harmful consequences through design changes.

10.5 Landscape of Digital Nudging in Digital Health

To better understand the current landscape of existing empirical research on digital nudges in the digital healthcare field, we performed a scoping review. The review also attempts to answer RQ1 and RQ2. This analysis is based on the three main grids of analysis presented above: digital nudging strategies, continuum of care and ethics of nudging. The inclusion criteria consisted of three main points: (1) the focus of the research had to be a digital intervention for behaviour change, (2) the intervention had to be evaluated empirically, and (3) the intervention had to target patients or healthcare professionals. A search for articles was conducted on the electronic database of JMIR (Journal of Medical Internet Research), which is the leading peer-reviewed journal for digital health and medicine. We searched for the term "nudging", "nudges" or "nudge" or "digital nudges" or "digital nudging" or "digital nudge" in the content of the articles.

The database search yielded a total of 150 articles, 131 articles were excluded based on not fulfilling inclusion criteria, resulting in 19 full-text articles for inclusion. The results in Fig. 10.8 seem to indicate that inclusion of digital nudging in digital health is increasing exponentially. For instance, the number of studies that include digital nudges have increased more than 160% since 2018. Among the 19 included studies, 30 nudges were used, as 7 studies employed two or more nudging techniques. In most of these 7 studies, nudging strategies were used in combination. The most common nudges used were feedback and reminders. Their application lied on prevention and post-acute care. Surprisingly, none of the studies investigated default nudges. Figure 10.9 provides a full overview of the analysis.

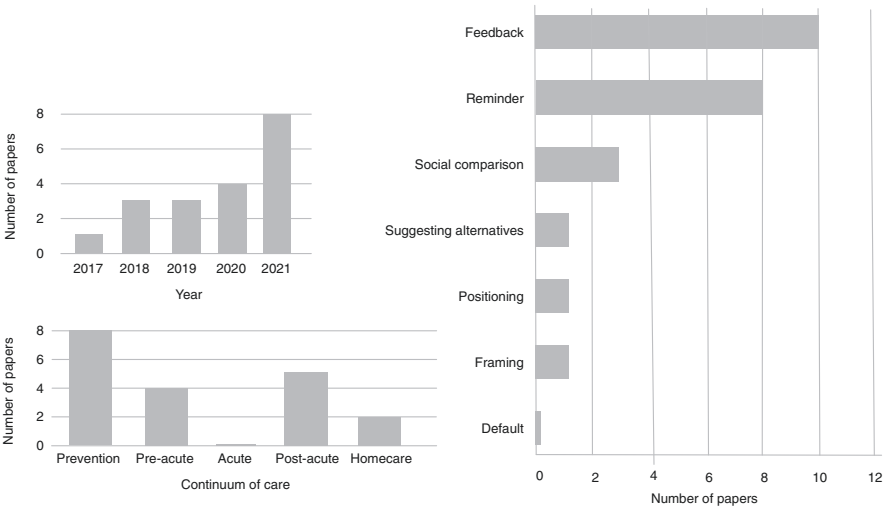

Fig. 10.8 Results of the scoping review

10.5.1 Increasing Desired Behaviour

The results of this review suggest that digital nudging can be applied to a wide variety of health objectives, i.e., from increasing the uptake of contraceptives in Africa to increasing treatment adherence to HIV treatment. It should be noted that most papers focus on increasing a desired behaviour (e.g., increase in vaccination rate, increase physical activity). Sometimes increasing a desired behaviour is coupled with a decrease in an unwanted behaviour, such as increasing activity is implicitly coupled with decreasing sedentary behaviour. Nevertheless, in the reviewed studies, nudges are not used to solely reduce an unwanted behaviour. This presents a potential opportunity for further investigation. There are several challenges in nudging patients away from an undesired behaviour, the first linked to the identification of such a behaviour (e.g., inferring when a smoker lights up a cigarette), and the second linked to providing adequate feedback on a negative behaviour (e.g., "you have not smoked today").

10.5.2 Personalized Mobile Feedback

In terms of nudging strategies, most research has focused on feedback nudges and reminders. Social comparison has also been investigated a few times, but the other strategies are only marginally studied (once in the reviewed papers). The rise of feedback nudges is not surprising given the wide adoption of smart devices such as wearable and smartphones, which allow tracking motion, steps, heart rate and other

Authors	Evaluation	Objective	Nudging strategy	Medium	Continuum of care	Transparent	Easy to opt-put	Wellbeing	Ethics discussed
André et al., (2021) [30]	RCT	Increase physical activity	SC		Prevention	✓	✓	✓	-
Azulay et al., (2019) [5]	RCT	Increase colonoscopy followup	R		Pre-acute	✓	X	✓	-
Belli et al., (2021) [7]	RCT	Improve Diabetes management	SC, SA		Post-acute	X	✓	✓	-
Bredbenner et al., (2017) [9]	RCT	Promote child growth	R		Prevention	X	✓	✓	-
Coorey et al., (2021) [13]	RCT	Improve cardiovascular disease management	F, R		Pre-acute	✓	✓	✓	-
Elnaggar et al., (2021) [15]	RCT	Motivating patients to sustain physical activity	F		Homecare	✓	✓	✓	-
Green et al., (2018) [21]	RCT	Increasing uptake of contraceptives	R		Prevention	✓	✓	✓	-
Manne et al., (2020) [31]	RCT	Improve sun protection behavior	F, SC		Prevention	✓	✓	✓	-
Neto et al., (2021) [36]	Longitudinal study	Promote optimal child growth	R		Prevention	✓	✓	✓	Yes
Nsagha et al., (2020) [37]	RCT	Increase treatment adherence to HIV treatment	R		Homecare	✓	X	✓	-
Orme et al., (2018) [40]	RCT	Reduction of sedentary behavior	F		Post-acute	✓	X	✓	-
Sankaran et al., (2019) [45]	Cross-over study	Motivate to achieve rehabilitation targets	P, R		Post-acute	✓	X	✓	-
Summers et al., (2021) [51]	Pre-post	Improving glycemic control and enabling weight loss	F		Homecare	✓	✓	✓	-
Suzuki et al., (2021) [53]	RCT	Increasing the willingness to take vaccine	FR		Prevention	X	X	✓	-
Signal et al., (2020) [58]	Cross-over study	Increase upper limb movement	F		Post-acute	✓	X	✓	-
Vandelanotte et al.., (2018) [60]	RCT	Increase physical activity	F		Prevention	X	X	✓	-
Whelan et al., (2019) [64]	RCT	Improve diabetes self-management	F		Pre-acute	✓	X	✓	-
Wyse et al., (2021) [66]	RCT	Increase intake of healthy food	PO, R, F		Prevention	✓	✓	✓	-
Xu et al., (2020) [67]	RCT	Improving dietary and physical behaviour	F		Pre-acute	✓	✓	✓	-

Fig. 10.9 Characteristics of the articles included in the review. Abbreviation of nudging strategies: F (Feedback), R (Reminders), SC (Social comparison), SA (Suggesting alternatives), PO (Positioning)

physiological metrics. Furthermore, these devices allow to easily reach users at any time (potentially an identified teachable moment) through push notifications, sounds or vibrations, which make them ideal delivery channels for reminder nudges. Moreover, this ubiquitous nature of devices has led to the use of digital nudges in the different phases of the continuum of care. For instance, from averting illness by

encouraging individuals to vaccinate in the prevention phase to using feedback nudging strategies to rehabilitate stroke patients in the post-acute phase. However there were no studies focused on acute care in the reviewed articles. This might not be surprising as this stage of the continuum of care is the most challenging to study empirically. Furthermore, in the acute phase, patients are potentially more passive than in other phases, and as such, nudges might have to focus on medical practitioners rather than patients. Future research could further investigate this phase, since nudge can present undeniable opportunities, as exemplified by the reminder nudge to improve checklist compliance during an event of surgery presented above (Boillat et al. 2019).

10.5.3 Ethical Nudging Boundaries

There is no denying that the omnipresence of connected devices can present opportunities for innovative and effective digital nudges along the continuum of care. However, there are ethical risks associated to these technologies in terms of privacy, autonomy, and consent. Understanding the amplitude of these risks requires in-depth analyses of the intervention design in their specific contexts, but the reviewed literature only rarely discuss these issues. Indeed, only 1 out of 19 studies conferred about ethical considerations while designing the intervention and others paid little or no attention to even explaining the mechanism and working of the nudge. The criteria of transparency work well with certain digital nudges such as feedback and reminders. For instance, provision of feedback to increase physical activity is pretty transparent in its objective like in the study by Xu et al. (2020). However, digital nudges such as framing, default and social comparison are inherently not transparent, as individuals are often unaware about the objective of the nudge until revealed before deployment. For instance, Suzuki et al. (2021) employed framing in a brief web-based educational intervention to increase vaccination rates. The participants were blind to the mechanism that was employed to change their mindset. The criterion of ease of opting out is also met in certain cases. For instance, in a study by Purohit and Holzer (2021) participants could opt out of the feedback nudge by just turning off the feedback automation themselves. The process to opt-out would become challenging for nudges like default, framing (Suzuki et al. 2021), positioning (Wyse et al. 2021b). Finally, surprisingly, as shown in Fig. 10.9, the ethical analysis reveals that out of 19 studies, only one study of Neto et al. (2021) explicitly discusses the nudge designs and ethical implications. Future research should further investigate this issue. It should also be noted that understanding the ethical boundaries of digital nudging will also allow practitioners to identify potential unintended nudges present on their digital support systems. This can typically happen as nudges such as positioning or defaults are unavoidable when a system is designed. The challenge is to make sure these design decisions are aligned with the welfare of the patient and are not so called dark patterns, manipulating them.

10.5.4 Limitations

It should be noted that this chapter is not without limitations. Despite carefully following the guidelines for scoping reviews, the results are confined to the initial search, as is inherent to their nature. For instance, the nursing field may have applied a type of digital nudge like feedback without calling it that. Moreover, our search for the scoping review was limited to JMIR database and mainly focused on digital nudging for patients. Future research could include other digital health databases and review digital nudging for clinicians to provide a full-fledged systematic review of the topic.

10.6 Conclusion

This chapter mapped the landscape of a growing topic, namely digital nudging in healthcare. This chapter allows practitioners and healthcare system designers to get a better understanding of possible applications of digital nudges to increase the effectiveness of health applications along the continuum of care. It first gave an overview of the potential opportunities offered by digital nudges through the continuum of care. It then discussed the current state of the empirical literature on digital nudging in healthcare through a scoping literature review. The review highlighted the fact that current research efforts mainly focus on feedback and reminder nudges applied to an increasingly desired behaviour for prevention and post-acute care. At the current stage, several otherwise effective nudging strategies such as defaults are absent from the reviewed literature and none of the interventions was applied to acute care. Furthermore, the review revealed that only one paper out of 19 discussed ethical aspects of nudging. As such it appears that the development and promotion of an ethical analysis grid that will guide practitioners and researchers in designing not only low cost and effective, but also *ethical* nudges is crucial to unleash the full power of nudging to improve digital health.

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Chapter 11
The Role of Design in Healthcare Innovation and Future Digital Health

Carlos Montana-Hoyos, Marianella Chamorro-Koc, and Lisa Scharoun

Abstract This chapter explores the role of design disciplines within healthcare innovation and digital health. Through defining design, we provide an overview of the evolution and current roles of design disciplines as a means to explore the contributions of different design disciplines to healthcare innovation. Furthermore, we discuss the ways that design can humanize technology and how inter and transdisciplinary collaborations, where designers from different specializations interact with engineers, health professionals, and others, can be powerful agents for creating current and future innovations in this sector. The chapter provides an overall view of types of applications and implementations of design disciplines in healthcare design and digital health, going from design of hospitals and health spaces to medical equipment, and others, with special emphasis in apps and wearables for digital health and wellbeing. Through a discussion of design projects, initiated and implemented by the authors, where designers and researchers collaborate with engineers, medical professionals and other disciplines, centred on health care and delivery; we reflect on the inter and transdisciplinary innovation processes. We highlight benefits and challenges of these types of collaborations and explore possible avenues for integrating and developing the projects further, through the use of emerging technologies. Future trends and forecasts, especially around new virtual lives afforded by emerging technology applications, offer new future scenarios by using design fiction narratives. The chapter ends with possible implications of future digital health applications, including a critique from social points of view.

Keywords Design · Digital Health · Healthcare Innovation · Design Fiction
Future-oriented Design for Health

C. Montana-Hoyos (✉)
Dubai Institute of Design and Innovation, Dubai, United Arab Emirates
e-mail: Carlos.Montana@didi.ac.ae

M. Chamorro-Koc · L. Scharoun
Queensland University of Technology, Brisbane City, QLD, Australia

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11.1 Introduction

In 2014 the World Health Organization (WHO) estimated a worldwide shortage of around 4.3 million health workers in the world (Aluttis et al. 2014) with the stress on health care systems posed by the Covid-19 pandemic - this is now estimated at 18 million (WHO 2021). As we reflect on these statistics and the world-changing events of the Covid-19 pandemic, the opportunities for both the integration and acceptance of digital health to tackle this challenge have come to the forefront and will continue to be a critical part of the health service delivery environment. Digital technologies in healthcare have the possibility to disrupt and transform the delivery and effectiveness of care on a universal scale. According to Meskó et al. (2017, p.1) "the cultural transformation of how disruptive technologies that provide digital and objective data accessible to both caregivers and patients leads to an equal level doctor-patient relationship with shared decision-making and the democratization of care." Development, acceptance, and performance of health digital interventions are largely dependent on good design. Through processes such as co-design and design thinking, a connection with empathy and the care experience can be mapped and then aligned with new technologies to provide improved patient journeys that can influence systemic changes in care. Large and small design interventions in this space can create profound changes in the way that people access and perceive healthcare.

11.2 Towards a Definition of Design

Design as defined by the Oxford Dictionary (2022) is:

"(1) the general arrangement of the different parts of something that is made, such as a building, book, machine, etc. (2) the art or process of deciding how something will look, work, etc. by drawing plans, making models, etc., (3) design (for something) a drawing or plan from which something may be made, (4) an arrangement of lines and shapes as a decoration and (5) a plan or an intention."

However, due to its broad definition and interpretations, the word design can have many different meanings and is often viewed differently depending on the role one plays in the design process. For instance, design can be seen by practitioners as a process in and of itself but it is more commonly seen by society as the result or creations from that process. Blackler et al. (2021) explored 20 years of ongoing discussion among design theorists and academics about what design is. Through a data mining process, they concluded that design continues to be an ill-defined term, and that it also means so many different things, from process, to theory to activity and more. As explained in Scharoun et al. (2020):

"The word 'design' is both an action and its result. As an action—to design—the term refers to a creative thinking and problem-solving process that enables the

creation and development of ideas through iteration, visualisation and materialisation into a reality, in a planned and methodical way. As a result—a design—the term also describes the outcome of the previous action."

As a fusion of art, culture, technology, engineering, business, innovation and many other disciplines; design is transdisciplinary by nature. In the post-industrial world, design is an entity that has moved from being one of solely physical experience (e.g., a book, building or piece of furniture) to one of the complete immersive experiences of the everyday as defined by the human centred approach to the understanding of the aesthetics and behavioural approach to our services, systems and use experiences. Design is not, and has never been, simply a style filter that makes something mundane more beautiful however embedded in the design process is the necessity for an aesthetic that appeals to and persuades the end user to form a bond with the product/service/communication strategy or space.

Design has been described by some researchers as having syntactic, pragmatic and semantic functions (Boucharenc 2008; Bonollo 2010). As related to linguistics, syntactic functions answer to how something is 'made' or constructed, pragmatic functions refer to how something is 'used', and semantic functions relate to how something is perceived, or what it 'communicates'. In terms of communication of designs, it is also pertinent to include the concept of 'affordances.' According to Butler et al. (2003), affordance is "a property in which the physical characteristics of an object or environment influence its function". When affordances are used well by designers, the use of the design is effectively communicated to the user.

Increasingly, designers have influence over how we perceive our virtual as well as our physical reality. As explained in Scharoun et al. (2020) 'We are experiencing the evolution of design towards social change while seeking the humanisation of multiple new disruptive technologies such as artificial intelligence (AI), internet of things (IoT), blockchain, and many others, which are changing our relationships with the world and creating new interfaces, digital environments, and even virtual and augmented realities.'

In exploring the definition of design, it is important to differentiate design disciplines from design process. Co-design and design thinking are processes that are both integrated in a design outcome but also can be separated as a discrete service in its own right. Co-design, also described as generative design, co-creation, participatory design, or co-operative design, is a process and not an outcome. Through a process of exploratory research and developmental design, it seeks to define a problem that requires a solution and to try and address that problem together with the end user. The process aims to achieve an outcome or series of outcomes of which have the potential to be rapidly tested in collaboration with the end user (NCOSS 2017). In co-design all participants are responsible for the effectiveness of the process. Similarly, Design Thinking is an iterative process in which we seek to understand the user, challenge assumptions, and redefine problems. It seeks to identify alternative strategies and solutions that might not be instantly apparent but that can be teased out during a multi-step process involving empathising or 'stepping in the

shoes' of the user, defining the users' needs, problem and insights; ideating a solution based on that insight; prototyping that solution and finally testing the solution (Dam and Siang 2021). Unlike co-design, however, it is not dependant on creating the solution with the end user.

When taken from a wholistic perspective, design can be defined as the original concept in everything. It is the driving concept behind a process of transformation and representations – giving our material culture its value, meaning and balance. In the context of the chapter and projects described, we define design as a conscious intention to modify our environment to benefit human progress and increase social good. Through strategic problem-solving process, we believe that designers go beyond invention and foster a culture of innovation. Through co-design with relevant stakeholders and end-users, designs can foster outcomes that lead to innovative systems, products and services which ultimately provide better experiences and thus a better quality of life.

11.3 The Role of Design in Healthcare Innovation

Digital technologies can give agency and power to patients. Previously healthcare functioned with a 'doctor hero' scenario in which the doctor makes all decisions with the patient having little or no agency in attaining an understanding of their own condition. In this traditional structure of healthcare, patients are not involved in decision making about their own health and disease management. "This insecurity and exposure to decisions out of their control served as the primary motivation behind patient empowerment that included the use of disruptive technologies, which were also becoming available" (Meskó et al. 2017: 3).

Healthcare, and the patient experience, is something that is strongly tied to emotion and sense of control. To have a successful treatment outcome, a positive patient experience is essential. If these experiences are left to chance, with no element of thought put into the overall feeling one gets from their delivery, outcomes can be dire. "Without design," explains Solis (2020), "experiences are left to chance, for someone to internalize our processes, policies, services, physical and digital touchpoints, on their own" Designers play many roles in the health care innovation space, including the design of tangible objects such as furniture but are also integral in the creation of digital systems and designed experiences. According to Solis (2020) "Design has a direct effect on how patients, and also caregivers, feel. When done right through intentionality – colors, art, furniture, process, technology, and staff training – patients can feel more at ease, calm, and secure."

Many of the issues being faced daily in the Healthcare sector are complex and systemic. They require a perspective that is difficult to attain for those that are working in the system and therefore too close to the problem. As described above in the design thinking process, design problems often begin with ambiguity, and it is the designer's ability to step through the phases of the iterative design thinking process that leads to a solution to a problem uncovered during the process. Designers can

navigate the system as a relative outsider to understand the parameters or conditions in which solutions can be developed. Explains Park (2020) "we look to clearly define a problem, and the reasons behind it, before jumping to solutions… designers know when and how to bring users along in the process. They ensure that there are questions and activities that give users effective entry points into the creative process and give users the opportunity to make amorphous ideas concrete."

Design methods, with their embedded reliance on stepping into the shoes of the user, help with public engagement and ultimately acceptance of a new service, delivery model or technological intervention. 'Being involved in the change conversation from the start means people (as citizens, taxpayers and service users) are more likely to feel a degree of ownership. This, in turn, means they are less likely to oppose the agreed solution, and will potentially be more willing to play a part in delivery (Design Commission 2013).' It is therefore crucial to engage designers in innovation processes.

11.4 Design in Healthcare Innovation and Digital Health

'Health,' as defined by the WHO (2022) is 'a state of complete physical, social and mental well-being and not merely the absence of disease or infirmity." Healthcare innovation driven by technological solutions such as the ones encompassed under the umbrella of digital health has become a popular topic of discussion. The literature on digital health and health technologies commonly refer to how such technologies would improve healthcare delivery. This is mainly because of the nature of digital health technologies that enables remote communication, incorporates Virtual Reality (VR), Artificial Intelligence (AI) and Augmented Reality (AR) technologies that facilitate medical training, providing solutions for remote tracking of health indicators from patients. Some examples of digital health are wearable technologies such as exercise trackers and mobile phone applications (Apps) (Birnbaum et al. 2015). There is also discussion in the literature about the risks around data privacy and security, as well as equitable access to those technologies. Lack of user engagement in the proposed solutions is one of the areas where the role of Design in Healthcare innovation has become necessary to work with end users in the process of design and implementation.

In Healthcare, design thinking approaches are now commonly employed where Design is understood as the strategy that can facilitate disruptive solutions to improve the quality of healthcare. Matthews (2015) discusses the role of Design in Healthcare and states that Design is a broad term with many definitions because it may be applied to an object, a process or a system and contribute to healthcare by improving safety, dignity, efficiency and sustainability. In the healthcare sector, patient-centered design is a multi-stage process that involves iterations from conceptualisation, to design, and to design testing.

The struggle of healthcare services and their need for drastic innovation became even more evident during the 2020 Covid-19 pandemic, when healthcare services

delivery collapsed globally. Patrício et al. (2019) stress that the complexity of the challenges faced by the healthcare sector demands profound system innovation and provides examples of how design plays a critical role in not only developing solutions, but also engaging people and multidisciplinary teams in co-creating valuable service solutions.

11.5 Design and Hospitals of the Future

A combination of factors such as demographic and economic changes, rapidly evolving technologies as well as the mass-adaption of digital and tele-health services during the Covid-19 pandemic, continue to challenge hospitals worldwide to think of new ways to deliver care. "A growing number of inpatient health care services are already being pushed to home and outpatient ambulatory facilities. However, many complex and very ill patients will continue to need acute inpatient services" (Deloitte 2017). These conditions assert a changing role and design of hospitals for the future. The re-design and re-thinking of hospitals is at the forefront of healthcare provision today.

"With a continually increasing and ageing patient population, tighter budgets, fewer doctors and higher patient expectations, many envisage that there could be significant challenges ahead. Equally, with more technology, better use of more data and some innovative new business models, there could also be some substantial opportunities to improve both the efficiency and the quality of delivering care (Future Agenda 2022)."

Hospitals are experimenting with design elements such as customized patient rooms using digital screens, automation and robotics for care and ancillary services, digital patient experience using AI and machine learning (ML) and refined care delivery through centralized clinical command centers with digital continuous monitoring - amongst others (Deloitte 2017). Designers are playing a large part in the overall development of these spaces and experiences.

11.6 Design Narratives and Design Fiction

Design is an interdisciplinary and integrative discipline and a process by which we devise courses of action aimed at changing existing situations into preferred ones (Simon 1988). It has the ability to capture both new knowledge and in the application of this knowledge to the creation of possible futures and scenarios. Scenarios have been employed in design-led innovation processes to provide a methodological framework to explore, investigate and depict people's current and future everyday practices, as well as devising alternative futures.

Scenarios is traditionally defined as 'a projection of a concrete narrative description of activity that the user engages in when performing a specific task, a

description sufficiently detailed so that design implications can be inferred and reasoned about' (Carroll 1997:385). From this perspective it is understood that scenarios are design representations focused on use situations. As such, scenarios can be employed in the evaluation of use cases and for many other purposes. Chamorro-Koc et al. 2012 discuss the concept of scenarios as a design tool that can be successfully employed by organisations as an innovative design led approach to: (i) understand people's everyday practices in current social contexts in order to identify opportunities and emerging markets, and (ii) reveal stakeholder relationships existing in the provision of services within current everyday practices. As an example, they discuss an industry project that explored opportunities for the development of future health care services. In this project, scenarios were employed to explore the opportunities for a medical device manufacturer to expand their services and compliment their product offering. As part of scenarios, design strategies such as personas, experiential journey maps, narrative, and video vignettes were employed to translate customer experiences into ideas and conceptualisations of future service development (Bucolo and Mathews 2010).

Depicting narratives about people's experiences and practices is also employed in the context of healthcare. Story and narrative are terms applied in nursing training, health communication and medical science. Patients' stories help depict a healthcare situation and the illness experience of patients, while the clinical narrative is representative of models of medical practice and healthcare. Sometimes referred to as 'vignettes', clinical narratives embed data and are not merely anecdotal, casual accounts, they connect theory with experience and represent the relationship between daily healthcare practice and knowledge (Wiltshire 1995).

While nowadays this term is stated as ambiguous and highly debated, the term design fiction was coined in 2005 by author Bruce Sterling, specialized in Science Fiction literature. Since its origins, design fiction has been widely adopted by a broad range of design and future-oriented disciplines (Lindley and Coulton 2015). Bosch (2012) defines design fiction as the "deliberate use of diegetic prototypes to suspend disbelief about change". Diegesis, the key component of design fiction according to Sterling, is a type of narrative and storytelling in which the narrator tells the story. Diegetic prototypes are elements of this fictional world. The focus is on the design and use of these objects and situations in the fictional world, rather than a focus in the macro story of the world, like political trends or geopolitical strategies (Bosch 2012). "Design Fiction" has become an established field of design research dedicated to creating, imagining, and visualizing possible futures and new worlds (Grand and Wiedmer 2010). Through simulated experiences, design fiction allows designers and users to engage with a world that does not yet exist—where radical new solutions are conceived and their potential benefits and consequences can be experienced first-hand. It has also become a widely used tool that uses a narrative to contextualize a future design, and the needs, values, and experiences associated with it (Ahmadpour et al. 2019), by enabling co-creation processes where possible applications, but most importantly, potential implications of interactions with future and emerging technologies can be explored. These discussions allow researchers to speculate about possible future socio-political contexts, direct or

indirect desirable or undesirable implications, and visualization of future scenarios with possible utopian or dystopian characteristics. While there are similarities and relationships between speculative critical design and design fiction, and these are often associated with participatory research, design fiction should not necessarily be equated to these. Furthermore, while design fiction can be used for speculative projects, professional designers have also been using related tools in day-to-day practice, such as future forecasting and trend spotting (Milton and Rodgers 2013).

In the context of Health Innovation and Digital Health, many researchers have reported the use of design narratives and design fiction for healthcare, medical devices, and related areas (Stead et al. 2018; Strachan 2016).

11.7 Future Healthcare Innovation and Digital Health Design Projects and Scenarios

Historically, design has focused on visualising the future. Futurist and designer Buckminster Fuller (1982) stated: "you never change things by fighting the existing reality. To change something, build a new model that makes the existing model obsolete." Special effects designers have created objects, transportation and new modes of life which have been portrayed by science-fiction movies. Researchers argue that many products, garments, vehicles and other designs showcased in some visionary sci-fi movies have shaped the reality of future life. Furthermore, this future-oriented role of design has been widely described in books like Design as Future Making (Yelavich and Adams 2014), or Design Futures (Quinn 2011) amongst many others. Both books provide ideas and essays about the future, with design-related topics like bio-architecture, robotics for manufacturing and other applications, interactive spaces, new materials, including but not limited to biomaterials, biomimetic design, self-replication, reactive surfaces, future fashion, biodesign, and many other topics.

In this section we discuss design projects that aimed to solve current issues in Healthcare but could be adapted and further evolved using new technologies. We outline the projects and original scope and then discuss future scenarios design fiction to provide rich possibilities for the hospitals of the future.

11.7.1 Futuristic Intensive Care Units

One example of future-oriented design for health, developed by the authors, is the 2013 project User-centered, Research-based Design of Futuristic Intensive Care Units. This design research project, developed with Industrial Design post-graduate students in collaboration with representatives of two hospitals in Canberra, Australia, used ergonomics and user-centred design approaches in health-services

environments, specifically Intensive Care Units (ICU) in Hospitals, to design innovative, futuristic ICU design concepts (Montana-Hoyos et al. 2016). While at the time the project did not explicitly use the Design Fiction methodology, current and futuristic visions for ICU spaces were illustrated and developed through examples from architecture and science fiction movies. This vision of the future, coupled with in situ user-observations, surveys and unstructured interviews of patients, family, and healthcare workers (mainly nurses and medical doctors) carried on at the Calvary John James Hospital (CJJH) and the Canberra Hospital (CH) provided the basis for futuristic conceptual design proposals. The project proposed a fully integrated ICU bedspace, which used emerging technologies (at the time) such as witricity and holograms (see Fig. 11.1, below). According to Gozalvez (2007), witricity, or wireless electricity, is a wireless power transfer developed by MIT researchers. In this project, this technology could avoid the spaghetti syndrome, or multiple chords, tubes and electric cables commonly found in today's hospitals. Furthermore, holograms can improve medical 3-D visualizations. In the future, this concept could be further developed to avoid the common disconnection between different technologies and medical equipment manufacturers, and to provide improved spaces for specialized intensive care, with inclusions of AI, IoT, and remote robotic surgery devices.

Fig. 11.1 Futuristic ICU design concepts (Source: Montana-Hoyos et al. 2016)

11.7.2 HealthPod

In 2016 two of the authors participated in a design research project where we developed and tested a Digital Health intervention. High quality patient data offers benefits to General Practices (GP) and patients. Such data can be used to identify patients at risk of disease and offer intervention opportunities. Despite quality assurance schemes, GP clinic datasets are often incomplete e.g. missing data on patient demographic and information on height, weight, and behavioural risk factors such as smoking, alcohol consumption and physical activity. This missing data makes population stratification (e.g. determination of populations at risk of diabetes or cardiovascular disease (CVD) risk) difficult and presents a barrier to optimal patient care (Volker et al. 2014). This becomes particularly relevant as the landscape of general practice changes with health reforms focusing on initiatives such as health care homes, where data driven improvement and patient-care team partnership form essential building blocks (Bodenheimer et al. 2014). Furthermore, patients have a limited role in engaging with their own health information to ensure its accuracy and relevance to their current health status. Manual interventions to improve GP data quality are time consuming for practice staff. It may be more efficient, less costly and more reliable to use information and communication technologies to streamline, automate and enhance the patient data collection process, especially technologies that include the patient in the collection of their own data. Considering all these factors, a multidisciplinary co-design approach was adopted for the design, development and implementation of a HealthPod intervention in a large multidisciplinary integrated general practice developed through funding from the Australian Department of Health's Superclinic program (see Fig. 11.2, below).

To enable the design of the HealthPod, we enacted a co-design approach involving patients, students and medical staff cooperating with designers, researchers and developers to inform the design and development the HealthPod. Engagement was required during several stages of this process including the initial design brief and conceptualisation to develop a patient kiosk. The process included a clear definition of the scope of the project and a focus on the end users, to help generate innovative ideas for potential solutions. This was done through a patient focus group which focused on issues surrounding patient empowerment and data quality and an interactive design workshop with design students focusing on the physical design of the pod. The multi-disciplinary team collaborated extensively during the co-development stage to ensure that all aspects of the design (including the overall user experience, the physical pod, the graphic user interface and software development, among others) were integrated. The design of the Pod was heavily influenced by the materials and interior design within the clinic, as the Pod was not meant to be perceived as an alien object inside the waiting room, but as part of it. Main considerations were also ergonomics, postures of the users, privacy and accessibility to the Pod. The Health Pod was used as a mechanism for improving data collection. It had a custom-built

Fig. 11.2 HealthPod physical structure, interface and print report card

program that fed into the clinic's database and a visually appealing graphical user interface that took into account potential accessibly concerns of the end user. It generated a physical 'report card' that patients could choose to print in the pod and take home with them to help empower patients to take action on the health issues identified.

The HealthPod could be adapted to a range of future purposes but mainly the functionality could be enhanced to deliver a full e-health experience. The inclusion of AI could further assist in a body-scanning and empowerment activity in which remote consultations with specialists could be more easily facilitated. In a hospital of the future scenario – the pods could become integral parts of a new hospital planning and design. To expedite waiting times, HealthPods could be used in Accident and Emergency units (A&E) or Day Surgery areas to facilitate initial assessment, triage, and pre-health scanning activities.

11.7.3 Design Fiction to Envision Life in 2050

While not exclusively focused on health, from 2018 to the moment of writing this book chapter, one of the authors has used design fiction to enable undergraduate design students analyse and better understand future and emerging technologies, and possible future applications in transdisciplinary design. By analysing emerging technologies, students created future design scenarios for life on earth, or other planets, in 2050. Some of the technologies which were mostly related to healthcare and mental health applications, were 4D printing, bio-printing and 3D printing of live tissues, emotion sensing artificial intelligence, electronic tattoos, mind readers, life-extension technologies, living materials, self-healing materials, and of course, robots.

Some results of these projects are illustrated below. For example, design student Zhara Akef researched self-healing materials and behaviours of growing new tissues or limbs, as in the case of some lizards, to propose future scenarios where self-healing textiles and clothing could have medical properties, and even facilitate the growth of injured tissues and limbs (see Fig. 11.3, below).

Another technology of choice for possible future medical applications was electronic tattoos. E-Tattoos, a new generation of thin, adhesive surfaces that behave like skin and have electronics embedded in them, has been seen as one of the wearables of the future, with sensors and data that can enhance well-being, and also with medical applications. These small, thin wearables could act like small bandages, helping skin heal, while simultaneously monitoring patients and sending key information to medical practitioners. Two possible visualizations were the concepts created by design students Alexandra Karakovskaya, who proposed e-tattoos for multiple applications including fitness and health monitoring (see Fig. 11.4, below) and the project “physio Ink” by Areeba Shahid, which proposed the use of electronic tattoos made with electricity-conductive inks, with applications in physiotherapy (see Fig. 11.5, below). It is worth noting that while these projects might appear far-fetched and without realistic applications in health or medicine, the objective was not at all to develop currently feasible, or commercially oriented design projects, but rather to get design students to think about the future, and most importantly, about the potential applications and implications of future uses of emerging technologies, how they will shape our lives, and how they can allow for great progress, new experiences and improvement of overall quality of life and extension of our lifespan, but also how in the wrong hands or due to unforeseen consequences, they can also create future problems in our society.

Fig. 11.3 2050 Future scenario of self-healing materials. Design fiction visualization

Fig. 11.4 Design Fiction visualization of E tattoos

11.7.4 Assessing Pain in Pediatric Hospital Wards

People experience and express pain differently, and in the context of a hospital, children might not be able to respond to the protocol of questions about pain accurately. This is of critical importance as this protocol is used to inform nurses and doctors the next steps of the therapeutic treatment. When expressing pain or emotional distress, children are a lot less articulated than adults. Unlike adults who can verbally express how they experience pain, young children who are pre-verbal can only express their feelings of anxiety only through crying. In some circumstances, children would become introverted and not be able to express their experience if they have preconceived ideas about a treatment; or on the other hand, children might not want to express pain if they had been taught to appear tough and not weak.

Pediatric pain is a factor that impacts negatively in the entire healthcare experience and recovery rates of the pediatric patient. Assessing pain in a pediatric environment is a core task that is currently informed by a 1 to 10 scale or a happy to sad faces; however, in hospital admissions, tiredness, business, and the heightened emotions of a child in pain might influence the nurse and clinician's accurate assessment

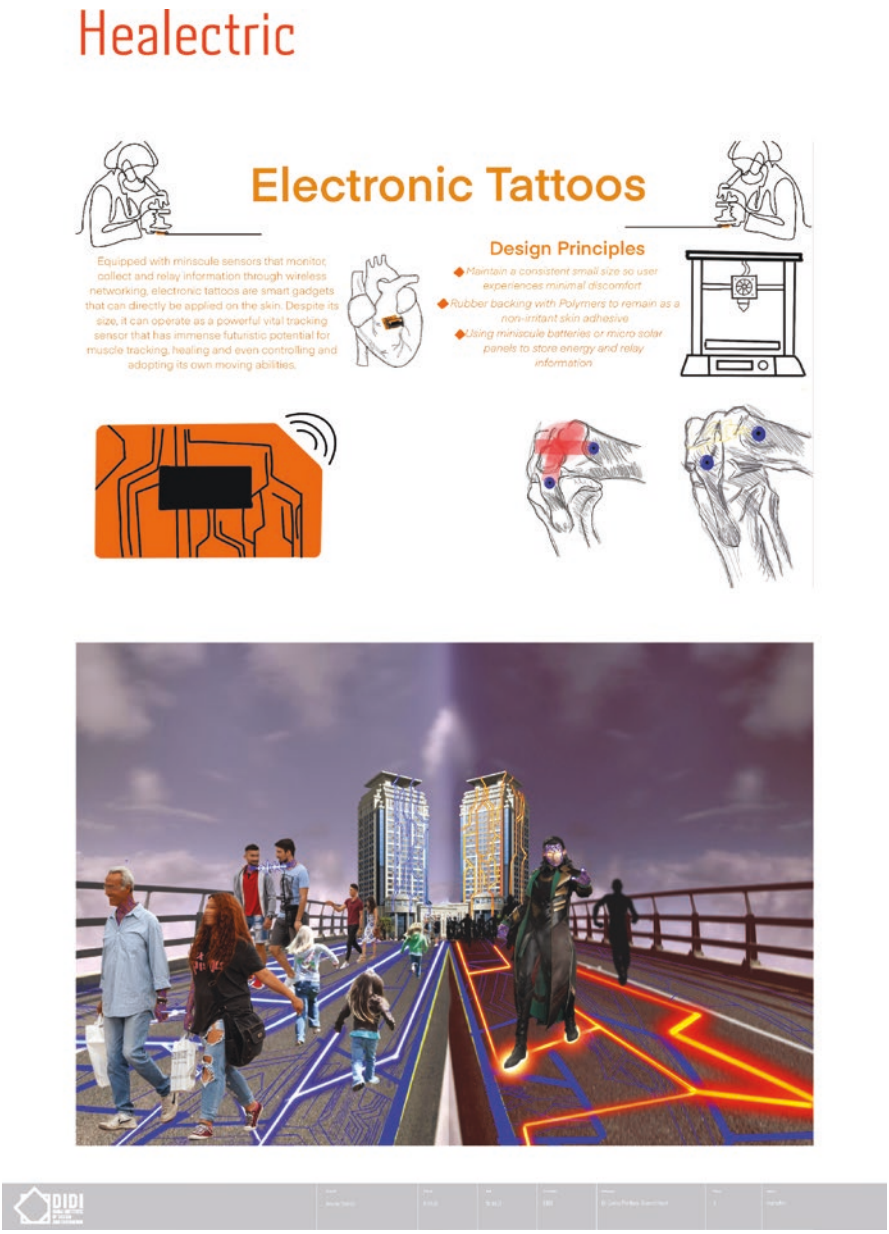

Fig. 11.5 Design Fiction visualization of E tattoos

of a child in pain. This project investigated the way pain is assessed in a pediatric population and whether the design of a pain assessment technology device could improve a more accurate and empathetic assessment of pain as well as provide a

strategy for rapport building with the child. The focus of the research was the context of Admissions to the Emergency room, at the initial stage or touchpoint when the nurse asks a child about how much pain they have. The research sought to enhance the decision-making of the clinician at the pain assessment moment by co-designing a technology tool to support healthcare professionals' expertise by enhancing their understanding of the child's pain and transforming that pain assessment moment in a more positive experience for the child and the clinician (Chamorro-Koc et al. 2021).

This project was initiated from the interest of hospitals in understanding children's pain journeys. Led by one of the Authors, this project was a transdisciplinary innovation process that brought together healthcare professionals and designers, involving end-users (nurses and doctors) and patients from the start of the process all the way to the development of research prototypes to facilitate end users input and discussion around potential solutions for the design of the device. The scenarios we considered corresponded to the current hospital context and services at the Emergency Department. Benefits of this collaboration were immediately evident as it opened opportunity to designers to work alongside with health professionals and understand the critical aspects of the problem from their perspective, expertise and regulatory framework (Fig. 11.6). A key challenge was presented due to restrictions imposed by Covid. This translated to our project in terms of our inability to run observations in the hospital grounds. Design thinking strategies were important in this circumstance as it allowed us to work out an alternative way to collect data

Fig. 11.6 The Pediatric Pain Metric

remotely, by utilising different design research strategies such as photo ethnography (to understand context from the participants' eyes) and retrospective interviews in combination with more traditional methods approaches such as Critical Incident Interviews. The result of our inter and transdisciplinary approach and collaboration led to the design of TAME, a Pediatric Pain Metric device that utilised sensors to gather basic patient data (temperature, tremors and heart rate), and employed a screen to facilitate the visualisation of such data in a simple manner and as an indication of pain and anxiety level of the child (Chamorro-Koc et al. 2021).

As healthcare innovations and digitization of healthcare services continue to progress and be implemented, future fiction narratives could help explore those emerging concepts of Future Hospitals, providing a platform to further understand healthcare professionals' experiences in those digitized contexts, and the way those technologies could facilitate pain assessment in pediatric care. For example, Desselle et al. (2020) discusses the design of a virtual reality (VR) experience in the context of anxiety and pain management of burns patients in hospitals. There are many examples of the use of VR in pain management, and it has mainly been used as a diversional therapy (Mallari et al. 2019). Although the use of VR is not new in the context of pain management, the potential of its application in other aspects of therapeutic treatment has not been fully explored. TAME demonstrated a different scenario of use, one that is not centred on the technology functionality, but one where technology affordances are applied to humanise how technology can be used for empathy building.

As stated by many authors, technology innovation in healthcare lags implementation, mainly due to the sector being highly regulated. However, opportunities exist to develop solutions that can be integrated within existing clinical workflows. A future fiction scenario for pain assessment in paediatric wards is suitable within the context of the concept of Hospitals of the Future, which are envisioned as organisations operating within smart environments, that are error-free, effective, and are patient-centered (Pickering et al. 2012). In such a future context, pain assessment would be pain-free, seamless and error-free. For example, imagine, a VR solution that helps to engage the pediatric patient -the child- into therapeutic treatment by providing a strategy for nurses or doctors to build rapport with their patient and be able to discuss the therapy with them. It would be a VR solution that not only helps healthcare professionals to assess pain more accurately, but also one that would help children to understand their pain in an engaging manner. Perhaps the VR solution can use data visualisation to transform their vital signals into enjoyable visual experiences, where the child has some agency during the pain relief therapeutic process.

11.8 Conclusions

While some of the projects described above were relatively low complexity projects, with the increasing use of AI, IoT, emotion sensing technologies, and new types of sensors and wearables, the possibilities of pre-screening of symptoms, medical triage, remote monitoring done by machines and not humans, as well as

remote procedures, robotic surgeries and even 3D and 4D printing of hyper-customized human tissues and organs is growing. In recent years, the Covid pandemic and lockdowns accelerated a move to digital and virtual meetings in industry, education and health. Many people, especially an ageing population not comfortable with digital services, quickly migrated to telehealth, phone or videoconference consultations. This opens future avenues for new generations of wearables, health pods, pediatric pain assistants or even robotic personal assistants in hospitals, where technology replaces face to face human contact.

Furthermore, a most recent boom of blockchain, cryptocurrencies and the emerging network of virtual worlds or Metaverse, with increasing participation of industry, businesses and the lay person in the creation of Non Fungible Tokens NFTs, Descentralized Autonomous Organizations DAOs and many others, is opening unimagined possibilities for a completely digital and immersive world and augmented virtual life.

While the possibilities of these emerging technologies are yet to be understood, researchers today can only imagine the extent to which these technologies will modify our future world and living. Thus, design fiction offers a tool to envision these alternative future scenarios, and especially allows speculation around possible applications, and implications of these technologies.

Potential benefits might include a democratization and wider coverage of basic health services, better possibilities of "hospital at home" opportunities, and hopefully a focus on preventive, rather than diagnostic healthcare. However, possible risks also include exclusion of people due to an increasing "digital divide", especially within the aging population, people living in remote areas, or people purposely isolated of the digital world, like in penitentiaries.

In this chapter we have discussed the concept of design and its role in healthcare innovation. Through the various examples, conceptual and applied, we have demonstrated our position about Design, as a conscious intention to modify our environment to benefit human progress and increase social good. The following points highlight possible implications of Design in the future of digital health:

- **Design is not just 'design thinking' but 'doing', and can demonstrate and test future technology applications through scenarios and prototyping**. Chamorro-Koc et al. (2012) demonstrated the use of design strategies and tools such as Personas and Role-playing to develop future scenarios that enable key stakeholders with different roles in the service process (service provider, service consumer, other agents in the process) to be involved in the concept development and prototyping of the final service design proposals. Technology makes possible to test initial concepts into virtual prototypes to help stakeholders and end-users envision the new healthcare solutions, supporting decision making, offering a cost-effective and expedient pathway to test new ideas.
- **Design works with ambiguity and transdisciplinary teams and can enable the exploration of person-centred future digital health solutions**. The value of design in the healthcare innovation process is manifested in the ability of the design process to work with ill-defined problems and with transdisciplinary

teams. Exploration with end-users is integral to the design process, from conceptualisation to testing of solutions. Current technology innovation processes bring end-uses at the end of the process once the solutions have been developed, for final prototype testing and correction of some functionality. Design has demonstrated how strategies and practices can be enhanced with technology to facilitate not only innovation processes across multiple teams, in transdisciplinary contexts, but also in ways that support empathy building and social change.

- **Design contributes to quality improvement in healthcare by being a catalyst for healthcare innovation**. The healthcare sector is a highly regulated environment, where technical innovations, systems and devices must be approved at different levels in order to be integrated into the existing operation workflows. Designing with technology through co-creation process with stakeholders and policy makers can provide a pathway to address the gaps between technology innovation and regulatory reform in healthcare sector.
- **Design champions the humanisation of technology through design and the focus on people.** Design, as a person-centred approach to innovation, brings technology, expertise and knowledge into the collaborative development of new technologies. With a focus on people, design ensures that future technologies are conceptualised with the end-users, being them the healthcare professionals or the healthcare patient.

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Chapter 12
Medical Schools and Digital Health

Thomas Boillat, Farah Otaki, and Catherine Kellett

Abstract There is no doubt that digital health is drawing the attention of both patients and medical professionals. Given that digital health technologies are somewhat new members of the medical technology landscape, it is reasonable to ask "Is digital health taught in medical schools?" This book chapter answers this question by first looking at the evolution and the nature of medical technologies. It then presents the results of a systematic analysis that investigated the extent to which top-ranked medical schools around the world offer digital health classes as part of their curricula. The topic is then analyzed through the lens of a physician and from a medical education perspective. Mindful that digital health offerings are limited, an example of a digital health curriculum is presented and described. This chapter ends with a discussion on the future of medical schools and the place of engineering and computing as part of medical education.

Keywords Digital health · Medical schools · Higher education · Medical education

12.1 Introduction

Medicine and technologies have always worked hand in hand since the construction of the first magnifying glass in 1250, the stethoscope in 1815, the X-Ray in 1895, and the pacemaker in 1936, to name but a few (The New York Times 2012). These technologies were designed for specific medical needs and have become part of a

T. Boillat (✉) · C. Kellett
Design Lab, College of Medicine, Mohammed Bin Rashid University of Medicine and Health Sciences, Dubai, United Arab Emirates
e-mail: Thomas.Boillat@mbru.ac.ae

F. Otaki
Department of Strategy and International Excellence, Mohammed Bin Rashid University of Medicine and Health Sciences, Dubai, United Arab Emirates

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physician's toolkit after demonstrating their positive impact on patients' care outcomes. Shortly after, these technologies became integrated into medical school teaching. The impact on patient care of some of these technologies, along their complexity have also led medicine to create specialties such as radiology or minimal invasive surgery.

When it comes to Digital Health Technologies (DHT), the amount of (scientific) evidence demonstrating their positive impact on patient care and medical outcomes is increasing, year after year. For instance, digital therapeutics (DTx)—the delivery of evidence-based therapeutic interventions to patients by means of qualified software programs to prevent, manage, and/ or treat medical conditions (Alliance 2018)—have received the approval from the U.S. Food and Drug Administration (FDA) and are being prescribed and reimbursed by some health insurance companies. Virtual Reality (VR) has been successfully used in clinical settings to help patient fight phobias, stress, and anxiety, as well as specific conditions, such as: eating disorders (Wiederhold and Bouchard 2014). It also has been used to reduce chronic and acute pain among adults and children (Ahmadpour et al. 2019). Moreover, wearable technology such as activity trackers have also shown their capability to detect Atrial Fibrillation in clinical trials, involving almost half a million participants (Perez et al. 2019).

Unlike stethoscopes that physicians carry with them, DHT can be used across different contexts by medical professionals and patients. DHT run on devices that were not designed exclusively for health care. As a result, it makes it more complicated for the healthcare sector and professionals to fully understand how to use them and to find situations where they can safely leverage DHT. This contributes to the persistently low adoption rate. On the other hand, patients and the population-at-large have been using DHT to collect data regarding their behavior such as physical activity, sleeping patterns, and heart rate variability that medical professionals are not able to leverage due to a lack of training (Aungst and Patel 2020). Educating medical professionals on the use and capabilities of DHT is thus key to ensuring that patients can benefit from these technologies. Medical schools are therefore instrumental to dissimilating this knowledge to their medical students. So far, however, feedback from students has not been reassuring. In a recent scoping review that investigated DHT initiatives in medical schools, the authors found that most of the studies focused on medical informatics and electronic health records. Only telehealth and mobile health have been discussed in 9% and 3% of the studies, respectively (Car et al. 2021). In another research, more than 50% of the medical students perceive their DHT competences as poor or very poor (Machleid et al. 2020).

This book chapter aims to shed light on the extent to which medical schools offer DHT teachings to their medical students. It systematically analyzes top medical schools around the world and investigates their coverage of DHT. It then describes the learning objectives of a 6-week curriculum designed to teach DHT to undergraduate medical students. This chapter ends with a critical discussion on the current role of medical schools and provides guidelines to further help the implementation of DHT as part of the teaching.

12.2 Background: Some Data

To have a better understanding of the extent to which medical schools around the world teach digital health, we conducted a systematic analysis of 60 curricula, representing the best 10 medical schools per continent according to the Times Higher Education. The results showed that only four medical schools are teaching some elements of digital health (according to their website). The university that is most active appeared to be Stanford University with three offerings taught through the Byers Center for Biodesign. The first, Biodesign for Digital Health, is a quarter-long course that requires multidisciplinary teams (i.e., medicine and bioengineer students) to identify needs and prototype digital health solutions that address health challenges. The second, Biodesign innovation, aims at teaching students the science of innovating in the field of health. Over two quarters, students from medicine, bioengineering, mechanical engineering, and operation and information technology learn and apply processes to identify and characterize unmet health needs in view of inventing and evaluating new solutions to address them. A shorter version of the program is also offered to medical students only. In addition, the Center of Biodesign offers a course on technology assessment and medical device regulations for medical students as well as engineers. All the above programs adopt a problem-based approach whereby short knowledge capsules are taught by faculty members and experts and activated through group projects. The programs are elective and carry between 3 to 4 credits. Similar to Stanford University, Johns Hopkins University offers DHT extra-curriculum classes. More specifically, as part of its dual degrees MBA/MD, the respective university offers a course called Design Lab that teaches students human-centered approaches in view of developing DHT. In addition, through the Johns Hopkins Technology Ventures, the university offers non-credit courses and initiatives that promote (health) innovation for undergraduate and post-graduate students. For instance, the FastForward provides students with resources including accelerator programs, seed funding, mentorship, and spaces. Yale University, as part of the School of Management, has develop a program on entrepreneurship open to any Yale student. Among its offering, the course New Ventures in Healthcare and the Life Sciences focuses on empowering medical students or any students interested in disrupting health care. It includes lectures on digital health and medical devices, as well as, case studies and projects that support students from needfinding to prototyping and commercialization. Finally, the University of Zurich, the only non-American institution, offers to second year medical students, as part of its elective offerings, a course on e-health and telemedicine as well as a course on artificial intelligence in medicine. In addition, students have access to the Innovation Hub that offers training and courses on innovation and entrepreneurship as well as accelerator programs.

As part of the medical schools we analyzed, we identified one university that was piloting a program in digital health with 10 medical students (Poncette et al. 2020). The program consists of 22 teaching units made up of small and large group sessions covering topics from telemedicine to health economics, augmented and virtual

realities, mobile health, wearables, and health innovation. In a systematic analysis investigating digital health offerings in American medical schools, the researchers identified seven additional universities (Aungst and Patel 2020). Among them, only one had the teaching integrated in the medical curriculum.

To summarize, a limited number of medical schools have included digital health teaching in their curriculum, while few offer it as an elective. In addition, the coverage of digital health topics is also limited and often taught as part of innovation classes that aim to address health challenges with technologies, sometimes focusing on one DHT only.

12.3 Why Should Medical Schools Teach Digital Health?

'The Flexner report: Medical education in the United States and Canada' constituted a transformative turning point in the development of medical education (Flexner 1910). This 1910 report was a culmination of an investigative journey across medical schools in the United States of America and Canada. These fruitful investigations were performed by Abraham Flexner, a nonphysician professional educator, who explored the state and quality of medical education (Duffy 2011; Halperin et al. 2010) in response to Henry Pritchett of the Carnegie Foundation for the Advancement of Teaching who reported that the lagging quality of medical schools and physicians' training were a direct reflection of substandard education (Duffy 2011; Senok et al. 2021). The report reflected a thorough understanding of the medical education sector and emphasized the necessity to incorporate scientific theory into medical school curriculum (Flexner 1910). Consequently, the biomedical model became the hallmark of modern medical education. The Flexnerian era was characterized with myriad of transformations which enabled medicine to become firmly anchored in biological science (Norman 2012). Although the Flexner's legacy is rightfully celebrated, several elements of his contribution continue to generate debates (Sullivan and Suez Mittman 2010). In fact, Flexner's report significantly benefitted the sector but concurrently resulted in significant gaps in the structure of medical education (Kirch 2010). The emphasis on medicine's rational world was not complemented by excellence in clinical caring. As such, considering the physician as a trusted healer started eroding following the implementation of the report's recommendations. As such, revisiting the Flexnerian movement through the lens of twenty-first century health care needs became a necessity (Arky 2007). An assessment of the external environment's trends, including the ones driven by technological advancements, is urgently needed to produce a future-ready doctor (Yeoh 2019). One of the answers came from the American Medical Association (AMA) with the Accelerating Change in Medical Education initiative launched in 2013 (AMA 2013). It was meant to support the transition of health care in the United States from acute to chronic care (Fig. 12.1). The AMA provided grants to medical schools across the country to support the implementation of new models and strategies for this transition.

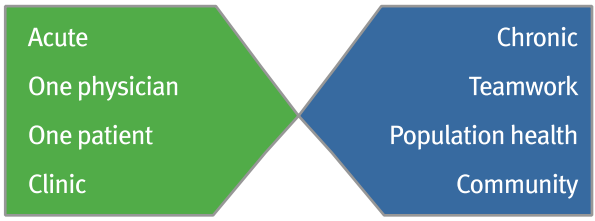

Fig. 12.1 Transition of health care in the United States. Adapted from the American Medical Association

One of the initiative's outcomes included in the Health System Science (HSS) framework presents the competences that twenty-first century medical students, trainees, and physicians should acquire and apply when rendering care (Borkan et al. 2021). This outcome "complements and integrates the basic and clinical sciences by leveraging systems thinking to provide students a view of the full complexity and context of a patient's health" (Gonzalo et al. 2017). The framework is made up of four domains namely (1) teaming, (2) leadership, (3) change agency, management, and advocacy, and (4) ethical and legal matters that surround the core of the framework—patient, family, and community. As part of the domain number 3 lies the sub-domain: clinical informatics and health technology, that refers to the use of information technology as part of the delivery of care. Most common topics taught include Electronic Medical Records, data analysis, digital libraries, and decision support tools (Banerjee et al. 2015). These topics appeared, from the systematic analysis reflected upon in this chapter, to be the most popular in terms of teaching health technology in top-ranked medical schools. However, as described in the background section, digital health is very often overlooked, while its positive impact has been repetitively established. Although medical education, in general, has acknowledged the need to rely on information technology to support the transition of healthcare, it remains unclear what path should medical schools follow.

12.4 Incorporating DHT: Challenges Faced by Medical Schools

The introduction of DHT in medical schools' curricula brings multi-dimensional challenges beyond scheduling and assessment:

- Definition and nature of DHT: Digital Health's definition is rather broad and prone to subjectivity. As a result, the technologies and concepts that should be covered in such course are unclear and will ultimately vary from one institution to the others. Eventually, the topics covered will depend on the university's competence, the medical school's vision, the population needs or the preferences of the lecturers.
- Multidisciplinary lecturers: For a medical school, DHT have two main dimensions: their technicality and their applicability. On one hand, the lecturer must be able to understand the pieces of hardware that form the device, while it is as

much important to understand how the technology can be used to add value in a medical context. Here again it is important to stress the broad nature of DHT. It is unlikely that one person has experienced artificial intelligence, wearable technologies and 3D printing. The lecturers will then have to either be a technical person with medical experience or physicians with technical knowledge. In both cases, such profiles are not easy to find.

- Equipment: we believe that universities and medical schools should be leading the way. However, many medical schools and teaching hospitals worldwide rely on outdated computing systems, making system integration difficult and reducing the interoperability. Software / hardware depreciation and lack of updates does not improve matters. Medical schools often do not have the technology that matches state-of-the-art technologies e.g. Augmented and virtual reality headsets, 3D printers. In addition, personnel is required in order to maintain these devices.

The challenges presented above assume that the medical school and its faculty and staff have an open mind and do not see DHT has a threat but rather has bringing new opportunities.

12.5 Next Steps: Course Curriculum

From our systematic investigation of the top-ranked medical schools' curricula and literature review, it became apparent that the amount of information regarding the implementation of a digital health technology course is rather limited. In this section, we present the curriculum implemented in the course entitled: "Innovation and Technologies for Health Sciences" taught to first year medical students of the Mohammed Bin Rashid University of Medicine and Health Sciences, Dubai, UAE. It was decided to integrate this course as part of the first year's offerings to equip the students with a digital health and innovation mindset as early as possible. It was believed that it helps medical students to reflect on how digital health could be implemented in clinical courses that are taught at a later stage. The course consists of two parts, the first one focusing on digital health, and the second on health innovation. In this chapter, we only concentrate on the first part. It consists of 6 weekly sessions of 50 min each (Table 12.1). The teaching delivery mode varies from lectures to tutorials and case studies. The course is not solely about the respective technologies, but more about their functionalities from the perspectives of a medical professional. For example, the medical student understands, through this course, how heart rate is taken from an activity tracker, and the differences between an electrocardiogram (ECG) taken from an Apple Watch or in an intensive care unit (ICU).

At the end of each lecture, students are asked to fill-in an electronic "3-2-1 feedback form" that asks them to descriptively identify: 3 new things they learnt in this course, 2 things that particularly caught their attention, and 1 further question. Such

Table 12.1 Integration of Digital Health as part of the curriculum

Weeks	Sessions	Description	Learning objectives
1	Digital health	The lecture starts with highlighting the limitations of a non-digital healthcare system. It follows with the introduction of Electronic Medical Records and continues with the definition of digital health. Some examples of digital health technologies are presented and contrasted with non-digital practices. The lecture ends with the presentation of the key components of a healthcare system and explains the role of DHT	• Define the concept of Digital Health • Identify the key components of a health system • Understand the status of digital health technologies
2	Persuasive computing and mobile health	The session starts with some facts related to non-communicable diseases and the role our lifestyle plays in developing those chronic diseases. The BJ Fogg's model, as a simple framework to understand behavioral change, is presented with application examples. The role of mobile devices in behavioral changes is then emphasized. Several examples where digital interventions are delivered through mobile devices are then presented and evaluated. Towards the end of the session, differences between low and high-fidelity digital interventions are discussed	• Identify what drives behavioral change • Relate to the role of persuasive technology in driving change • Learn why and how mobile devices have empowered patients and medical staff
3	Wearable technologies	The lecture starts with the description of distinct types of wearable technologies and how they can help in better understanding people's Quality of Life. Time is then dedicated to developing a thorough understanding of the characteristics and functionalities of activity trackers, describing how step counting, heart rate monitoring, and energy expenditure are calculated. The limitations of activity trackers are then discussed. The lecture ends with the presentation of use cases where body sensors, smart clothing, smart jewelry, and bio-tattoos are used	• Describe wearable technology • Explain why wearables are important in supporting people's Quality of Life • Explain the characteristics, benefits, and limitations of wearables

(continued)

Table 12.1 (continued)

Weeks	Sessions	Description	Learning objectives
4	Augmented and virtual realities	The session starts with a case-study where smart glasses are used to increase the usability and completion of surgical safety checklists in operating theaters. It then continues with defining and contrasting augmented and virtual realities. Several case studies where both types of realities are presented, and compared and contrasted, and their benefits and limitations discussed	• Define the meaning of augmented and virtual realities • Describe the benefits and limitations of both technologies • Investigate use cases where both technologies are beneficial, and oppositely: are cumbersome
5	Artificial intelligence in medicine	The lecture begins with a discussion regarding the age of Artificial Intelligence (AI). It continues with presenting underlying AI concepts from machine learning to deep learning. Then different examples of machine learning are presented, namely supervised and unsupervised algorithms. An example of a supervised algorithm is discussed. From scientific literature, different research is presented highlighting the benefits and the limitations of AI.	• Define the concept of AI and its origins • Explain the role of AI in general and why it is particularly relevant in medicine • Describe the limitations of AI • Analyze successful and less successful eHealth apps relying on AI
6	The future of care delivery	The session starts with describing a typical journey of a patient waiting to visit a general practitioner due to flu symptoms. Using journey mapping, the activities and touchpoints are explained. Then, three DHTs are presented – telehealth, focused on AI-based chatbots; 3D printing; and drones are presented. The benefits and limitations of these three DHTs are discussed. Then, how the journey of the patient will change through introducing the three innovations is discussed	• Analyze successful and less successful eHealth apps relying on AI • Identify what drones can and cannot do in supporting healthcare • Discuss how 3D printing, another means to deliver care, is changing pharmaceutical business models

feedback allows the instructor to know whether the students' emphasis was aligned with the course objectives and highlight some potential areas of the course content and/ or delivery that requires more attention. In addition to group projects, the course included an in-class assessment as well as an end-of-course assessment comprising multiple choice questions and simple answer questions.

12.6 Discussion and Conclusion

In the last years, digital health technologies have shown their capacity to support and monitor patient's lifestyle, while guiding medical professionals alongside their clinical care provision routines. Though existing research demonstrates the capacity of digital interventions to support patients' behavioral change, medical practitioners are yet to be equipped to leverage such mechanisms. In this book chapter, we argue that medical schools play a key role in enabling digital health technologies to reach their full potential. However, the journey ahead for medical schools, in terms of adopting DHT as part of their curriculum, is still long, and for good reasons.

First, the nature of DHT is very different compared to traditional medical technologies such as X-Ray, MRI, or laparoscopic surgery. DHT are consumer products developed by technology companies with different manufacturing, testing, and certification processes as well as sales channels compared to medical devices. From a medical perspective, the clinical use cases of DHT are then less obvious. Second, the pace with which DHT evolve is much faster compared to medical technologies. For instance, in 2020 only almost 100,000 new digital health apps were released on the different app stores (Olsen 2021). It is thus very difficult to keep track of what is new, what is not available and what has been scientific tested. Some private institutions gather information to help patients and physicians select digital applications based on the thoroughness of their evaluation (ORCHA 2020), but there is no such classification at the app store's level. Additionally, from a hardware viewpoint, the number of options is almost unlimited. It is very difficult to navigate the spectrum of brands, functionalities, and price. For instance, from a "no-name" activity tracker available for $5 to an Apple Watch sold at $749, it is not always easy to know what makes the price.

With the implementation of the Health System Science framework, medical schools have realized the importance of complementing the traditional basic sciences + clinical sciences curriculum. However, we argue that a profound restructuration of medical curriculum is required, focusing on integrating technologies as a core pillars. Currently, clinical informatics is one of the seven HSS framework's sub-domains, which is materialized by a limited number of credit hours, most of the time offered as electives. It, however, does not reflect the impact of concepts such as Artificial Intelligence, which will become embedded in most of the decision making in a near future. Similarly, virtual reality has shown interesting use cases throughout different verticals from pain management to stress and anxiety disorders as well as simulation. Some medical schools have taken the opportunity to offer unique degrees such as Texas A&M University that graduates "Physicianeers". The program was built in collaboration between the College of Engineering, College of Medicine, and the state's hospital. Graduates receive a master's degree in engineering in addition to a Doctor of Medicine (Texas A&M 2022). Duke University is another example of a dual program (MD-MEng) offered by the Duke's Pratt School of Engineering and the School of Medicine (Duke 2022).

Some smaller steps could be undertaken, such as promoting the "engineer to physician" path, for medical postgraduate programs in particular. In the United States, only 1–2% of graduating engineers apply to medical school, majors such as biological sciences make up an overwhelming majority of medical school applicants (Rambukwella et al. 2021). It would imply that both engineering and medical colleges engage in awareness and promotional campaigns to explain the value of such combination. In the meantime, Massive Open Online Course (MOOC) platforms offer different courses to either introduce medical students to the basics of engineering or engineers to the basics of medicine.

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Chapter 13
Opportunities and Challenges of Digital Global Health

Julian Euma Ishii-Rousseau and Shion Seino

Abstract As interest for digital transformations in healthcare continues to grow, global health approaches have been identified as aligned with the implementation of digital health solutions. "Global health" is a multidisciplinary field that aims to achieve equitable healthcare access for all, predominantly operating in low- to middle-income countries (LMICs). Traditionally, global health innovation is centralized on delivery of care in lieu of novel technologies developed in high-resources settings that may lead to further displacement of the marginalized. However, the sharing of lessons learned from digital global health approaches can lead to the development of new technologies that improve health access and the delivery of value-based patient care. Furthermore, digital health experiences in LMICs may provide insights to develop a borderless ecosystem for capacity building of global collaborations in research and development for patient-centric solutions. This chapter discusses the advancements made in digital global health and its challenges, and provides a framework for digitization in global health settings.

Keywords Global health innovation · Digital health · Digital transformation
Global health informatics

J. E. Ishii-Rousseau (✉)
Department of Global Health Promotion, Tokyo Medical and Dental University, Tokyo, Japan

General Incorporated Association Liaison, Yokohama, Japan

MIT Critical Data, Cambridge, MA, USA

S. Seino
General Incorporated Association Liaison, Yokohama, Japan

MIT Critical Data, Cambridge, MA, USA

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13.1 Introduction

Technology can irrigate clinical deserts.–Dr. Paul Farmer

As Dr. Hans Rosling pointed out in *Factfulness*, the state of the world has often been incorrectly understood due to the "gap instinct," causing false assumptions that the boundaries dividing countries are unchanged and prevalent in the twenty-first century (Rosling 2019). Digitization and technology have permitted and promoted a more accurate and "fact-based worldview," and the emergence of the United Nations Sustainable Development Goals (SDGs) in 2015 and the World Bank's Human Capital Index (HCI) in 2018 have provided frameworks and indices to consider when tackling the challenges of our shared world (Sachs 2012; Rosling 2019; Kraay 2019). Although the list of actions required to create a more peaceful and equitable society is still long, there are high expectations for digital solutions in improving socioeconomic situations in low- to middle-income countries (LMICs), especially with the emergence of low-cost mobile-based technologies.

Significant health inequities persist in the twenty-first century, which has been coined as the "golden age for global health" (Maes 2014). Challenges include combating the global burden of cardiovascular disease, injuries, cancer, infectious disease, and mental illnesses, especially in LMICs (Vos et al. 2020). Key global health priorities include topics that overarch these diseases, from maternal and child health, infectious disease prevention and elimination, emerging non-communicable disease burdens, drug production and equitable distribution, and access to surgical care to the procurement of resources required to cover the aforementioned (Maes 2014).

The purpose of digital innovation and technology applications to global health is not to replace or displace, but to enhance healthcare access and patient-centric care. Value-based approaches in lieu of excessive prioritization on costs generate excellent opportunities for innovations that bridge the divide in health disparities in a sustainable manner. As with effective global health interventions, wielding a background understanding of the extraordinary advances in the computer and information technology industry is valuable for appreciating the opportunities in its applications to global health.

The expansion of computing speed and digital capabilities since the emergence of the first electromechanical digital computers in the late 1930s translates to not only the continuous surge of digitization, but also its affordability as exemplified by its permeation through multiple aspects of our everyday life. Digitization has brought a level of societal optimization in areas that once required more than one person through automation (Attaran 2021). The mobile phone penetration success story with the inception of the Internet, email, ecommerce, and online banking systems are examples of this phenomenon. Over the past two decades, increased Internet access and mobile phone affordability have permitted developing countries to join the online community, and mobile phones are regarded as the key for the "next billion" of global citizens to go online (Sambuli 2016).

Since 2019, mobile companies have been deploying the fifth-generation (5G) mobile network, theoretically increasing network speed from the previous generation's (4G) 300 megabytes per second (Mbps) to approximately 10–30 gigabytes

per second (Gbps) (Dananjayan and Raj 2020). 5G's ultra-fast Internet, low-latency, decreased energy usage, and improved reliability expands the possibility of further digitization of every industry and permits the introduction of myriad new innovations. There are especially high expectations for its use in low-resourced settings, especially for further economic activity and growth via instant communication, online marketing and selling, and alternative payment methods (Group and World Bank Group 2016).

While Internet and 5G applications to healthcare have positive outlooks, there are particular opportunities for global health interventions and solutions that aim to achieve equitable health access for all. One reason behind this is the emergence of "non-cellular" 5G, which can realize a low-cost, high-functioning, seamless, and decentralized environment for digital health innovation (Aijaz 2020; Fossati et al. 2020; Peña et al. 2021). The combination of digital interventions with global health challenges is an exhilarating up and coming area, and can lead to enhanced optimization of difficult technologies with lower energy input. This in turn contributes to improved health access and eco-friendly solutions in urban or developed societies that currently seek alternative methods to combat issues related to urbanization such as climate change, overcrowding, and growing income gaps (Cho and Kim 1983; Cohen 2006). However, while digitization has rapidly shown substantial changes in the way society consumes products and conducts business, health has yet to be effectively integrated in the information technology circuit (Winter and Davidson 2019). Furthermore, although there has been a surge in the number of health apps, the global health settings have yet to fully benefit from these more affordable tools due to challenges in smartphone and broadband availability (Connected Society Programme 2021).

Here we discuss the opportunities and challenges in digitization in global health settings, and the future possibilities to equitize access to health through digital health solutions.

13.2 Opportunities for Digitization in Global Health

Currently, digitization in global health settings has been shown to be effective in the areas of medication management (Anstey Watkins et al. 2018), emergency response during injuries or pregnancies (Oyeyemi and Wynn 2015; Anstey Watkins et al. 2018), vaccinations (Sondaal et al. 2016), adoption of safer sexual practices (Ippoliti and L'Engle 2017), disease surveillance (Ippoliti and L'Engle 2017; van Heerden and Young 2020), and clinical imaging (Gallay et al. 2017; Gheza et al. 2018). These have contributed to enhanced facility triage and management, reduced delays in emergency response (Oyeyemi and Wynn 2015), improved vaccine coverage (Uddin et al. 2016), and lowered costs (Rajput et al. 2012; Ngwatu et al. 2018). The COVID-19 pandemic exacerbated the need for increased deployment of digital health for public health responses, especially in LMICs where there are large discrepancies among regions in health resource availability.

With the high penetration levels of mobile phones in LMICs, there have been increased developments in cloud computing and adoption of mobile health (mHealth) applications (The World Bank Group 2020; Rundqvist 2020). Studies on the effectiveness and value of digital health solutions have been reported with high optimism for further implementation of information and communication technologies (ICT) in global health. A scoping review of digital health interventions in LMICs recommended the national scaling up of projects that end as small pilots while also evaluating the costs for nationwide implementation and the return on investment (ROI) (Long et al. 2018). Other areas that were highlighted for further research included quantifying the value of scaling up digital health approaches to health human resources management, identifying digital health impact on current donor and government procurement policies, and the role of the private sector and philanthropists. Furthermore, discourse to establish standards for digital health evaluations in global health settings have encouraged LMICs to provide evidence (e.g., peer-reviewed literature, data) on digitization in health, permitting the creation of frameworks and references to decrease risks and amplify the impact of investments in the field (Labrique et al. 2018). Such digital health interventions empower LMICs to leapfrog and accelerate development in a self-sufficient manner.

13.2.1 Case Study 17.1: Health Digitization in Uganda

Uganda is one of the fastest growing nations as well as one of the larger host countries in the continent for refugees and patient referrals from its neighboring countries (UNFPA 2017; Uganda Ministry of Health 2019). With the aim to provide universal health coverage to the diverse communities within its national borders, the Ministry of Health in Uganda launched the Health Management Information System (HMIS) to accumulate and analyze health data from public and private health facilities. The HMIS has been improved over the years with the introduction of ICT policies since the early 2000s (Kimera et al. 2020). While stakeholders have reported that the HMIS technology is user-friendly, challenges persist in promoting data utilization and technical skills training (Wandera et al. 2019). If resolved, the system has the potential of providing insights on the planning, monitoring, and evaluation of health programs within Uganda, and to inform future public health policies (Monitoring and Evaluation Technical Support (METS) Program 2018; Wandera et al. 2019). Studies on similar systems in South Africa, Kenya, Tanzania, Zambia, Mozambique, and Nigeria showed improved patient data retrieval and reporting through system integration and training (Ndabarora et al. 2014). Health information technology was also proven to improve quality of care and efficiency through adherence to diagnosis guidelines and protocols in India (Chaudhry et al. 2006); hence, incorporating best practices from within and beyond Uganda may promote HMIS utilization and deployment.

These government efforts are complemented further with new solutions and technologies developed by universities and startups. Tools such as a digital

pathology platform for automated diagnosis and classification of cervical cancer from pap smear images as well as a mobile ambulance service dispatch system aim to support the national health system by reducing the time, cost, and errors in delivering patient care (William n.d.; Edmond 2019). Additionally, there are efforts to increase public–private partnerships via small pilots, such as the United Nations Children's Fund (UNICEF)-backed clinical data ecosystem that Global Auto Systems' Digital Health (n.d.) Uganda provides across four hospitals in Uganda, to showcase the possibilities of gathering and utilizing hospital data (Global Auto Systems Ltd.). The system is currently being expanded to collect and track information regarding patients with cancer in order to develop better policies and solutions for treatment and care.

Various digital health solutions are currently being deployed to combat the top health challenges of the 2020s (Pathan 2020). The COVID-19 pandemic spurred myriad creative methods to work across these issues while also following pandemic guidelines and bypassing political, cultural, and institutional hurdles (Jayakumar 2020; Thomason 2021). Table 13.1 summarizes the areas outlined by the World Health Organization (WHO) while providing examples of the challenges in LMICs and potential digital solutions to address them.

Table 13.1 Digital health solutions to combat global health challenges

Challenge	Examples	Need	Potential digital health solution
Infectious disease and epidemics	COVID-19, influenza	Increased financing and international cooperation to strengthen health systems in endemic countries as well as increase research and development of novel tools for containment	Real-time visualizations and monitoring of disease burden and spread; Rapid communication and information dissemination in emergencies
Health access inequities	Access to medications, cost of care	Improved governance of public and private health services; Capacity building in low- to middle-income countries	Deployment of low-cost and secure telehealth solutions; Increased use of data analysis to pinpoint discrepancies in health needs and availability of medications and other health resources
Health worker shortages	Health worker exhaustion, low-quality care	Increased investment in education and employment of health workers; Improved deployment and allocation of resources; Creation of health intermediaries	Implementation of low-cost educational and data sharing platforms; Improved resource management tools for improved allocation; Adoption of telehealth solutions

(continued)

Table 13.1 (continued)

Challenge	Examples	Need	Potential digital health solution
Non-communicable diseases	Obesity, cancer, cardiovascular disease	Further development of evidence-based health policies; Improved support for mental health; Increasing science and health literacy	Delivery of healthier life habits and routines via mobile solutions
Climate change	Hunger and starvation, increased gastro-intestinal, infectious, and respiratory disease burdens	Coordinated global response from public and private sectors to clean the air and prevent further climate change; Development of novel sanitary methods; Improved access to clean water	Deployment of low-cost diagnostic tools for rapid and early detection of disease onset; Dashboard utilization to increase transparency between climate change and health
Other	Provision of care in conflict, mis-information	Deployment of swift and effective medical teams and political action to end internal and cross-border conflicts; Increased monitoring and regulation of health information	Utilization of telemedicine and mobility tools for swift and safe healthcare delivery

Particular areas for cost-effective mHealth and digital health deployment within global health settings include: (1) **patient data management:** electronic and personal health record systems (EHR, PHR), healthcare platforms and infrastructure to track and analyze health indices as well as environmental factors (e.g., socioeconomic, regional, cultural, etc.), and health data security via biometrics and blockchain technologies; (2) **improved clinical patient care and flow:** utilization of artificial intelligence (AI)-based imaging and triage solutions as well as natural language processing on unstructured health data; and (3) **innovative care delivery:** drone or digital mobility technologies. Although these digital health approaches require long-term planning, many are easily achievable solutions that can be implemented simply through mobile phones, personal computers, and a stable Internet connection.

While applications of telehealth, AI, and big data analytics have been theorized as key tools to dramatically revamp global health settings, further pragmatic real-world investigations have been deemed necessary for their effective implementation, scale-up, and integration into healthcare systems (Gunasekeran et al. 2021). In addition, careful observation must be made to identify the bottlenecks in scaling such efforts. Table 13.2 introduces the areas of digital solutions that have been adopted in LMICs and the current trajectories for their implementation and deployment.

The aforementioned solutions represent a fraction of the technologies emerging to support health and medical delivery in low-resource areas. Since 2011, the WHO

Table 13.2 Digital solutions in LMICs

Health challenge	Solution	Description
Treatment delivery	Drone delivery (e.g., Zipline, Matternet)	Drones have been deployed to deliver a variety of resources and medications in low-resource areas such as urgent blood supplies, prescription medicine, vaccines, and automated external defibrillators (AEDs)
Remote medicine	Telemedicine platforms and diagnostic kits (e.g., Ghana Healthcenter Telemedicine, VSee)	Telemedicine kits including tablets, stethoscopes, oximeters, ultrasounds, etc. that permit full medical examinations in inaccessible remote areas such as conflict zones
Health data management	Electronic health records/ Personal health records (e.g., Possible Health)	Electronic health record created and maintained through a public–private partnership utilizing open-source components for patient tracking, clinical protocols, pharmacy, laboratory, imaging, financial management, and supply logistics
Patient handover and care coordination	Doctor-to-doctor communication platform (e.g., Allm Inc.)	Secure smart device platform to share patient data between or within healthcare facilities for seamless patient handoff and care coordination even in areas with few specialists
Patient identification and disease surveillance	Child fingerprint identification (e.g., NEC and Simprints)	Biometric identification tool leveraging smart devices to ensure patient care and administration of routine vaccinations in areas where few children are officially registered at birth and thus have no official government identification
Patient security	Blockchain solutions for information sharing (e.g., Factom, MIT MedRec)	Decentralized ledger network with encrypted data chains that permit (1) proof of work/ identification, and (2) smart contract or economic model applications, and guarantee data integrity

has compiled the Compendium of Innovative Health Technologies for Low-Resource Settings to introduce health technologies that are high-quality, accessible, and affordable to LMICs along with case studies of their deployment (World Health Organization 2015). Innovations include equipment for facilities, imaging devices, surveillance devices, surgical tools, and treatment as well as assistive solutions for improved quality of life.

13.3 Implementation Challenges for Digital Global Health

The implementation challenges in digitizing healthcare data in global health settings require international attention and multisectoral collaborative efforts. These include environmental/infrastructural, financial, educational, cultural, and political hurdles that if unanswered, could possibly exacerbate existing ethnic,

socioeconomic, and gender inequities. Further, increasing transparency regarding these challenges and combating short-sighted biases against digital health innovations in LMICs will become increasingly vital.

Countless innovations are developed to solve health issues across the globe, yet deciding the timing and process for digitization as well as resources required calls for a definition and understanding of the needs and clinical problems at hand. Because digital health solutions aid the creation and discovery of such baselines, some say that digital health implementation causes a "chicken or the egg" dilemma. However, methods such as the U.S. Agency for International Development's (USAID) typology of innovation permits flexibility in order to pivot quickly when there is a discrepancy between the technology implemented and the needs on the ground, and can be used to guide decisions regarding which technologies to prioritize (Center for Innovation and Impact 2020). Furthermore, the essential inclusion of local academia, public and private sector, and non-profit sector early on in the discussion should be a fundamental requirement when working across digital health transformations in LMICs to prevent such errors. Figure 13.1 provides an overview of the broad set of implementation challenges in digital global health.

The development of effective and scalable global health innovation implementations require robust data infrastructure, data sharing, and usage capabilities that do not compromise patient confidentiality, and flexibility in creating partnerships across various departments, industries, and sectors (Center for Innovation and Impact 2020). This includes the rearing of digitally literate vendors, healthcare providers, and patients as well as deployment of hardware that can be leveraged to use a variety of software and applications regardless of connectivity. The MIT Critical Data (MIT-CD) consortium's "Ecosystem as a Service (EaaS)" approach provides examples of global efforts that can aid as a low-cost and sustainable solution in combating this challenge (Ishii-Rousseau et al. 2022).

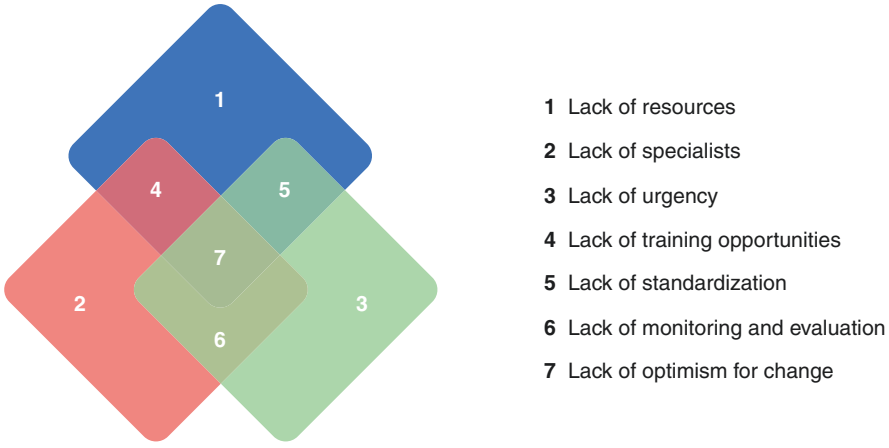

Fig. 13.1 Implementation challenges in digital global health

Furthermore, meticulous studies on the availability of resources and infrastructure are also crucial when aiming to rear clinical informaticians that can implement and wield digital health solutions. Although mobile penetration has shown high promise, developed countries have shifted from solely computer-based to smart device- and cloud-based technologies in health, continuously widening the capacity divide within the realm of digital health and mHealth technologies (Connected Society Programme 2021). According to a 2021 report on the cost of fixed-line broadband across 211 countries, Sub-Saharan Africa fared worst with the majority of its countries categorized as highly expensive, ranging from a monthly average of 370 to 710 USD per broadband package (Howdle 2021). Clusters of countries within Central and West Africa were also excluded from the study as they could not provide sufficient information. Therefore, digitization in global health challenges may at times require the primary step of realizing better Internet and broadband coverage in addition to the tools required to benefit from online services.

13.3.1 Case Study 17.2: Rearing Data-literate Clinicians in Mexico

Mexico, the second largest economy in Latin America, is currently classified by the World Bank as an upper middle-income country. In 2020, 93 per 100 capita were subscribed to mobile cellular services (The World Bank Group 2020). However, in a 2019 report, 69% of people living in rural areas in Mexico did not have access to the Internet and only 60–70% of people living in urban areas were connected (El Instituto Federal de Telecomunicaciones (IFT) 2020). Furthermore, within the country, only one private university was found with the capacity to provide AI and data science education. Specialists in the country attribute this situation to a lack of sufficient evidence to convince government officials and stakeholders to promote higher uptake of digitization and use of data combined with low levels of knowledge about digital health and its possibilities. Currently, the MIT-CD consortium is collaborating with researchers in Mexico to participate in global research on data science and digital health opportunities, and to increase exposure, literacy, and interest in the field. Regarding the COVID-19 pandemic, private sector efforts in Mexico for improved digitization and online resources to detect, isolate, and monitor COVID-19 patients have also been deployed; however, increased efforts for raising the urgency and prioritization for ICT, including digital health, are still imperative to realize nationwide digitization and data literacy (Betancourt-Cravioto et al. 2022).

Financing to purchase, deploy, implement, and sustain digital health technologies is another area of debate. While on one hand governments have been identified as the key financier of digital health transformation, private sector donations and corporate social responsibility (CSR) contributions have also increased in supporting local efforts for improved health access. However, sustainable financing for

long-term implementation requires the combination of all of these efforts, including discussions around the timeline and exit strategies for reliance on donor governments and aid. Combined with the aforementioned challenges, examination over solutions that prioritize the patients, population, culture, and ecosystem over cost-effectiveness and speed is how true "value-based equitable basic healthcare delivery" can be realized (Gary Bisbee 2022). This would further be streamlined by the support of technology that accompanies "the accompagnateur," an innovative Community Health Worker (CHW) process for healthcare delivery spearheaded by Partners in Health (PIH) (Palazuelos et al. 2018).

Finally, the involvement of local voices in health digitization is critical yet often overlooked. Developing countries are often supported by donor countries and overseas institutions, advised by international agencies and consultants, and informed through numerous whitepapers, guidelines, standards, and best practices created for very different populations (Hanafizadeh et al. 2019). Limited experience and lack of confidence in the field have led to greater reliance on the global players, with little input from local actors. Yet, health systems and the technology used to both provide care as well as gather insights must reflect specific clinical and cultural needs of the populations they serve. This includes the heightened urgency and call for local researchers from developing nations to play a greater role in the literature produced regarding their countries. LMICs and the global community must also review mainstream criteria and guidelines provided for ICT and digital health, and encouragements must be made for LMICs to approach their digitization efforts more radically and inclusively (Hanafizadeh et al. 2019).

13.4 Future Directions

Digital health adoption in global health settings will most likely continue to persist and increase over the next decade. However, in order to prevent the risk of facing challenges currently seen across high-income countries, such as issues of interoperability and the lack of data sharing, the sharing of perspectives, experiences, and expertise, can and will lead to the development of new technologies that are clinically meaningful and contribute to improved health access and the realization of value-based patient care. Furthermore, lessons learned from digital health experiences in LMICs may provide insights to not only spearhead further developments in the country, but also contribute to building global capacity for collaborative research and patient-centric tools.

To achieve an equitable and sustainable digital health ecosystem in global health settings, a combination of research, partnerships, advocacy, and scaling will likely be required. The authors of this chapter suggest the following steps be considered at any stage of the digital health implementation spectrum. The process has been developed from the application of PIH's "Accompaniment Approach" principles

and the "Advocate's Toolkit" recommended by global health leaders such as Dr. Paul Farmer and Dr. Joia Mukherjee along with Matthew Basilico and others (Maes 2014).

1. Learn from the locals

   The "Accompaniment Approach" starts with listening and learning from local individuals and stakeholders. Find out about the best practices, the bottlenecks, the priority needs, and the areas that suffer from implementations that are theoretically good yet poorly executed. Learn about currently available resources and how capacity building is taking place. In particular, observe and seek guidance from communities that are most marginalized to ensure their pain points are addressed. In other words, go to the source to find out what the problems are in order to come up with relevant solutions.
2. Find local and global partners

   Foreign aid projects have been called out for procuring resources outside the countries they serve, thus not only missing the opportunity to stimulate local economies but also the chance to gain insight on the cultural and political hurdles or shortcuts. Gathering local partners can contribute to sustainable capacity building and knowledge transfer and rear the next generation of digital global health entrepreneur. Furthermore, the combination of global and local partners provides the opportunity for local voices to be heard more in the global health arena. Finally, local partners are critical for future scaling.
3. Discuss strategies with policymakers

   Digital health is challenging to implement without governmental support and relevant policies for scaling in any country, regardless of income level. Discussions with relevant ministries and policymakers from an early stage may aid leapfrogging in addition to coordinating siloed efforts. Policymakers can also help identify pain points and bottlenecks in digitization, which will be necessary in order to achieve equitable digital health implementation and usage.
4. Co-invest with governments for sustainability and national growth

   While donor governments and private sector capital are helpful in kickstarting digital health implementations, sole reliance on financial support from such sources increases the risk of discontinuation, gaps in knowledge creation, uneven distribution of resources, and lowered in-country capacity. Discovering ways to co-invest with governments may increase government support in achieving the desired outcomes and goals as seen with various practices in infectious disease prevention and control. It may also contribute to job creation for local communities, thus positively impacting the local economy.
5. Evaluate and disseminate information regarding best practices

   Digital health implementation and realization can be assumed to be costly and time-consuming. A greater number of published studies that discuss best practices in implementation and scaling can aid countries to overcome such fears. In addition, creating discourse and increasing the transparency of current

efforts can invite external partners and individuals to offer support as well as guidance. Furthermore, the pooling and open-sourcing of information and best practices aids in creating an ecosystem for digital global health practices to thrive.

13.4.1 Case Study 17.3: Medicine Adherence in India

Medicine and treatment adherence has been a long-standing issue in India, especially among younger populations and those with lower levels of understanding regarding their medical conditions along with the consequences (Sarna et al. 2008; Venkatachalam et al. 2015; Santra et al. 2021). This imposes a threat in eliminating disease burdens and the risk of treatment failure can at times lead to premature death. In a study conducted in 2015 on patients with hypertension, drug adherence was found more commonly among patients who were closer to health facilities while in a 2020 study on antiretroviral drugs, patients who had familial support were found to be more adherent to treatment regimens (Sakthivel et al. 2020).

In 2018, India's Prime Minister Narendra Modi announced India's ambitious target to complete the elimination of tuberculosis (TB) by 2025, 5 years ahead of the global target of 2030 (World Health Organization 2021). With this decision, the country reviewed its strategy on TB elimination and established the National Strategic Plan (NSP) for TB 2020–2025 with revised actions and bolder commitments (Central Tuberculosis Division, Ministry of Health, and Family Welfare, Government of India 2021). Although India has the highest TB burden globally, with approximately 40% of the population infected, it also has a particular opportunity to eliminate TB through renewed government interest and commitment. mHealth solutions, such as the use of low-cost technology that can deliver reminders via short message service (SMS) and voice calls to almost all types of mobile phones even in low-resourced settings, have been proven useful in improving drug adherence in India and can now be scaled with additional government funding (Narasimhan et al. 2014). Such systems also show promise in the surveillance and treatment of other diseases, even in areas with low bandwidth and low penetration of smartphones.

13.5 Conclusion

Digital transformations in healthcare have political, technical, and cultural barriers regardless of geography. Although the technical hurdle may seem unrealistic, the opportunities that will come from these solutions are extraordinary. The true challenge in these approaches lies in the mechanism behind the design and implementation of solutions. However, patient-centric visions that integrate the accompaniment method for healthcare delivery permits the incentivized sharing of perspectives, experiences, and expertise of implementing digital health in global health

approaches. These can lead to the development of new technologies that are clinically meaningful and contribute to improved health access and the realization of value-based patient care. The authors of this chapter hereby humbly request that the world turn not only inwards domestically, but also externally, to partner with local stakeholders in low-resource settings, as the solutions devised would be applicable ubiquitously.

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Chapter 14
Future Landscape in Digital Health

Homero Rivas and Thomas Boillat

Abstract The future, as much as beauty, is in the eye of the beholder. For some, we already live in the future of others, where digital health, including artificial intelligence, telemedicine, robotics, genomics, and other technologies will somehow integrate into healthcare. It is how we see and shape our present and future that matters. One thing is certain: no matter how much we try and prepare, most predictions about the future will always be wrong. In this chapter we venture into just another prediction about the future of digital healthcare.

Keywords Digital health · Future - artificial intelligence · Computer vision Machine learning · Neural networks · Robotic surgery · Laparoscopic surgery

14.1 Introduction

Having a crystal ball that can predict into the future has always been a fantasy and part of many fiction novels. Even the most educated prediction about the future, one based on experience, statistics, and facts, will likely be wrong (The perils of prediction 2009). Furthermore, most forecasts will be rather conservative unless they are predicted for the very long-term future, when so-called "futurists" can add imagination to knowledge and experience, and propose rather optimistic predictions; regrettably, such futurists will not be alive to experience their forecast much less be accountable for their predictions. Shorter-term predictions will always be calculated and tailored to known trends and tend toward being more conservative.

Successful innovators must bet into the future and embrace risk. In statistics, all forecasts are essentially wrong and in baseball as in life, as legendary baseball

H. Rivas · T. Boillat (✉)
Design Lab, Mohammed Bin Rashid University of Medicine and Health Sciences, Dubai, United Arab Emirates
e-mail: Homero.Rivas@mbru.ac.ae; Thomas.Boillat@mbru.ac.ae

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player and coach, Yogi Berra popularized, it's tough to make predictions especially about the future (Bussel and Team Hewins 2020). During 2011, only a few years ago, StarCraft, a very popular online game, had a cyber tournament with a winning pool of US $1000 for the few winners, but also 25 bitcoins for the losers. No one would have then imagined that only in a few years those bitcoins would be worth a bit more than US $1,000,000 (Cade Onder 2021). Especially in healthcare, predicting the future can be a very tricky business and being wrong may be the natural state of a forecast.

14.2 The Future Landscape of Digital Health

In healthcare, most innovations come into our day-to-day practice at a much slower pace than in most other industries. There are sensible reasons for this phenomenon, including the nearly standardized need for long-term clinical trials before implementing innovations and the fact that care providers must implement those innovations in human beings and not in media, electronics, commodities, market, etc. While many other reasons could be added into the mix, perhaps the most important reason for the slow adoption of innovations in healthcare is a prevalent mindset of risk-aversion that is ingrained in most physicians' and care providers' minds (Rivas 2018; Rivas 2020).

To systematically talk about the future in healthcare, we include three cornerstones of healthcare: discovery or research, education, and clinical care. Without hesitation, the last one presents the biggest challenges and opportunities as described before.

Digital health has a distinct differentiator to conventional health practice as it is uniquely portable; therefore, it can provide extensive access to care to the masses. In the near future, most if not all clinical trials will include digital health. Furthermore, for many well-designed investigational clinical trials, there will be no need for human research subjects to ever have to set foot in a clinic or hospital, or to be in close geographical proximity to the main investigator's healthcare center. Basic and sophisticated, low-cost medical devices will be provided to patients to have at home, and different software will be easily accessed through their mobile devices, desktop, Wi-Fi network, server, etc. This will not be a simple transition, as many conservative regulators (i.e., licensing boards, governments, etc.) may limit restrictions to such innovative form of research. Nevertheless, as experienced during the COVID-19 pandemic, barriers to digital health innovation have been dramatically removed by even the strictest regulators. Security concerns about the cloud have been lessened by the use of regional servers within the boundaries of concerned nations. As expected, nations with fewer resources and regulations continue to be much better implementers of innovation.

The education and digital health sectors have and will probably continue to experience high growth in the future. In many ways, this is occurring from the bottom up as many learners seek knowledge about digital health themselves regardless of any

established school curriculums. In a few years, however, most medical schools, nursing schools, allied health schools, etc. will have core curriculums that include digital health with as much relevance and value as courses in anatomy, physiology, and other core subjects. Failing to provide such relevance to digital health will fail our efforts to create well-aligned care providers to the future. Going back to Yogi Berra, *"The future ain't what it used to be." (*Nate Scott 2019*)*.

Probably, the biggest potential and the biggest challenges will be found in the future of clinical care and digital health. Up until now, most digital health innovations have been directed toward diagnostic and screening devices that measure different biometrics. This has been basically a miniaturization for portability of vital signs monitoring systems into commercially available wearable devices. For instance, the latest activity trackers embed an electrocardiogram as well as oxygen saturation and blood pressure monitoring capabilities. Even further, only a few of these devices are medical-grade or as accurate as their conventional counterparts. Therefore, to bypass many FDA regulations, most digital health innovations are portrayed and marketed as wellness devices in order to attract a much larger direct-to-consumer market.

We must view the future landscape of digital health with great optimism, the same optimism inspired by His Highness Sheikh Mohammed Bin Rashid Al Maktoum, Vice President and Prime Minister of the UAE and Ruler of Dubai, when saying that "the best is still to come" and that "the future belongs to those who can imagine it, design it, and execute it. It isn't something you await, but rather create" (Sheikh Mohammed bin Rashid Al Maktoum 2015). Throughout the first and second editions of these two books on Digital Health, many different innovative technologies have been reviewed. Among them, perhaps the highest exponential growth and evolution in clinical care will come from genomics, machine learning, and autonomous robotics (Rivas 2018; Rivas 2020; The Topol Review 2018).

14.3 Delivery of Care in the Future of Digital Health

People in general, before they could be considered patients, will be genomically predesigned, screened, and selected much earlier than birth. Even then, extensive genomic assessment at birth will identify potential ailments to be suffered through life. Continuous monitoring through implantable and wearable devices will autonomously monitor and implement interventions as needed throughout life in accordance to machine learning algorithms. Life expectancy will be prolonged; however, regardless of all these innovations, chronic diseases will still prevail, and some new ones will develop. A great portion of the patient–physician interaction will be automated, and it will rely purely on digital health platforms. Clinical decision support systems, computer vision, and computer-assisted diagnosis—all the result of deep neural networks of artificial intelligence—will be prevalent in all societies, even those with limited resources. Some professions will flourish, such as Geneticists, Artificial Intelligence Medical Informaticians, etc., and some new medical super

specialists will be created, such as Genomic Planners, Genomic Curators, Genomic Editors, Tissue Engineers, Healthcare Designers, Brain Computer Interface Specialists, etc. (Beck 2016; Cabitza et al. 2017; Stanford University 2015; Gouda and Steinhubl 2018; Mesko 2014)

Surgery will always exist because many other diseases require surgical intervention, such as trauma, obstetrics, and some types of cancer. However, over time, digital surgeons will prevail. The first implementations began 20 years ago with master–slave robotic platforms. Soon, however, machine learning algorithms will eventually augment surgeons' cognitive and technical capabilities until fully autonomous surgical platforms take over. Surgeons will then be mere digital supervisors of many of these autonomous devices, which will finally be able to scale not only to medicine but, in this case, surgery.

The future of digital health and healthcare in general is most probably a world where the notion of patients and hospitals does not exist *per se* but rather where these become elements in a continuum of care. The first step will be to concentrate on changing mindsets. The current model of care focuses on the concept of a patient as someone who is "ill or injured and in need of treatment". This binary vision of perceived wellbeing hinders the complexity of health. If a person who needs treatment is called a "patient," then how should a person who is reducing his or her risk to be sick through healthy life choices, such as non-smoking, no alcohol, healthy diet, and exercise called? As part of this new approach, how will digital health disrupt the patient and acute care model? Given the cutting-edge digital health research and solutions presented throughout this book, what will the health system of tomorrow look like when all these digital health advancements collaborate and communicate? Our attempt is presented in Fig. 14.1 and explain underneath it. Purposefully, our model focuses on the connections between digital health entities and is not meant to be exhaustive.

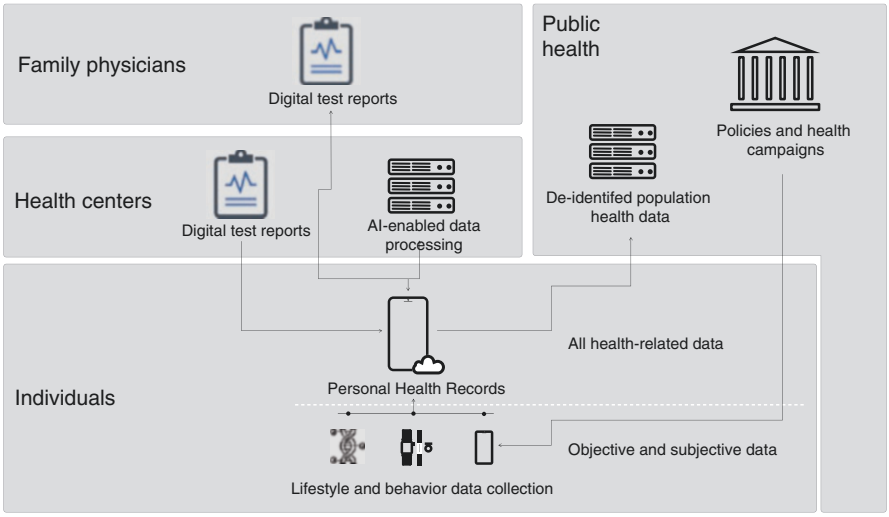

Fig. 14.1 Integration of digital health technologies – Our attempt

In a near future, health systems will not focus on people who are currently sick but simply on individuals—all individuals. At birth, the genome of each baby will be sequenced and comprehensively analyzed, and then transferred and explained in a Personal Medical Record (PMR). PMRs store all medical results and are owned by the individuals, who decide what data to share and with whom (e.g., health centers, government, family physician). To enable data sharing, the PMR is stored in a secured cloud platform while blockchain ensures that data are not being altered. The PMR will be linked to Artificial Intelligence algorithms that learn the person's lifestyle in order to identify any deviation or abnormal behavior. If the algorithm, based on a centralized large dataset, identifies deviations as worrisome, then the data will be automatically sent to a health center where it will be analyzed manually by health professionals. In our approach, health centers play an active role at the interface of health insurers (not represented in the schema) and family physicians. Health centers are centralized hubs where health tests are conducted and health data in general are analyzed. Relying on AI and robots, the health centers will promote dialog and employ medical professionals for tasks that machines cannot or should not be used to do. Health centers are also home to medical specialists from mental to physical and physiological health. Directly connected to public health entities, health centers intend to inform and implement health recommendations. Though to date public health departments are only informed about the population's lifestyle through subjective data, each PMR owner will have the choice to share data to receive more customized recommendations. These recommendations, if relevant, will be communicated to people via mobile notifications as well as to the family physician. Along with the person's lifestyle, personalized digital interventions will be sent to reduce the person's risk to become ill. Data used for these interventions will be sourced from a person's PMR where genetic data as well as wearables and mobile app data is centralized. Hospitals will still exist, but they will be limited to specific tasks such as surgery or obstetrics. This view is, of course, oversimplified but it highlights how digital health can disrupt the health system when implemented and adopted by health stakeholders.

Innovative insurance and revenue models will engage individuals and physicians in shaping better lifestyles and promoting a better state of wellness and disease prevention, in contrast to traditional models that support the treatment of disease but do not invest much in prevention (Rivas 2020). Probably since the inception of the concept of AI, there has been a general paranoia that AI may replace most professions, including medicine. In healthcare, with no doubt, physicians who do not embrace digital health technologies and AI may soon be replaced by those who do. This transition will be generational and geographic. Digital native generations of patients and medical providers will lead the way as well as small, visionary countries. Places like the United Arab Emirates have already incorporated Ministers of Artificial Intelligence, Happiness, Future, etc. into their government cabinets, which will allow them to innovate at a much bigger scale by implementing such technologies. Other places, like Singapore or Kuwait, may do the same as they attempt to obtain genomic profiles of all their population. On the contrary and ironically, for larger countries, where most innovating technologies are being created every day like in the United States, their implementation strategies will be laggards in this race due to regulation, litigation, a risk-averse culture in healthcare, etc.

14.4 Final Words

We live in exciting times where some previous predictions have crystalized in reality while many others have not. Healthcare is changing by the minute, not only in response to technological advancements, but also dynamically to the many different factors that we typically do not consider in daily clinical practice (i.e., societal, political, economic, generational, geographical, etc.). All stakeholders in healthcare have now nearly universal ready access to some kind and degree of healthcare thanks to digital health. This was not the case only a few years ago, even though we had most present technologies already available.

While the core model of medical practice will maintain a quintessential relationship between care receivers and care providers, this model will transform in time and space, and before or after any evidence of disease may even show up or exist. Digital health will soon become an essential part of the core model of healthcare. All digital health technologies, some more than others, will intertwine and become an invisible part of the routine practice of medicine. Most of these technologies will prevail while others may be a preamble to those not yet conceptualized. Artificial intelligence and genomics may seem to provide the most value of all; nevertheless, even simple technologies that for some are now commodities, like mobile phones, wearables, social media, telemedicine, etc., will truly become omnipresent. Good or bad, in the future, digital health will co-exist with most current forms of healthcare.

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