



# IDIH

INTERNATIONAL COLLABORATION  
DIGITAL TRANSFORMATION  
HEALTHY AGEING

## D1.1

# Trends, Drivers, and Enablers of Digital Health

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### Abstract

The growing elder population worldwide has unique implications for health services and, in recent years, has spurred demand for innovative technologies that support active and healthy ageing. As older individuals continue to experience longer life spans, this will be accompanied by an increased prevalence of chronic conditions that will strain health care systems and economies. The current state of technology is building on the foundation of electronic medical records (EMR) and focusing on empowering health care stakeholders through social media, mobile applications, analytics, and cloud computing (SMAC) technologies, including telehealth, remote monitoring and enhanced communications. Concurrently, technologies have begun to shift care to environments that are most convenient for consumers such as homes, local communities, and personal mobile devices. With consumer demand to age in place, future technologies will be expected to advance this shift and enable continuous at-home care. This will be fuelled by the development of new digital health tool such as advanced Internet of Things (IoT), artificial intelligence (AI), augmented and virtual reality (AR/VR), blockchain, fast health interoperability resources (FHIR), and more. Upcoming trends are pointing towards consumers expecting “Smart Homes” and environments that enable people to age wherever they desire. The combination of interface-agnostic devices, sensors embedded into everyday objects, as well as AI technologies, will allow patients to be continuously monitored and will alert clinicians and caregivers about the onset or progression of health conditions. This report examines these concepts, including current trends, emerging technologies, and the factors that will enable or hinder the adoption of digital health.

### Keywords

Digital health, health technology, electronic medical records, internet of things, telehealth, artificial intelligence, blockchain, virtual reality, FHIR, active and health ageing, connected care, age in place

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## Abbreviations and Acronyms

Abbreviation, Acronym	Description
ACO	Accountable Care Organization
ADHD	Attention Deficit- Hyperactivity Disorder
AHA	Active and Healthy Ageing
AI	Artificial Intelligence
API	Application Programming Interface
AR	Augmented Reality
CDC	Centre for Disease Control and Prevention
CMS	Centre for Medicaid and Medicare Services
DTx	Digital Therapeutics
EKG	Electrocardiogram
EMR/ EHR	Electronic Health Records
EU	European Union
FDA	Food Drug Administration
FHIR	Fast Health Interoperability Resources
HITECH	Health Information Technology for Economic and Clinical Health Act
IDIH	International Digital Health Cooperation for Preventive, Integrated, Independent and Inclusive Living
IoT	Internet of Things
MA	Medicare Advantage
NGO	Non-governmental Organization
RPM	Remote Patient Monitoring
SMAC	Social, Mobile Applications, Analytics, and Cloud Computing
UI	User Interface
US	United States



Abbreviation, Acronym	Description
UX	User Experience
VDC	Virtual Diabetes Clinic
VR	Virtual Reality
WHO	World Health Organization



## Executive Summary

This report is part of the *International Digital Health Cooperation for Preventive, Integrated, Independent and Inclusive Living* (IDIH) project funded under the European Union Horizon 2020 Research and Innovation Programme. It examines current trends, emerging technologies, and the factors that will enable or hinder the adoption of digital health.

The growing elder population worldwide has unique implications for health services and, in recent years, has spurred demand for innovative technologies that support active and healthy ageing. As older individuals continue to experience longer life spans, this will be accompanied by an increased prevalence of chronic conditions that will strain health care systems and economies. Through our research, we have found that patients are increasingly demanding home and mobile-based care that supports ageing in place and believe that there will be continued global demand for clinically useful technologies that support active and health ageing.

The current state of health technology builds on the foundation of the now commonplace electronic medical records (EMR) and is focusing on empowering health care stakeholders through social media, mobile applications, analytics, and cloud computing (SMAC) technologies, including telehealth, remote monitoring and enhanced communications. With these technologies, consumers are becoming equipped with tools that allow them to access their health data, understand their own health, and manage ongoing care outside of traditional medical settings.

In the next five to ten years, consumers will further steer away from an event-driven care model to a continuous care process mediated by technology. Instead of face to face encounters acting as the main vehicle for care delivery, technologies (with additional services and digitization layers), will automate certain key aspects of care management. These services will then be combined with in-person care management, a concept we have named “Flipping the Stack.”

This preventative model will be powered by technologies such as sensors, advanced Internet of things (IoT), artificial intelligence (AI), augmented and virtual reality (AR/VR), blockchain, fast health interoperability resources, and other digital health solutions. IoT combined with sensors and wearables will become an integral part of care delivery and create “smart” environments that monitor a patient’s health, onset of diseases, and disease progression. AI will automatically alert care providers of problems, ideally in advance of serious or life-threatening issues. If any interventions are needed, face to face care can be provided on-demand and managed by hybrid health models and/or technology-based service organizations.

Digital health adoption is gaining traction but is heavily reliant on support and funding from a variety of health care stakeholders—governments, regulatory bodies, insurers, investors, and the consumers themselves. The interaction between these players vary from country to country largely due to different regulations and priorities. However, with the global population ageing rapidly, each country will share a common interest in promoting active and healthy societies. Hence, it is vital for international partners to convene and construct a roadmap for global digital health development that will support citizens in living and ageing well.



# Trends, Drivers, and Enablers of Digital Health

## 1 Preface and methodology

The *International Digital Health Cooperation for Preventive, Integrated, Independent and Inclusive Living* (IDIH) project is a multipart international initiative designed to assess and investigate the emergence of digital health and its impact on active and healthy ageing. This report focuses on emerging technologies in digital health and describes how they are beginning to be used in society, with implications about how this impacts elder communities. The report's goal is to identify specific, innovative technologies for health care while examining what may enable or hinder their widespread adoption. This is intended to be a general overview while future reports from IDHI will examine specific activities of technology related to active and healthy ageing and dive deeper into specific geographic regions, notably the European Union, United States, Canada, South Korea, Japan and China.

To prepare this report Catalyst @ Health 2.0 (Catalyst) conducted eleven interviews with professionals and industry experts from the US, Europe, India, Japan, Singapore, and Australia. Catalyst also conducted a wide-range review of current literature and utilized our proprietary SourceDB database of health technology companies. Furthermore, this writing is built on previous research we have conducted during our efforts that have spanned over two decades focusing on digital health tools and the expanding health technology industry.

## 2 Introduction

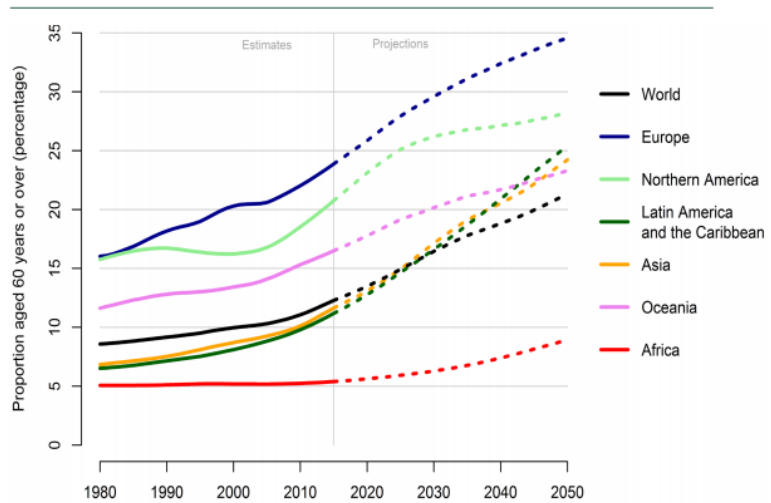
According to the World Health Organization (WHO), the proportion of the world's population over 60 years old will nearly double from 12% to 22% between 2015 and 2050.<sup>1</sup> This drastic demographic change presents new challenges for governments and health care systems, as elder populations tend to be subject to more physiological, mental, and social issues than their younger counterparts.





While every nation is facing growth in its older population, this is occurring quicker in certain regions. This situation is particularly relevant in Japan, Spain, Portugal, Italy, Greece, Taiwan, and South Korea. Japan was previously the youngest industrialised nation, however, in under 30 years it came to have the largest elder population in the world. In 2017, 33% of the Japanese population was over the age of 60 and it is projected to reach 42% by 2050. In the EU, 25% of the population was over 60 in 2017 but that figure is estimated to increase to 35% by 2050. Even the USA, which has historically younger populations and a higher natural birth rate than the EU, will see its 65+ population extend from 22% to 28% by 2050<sup>2</sup>.

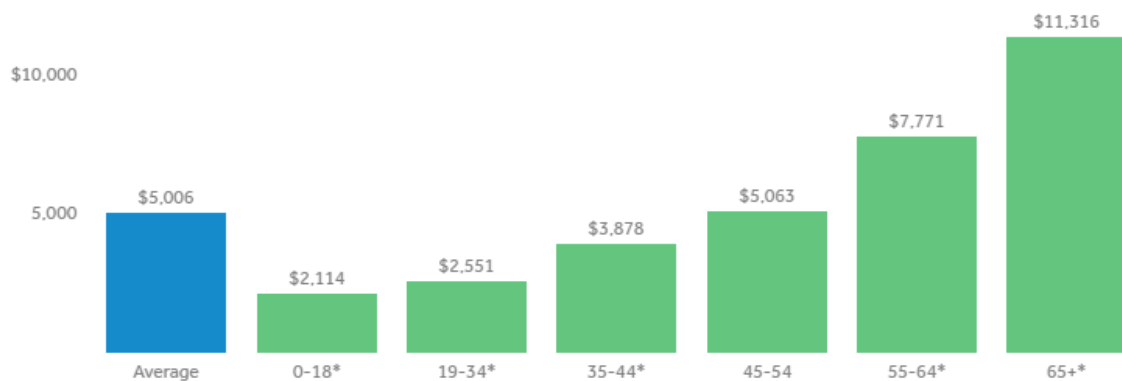
Percentage of population aged 60 years or over by region, from 1980 to 2050



Data source: United Nations (2017). World Population Prospects: the 2017 Revision.

Figure 1: Percentage of Population Aged 60 Years or Over (1980 to 2050)

This increase in life span is coupled with an increase in chronic and neurodegenerative diseases, along with related social issues like isolation, loneliness, and caregiver burden. Notably, this will likely result in a substantial increase in expenditure on health care as older people consume more health-related resources than younger individuals. Data from the Kaiser Family Foundation indicates that on average, the over-65 population spends more than double on health care than the average per year, USD \$11,316 (€10,169) and USD \$5,006 (€4,499) respectively.<sup>3</sup> When evaluating this concept globally, the ratio is similar in other developed nations.



\*The average value age group is statistically significant from the population average (p<0.05).

Source: KFF analysis of Medical Expenditure Panel Survey • Get the data • PNG

Peterson-Kaiser  
Health System Tracker

Figure 2: Average US Health Spending by Age (2016)

Across the globe, many countries are reassessing their ability to care for ageing citizens and are seeking innovative ways to provide sustainable, quality, and cost-efficient health care. However, this is not just a health care problem. It is also linked to the desire of today’s and tomorrow’s seniors to live active and healthy lives while being connected to their families and communities. In the U.S., the slogan “70 is the new 50” began to appear around the year 2000, and indicates that activities like exercise, sports, travel, and sex, which were previously considered the domain of younger people, are now part of the lives of many seniors.<sup>4</sup> Several technologies and services will continue to help promote these activities, but they are still dependent upon seniors’ good health and active lifestyles.

### 3 The Technological Backdrop

Since the dawn of the mobile/cellular phone and Internet era at the start of the 1990s, there has been a major transformation in how governments, non-governmental organizations (NGOs), corporations and consumers have used technology. In particular, the period has seen a rapid adoption of computers, cell phones, and smart phones in both business and consumer use. Along with this, software has transformed from being focused on business processing tasks to acting as a gateway to communication and collaboration. Since the late-2000s, the explosion in social media, mobile applications, analytics and cloud computing (known by the acronym “SMAC”) has further transformed many industries and the consumer experience.

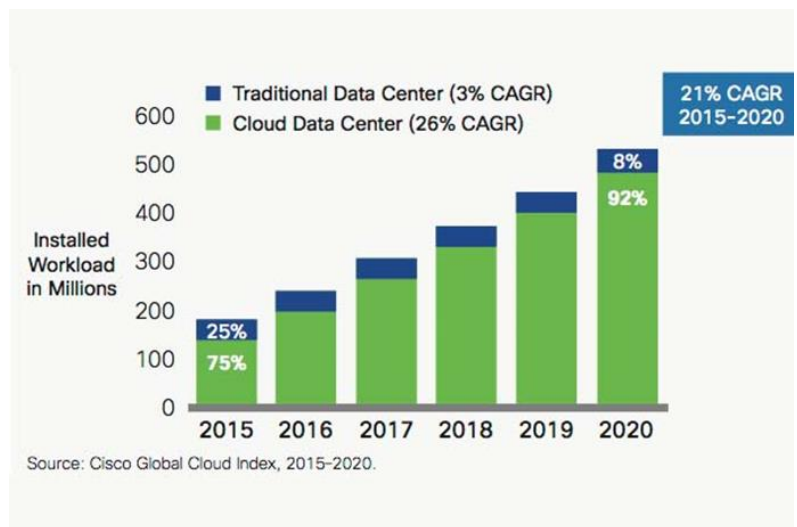


Figure 3: Traditional vs. Cloud Data Centre Installation

This has been reflected in the health sector which was traditionally a paper-based industry and now mainly uses computers to handle its workflow. However, health care still remains behind many industries in its adoption of new technologies and use of data. In fact, it wasn’t until this decade that the biggest health care market (the USA) made a significant move to adopt the use of EMRs in day to day medical practice—something that had happened more than a decade previously in several other countries (e.g. the Nordics, Netherlands, New Zealand). Nonetheless, over the past decade, there has been a dramatic uptake both in the use of EMR, SMAC technologies, and digital applications in health care.

#### 3.1 Flipping the Stack

Our research and analysis reveals a likely future path for the use of technology in health care in the coming decade, which we describe as “Flipping the Stack.”

Traditionally, health care was delivered and received face to face, typically during a one-time event in a clinician’s office or in a hospital. Over time, more and more services (such as nurse visits to the home, calls from pharmacists or case managers, and post discharge monitoring) were added to the mix. Finally, a system of technology was overlaid across the care continuum—notably the EMR—which in general was used to track these activities, and in most cases, financially bill for them.

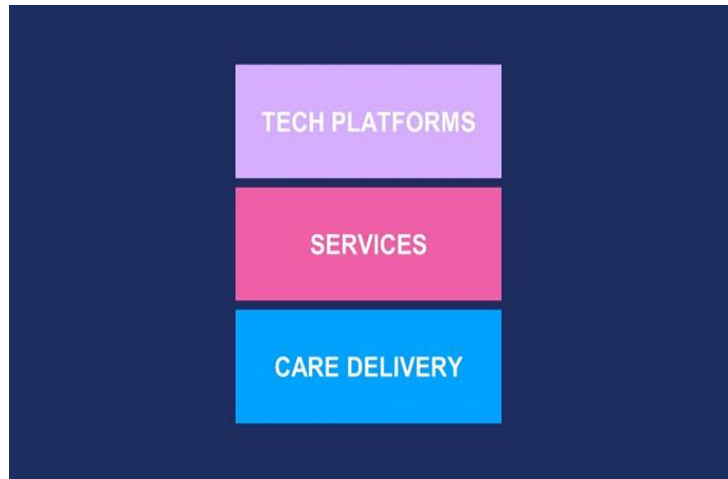


Figure 4: Traditional Health care Stack

To create a visual, imagine this as a three-layer stack where the stack is increasingly inverting (or flipping).

Sensors, trackers, and video/text communications are now allowing care management, remote tracking and messaging to become a continuous process where a patient is constantly monitored wherever they are. AI is beginning to allow for automatic alerts to care providers, with the hope that this technology will advance to flag issues ahead of serious events. In other words, *technology* is becoming the base layer for care. If there is need for personal intervention, *services* such as remote coaching or medication adjustment can be provided at home. Finally, actual face to face *care delivery*, either in the form of a home visit or connected transportation to a clinic or hospital, is reserved for those who have been filtered through the other layers and will likely be provided on-demand, managed by a technology-based service organization. The aim of technology-based delivery is to change event-driven health care into a continuous, preventative, high-touch care process.

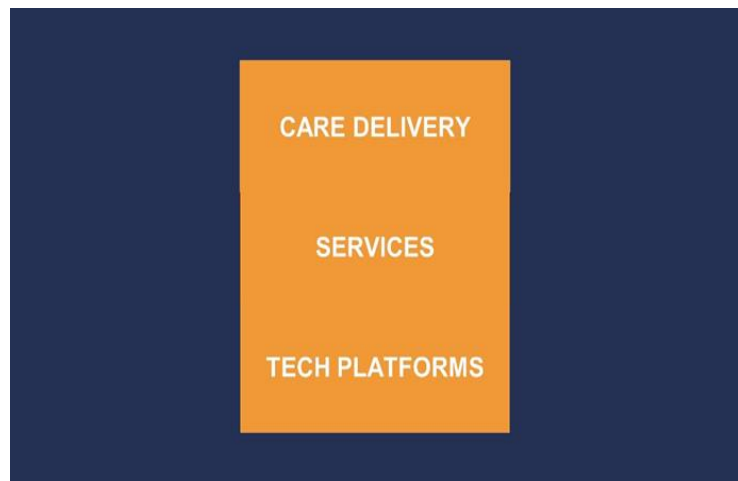


Figure 5: Flipped Stack

Eventually, more and more lives will be improved as seniors ageing-in-place are encouraged to take preventative measures, including behavioural change that will impact their diet, exercise, mental health, medication use, and more. This new way of delivering care 24/7 will free up human capacity to enable people to have better quality, healthier, and longer lives.

## 4 Health Technology Trends

### 4.1 Current Market and Research Trends

#### 4.1.1 The Current State of the Electronic Medical Records

The most notable health technology trend of the last decade has been the adoption of the EMR and electronic health record (EHR), terms which we use interchangeably. Prior to the introduction of EMR, medical records were mostly documented and retained on paper. This meant that patients' health data were not easily transferrable and vulnerable to loss or damage. The data's immobility hindered health information exchange (HIE) and when data were missing or inaccessible, procedures and tests were often repeated. Additionally, harmful medication interactions were more common pre-electronic adoption, as clinicians were often unaware of drugs patients had been historically prescribed by others. Health care stakeholders viewed the EMR as a possible solution to bridge the gaps in HIE and provide clinicians and patients with the most accurate and current health data.

From 2000-2015, EMR were steadily adopted, albeit at varying rates in different countries (usually depending on government funding and regulations). In the EU, more than 85% of hospitals have now adopted EMR. Among these European countries, the Nordic and the Netherlands have reported the highest EMR adoption rates.<sup>5</sup> In North America, 62% of Canadian physicians<sup>6</sup> and 86% of American physicians<sup>7</sup> are using EMRs, with the American adoption increasing dramatically following government funding in the 2009 Health Information Technology for Economic and Clinical Health (HITECH) act passed in 2009. In Asia, EMR use has varied drastically from country to country. Korea is the current leader, with EMR in over 95% of hospitals and clinics.<sup>8</sup> China reports a 90% EMR adoption rate<sup>9</sup>, whereas Japan is a laggard at 34% adoption.<sup>10</sup>

Research on EMR efficacy and impact on clinical outcomes is decidedly mixed. Some studies have cited that EMRs use has improved relationships between physicians and their team members<sup>11</sup>, whereas other work has suggested that EMRs increased administrative burden as well as physician burnout.<sup>12</sup> However, some interviewees noted that the results of these studies are dependent on the quality of the EMR implementation. For example, organizations that quickly adopted EMRs in order to comply with new regulations may be less likely to achieve positive outcomes than those which carefully planned tactical and strategic EMR adoption that best fit their organizational structure.

In terms of technology, almost all EMRs to date have used client server-based technology and focused on the overall enterprise (generally hospitals or clinics). However, as cloud-based technologies have swept through the business sector, hospitals and EMR vendors are also joining this movement. The two biggest global EMR vendors, Epic and Cerner, have begun to host EMRs on a private cloud environment, although the majority of their customers still have local client-server installations. Other vendors such as Allscripts have been moving into a public cloud via Microsoft Azure, whereas AthenaHealth has been cloud-only from its inception in the early 2000s. Additionally, these vendors are introducing application stores (app stores) which allow third-party companies to provide services to clients and move data between the EMR and their own applications. Many of these app stores mimic the Apple or Android user experience.

While EMRs have received mixed reactions from clinicians, in the longer term, patients may have a different perspective. In some countries, health care systems have been using EMRs to restore patient ownership of their health and give them on-demand access to their records. In Australia, the government created the “My Health Record” portal where patients can log in to retrieve their medical records.<sup>13</sup> This lays the foundation for a digitized care experience and allows patients to have access to their personal health information regardless of where they receive care. Many other countries and providers have similar systems, and in the USA and elsewhere, there has been an activist patient-led data rights movement.<sup>14</sup> While some people are concerned about the privacy implications of online records, in Australia only about 10% of the population opted out of making their records available.<sup>15</sup>

In general, consensus shows that the adoption of EMRs has created a base level of data access that can be used to track and improve people’s health at both an individual and population level. In time, this will allow people to better control their own health information and experience. Clinicians, providers, insurers, and governments will also be better equipped to assess, understand and improve care delivery.

#### 4.1.2 Fast Health Interoperability Resources and the Future of the EMR

Those who have implemented EMR resources continue to face data interoperability issues as EMR systems have historically failed to communicate with one another without a common method for data exchange. Data standards vary from one system to another, even within the same vendor, and there has been an increased mandate to build centralized frameworks for efficient data exchange. To alleviate interoperability concerns, a group of innovators, led by Australian programmer Graham Grieve, created Fast Health Interoperability Resources (“FHIR”).<sup>16</sup>

FHIR (pronounced “fire”) is a framework built around the concept of standardized elements and resources—modular components built using modern web programming languages. Essentially, FHIR allows data transfer from one system to another. Although FHIR is fairly new, it is already being used by Apple to extract data from EMRs in over 100 participating hospitals for their personal health record app. According to a 2018 survey among health care executives in the USA, 8% of hospital organizations are already using FHIR, 29% are very likely to use it, and 24% are likely to use it.<sup>17</sup> Interviewed experts predict that FHIR will become more prevalent in a global context and that, along with the USA, the Nordic countries will likely be early adopters.

To further mitigate data interoperability, Substitutable Medical Applications and Reusable Technologies (SMART) on FHIR was launched in 2010 by a group led by Zak Kohane, Ken Mandl and Josh Mandel at Boston’s Children’s Hospital and Harvard Medical School.<sup>18</sup> SMART institutes a protocol that allows third-party applications to be launched from within a host application, typically an EMR, and provide a flow of data exchange seamlessly back to the end user.<sup>18</sup>

Since the inception of FHIR and SMART, several studies have surfaced in the *Journal of the American Medical Informatics Association*, *European Journal of Biomedical Informatics*, *International Journal of Medical Informatics*, and more, to evaluate its usability. The studies demonstrated that SMART on FHIR was successfully integrated into EHRs and facilitated the development and/or integration of different provider/patient-facing apps.<sup>19,20</sup> With the combination of FHIR and SMART, consumers can expect more collaborate partnerships between health systems, EMR vendors, and third-party application vendors, and fast growth in new apps and services.

### 4.1.3 The Impact of the EMR on Active and Healthy Ageing

The impact of EMRs on the future of healthy ageing remains an open question. The two major criticisms of EMRs are: 1) they are difficult to use and break up the clinician workflow, and 2) the data they record is siloed, just like data on paper used to be. The increase use of application programming interfaces (API) and the Fast Health Interoperability Resources (FHIR) standard internationally should begin to alleviate these problems.

Consequently, data stored in EMRs should become the foundation for digitally connected care of seniors. Efficient data exchange will ultimately enable improved care delivery and help the facilitation of integrated care coordination. Finally, the EMR should begin to integrate with other sources of patient generated data allowing for improved workflows to support care for the ageing population.

### 4.1.4 Technology Supporting the Move Away from Institutions to the Home

More convenient and accessible care is favourable for all patient populations as well as professionals delivering care. For patients with disabilities, mobility restrictions or living in rural areas, access can especially be limited due to physical, cognitive, or financial constraints. Health care stakeholders are increasingly exploring how existing technology could be leveraged to better provide care access and shift health services away from institutions to homes and other settings. While these tools were initially focused on patients in remote areas and prisons, the mainstreaming of communication technology via the Internet have shifted on-demand digital health solutions to reach widespread populations globally.

#### 4.1.4.1 Telehealth

Telehealth or telemedicine is defined as “the concept of shared video, audio, secure messaging, and other data exchanges to transfer information between patients and clinicians.”<sup>21</sup> Telehealth’s use began in the military and in rural areas as a means to combat health disparities related to access to care. However, telemedicine has now expanded to other populations and studies suggest that telehealth has improved patient access to care, reduced health care costs, and enhanced patient-doctor relationships.<sup>22</sup>

The evidence base for telehealth has grown substantially considering that its potential benefits drew interest from international health organizations. Since 1996, the United States Institute of Medicine (IOM) has been a strong proponent of telecommunications in health and encouraged the utilization and research of telehealth. By 2012, the IOM established a workshop to share the findings from existing evidence and construct a framework for the future of telehealth.<sup>23,24</sup>

Over time, telemedicine has gathered a large enough body of evidence to generate peer-reviewed systematic reviews and meta-analyses. In a study funded by the US Agency for Health care Research and Quality and the Department of Health and Human Services (DHS), an analysis of 58 systematic reviews found that telehealth improved outcomes when used in remote patient monitoring (RPM) for chronic conditions such as cardiovascular disease, diabetes, respiratory disease, and mixed chronic illnesses.<sup>25</sup> In particular, the study suggested that telehealth reduced mortality for heart failure, improved the quality of life for COPD patients, and reduced hospital admissions for those with mixed chronic illnesses. With 85% of older adults with one chronic illness and 60% with two or more chronic conditions,<sup>26</sup> it is no surprise that seniors will be one of telehealth’s target population.





Due to the increase in deaths related to chronic illnesses, telehealth's impact on palliative care has also been studied. Palliative care is an approach that improves the quality of life of patients and their families facing the problem associated with life-threatening illness. Palliative care prevents and relieves suffering by means of early identification and impeccable assessment and treatment of pain and other problems, physical, psychosocial and spiritual. According to WHO, noncommunicable diseases cause 70% of all deaths and generate 93% of adult palliative care need.<sup>27</sup> It is estimated that 37% of all deaths need palliative care<sup>21</sup> and many nations have prioritized evidence based research on palliative medicine.<sup>28</sup> Findings on best practices for telehealth use in palliative care is still in development, with studies mainly focusing on the use and reception of the care delivery model. Research on telehealth's role in palliative care from the caregiver's perspective are also common and becoming a greater focus in the literature. In a systematic review by Zheng et al., it was found that telehealth modalities increased the quality of life for caregivers and successfully reduced caregiver burden and anxiety.<sup>29</sup> These findings have strong implications for the possibility of providing high quality and clinically effective end-of-life care for the elderly—many of whom rely on their caregivers.

Given the growing body of evidence suggesting telehealth's benefits, it is no surprise that telehealth adoption has been on the rise. Since 2015, physician telehealth adoption increased by 340% in the U.S.<sup>30</sup> On a global scale, countries with low physician density are particularly receptive to adopting telehealth. According to one study, there are 1.8 physicians per 1,000 persons in China and an astonishing 89% of health care professionals have adopted telehealth.<sup>25</sup> Nearly 45% of Chinese citizens prefer a remote consultation via a digital platform for non-urgent care.<sup>25</sup>

In India, where there is a dramatic shortage of physicians and fewer than 1 physician per 1,000 residents, 67% of providers have included telehealth in care delivery and 26% of patients prefer virtual visits.<sup>25</sup> Other countries such as Saudi Arabia and Russia have also demonstrated high telehealth adoption (75% and 65% respectively) as a means to mitigate their nations' low physician density.<sup>28</sup> Furthermore, an international study surveying 3,100 health care professionals across 15 countries found that 61% of the respondents currently use telehealth.<sup>31</sup>

Telehealth vendors are following this global demand closely and certainly see the telemedicine market as an area for potential business opportunity. AMD Global Telemedicine now services 98 countries and have developed a new direct to consumer telehealth platform. Meanwhile, Teladoc has launched a Global Care platform to offer their services for those who live outside of the US. China-based services like WeDoctor and Good Doctor have significant market penetration. Phillips not only offers their services across the globe, but they have been studying the best practices for telehealth deployment. It recently ran the three-year Advancing Care Coordination & Telehealth Deployment at Scale (ACT @ Scale) study with over 100,000 participants in six European regions in order to create a handbook with evidence-based recommendations to achieve large-scale connected care.<sup>32</sup>

As telehealth's potential continues to unfold, consumers can expect virtual medical visits to become more commonplace and further integrated into their patient experience. This will include many forms of virtual care such as synchronous and asynchronous text messaging, eConsults with specialists, live video (today's prominent format) and the increasing use of chatbots. The location of telehealth will also change to more or less anywhere, including nursing homes, retirement communities and other places where seniors live.





#### 4.1.4.2 Internet of Things (IoT)

The Internet of Things (IoT) refers to any physical device connected to the internet that collects and shares data. In health care, examples of IoT include wearables, fitness trackers, monitors, and sensors that measure and track heart rate, physical activity, breathing, etc. For example, consumer wearables such as the Apple or Samsung Smartwatches and FitBit wearables have attracted nearly 600 million users worldwide, creating a framework for users to collect and access their activity and biometrics.<sup>33</sup> Users can generate data on their health and be informed of their lifestyle habits, physical activity, and potential health concerns. Other devices such as smart scales, blood glucose meters, blood pressure cuffs, and even thermostats have also been developed to provide further analysis and tracking for health.

Wearables have created a new wave of patient self-awareness and engagement. For those who wish to lead a healthier lifestyle, such technologies provide the ability for them to quantify their progress. For those with chronic conditions, IoT can assist by providing longitudinal data that tracks their health over time. For example, a series of updates to the Apple Watch now position it as a health-focused device. Its sensors and gyroscope technology have bolstered features such as heart rate monitoring, electrocardiogram (EKG), fall detection, sleep tracking, and many more.

These features are still relatively new, and many clinicians are still sceptical of their usefulness given the potential increase in false positives. However, there are anecdotal stories of patients discovering life-threatening complications from their wearables.<sup>34</sup> Meanwhile, Apple has partnered with Stanford University School of Medicine to conduct an unprecedented virtual cardiac study with 400,000 enrolled participants. The Apple Heart Study aimed to evaluate Apple Watch's ability to safely identify heart rate irregularities and consequently, detect Atrial Fibrillation. The study reported that the Apple Watch and an EKG patch showed a pulse detection algorithm with a 71% positive predictive value and 0.5% of participants received irregular pulse notification.<sup>35</sup> Of that population, 34% were found to have Atrial Fibrillation and 57% sought medical attention.<sup>32</sup> This large virtual study sets a precedent for research on consumer wearables in health and will likely be a model for other consumer tech providers to prove their products' usefulness in medicine.

IoT is also increasingly present while collecting and delivering remote patient monitoring (RPM), a type of tracking that is often used in conjunction with telehealth services. Sensors and connected devices can collect a constant stream of patient data and transmit it to provider systems. Through this modality, clinicians will be able to manage their patients remotely and be alerted if there are any changes in a patient's status. Often, IoT works with telehealth to provide immediate consultations and ongoing, long-term care.

#### 4.1.5 Digital Therapeutics (DTx)

Applications are now being designed and adopted to prevent, manage, or treat a broad spectrum of physical, mental, and behavioural conditions. Digital applications are not just monitoring patients or informing them about healthy behaviours, but are actually treating conditions either in conjunction with or as a replacement for a drug or other traditional therapy. These are collectively called Digital Therapeutics (DTx) and the companies marketing them are actively trying to validate their interventions by seeking government agency approval, particularly from the United States Food and Drug Administration (FDA) or running other prospective trials and studies.



For example, Akili Interactive focuses on cognitive as well as psychiatric diseases through gamification. Akili began targeting Alzheimer's disease and dementia by developing a mobile video game named "Project EVO" which improved cognitive differences in healthy elderly people at risk of developing Alzheimer's.<sup>36</sup> For Attention Deficit Hyperactivity Disorder (ADHD), Akili tested their AKL-T01 product in a multi-centre randomized control trial to test the efficacy and safety of the software as a treatment for ADHD. The RCT proved that AKL-T01 improved paediatric ADHD patients' attention performance measured by Test of Variables of Attention Performance Index.<sup>37</sup> The company is currently working to expand its technology to treat other conditions, such as depression and anxiety.

Pear Therapeutics created Re-Set, one of the first FDA-recognized digital programs tools to treat substance use disorder. In 2018, Pear showed evidence that Re-Set was roughly twice as effective at preventing relapse as the standard of care over a 12-week period.<sup>38</sup> Pear is developing a range of related products aimed at mental health and other conditions. Similarly, Click Therapeutics is an exemplar in digital therapeutics especially for smoking cessation, as well as mood and anxiety disorders. In a proof of concept study, Click's cognitive-emotional training program exhibited greater reduction in major depressive disorder (MDD) symptoms and achieved greater than 50% reduction in symptoms in 6 out of 11 participants that used their program.<sup>39</sup> In a different clinical pilot study, Click's cognitive-emotional training was also found to be an effective intervention for medication resistant depression and optimized antidepressant efficacy.<sup>40</sup> Click has also entered into a multi-center, randomized, controlled, phase II FDA trial for the treatment of MDD in adults.

Meanwhile coaching-based programs, such as those from Omada Health and Livongo, have shown significant impacts on the outcomes and costs of those with pre-diabetes and diabetes.<sup>41,34</sup> Omada Health's study was conducted to enhance the CDC's Diabetes Prevention Program and ultimately simulated return on investment (ROI) of USD \$9 and USD \$1,565 at years 3 and 5, respectively, per pre-diabetic patient.<sup>42</sup> While coaching programs vary from DTx in that they are self-completed by patients, the concept a software-based self-management program with coaching and other support is becoming increasingly popular. For example, the German insurance company *Barmer* is now reimbursing Kaia Health's program for back pain<sup>43</sup> after a randomized control trial found that Kaia outperformed physical therapy and significant decreased pain symptoms in patients with lower back pain.<sup>44</sup>

The convergence of software and medicine have strong implications for the future of the health care ecosystem. For the first time, life sciences companies are beginning to capitalize on digital technology to deliver value "beyond the pill."<sup>45</sup> DTx offers the ability to differentiate traditional drug products and address gaps that pharmaceutical medicine has been unable to fill. In the US, Sanofi has invested \$500m with Alphabet's subsidiary, Verily, for a joint venture called Onduo.<sup>46</sup> Onduo offers a Virtual Diabetes Clinic with a suite of diabetes management services including diabetes tools, coaching, and clinical support all accessed via its software application. The tools include a connected blood glucose meter, glucose test strips, an A1cc test kit, and if eligible, a continuous glucose monitoring system. Onduo is also collaborating with Orpyx Medical Technologies, which offers sensors to those with diabetes, as well as Dexcom, a continuous glucose monitoring system to provide more targeted care to high-need diabetic patients. Their program is currently undergoing a clinical trial to test its Onduo App and its effect on the mean change in haemoglobin A1c over a four-month period.<sup>47</sup>



These type of partnerships as well as clinical trials to test DTx are becoming increasingly popular and set the stage for new collaborations between different health care organisations and government agencies. Consequently, more and more patients will be prescribed these programs and we can expect them to play a unique role in caring for the senior population.

## 4.2 Future Market and Research Trends

Over the next decade, it is expected that more digital health technologies will move from the experimental stage to widespread deployment. While the timing of their mainstream use cannot be exactly known, we are seeing significant growth and evolution from these technologies.

### 4.2.1 Advances in the Internet of Things (IoT)

The Internet of Things (IoT) is expected to evolve and become interface agnostic. Voice, text, image, video, and gestures will generate data that can be stored, managed, and repackaged. With the introduction of virtual assistants such as Google Home and Amazon Echo, voice-enabled tech will have a larger presence in a patient's journey. Individuals with physical disabilities or cognitive disabilities may benefit the most from this new interface.

Health care providers are also leveraging voice-tech to assist in care delivery. A company named Aiva, is replacing nurse call systems in hospital rooms. In their pilot with Cedars-Sinai Hospital in Los Angeles, CA, Aiva is being used in 100 patients' rooms. Patients can give verbal commands to control their environment or alert a nurse.<sup>48</sup> Different requests are routed to different care providers. For example, a request for assistance to go to the restroom is sent to an aid whereas a request for pain medication is routed to a registered nurse (RN). Other requests such as changing television channels or turning off a light are processed with Alexa-controlled products. This allows patients to have control over their environment while empowering nurses to focus on important care components. Other companies are exploring similar models where providers use voice technology to assist in clinical procedures or administrative tasks.

Advancement in the IoT, has also generated the concept of "Smart Homes" or "Smart Places," a connected environment where seniors can age in place. Sensors embedded into everyday items such as carpets, handrails, and floor mats will offer a constant monitoring mechanism. They will be able to detect changes in a person's health and potentially detect the onset of illness. For example, a team led by Patricia Scully at the University of Manchester unveiled a geospatial carpet. It has sensors to detect foot patterns and identify when an individual favours one leg. So early intervention for possible knee and hip issues can be provided.<sup>49</sup>

At-home wireless radio wave sensors to detect a person's postures and movement are also in development.<sup>50</sup> The project "RF-Pose" analyses radio signals from a person's body and creates a model of the individual's movement. The technology can be leveraged to assist providers in understanding the disease proregration of Parkinson's, Multiple Sclerosis, and muscular dystrophy. It can also be used to detect patients' falls and changes in their activity

Another example of an advance in IoT is SafeLight, a lightbulb that can monitor a senior's sleep, respiration, or falls. It also receives voice instructions or deliver alerts to care givers.<sup>51</sup>

Future technology aims to prevent disease by early detection and provide continuous monitoring for those who are already ill. A recent literature review by Ahmadi et al. highlighted the application of IoT in health care. Based on this review, information regarding the architecture of IoT is readily available especially for home health care, mHealth/e-health, and hospital management.<sup>52</sup> However, research on the clinical effects of IoT-enabled smart environments is rare.

#### 4.2.2 Artificial Intelligence (AI)

Artificial intelligence (AI) has been one of the most common buzzwords in health technology during the past few years. AI enables computations of vast amounts of data to identify patterns and algorithms. It then uses the patterns to make suggestions or acts upon them. AI often serves as the tech layer behind digital health products. It is increasingly being combined with IoT to turn the large quantity of device-generated data into actionable information.

Given AI's ability to process complex data, it has been prominently used in radiology (e.g. cancer detection), symptom assessments, clinical decision support, genetics, and workflow optimization. In recent years, there has been a significant increase in publications regarding the use of AI in medicine and health care. Studies evaluating AI's effect have shown that AI performing as well as board-certified dermatologists in detecting skin cancer<sup>53</sup> and increased medication adherence in stroke patients<sup>54</sup> as well as patients with schizophrenia<sup>55</sup>.

Most studies have focused on clinical outcomes of AI in health care. However, there is also a demand for research regarding the usability and acceptance of AI as well as best practices for the implementation of AI. For example, the National Natural Science Foundation of China supported a study which investigated the factors impacting if health care professionals will adopt AI-based medical diagnosis support systems in China.<sup>56</sup> Other researchers have explored the economic, legal, and social implications of AI in health care in different regions.<sup>57,58</sup>

According to the Future Health Index (2019), health care professionals are most comfortable using AI for administrative tasks such as staffing and patient scheduling (64%).<sup>26</sup> For clinical purposes, 59% of providers are comfortable using AI to flag anomalies. In addition, 47% are comfortable using the technology to recommend treatment plans and for diagnoses.<sup>26</sup>

Startups currently utilizing AI include: *Prognos*, which uses lab, medical, and claims data to predict the onset of disease; *Surveyor Health*, which personalizes complex drug regimens to lower risk and improve outcomes; as well as *Babylon Health* and *Woebot*, two examples of the many companies that have AI-powered chatbots which ask users about their symptoms, deliver a diagnoses, and suggest follow up. In the coming years, it is likely that AI used in conjunction with sensors, wearables, and other devices will act as diagnostic tools and/or medical assistants.

For example, initiatives like *Project Euphonia* by Google AI for Social Good, uses voice-enabled tech and AI to empower those with speech impairments by improving a computer's ability to understand diverse speech patterns.<sup>59</sup> The specialized software turns recorded voice samples into a spectrogram, or a visual representation of the sound. The spectrogram is used to "train" the system to better recognize less common types of speech patterns. Google's personalized AI algorithms are working to detect facial movements and gestures which would benefit individuals with severe disability or individuals who are nonverbal. Euphonia could then take actions such as generating spoken commands to Google Home or sending text messages.

### 4.2.3 Augmented Reality and Virtual Reality

Augmented Reality (AR) superimposes computer-generated image or data over a view of the real-world using ocular devices (e.g. the Microsoft HoloLens or Google Glass). Medical schools and teaching hospitals have been particularly interested in AR to train medical students. For example, Mayo Clinic instructors have used AR in their simulation centre to teach students how to interpret ultrasound images.<sup>60</sup>

Belgian startup LucidWeb is experimenting with a different use case for AR which is targeting patients. Their technology assists patients in visualizing surgical procedures. LucidWeb's goal is to simplify complex medical procedures for patients who have difficulty understanding or imagining their surgery.<sup>61</sup> The medical scribes for the US startup Augmedix use AR to remotely record and support visits with Google Glass.

In contrast to AR, Virtual Reality (VR) places the user in a completely artificial environment using a system of headsets (e.g. Oculus Rift, HTC Vive), controllers, and gloves. In the medical context, VR has primarily been used to target pain management, rehabilitation, and mental health. Applications of VR has been studied by researchers from leading hospitals and universities in the Netherlands. They have evaluated the effectiveness of VR in reducing pain and anxiety in paediatric patients. In their systematic review and meta-analysis on VR, the technology was shown to be an effective intervention to reduce pain and anxiety.<sup>62</sup> From a health care system lens, researchers from Cedars Sinai Medical Centre as well as the University of California, Los Angeles School of Medicine, sought to evaluate the potential cost-savings of VR therapy for pain in hospitalized patients. They found that implementing a VR therapy program in an inpatient setting provided an average of USD \$5.39 (€4.84) in cost-savings per patient when compared to usual care.<sup>63</sup> Among the sub-group of patients both eligible to receive and willing to use VR, there was on average USD \$98.49 (€88.49) savings per patient.<sup>48</sup> The positive outcomes for VR in pain management has led to increased exploration of VR's impact on other health disciplines.

Although AR/VR are typically not associated with the geriatric population, interviewees have noted that AR/VR may be a useful tool to provide rehabilitation services and combat social isolation/loneliness among elderly populations. For those who suffered from stroke, VR may offer a novel rehabilitation experience. Eodyne, a startup based in Spain, has designed the Rehabilitation Gaming System (RGS) as part of their treatment for brain damage, Cerebral Palsy, Parkinson's, Multiple Sclerosis and Ataxia, as well as other illnesses. The RGS is a science-based neuro-rehabilitation solution combining AR/VR, sensors and AI. To date, the company's solution has been validated by over 30 clinical studies and their findings have been presented in international conferences such as the European Stroke Conference, International Congress on Neurotechnology, Electronics and Informatics, International Conference on Disability, Virtual Reality and Associated Technologies, and others. The studies have suggested that RGS helps to improve speed and fluidity of movement and that RGS combined with standard therapy is more effective in promoting recovery of function than occupational therapy alone.<sup>64</sup> Therefore, VR may be a valuable tool for seniors' rehabilitation in hospitals and at home.

AR/VR is also projected to play a role in combatting social isolation and loneliness. According to the US National Institute of Ageing, social isolation and loneliness is linked to higher risks for multiple physical and mental conditions: high blood pressure, heart disease, obesity, a weakened immune system, anxiety, depression, cognitive decline, Alzheimer's disease, and even death.<sup>65</sup> The elderly are most



vulnerable to social isolation. Hence, technologies that can help alleviate the effects of social isolation can greatly benefit seniors. It is thought that AR/VR can create immersive experiences for home-bound seniors to explore locations beyond their physical capabilities and connect them with others using the technology. This use case is just now emerging, so evidence-based outcomes are not yet available.

#### 4.2.4 Blockchain

Blockchain was popularized by its use to store cryptocurrencies (notably Bitcoin) and its applicability to health care has been heavily promoted. Blockchain records every data exchange or transaction in real time on multiple “nodes” of a distributed database—making it extremely difficult to alter or hack. Information is decentralized whereby there are no intermediaries or owners of the data; every participant is a “neutral” third party. Blockchain operates using several interrelated components and characteristics:

- Distributed ledger – an account of transactions is displayed in real time and the same information is distributed to all participating users.
- Security and Privacy – all information and data exchanged is encrypted, and only permissioned users may access the blockchain. In addition, all participants must agree and reach consensus on transactions to publish them.
- Smart Contracts – business rules and guidelines are established among users to give them control of what information is shared and automatically generate pre-agreed transactions.

Blockchain has been suggested as a solution for managing clinical trial records, pharmacy supply chain regulation and compliance, accessing and storing medical records, and capturing medical device data. For providers, complete access to patient history, medical records, and insurance network information should allow them to make informed medical decisions sensitive to the patient’s insurance coverage. For pharmaceutical companies, distributed patient consent and clinical trial data records could enhance and quicken the discovery and approval of treatments. For patients, storing (at least parts of) their record on the blockchain would show them who accesses and uses their health information. It may even enable patients to sell their health data to researchers—the business model of startup Nebula Genomics.

Health care executives have expressed interest in utilizing distributed ledger technology. In a 2018 study, 38% of health care executives stated blockchain is one of their top five priorities.<sup>66</sup> However, to date little has been achieved using the blockchain in health care and several experts believe that distributed databases will not provide health gains.<sup>67</sup> As the evidence for blockchain in health care is lacking, more research is needed in this area.

#### 4.2.5 Other Emerging Tech Trends

Other future trends identified through research and/or expert interviews include:

- *Robotics:* As described by one of our interviewed experts, robots can serve multiple functions. They can “simulate people (e.g. patients, doctors, etc.) and situations, act as a reference directory, and process information into easily digestible information.” They can also serve as care companions to patients who have limited mobility and/or experiencing loneliness or social isolation. In combination with artificial intelligence, robots have the potential to engage





in human-like conversations and act as companions. Companies that have already begun experimenting with robotics in the health care setting include “PARO,” an interactive robotic seal that provides animal therapy in medical environments as well as “SAM,” a human-sized robot that provides check-ins and non-medical assistance for long term care patients.<sup>68</sup>

- *5G technology:* 5G will enable real-time wireless data transfer. 5G’s speed combined with AI and IoT is poised to become a revolutionary addition to health care, especially in emergency care. However, our experts have noted that this technology is very new and it may be too early to project its application in health care.
- *InsureTech:* InsureTech is the use of technology in insurance (e.g. smartphone apps, consumer activity wearables, claim acceleration tools, individual consumer risk development systems, online policy handling, and automated compliance processing).
- *Virtual clinical trials:* Virtual clinical trials are digitally conducted via technology. They identify eligible participants through EMRs and other data analytic techniques, and collect data from their homes and other remote locations using sensors and wearables.
- *Digital biomarkers:* Digital biomarkers are data directly collected from consumers and patients via the use of digital health technologies regarding their health which explain, influence, or predict health-related outcomes. This might include data generated from wearables to quantify chronic pain, analysis of the voice to detect dementia or mental illness, or video of movement to analyse a person’s gait in to potentially predict falls.

## 4.3 The Pace of Adoption

Technologies are not always adopted or adopted uniformly across regions. The next section of this report assesses the main drivers and enablers of the adoption of digital health for active and healthy aging.

### 4.3.1 Drivers and Enablers

#### 4.3.1.1 Consumer Demand

Patients and their caregivers are the likeliest beneficiaries of digital health. They have a natural desire for well-being and a high quality of life. Nearly 90 percent of individuals over the age of 65 want to age in place and remain in their home for as long as possible.<sup>69</sup> Hence, it is likely that patients will continue to push for tools and services that enable care outside of traditional settings.

Patients who have high out of pocket costs are also financially motivated to seek cost-effective care. According to the World Health Organization, out of pocket expenditures account for 32% of total health care expenditures across the world.<sup>70</sup> Patients with high deductible plans or high co-pays (which are particularly common in the US and in Asian countries) are more likely to seek technologies that help them receive quality care at a lower price point.



In Accenture’s Digital Health Consumer Survey (2019), modern consumers not only said that they want health care providers with digital capabilities but they also expect them. The survey interviewed nearly 8,000 people across Australia, England, Finland, Singapore, Norway, Spain, and the USA. On average, 70% of consumers said they were more likely to choose a provider if they offer the ability to request prescription refills electronically, send reminders via email or text, or communicate with them via secure email.<sup>71</sup> Over half of the respondents also preferred providers who use remote or telemonitoring devices as part of their care delivery. In this era, patients and their caregivers and families are growing accustomed to tech-enabled care delivery and the benefits that follow.

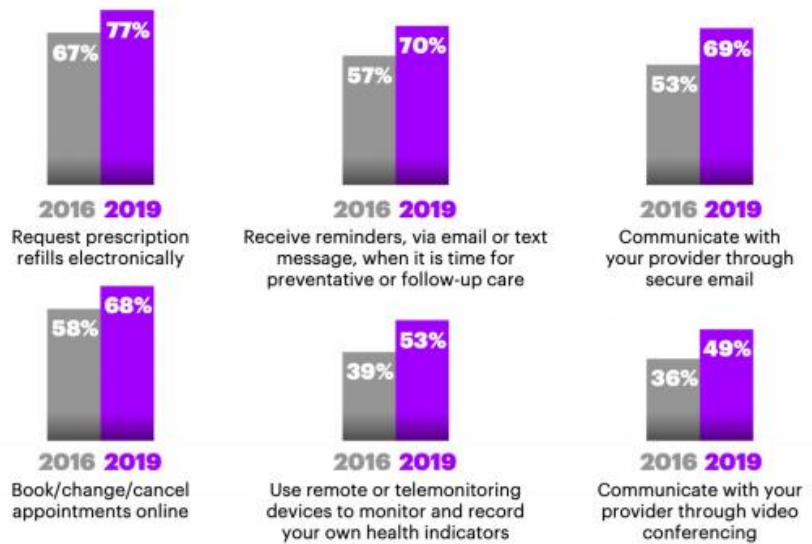


Figure 6 Consumer Survey on HCP Digital Capabilities

#### 4.3.1.2 Government Regulations and Funding

Government regulations and policies differ across countries but their impact on digital health is undisputed. They dictate whether or not a digital health tool will be approved and what can be marketed, tested, and commercialized. Policies also steer the direction of health care systems and outline priorities and funding. We believe that different countries and regions can learn from one another to identify policies that have advanced health technology and achieved quality, accessible, and low-cost health care. Part of the role of the IDIH project will be to assist in this effort.

For example, in the USA, the 2009 HITECH Act was a critical moment for health technology. The act provided almost \$40 billion in financial incentives to eligible professionals for “meaningful use” of qualified EMRs. The goal of the HITECH Act was to improve the quality and cost of health care. As a result, certified EMR technology in hospitals increased from 15.6% in 2010 to 97% in 2014.<sup>7</sup>

In Europe, the European Commission declared its priorities and commitment to its Digital Single Market strategy by issuing the Transformation of Health and Care in the Digital Single Market working paper. In the brief, the Commission shared three priorities: securing access and exchange of health data, pooling health data for research and personalised medicine, and providing digital tools for citizen empowerment and patient-centred care.<sup>72</sup> The EU will invest €9.2 billion from 2021 to 2027 on key digital challenges, including e-health care and citizen empowerment.<sup>57</sup>

Financial incentives are one of the strongest drivers of digital transformation. Governments not only directly fund the adoption of digital tools but often play the leading role in how health care reimbursements are structured and which services are covered.

In a public-private system, reimbursement models focus on incentives that mutually benefit both public and private health care stakeholders. For example, the U.S. Centre for Medicaid and Medicare



Services (CMS) funds private insurers offering Medicare Advantage (MA) plans. Through this relationship, private payers can provide insurance to those over the age of 65 and are reimbursed by Medicare. Often, at-home services or services related to patients' social determinants of health were not covered under these plans. However, beginning in 2019, CMS added new language that allowed supplemental benefits, "that have a reasonable expectation of improving or maintaining the health or overall function."<sup>73</sup> This clause paved the way for services to shift care to the home using digital health tools (e.g. telehealth) and to allow providers to target social determinants of health such as food security, social isolation, transportation, and housing.

Also in the US, regulation in the 2010 Affordable Care Act designed to promote value-based care led to the rise of Accountable Care Organizations (ACOs), where groups of doctors, hospitals, and other health care provide coordinated, (and presumably) high quality care. This model incentivizes ACOs to focus on the overall health of an individual and correspond with all relevant partners to deliver care beyond the clinical setting. ACOs are financially incentivized to address social determinants of health and deliver preventative services, and so, have been more willing to adopt digital health tools.

In nationalized health care systems, public health officials have an even greater interest in keeping their citizens healthy. To do so, governments need to create new models that encourage technology companies to co-design digital solutions to support their population health goals. One possible model under consideration suggested by an interviewee is the creation of "social impact bonds." For social impact bonds, the government evaluates the potential cost of inefficient care delivery (i.e. missed appointments from elderly patients) and issue a corresponding bond to companies who can co-create a successful intervention to the problem.

With the massive growth of the senior population, health care stakeholders can no longer rely on a reactive approach. They will likely consider directing investments that target preventative efforts and will lead to cost savings in the future. Governments are likely to prioritize digital health tools and services, making them a positive driver of health technology.

#### **4.3.1.3 Pressure from New Market Entrants**

Modern technology has created an on-demand mentality where people desire convenient, accessible, and automated services. Patterns of consumer behaviour in information, travel, banking, retail and many other industries have been transformed by new technologies usually introduced by new market entrants. Health care has tended to be an exception to this rule so far but is unlikely to stay that way in the future.

Well-funded start-ups and consumer tech giants such as Amazon, Apple, and Google have been increasingly active in the health care space. In a survey done by the Society for Health care Strategy and Market Development, 38% of current health care executives indicated that it is very likely that major technology companies will compete directly with their organizations.<sup>17</sup> Although the experts we interviewed didn't think that the tech giants nor small-medium enterprises will soon replace the current health care delivery incumbents, they foresee an altered health care landscape. One of the interviewees indicated that it is likely that major tech companies will become the infrastructure provider while third party service providers will build on their tools to offer novel care experiences. In general, there is no certainty as to how these tech giants and startups will impact the health ecosystem,



but as technology and health become increasingly intertwined, it is likely that the future availability of these services will, in a sense, create their own demand.

#### 4.3.1.4 Investment Activity

Investment activity is a strong indicator of the digital health market's growth and trajectory. According to StartUp Health, global digital health funding in 2018 grew to a record €13 billion in funding over 765 investment deals.<sup>74</sup> Most investment is made in the US, accounting for nearly 70% of the total in 2018. However, in recent years there has been significant growth in the number and size of digital health deals in international metro hubs such as London, Beijing, Bengaluru, and Toronto. Most notably, China accounted for more than half of the largest international deals in 2018 and saw a total of €843 million in digital health investment.

Investment deals also offer a snapshot of which digital health technologies are most relevant. Based on funding activity, the most pertinent digital health functions include: patient empowerment (telehealth, patient engagement, primary care), diagnostics and screening tools, machine learning, and mental health. With the investments in these digital health trends, it is likely that more digital health companies will begin accelerating the development of products that incorporate AI, machine learning, blockchain, and IoT.

## 4.4 Challenges and Barriers

### 4.4.1 Cost and Health Care Provider Buy-in

While digital health offers promising solutions for many areas of care, health care organizations have been relatively slow in committing to them. Our expert interviewees believe health care providers are not likely to adopt digital health tools unless they perceive a sense of urgency to do so. This urgency is typically derived from regulatory mandates and financial incentives. This contrasts with many other industries where companies attempt to maintain market share by rapidly introducing new technologies.

One of the main deterrents to digital health adoption is the cost associated with adopting new technology. The implementation of digital health tools requires upfront investments in technological infrastructure as well as labour costs for training and/or hiring staff. In addition, utilizing new technology may introduce radically new workflows that add to health care organizations' staff's burden. Organizations have struggled to justify the return on investment for novel technologies and often there are few market dynamics forcing them to change.

A significant contributing factor is that evidence-based information about the cost and outcomes of emerging health tech innovations are difficult to find. Although the evidence base is growing, particularly in telehealth and digital therapeutics, many novel innovations do not have a robust body of research to support their claims. Although piloting such technologies can help providers evaluate a tool's usefulness to their organization, many of our interviewees expressed concern that many partnerships do not move past the pilot phase. To overcome this, they suggest provider organizations and innovators critically evaluate what metrics they need to measure in order to prove or disprove a technology's value to their organization.

#### 4.4.2 Regulation and Certification

The underlying ethos of drug and medical device regulation in the developed world has been to protect patients from harm. This has resulted in the current lengthy approval process in which pharmaceuticals and medical devices are subject to testing and clinical trials before being allowed onto the market. Digital health tends to operate like software, in which existing products are improved by frequent changes and updates. Given this contradiction, many digital health companies initially did not fall under the purview of regulators like the Food and Drug Administration (FDA) and the European Medicines Agency (EMA).

Most health technology, including all EMRs, remains unregulated by those bodies. However, some experts argue that the lack of an official government or well-regarded organization's "stamp of approval" is holding back market adoption. Some major players like the American Medical Association in the USA and the National Health Service in the UK have made early steps towards certification programmes.<sup>75</sup>

In recent years, the FDA has developed a system for regulating software that can be used for digital therapeutics and other diagnostic and tracking systems. The FDA Digital Health Software Precertification (Pre-Cert) Program *"aims to look first at the software developer or digital health technology developer, rather than primarily at the product, which is what we currently do for traditional medical devices"*.<sup>76</sup> The idea is that devices and therapeutics that directly impact patients can be pre-approved so long as the company making them has demonstrated *"a robust culture of quality and organizational excellence"* and so they may not need to submit to standard trials and approval.

#### 4.4.3 Data Governance and Sovereignty

Government entities as well as large health care systems hold valuable data that can facilitate the discovery and creation of new digital health tools. If they are willing to open their application programming interfaces (API), third parties will be able to access this data and collaborate on novel ideas. This process enables a broader range of options for consumers and ensure the best ideas are brought to the market. However, regulations and rules must be in place to ensure third party apps have proper authorization as well as credentials to use the data. A lack of consensus on regulation and the public's misunderstanding of regulations around their personal data have heightened, especially following the Facebook and Cambridge Analytica scandals in recent years.

Discussions on data ownership will also determine how players in the health care system will interact. According to study done by the European Commission, 90% of EU citizens expect to be able to access their own data and 80% agree that they should be able to share their health and provide feedback.<sup>70</sup> Although this study does not specifically ask participants regarding who should own the data, it is evident that people would like control over their information. The potential for patients to own their data will not only guarantee access to their records but also commercialize their data for clinical trials, research, and other uses.

At the moment, data ownership is ambiguous. If patients have the capability to own their data, there may be more opportunities for them to identify clinical trial opportunities as well as participate in virtual clinical trials.

#### 4.4.4 Consumer Concerns Around Usefulness, Cost, and Privacy

While there is general optimism about the impact of digital health technologies and in particular about its impact on active and healthy aging, it is clear that there are factors holding back consumer adoption. This contrasts with consumers' rapid adoption of digital tools and services, such as smartphones, ridesharing apps, online payment tools, etc. However, when surveyed, consumers generally express great interest in using these tools compared to traditional health services.

Our research identified four main concerns that might be holding back consumer adoption:

- *Cost* – Most patients are unused to paying for health care out of pocket. Even in the USA, there is reticence to pay for services out of pocket that insurance has previously covered. The subscription model used by many other services does not work well in digital health. In Europe the physical equivalent of services like telehealth are frequently provided for free. Hence digital health companies tend to look to sell directly to enterprises or governments—which delays the process. Note that this does not appear to be the case in China and may be why digital health has been adopted more quickly there.
- *Utility* – Low health literacy is endemic in many countries. People with low health and technical literacy may find limited usefulness in digital health tools. Even consumers with higher levels of health literacy may find that the tools do not have the desired effect. Often digital health tools are attempting to solve very complex human problems, such as weight loss and addiction. Users may get discouraged and cease using them.
- *Access and market presence* – Despite the ubiquity of smart phones and other digital tools, it has been hard for companies and organizations promoting digital health tools to make a market breakthrough. There has not been the equivalent of an Uber or AirBnB for health. Therefore, the awareness those types of companies have created in their market does not translate to health care.
- *Privacy concerns* – With recent news of tech giants commercializing and leaking consumer data without their consent, consumers have begun to fear what companies do with their information. Consumers tend to consistently claim they are more concerned about their health data than other types of data, probably because certain illnesses carry stigma, or that they fear that their health conditions may be used against them by employers and insurers.

#### 4.5 The Balance between Drivers and Barriers

As in any analysis of technology adoption and societal change, there will continue to be some balance between drivers and barriers. However, we believe that the underlying trend is towards greater adoption of digital health technologies, even though it may be uneven across and within different regions.

As the evidence for digital technologies builds, a combination of consumer demand, regulation, private and public funding and professional acceptance will see these new generation of tools come on-line. One important role for the IDIH project is to work with stakeholders to not only identify what tools will be useful for the future of active and healthy ageing, but how to support stakeholders as they adopt these tools and services. The goal is to enable health care systems to provide preventative, integrated, connected, and inclusive care—ultimately, supporting their ageing citizens.



## 5 Conclusion

The growing elderly population worldwide will be accompanied by an increased prevalence of chronic conditions which will strain health care systems and economies. Hence, there is a global demand to seek technologies that support active and healthy ageing. The current state of technology is building on the foundation of the now commonplace Electronic Medical Records (EMR) and is focusing on empowering health care stakeholders through social media, mobile applications, analytics, and cloud computing (SMAC) technologies, including telehealth, remote monitoring and enhanced communications.

Technologies such Internet of Things (IoT) including wearables and sensors, telehealth, and digital therapeutics (DTx) have created tools that allow patients to engage in their own health and benefit from different care delivery models. Through these technologies, health care delivery has started to shift away from institutions to home and mobile-based care. This shift in care setting is derived from patients' concerns. Individuals wish to live long yet active, healthy, and dignified lives. They want to age in place where they feel comfortable and supported. This demand has fuelled the development of new digital health tools—advanced Internet of Things (IoT), artificial intelligence, augmented and virtual reality (AR/VR), blockchain, fast health interoperability resources (FHIR), and more. Consumers will expect “Smart Homes” and environments that enable them to age at home. The combination of interface-agnostic devices and sensors embedded into everyday objects, as well as AI, will allow patients to be continuously monitored and providers to be alerted to the onset of disease or a disease's progression. If any interventions are needed, face to face care can be provided on-demand and managed by hybrid health models and/or technology-based service organizations.

As exciting as the emerging health technology trends are, they will not come to fruition without the proper policies, regulations, reimbursement models, and incentives. Each nation has its own approach towards care delivery and how health technology will be used and paid for; each has its own strengths and weaknesses. Therefore, international collaboration is necessary to foster an understanding of what, how, when, and where health technology can best be leveraged. The aim of this mutual learning is to enable health care systems to provide preventative, integrated, connected, and inclusive care—ultimately, supporting their ageing citizens.



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