

Future of Business and Finance

Kota Kodama
Shintaro Sengoku *Editors*

Mobile Health (mHealth)

Rethinking Innovation Management
to Harmonize AI and Social Design

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Future of Business and Finance

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to Harmonize AI and Social Design

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ISSN 2662-2467

Future of Business and Finance

ISBN 978-981-19-4229-7

<https://doi.org/10.1007/978-981-19-4230-3>

ISSN 2662-2475 (electronic)

ISBN 978-981-19-4230-3 (eBook)

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Preface

This book is dedicated to students, researchers, practitioners, and policymakers who strive for the development and implementation of AI technology in the mHealth field. Our purpose of this book is to raise awareness of regulation development as well technological development must be more conscious with user information including biometric information which has potential of being revealed to the third party. This book serves as a platform for comprehensive visualization and discussion of global regulations regards to mHealth. We hope that many local governments, school institutions, and companies will cooperate in establishing regulations and rules that guarantee efficient safety, which will become clear as discussions progress.

This book is consisted of two parts. The first half of the chapter follows by comparing the regulations dedicated to mHealth in each region. The latter half of the chapters consists of the case study of successful mHealth development and its implementation to people. The AI technology in the mHealth field is still considered in the early stage of its development. Moreover, we believe that to create a future where our health can be accessible and easy to monitor on us with the help of professionals, it is necessary for the development of how we can develop, use, and implement it. Through discussing different aspects of the matter with this, we hope to help you with the standardized ideas for people who will improve in the coming years.

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Acknowledgments

This work was financially supported by the Ministry of Land, Infrastructure, Transport and Tourism (FY2019-FY2021 research and development for construction technology subsidy program policy issue solving type “Analytical evaluation system for improving productivity using lifelog information in unmanned construction”) and Grants-in-Aid for Scientific Research (grant numbers 20K20769, 26301022, and 21H00739). Also, this work was supported by the Foundation France-Japon/Air Liquide Fellowship. The authors gratefully acknowledge the generous support and assistance of the Fondation France-Japon de École des Hautes Études en Sciences Sociales and Air Liquide. I deeply appreciate the cooperation of Prof. Sebastien Lechevalier, President of Fondation France Japon.

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Global Scale Comparison of mHealth Regulation



Introduction of the Concept of AI in the Field of mHealth While Discovering the Trends in the mHealth Research Field

Kota Kodama, Karin Kurata, and Jianfei CAO

ABSTRACT

Smartphones have become an integral part of our lives with a diverse selection of apps. The continuous upgrade of information technology has enabled smartphones to display potential in the field of health care. First, we analyzed the research trends and the latest research hotspots in mobile health to understand the global trends. This chapter collected mHealth-related literature published between 2000 and 2020 from the Web of Science database. We constructed visualization network maps of country collaborations and author-provided keyword co-occurrences, as well as overlay visualization maps of the average publication year of author-provided keywords to analyze the hotspots and research trends in mHealth research. In total, 12,593 mHealth-related research papers were extracted. The research trends revealed a gradual shift in mHealth research from health policy and improving public health care to the development and social application of mHealth technologies. To the best of our knowledge, the most current bibliometric analysis dates back to 2016. The results of this study shed light on the latest hotspots and trends in mHealth research. These findings provide a useful overview for researchers in the digital health field.

The original version of this chapter was published as an Open Access article in Vol 9, Issue 9 of JMIR Mhealth Uhealth, JMIR Publications, 2022, under the terms of the Creative Commons Attribution License (<https://creativecommons.org/licenses/by/4.0/>), <https://doi.org/10.2196/31097>.

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1 Introduction

With the rapid increase in the penetration rate of mobile phones over the past 10 years, almost every person in developed countries owns a mobile phone (Donner, 2008). The lifestyle has become more common to use various services such as e-commerce and finance. With the spread of smartphones, there are increasing opportunities for health promotion, especially in the medical field, due to the abundance of smartphone application functions and the ability to operate anytime, anywhere. The health services for medical and public health supported by such mobile devices are defined as mobile health (mHealth).

The introduction of mHealth has transformed the management style of our health. Also, mHealth devices and services have allowed us to communicate and cooperate through multiple sectors of the society (Hoque & Sorwar, 2017). The global pandemic of coronavirus 2019 (COVID-19) in 2020 reveals a shortage of medical resources in each country. Under these circumstances, the mHealth application can monitor various physical information such as heart rate and behavioral information such as acceleration (ACC) in real time through mobile devices such as smartphones and smartwatches. This allows people to check their health at any time and provide a reference data to their medical staff. Therefore, mHealth development can alleviate medical resource shortages to some extent.

Through this phenomenon, seamlessly linking health and medical services has been initiated by integrating and centrally managing health information and medical information. However, the institutional design requires the intervention of a doctor worldwide for disease diagnosis, and significant deregulation is required to apply IoT and AI technologies to this field of mHealth. For this reason, the introduction of AI in the mHealth field had been failing to replace existing medical services. Under these circumstances, from the beginning of 2020, the widespread corona pandemic has dramatically transformed the social implementation of mHealth as an emergency measure such as telemedicine and tracking of close contacts.

The challenge to harmonize the conventional regulation to implement AI in the field of mHealth will occur in the future worldwide. In addition, the recent progress in mobile technology, represented by smartphones and smartwatches, has been remarkable. The mHealth service, which utilizes mobile technology to manage health is becoming a reality. Although the accuracy of medical devices is not as accurate as those used in medicine, however, biometric information such as heart rate and SpO2 can already be monitored over a long period of time. The mHealth is maturing to the point where it can be implemented in society, however, the medical care and services still remain unapproved in most countries. The development and social implementation of mHealth are most active in the US, but social implementation is gradually progressing in other countries as well (Hoque & Sorwar, 2017). Researchers from various countries are paying attention to the great potential of mHealth in the medical field. Also, how to rationally develop the mHealth services and products while creating social value of significant interest

to researchers. Therefore, it is necessary to have a deep understanding of current mHealth research trends and hotspots.

In this book, we will first discuss what kind of harmonized regulations are desirable by comparing the regulatory reforms necessary for the social implementation of mHealth on a global scale.

Next, the discussion of mHealth while raising privacy concerns because the usual behavior and biometric information of subjects were utilized by private companies in reviewing case studies (Joo et al., 2021). In addition, it is important to note that the behavior and biometric information of subjects collected by smart devices were automatically analyzed by AI technology, mainly machine learning, which is the analysis of a black box. Therefore, in this book, the focus of this book is to identify the factors which can mitigate the challenge faced by the process of implementing AI in the mHealth field effectively and efficiently. While comparatively analyzing the factors including the status of mHealth development, the national regulations, and the social background of each nation including Japan, South Korea, and China with the United States and the European Union as well as analyzing the current research trends in mHealth field. Therefore, the purpose of this book is to bring awareness of safety for the general public to utilize AI technologies in daily lifestyles in the future. This book will support the policy-makers, researchers, and practitioners as well as students who will initiate in developing AI in the field of mHealth.

2 Definition of AI Handled in this Book

The term artificial intelligence (AI) was explicitly proposed at the Dartmouth Conference in 1956. At that time, the proposal for the conference included this assertion: “every aspect of learning or any other feature of intelligence can be so precisely described that a machine can be made to simulate it” (McCarthy et al., 2006). With the recent increase in the amount of data that can be handled, the sophistication of algorithms, and the development of related technologies such as computer performance and storage technology, and cloud computing, the abbreviation AI has become more widely known. Through many years of technological development, it has led to the realization of decision support systems and smart search systems aimed at complementing and strengthening human abilities. In parallel with the widespread penetration of AI technology into society, the story of robots and systems equipped with AI in Hollywood movies and science fiction novels conquering human society is also depicted. In addition, there are many reports in the media that AI will rob humans of their jobs in the future. However, the current evolutionary stage of AI technology has not reached such level. In this way, in modern society, the word “AI” has various meanings, so the definition of “AI” used in this book is strictly defined as AI technology. We also want to clarify the scope of applicable medical fields. First, I will briefly outline the word “AI”. However, the author specializes in health care, and of course he does research

using AI in this specialized field, however, he is not an expert in information engineering or AI. In addition, in the current situation where “AI” has a wide range of meanings and is being defined including philosophical discussions, I will not give an authoritative definition, but only a brief overview of the term “AI” for ease of explanation in this book.

Here, we define the contents of “AI” handled in this book and outline the contents. The definitions of “Strong AI” and “Weak AI” in Fig. 1 are terms coined by John Rogers Searle, and it is Strong AI that comes to mind when the public, as nonspecialists, hear the term “artificial intelligence” (McCarthy, 2004) (Searle, 1980). From the influence of science fiction novels and movies, it seems that computers that can do human work and have a wide range of knowledge and some self-consciousness are generally regarded as “artificial intelligence”. Such “artificial intelligence” (“artificial intelligence” here means Strong AI) has not been realized as of 2021. Currently, the “artificial intelligence” that is being used in society is the Weak AI in Fig. 1, and the “artificial intelligence” in this book, which is a specialized book, all means Weak AI. The most important technical term in Weak AI is “machine learning”.

Machine learning is a computer algorithm that automatically improves through experience (Mohr et al., 2017). Machine learning algorithms build models based on information called “learning data” that enables predictions and decisions without being explicitly programmed. This basically means that the prediction accuracy increases as the amount of training data increases. It also means that if the quality and properties of “learning data” change, the system will be completely different. In the healthcare world, which is the subject of this book, this characteristic of machine learning is one of the factors slowing down the social implementation in this field.

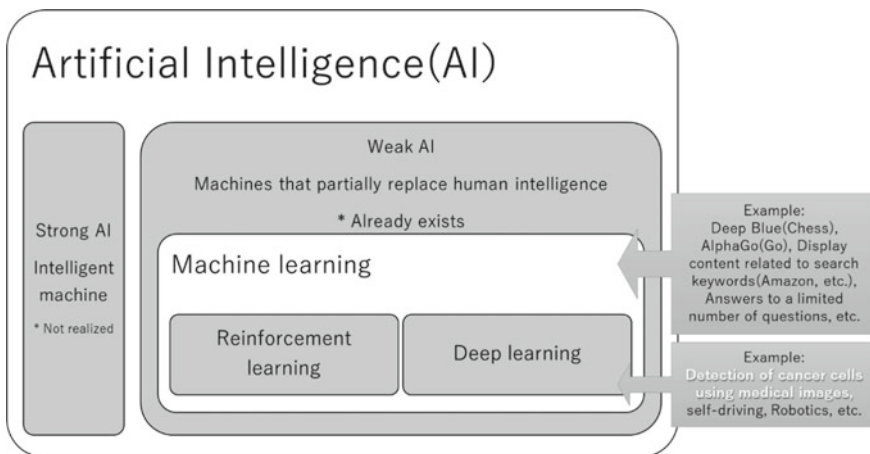


Fig. 1 Positioning of AI and related terms in this book. *Source* Reproduced from McCarthy (2004)

In the medical field discussed in this book, AI technology is truly starting to be used in various fields such as treatment, medication, and roentgen image diagnosis. One of the earliest socially implemented areas in the medical field is the use of AI in diagnostic imaging. When diagnosing a disease from a radiologist, especially from medical images, AI can directly reduce the workload by helping the radiologist to interpret. However, it is only used to support the diagnosis, and the final diagnosis is made by the doctor. In addition, it is considered inappropriate from the technical and ethical points of view that AI makes autonomous decisions in the medical practice of the current medical system. For this reason, our discussion area will focus on AI used for disease prevention and health promotion outside of the current medical practice of the healthcare system, or for daily biometric information that cannot be monitored by doctors and other medical professionals, especially AI used in mobile devices.

Interest in applications that apply machine learning and deep learning technology called AI continues to grow worldwide, and applications in the healthcare field are particularly attracting attention. With the addition of the situation where it is becoming easier to collect consumer/patient data from smartphones, etc., there are increasing interests in utilizing these technologies to evaluate the effects and side effects of medicines and to improve the accuracy and adaptability of medical devices.

3 Literature Review

The global related market is also growing and according to the medical devices market report published by Lucintel in April 2018, the medical devices market is expected to grow at a CAGR of 4.5% from 2018 to 2023 (Cision, 2018). The market size is estimated to reach \$ 409.5 billion in 2023, creating investment opportunities and progress prospects in this area. However, medical products have traditionally been developed under very strict regulations because they have a direct impact on human health and life. In mHealth, which is a medical system that utilizes mobile wireless devices, it is possible to approach patients without going through a medical staff, and the AI algorithm used for that judgment.

Many countries have yet to determine how to regulate the fact that algorithms are continually updated based on the existence of new data sets by their nature and cannot be dealt with by traditional management methods. This makes it difficult for new entrants to comply with regulations. To overcome this challenge, governments have already started working on special legislative systems for AI-based medicine. One of the key initiatives in this area is the activities of the US, Food and Drug Administration (FDA), which began its consideration in April 2019.

The FDA advocates a Total Product Life Cycle (TPLC) that includes post-implementation monitoring to accommodate AI-based medical services that could adapt and improve using user data (FDA, 2019). This approach enables product reviews and monitoring from pre-market to post-market launch, allowing the continuous review to match the operator's internal policies and level of operational

excellence. The implementation of the 21st century cures act: health information technology. u.s, government publishing office has set up a Breakthrough Devices Program in 2016, 21st Century Cures Act to promote the social implementation of innovative devices, as well as clarify the distinction between types that should be treated as truly medical devices and those that do not require regulation. It shows the intention to eliminate the innovation hindrance due to its ambiguity (U.S. Senate, 2017; U.S. Food & Drug Administration, 2018).

The areas of disease for which mHealth is most expected to be indicated in the future are the mental health areas such as dementia, bipolar affective disorder, schizophrenia, and mainly depression. Figure 2 shows the number of clinical trials started on ClinicalTrials.gov. But the number of clinical trials for psychiatric disorders is increasing year by year. According to the World Health Organization (WHO), depression alone affects at least 300 million people worldwide and causes hundreds of billions of dollars in economic losses each year in the United States (WHO, 2017).

Despite treatments and social services, many people with mental illness tend to avoid seeing them for fear of degrading their social reputation. To support

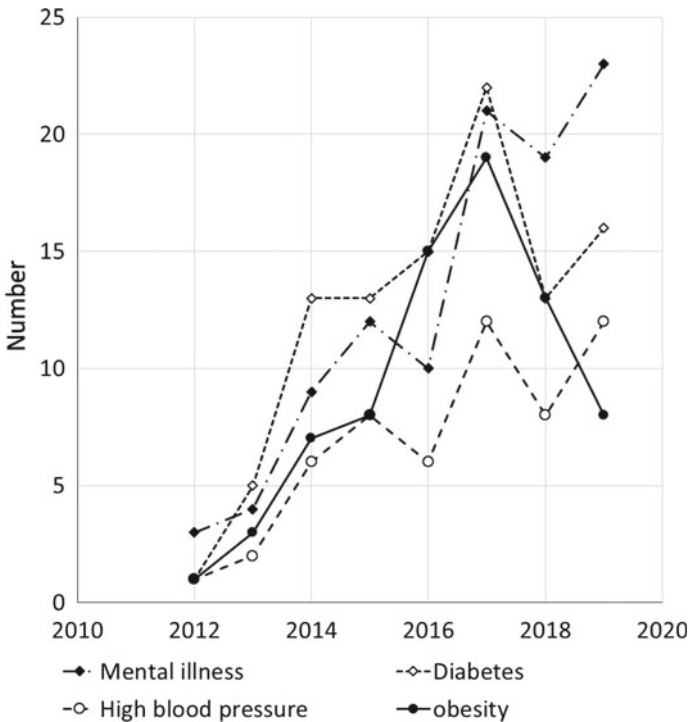


Fig. 2 Number of mHealth-related clinical trials initiated by disease. *Source* Reproduced by the author from ClinicalTrials.gov

such patients with mental illness, mobile applications are being developed to perform therapeutic interventions while maintaining the privacy of patients (Depp et al., 2010). In these services, a 24-h automated conversation program listens to patients and provides support and advice as needed. These are highly dependent on machine learning, deep learning, etc., and there are concerns among regulators in terms of the above-mentioned continuous change and the delicacy of the value provided.

4 Methods

4.1 Bibliometric Analysis

Bibliometrics can quantify comprehensive textual information and provide a variety of numerical statistics on the evolutionary process of a particular topic (Daim et al., 2006). The quantified information also helps scholars identify future trends in the subject. Bibliometrics is widely used in academia, especially for detailed analysis of journal articles. In recent years, researchers have developed many bibliographic analysis tools that meet the needs of bibliographic analysis and enrich bibliographic processing. For example, analysis of co-authors' countries/regions and research institutes to elucidate partnerships between different countries/regions or research institutes, for co-occurrence analysis to identify research hotspots. Keyword extraction and keyword clustering analysis are used to identify the direction of major research in a field. In this way, bibliometrics plays an important role both in providing an overview of the past and in predicting the future.

There are currently few papers on bibliometric analysis of mHealth-related literature. Among the few, Sweileh searched Scopus for articles on mHealth published between 2006 and 2016, analyzed the increase in publications and citations by data visualization, and used bibliometric indicators to clarify research efficiency (Sweileh et al., 2017). As a result of the research, it was found that among the related papers on mHealth, there are many keywords related to diabetes, medication adherence, and obesity. The study also found that the mHealth literature has grown exponentially.

As of 2016, Shen collected 2,704 mHealth-related papers from the Web of Science database (Shen et al., 2018). Although different from the database Sweileh searched, the results of the two studies were similar in that the United States was found to be the most active country in mHealth research worldwide. There was also an exponential growth trend in the papers on mHealth in the Web of Science database. By identifying keywords, mHealth research hotspots were categorized into four main areas: (1) Patient Engagement and Patient Intervention, (2) Health Monitoring and Self Care, (3) Mobile Devices and Mobile Computing, and (4) Security and Privacy.

The results of a bibliometric analysis of mHealth-related literature by Peng were recently published in 2020. Peng focused on a publication related to the mHealth app (Peng et al., 2020). They collected a total of 2,802 papers published between

2000 and 2019 from the Web of Science. The status of research on mHealth apps, research trends, hotspots, and co-authored networks have been clarified. However, there are still gaps in the bibliographic analysis of mHealth research from 2017 to 2020. Both Sweileh's and Shen's studies point to an exponential growth trend in publications on mHealth studies (Sweileh et al., 2017; Shen et al., 2018). Therefore, we can predict that the number of mHealth-related publications will increase exponentially from 2017 to 2020. In fact, the number of publications from mid-2017 to 2020 is higher than ever. For this reason, we thought it is necessary to re-examine the bibliographic analysis of mHealth studies from 2000 to 2020. Another reason for choosing 2000–2020 as the analysis period, not just 2017–2020, is that the 2000–2020 period analysis is to identify research hotspots and research trends in this area. This is because the average publication year of the author keyword can be grasped more intuitively.

4.2 Data Collection

The first step for data collection in bibliometrics analysis is to collect primary source metadata. This metadata may include the title of the article, abstracts, author keywords, author information, country, and references. In this study, we collected data from mHealth-related papers published between 2000 and 2020 from the Web of Science database (Agarwal et al., 2016). The Web of Science database was chosen because it covers a wide range of research, including 21,000 peer-reviewed high-quality journals. In addition, the Web of Science includes six high-impact citation databases in its core collection, including the Science Citation Index extension, the Social Science Citation Index, and many regional databases. In this way, the reliability of the database was guaranteed.

As with most studies, using mHealth and its synonyms as search topic keywords (search by title, abstract, author keyword) to find potential publications related to mHealth, we conducted publication searches. However, this simple approach has major limitations. As Sweileh suggested, for reasons such as personal understanding and habits, many researchers might not recognize that their publications focus on mHealth when introducing mHealth-related publications (Sweileh et al., 2017). Therefore, the second search strategy was also used in this study. Because mHealth depends on a variety of mobile devices, we searched for author keywords related to both mobile devices and mHealth (smartphones, mobile phones, etc.), and general health (health, healthcare, etc.). Prioritizing author keyword search over the topic search, the latter may include articles that do not focus on mobile devices and health research. The former, on the other hand, is a keyword that the author presents to emphasize the content of the publications. Therefore, if the author's keywords include both "mobile device" and "health", the author can be considered to emphasize the publications on these keywords. In this way, we decided that it would be more appropriate to search by author keyword to ensure the reliability of the data.

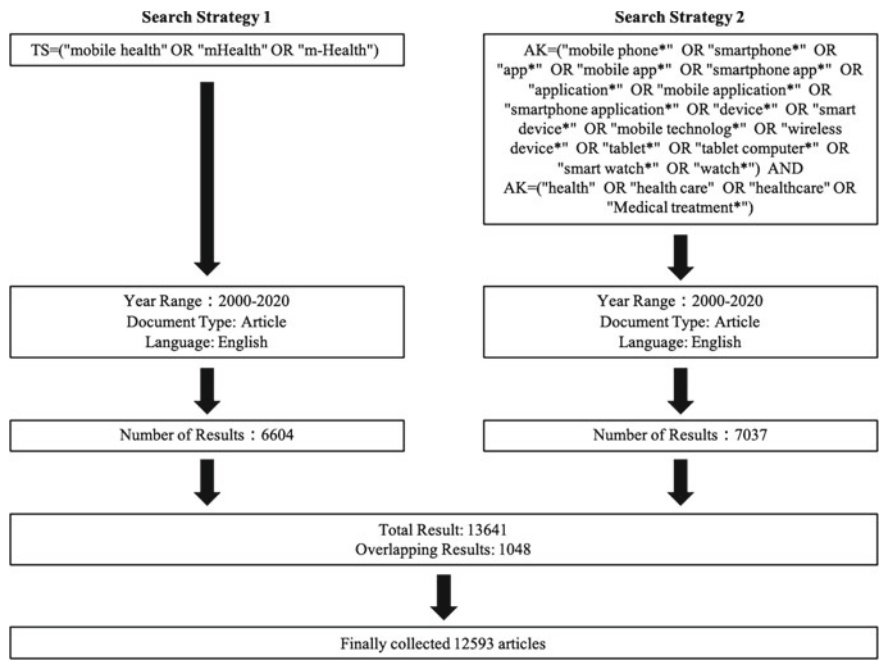


Fig. 3 Data collection strategy for the bibliometric analysis of mHealth research

In addition, all search strategies set the search year range from 2000 to 2020, and searched only articles published in English. Documents were collected on March 2, 2021. The first search strategy yielded 6,604 search results, and the second search strategy yielded 7,037 search results. Of these, 1,048 documents were duplicated in the search results of the two search strategies, and the duplicated parts were deleted to finally collect 12,593 documents. The specific search process is shown in Fig. 3.

4.3 Data Analysis

In this study, we used VOSviewer version 1.6.15 as a data analysis tool. Of the many tools applied to bibliometric analysis, mapping and clustering techniques that provide insight into network structure are usually used together as the most common combination (He & Hui, 2002; Uribe-Toril et al., 2021). However, these two technologies are usually developed independently of each other and rely on different ideas and assumptions. Waltman combined the two and proposed a unified mapping approach and clustering that applies to VOSviewer. With powerful data processing and data visualization capabilities, this analytical tool has been applied to many disciplines of bibliometric analysis (Waltman et al., 2010).

In this study, we first calculated the annual number of papers and the annual growth rate and observed the publishing tendency of mHealth-related literature. Furthermore, we analyzed the tendency of publications by country/region and the distribution of publications by journal based on the number of papers. We created various bibliometric maps using VOSviewer. In addition, to clarify the hot spots of research in the field of mHealth, we visualized this network based on co-occurrence keywords created from author keywords, classified research topics by clustering analysis of author keywords. Finally, we analyzed research trends by visualizing the average year of publication of keywords.

5 Results

5.1 Number of Publications in the mHealth Field

We analyzed the annual growth trends of the publications according to the search strategy described above (Table 1 and Fig. 4). As a result, it was found that the number of papers related to mHealth has increased since 2004 and shows a similar exponential growth trend. Applying this to the exponential formula, the growth curve of the literature is $y = 37e^{0.3062x}$, $R^2 = 0.9935$, where x is the number of years of growth since 2000 and y is the cumulative number of publications. Specifically, 2015 was a turning point. The number of documents published in 2015 increased by 366 compared to 2014, and the annual growth rate reached 61%, the highest annual growth rate in the last 20 years. Overall, the mHealth literature has a compound annual growth rate of 25%, indicating that the mHealth field is drawing the attention of scholars.

5.2 Number of Publications in Countries and Regions

As a result, it was found that researchers in 166 countries/regions contributed to publications on mHealth. As revealed in the previous bibliometric analysis, the United States remains the country with the most publications, accounting for 42% of the total (5,294/12,593). The United Kingdom came in second with 1,372 cases, accounting for 11% of the total (1,372/12,593 cases). Australia (979/12,593, 8%), China (842/12,593, 7%) and Canada (828/12,593, 7%) are closely followed. It also shows the changes in the annual number of papers in the top 10 countries/regions since 2000 (Fig. 5). As can be seen from the change curve in Fig. 5, the growth curve of the United States shows explosive growth compared to other countries. This reflects the early focus of American researchers on mHealth and it is still of increasing interest. The annual number of publications in other countries/regions is increasing, though not as much as in the United States.

Table 1 Descriptive statistics of the collected mHealth literature

Year	NP ^a	AG ^b	AGR ^c	CNP ^d
2000	37	–	–	37
2001	29	–8	–22%	66
2002	41	12	41%	107
2003	37	–4	–10%	144
2004	50	13	35%	194
2005	77	27	54%	271
2006	86	9	12%	357
2007	96	10	12%	453
2008	123	27	28%	576
2009	158	35	28%	734
2010	184	26	16%	918
2011	236	52	28%	1,154
2012	302	66	28%	1,456
2013	437	135	45%	1,893
2014	603	166	38%	2,496
2015	970	367	61%	3,466
2016	1,206	236	24%	4,672
2017	1,383	177	15%	6,055
2018	1,725	342	25%	7,780
2019	2,132	407	24%	9,912
2020	2,681	549	26%	12,593

^aNP = number of publications^bAG = annual growth^cAGR = annual growth rate^dCNP = cumulative number of publications

5.3 Partnering Networks of Countries and Regions

A visual network diagram showing partnerships between countries/regions is shown in Fig. 6. This shows the partnerships of the top 50 countries in terms of publication volume. The size of the circle indicates the number of publications. The larger the circle, the greater the number of publications. The length and thickness of the link between circles indicate the strength of the partnership between countries. In general, the closer the two circles are to each other, the thicker the link and the stronger the relationship between the countries/regions. Different colors indicate different clusters, and circles belonging to the same cluster usually have similar properties and characteristics. All countries in the figure are linked to the United States, which means that all countries are in partnership with the United States. From Fig. 6, we can see that the network diagram has a triangular shape, with the four countries occupying the center of it: the United States, the United

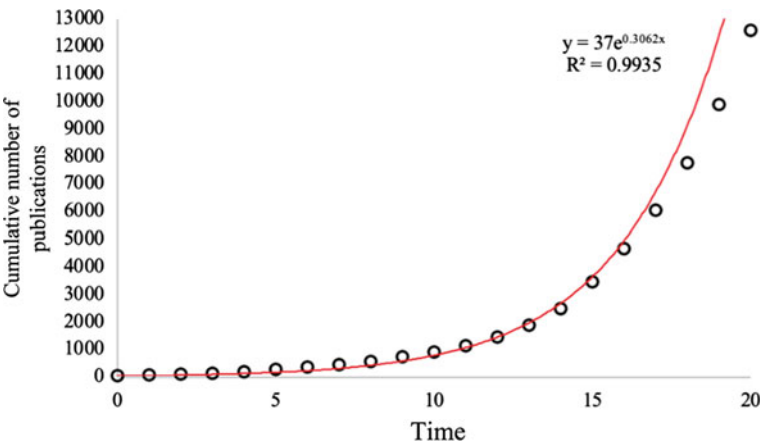


Fig. 4 Growth curve of the cumulative number of publications in mHealth literature

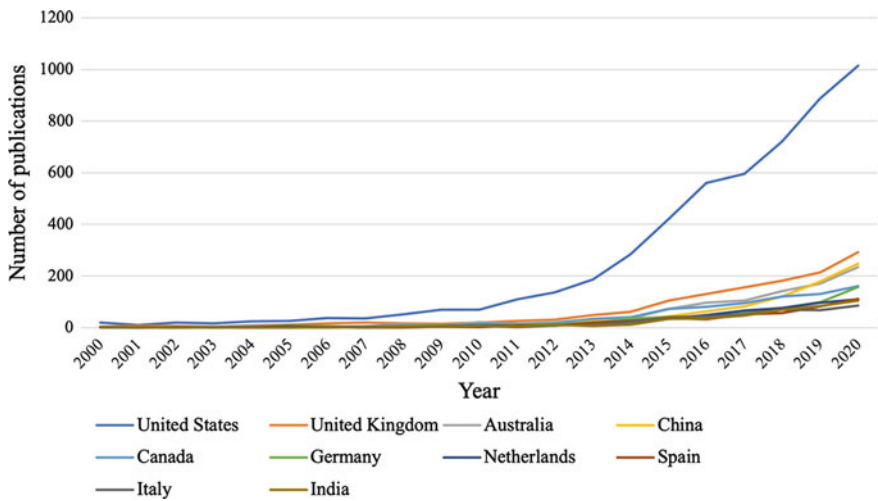


Fig. 5 Comparison of the growth trends of mHealth-related research publications in various countries between 2000 and 2020. *Note* Due to research cooperation between scholars of different nationalities, some papers have been counted more than once

Kingdom, Canada, and Australia. In other words, of the top five countries with the largest number of publications, these four countries were located in the center of the network diagram, and the distances between the nodes are almost the same. This suggests that these four highly productive countries have strong cooperation. Furthermore, from the position of the country node, the cooperative relationship between countries/regions is clear, such as the Asian countries/regions represented by red clusters and the European countries/regions represented by green clusters.

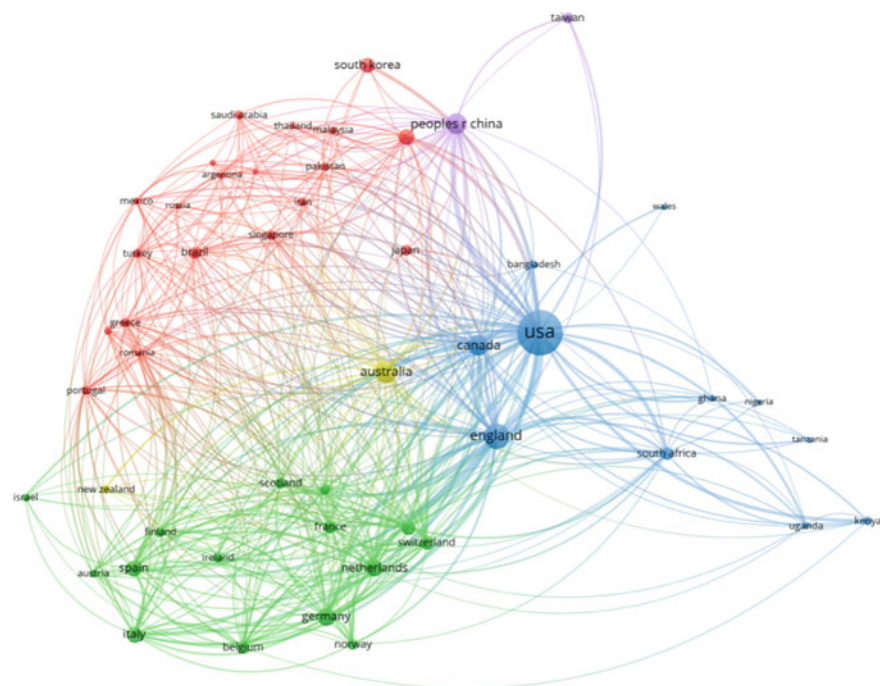


Fig. 6 Visual network diagram of cooperation between countries/regions

5.4 Top Journals in the mHealth Field

According to the search results, the literature related to mHealth was distributed in 3,268 journals. Table 2 shows the information of the top 10 journals by the number of publications. Of the top 10 journals, the Canadian Journal of Medical Internet Research and its sister journals, JMIR mHealth and uHealth, JMIR Research Protocols, and JMIR Mental Health, fall under this category. The number of joint publications is 1,763, accounting for 14% of all publications. In addition, the impact factor of the top 10 journals excluding JMIR Research Protocols exceeds impact factors of 2.

Author keywords are commonly thought of as abbreviations for the topic of a publication written by the author. Author keyword co-occurrence analysis can accurately provide hotspots for current research in the field. In this study, we used VOSviewer's author keyword co-occurrence analysis and set the minimum number of co-occurrences to 50. Keywords with mHealth and smartphones, and keywords with similar meanings to mHealth and smartphones, appeared frequently in search strategies and occupy a large weight in the co-occurrence network graph. We have removed the keywords used in the displayed search bar in the search results because such keywords are likely to affect the distribution of the remaining keywords. In addition, we intended to pinpoint the buzzwords of more valuable

Table 2 Top 10 journals in terms of the number of publications of mHealth literature between 2000 and 2020

Rank	Journal	Country	Two-year impact factor (2019)	NP ^a	% of 12,593, i.e., total number of articles	Journal website
1	JMIR mHealth and uHealth	Canada	4.31	956	7.59	https://mhealth.jmir.org/
2	Journal of Medical Internet Research	Canada	5.03	463	3.676	https://www.jmir.org/
3	JMIR Research Protocols	Canada	–	235	1.866	https://www.researchprotocols.org/
4	Telemedicine and e-Health	The United States	2.841	202	1.604	https://home.liebertpub.com/publications/telemedicine-and-e-health/54
5	International Journal of Environmental Research and Public Health	Switzerland	2.849	145	1.151	https://www.mdpi.com/journal/ijerph
6	BMC Public Health	The United Kingdom	2.69	139	1.104	https://bmcpublikealth.biomedcentral.com/about?gclid=Cj0KCQiAmpyRBhC-ARIsABs2EAoRtI8dKf_E5rDxl6uvmmhqUuVp6SjPgKPF-q2mJp24irQqcGkpSd0aAvzBEALw_wcB
7	JMIR Mental Health	Canada	3.54	109	0.865	https://mental.jmir.org/
8	International Journal of Medical Informatics	Ireland	3.025	106	0.842	https://www.journals.elsevier.com/international-journal-of-medical-informatics

(continued)

Table 2 (continued)

Rank	Journal	Country	Two-year impact factor (2019)	NP ^a	% of 12,593, i.e., total number of articles	Journal website
9	BMC Medical Informatics and Decision Making	The United Kingdom	2.317	101	0.802	https://bmcmmedinformdecismak.biomedcentral.com/
10	Sensors	Switzerland	3.275	99	0.786	https://www.mdpi.com/journal/sensors

^aNP = number of publications

research topics. Then, we extracted the top 100 keywords and mapped them to the keyword co-occurrence network. The result of the keyword contribution network graph is shown in Fig. 7.

The top 100 keywords were classified into 5 clusters by keyword clustering analysis, and the top 10 keywords with co-occurrence frequency are shown in Table 3. The average year of publication of the keywords shown in Table 3 was 2015.26 to 2017.90, and the average number of citations was 10.75 to 17.98. The most frequent keyword was “mental health”, with 449 co-occurrences, followed by “physical activity” with 285 co-occurrences.

5.5 Top Keywords and Networks of mHealth Publications

From the average year of the appearance of keywords, it is possible to infer the secular change of mHealth research hotspots. The top 100 author keywords in mHealth research are visualized in Fig. 8 according to the average publication year. The size of the node indicates the number of times the author’s keyword has appeared, and the color of the node is gradually distinguished according to the average year of publication. As shown in Fig. 8, the more node displayed in the yellow gradient, the higher the average publication year of the keyword. Table 4 shows the top 15 and bottom 15 author keywords. The average publication year range for the top 15 author keywords is 2017.98 to 2020.05, and the frequency range is 41 to 135 times. Of the top 15 keywords, 8 belong to cluster red, 5 belong to cluster purple, 1 belongs to cluster yellow, and 1 belongs to cluster green. The average publication year range of the bottom 15 author keywords is 2015.26 to 2016.19, and the appearance range is 46–243. Of the bottom 15 keywords, 10 belong to cluster green, 2 to cluster red, 2 to cluster yellow, and 1 to cluster purple.

In addition, to better understand the direction of AI-related research in the mobile health field, we focused on AI and narrowed down the research targets

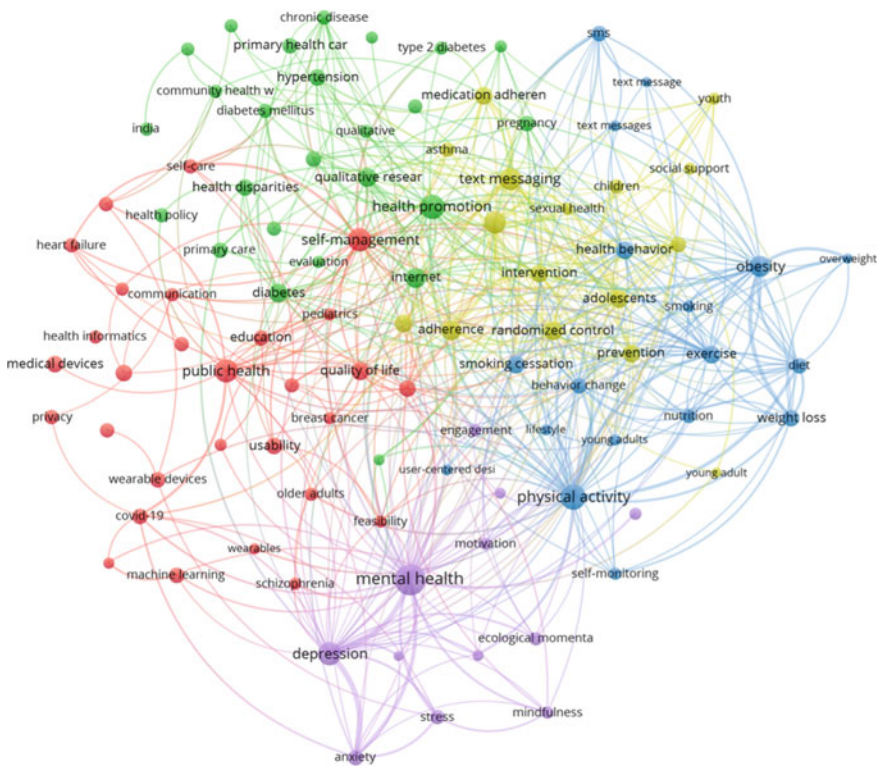


Fig.7 Co-occurrence network diagram of the top 100 author keywords in mHealth research between 2000 and 2020

Table 3 Top 10 author keywords of mHealth research between 2000 and 2020

Rank	Keyword	Cluster	Occurrences	Average year of publication	Average number of citations
1	Mental health	Purple	449	2017.30	12.48
2	Physical activity	Blue	285	2017.46	14.00
3	Health promotion	Green	243	2015.26	14.97
4	Self-management	Red	234	2017.90	10.75
5	Public health	Red	232	2016.29	13.41
6	Depression	Purple	227	2017.51	17.98
7	Hiv	Yellow	208	2017.57	11.37
8	Text messaging	Yellow	207	2016.90	13.22
9	Obesity	Blue	173	2016.65	13.81
10	Adherence	Yellow	157	2017.48	13.85

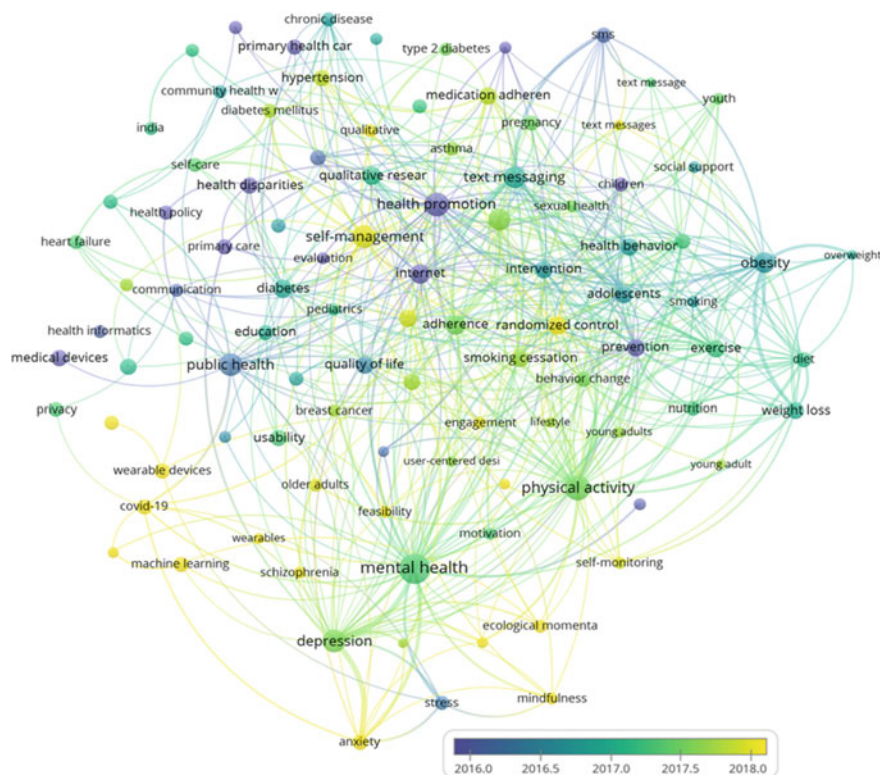


Fig. 8 Overlay visualization maps of the average publication year of the top 100 author keywords

from the above research results using the procedure shown in Fig. 9. After manual checking, we finally came up with 555 related articles.

Looking at Fig. 10, we can see that machine learning is the most frequently used related keyword in AI-related articles in the field of mobile health. In addition, Fig. 11 shows that the overall average of high-frequency author keywords appearing in AI-related articles is after 2017. The author keywords are divided into eight clusters, with machine learning and deep learning at the center. In addition, the new keyword covid-19 has appeared and belongs to a high-frequency vocabulary. In addition to covid-19, the newest average keywords are monitoring, digital phenotype, and digital health.

5.6 Chronological Trends of mHealth Publication in Countries and Regions

In European countries such as the United Kingdom, Spain, and Italy, the annual number of papers has not been increasing, and the average number of papers per

Table 4 Comparison of the top 15 and bottom 15 author keywords as categorized by average publication year

Top 15 author keywords				Bottom 15 author keywords			
Cluster	OC ^a	APY ^b	Keyword	Keyword	APY ^a	OC ^b	Cluster
Red	86	2020.05	Covid-19	Health promotion	2015.26	243	Green
Red	41	2019.05	Artificial intelligence	Primary healthcare	2015.35	95	Green
Red	43	2018.79	Wearables	Health policy	2015.40	81	Green
Red	85	2018.55	Machine learning	Evaluation	2015.45	55	Green
Purple	42	2018.54	Gamification	Children	2015.53	80	Yellow
Red	47	2018.48	Feasibility	Medical devices	2015.58	103	Red
Red	87	2018.31	Wearable devices	Prevention	2015.79	117	Yellow
Purple	67	2018.26	Ecological momentary assessment	Health disparities	2015.82	97	Green
Yellow	135	2018.24	Randomized controlled trial	Internet	2015.84	152	Green
Red	69	2018.22	Internet of things	Focus groups	2015.94	50	Green
Purple	54	2018.16	Mindfulness	Primary care	2015.97	87	Green
Purple	45	2018.09	Sleep	Developing countries	2016.00	67	Green
Purple	93	2018.05	Anxiety	Well-being	2016.07	46	Purple
Green	59	2018.04	Qualitative	Health informatics	2016.15	59	Red
Red	55	2017.98	Schizophrenia	Health education	2016.19	84	Green

^aOC = occurrences^bAPY = average publication year

year is relatively small. Conversely, Asian countries such as Singapore, India, and South Korea are growing more than before as emerging countries. Perhaps development will be more active in countries that are trying to make effective use of such information than in countries that have regulations that take personal information and security into consideration.

AI technology has the characteristic of black boxing personal information, which has the unpleasant feeling that the content of it has not been fully understood, however, the advantage is that personal information is mixed into as a main information and individuals' information cannot be identified.

According to the results, it is suggested that the development of mobile health and AI is mainly based on the development of machine learning. In the cooperation between mobile health and AI countries, there is a good tendency for countries on different continents to work closely together, which will undoubtedly promote the rapid development of this industry.

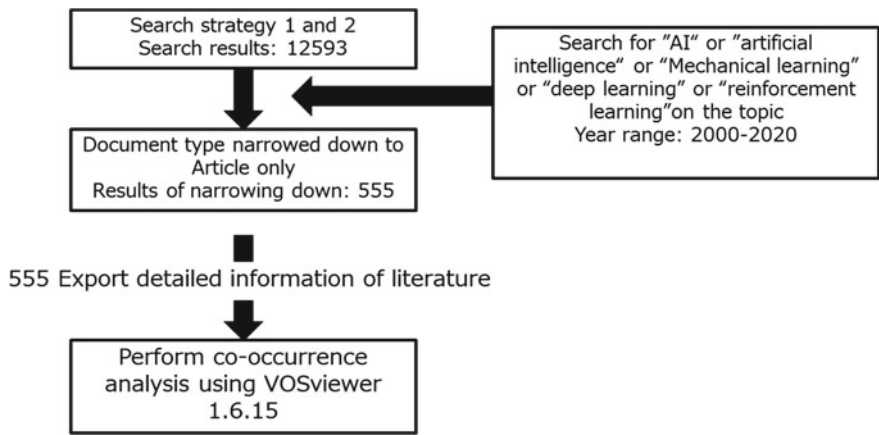


Fig.9 Data collection strategy for bibliometric analysis of the relationship between mHealth and AI

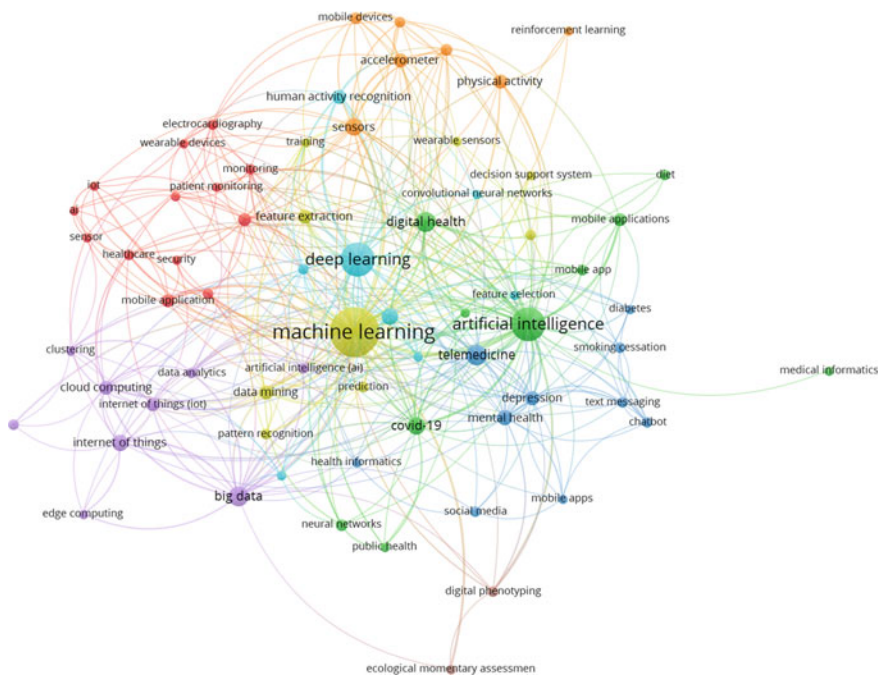


Fig.10 The co-occurrence network of the top 100 Author Keywords 2000–2020

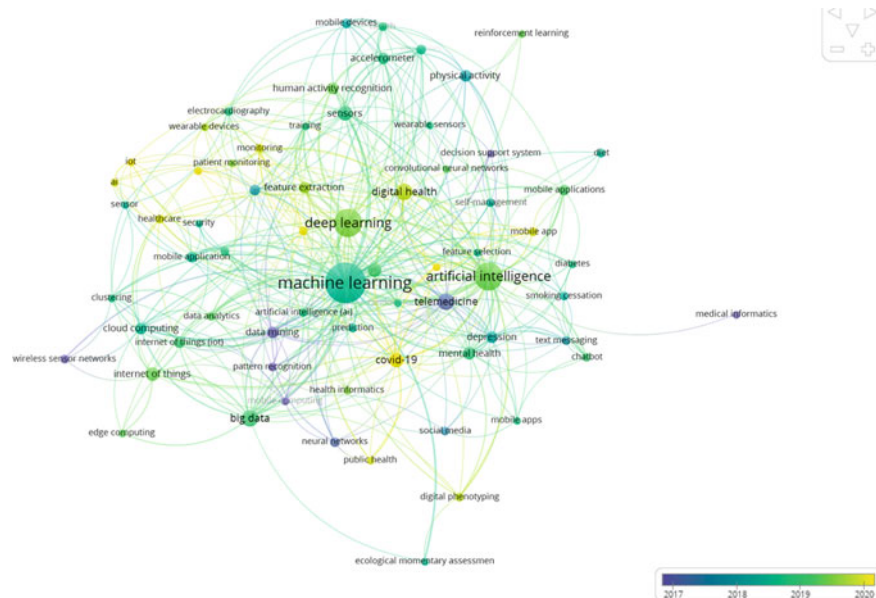


Fig. 11 Keyword co-occurrence network appeared according to Average year 2000–2020

Asian countries such as China are gradually paying attention to this field and are becoming emerging forces in the development of mobile health and AI. This phenomenon is very exciting as Asia has a huge population base and continues to suffer from medical and health problems. This trend is expected to accelerate the rapid development of mobile health to the stage of social implementation. And it is thought to bring new solutions to medical and health problems.

6 Discussion

This chapter provides a bird's-eye view of trends in the development of mHealth and related AI technologies by conducting a bibliometric analysis of literature published in the field of mHealth research. As a result, the tendency of publication of mHealth research papers, cooperation between countries, research hotspots, research trends in this field, etc. was clarified.

The advent of mHealth is a major innovation in the rapid development of information technology. mHealth has avoided location issues and disruptions to medical resources in traditional health care, giving more people access to health care. According to the logical curve of literature growth published between 2000 and 2020, the trend of cumulative publications is similar to the exponential curve (Rogers, 2003). Based on Rogers' theory of innovation dissemination, it can be inferred that the development of mHealth technology is currently in the early stages of rapid growth. Also, the advent of the 5G era will bring endless possibilities to

mHealth. Therefore, it is expected that mHealth technology will continue to attract academic attention and make great progress in the healthcare field.

Comparing this result with a bibliometric analysis of mHealth studies up to 2016, we found that the United States remains the most productive country in this area (Shen et al., 2018). The annual number of papers in the United States continues to show a steady increasing trend. This is followed by the United Kingdom, China, Australia, and Canada, where publication trends are growing rapidly (Fig. 5).

7 Conclusion

The key takeaways from each of the analyses are in the following section. First is the number of publications in the mHealth literature. There is an exponential growth trend in mHealth research since 2004 with an annual growth rate of 35%. The compound annual growth rate is 25%, therefore, it is clear that research in the mHealth field is drawing the attention of scholars in recent years.

The analysis of the number of publications in each country and region. Following the United States, the United Kingdom is the country with a large number of publications in the fields of mHealth. Subsequent countries are Australia, China, and Canada. There is rapid growth in the number of publications in the United States in mHealth research field. Compared to the American researchers, they are experiencing gradual growth with the rest of the countries. Regarding the tendency of cooperation between countries/regions, the four highly productive countries (the USA, the UK, Canada, and Australia) are in close cooperation with each other. On the other hand, clear geographical patterns were seen in other countries/regions. As shown in Fig. 12, the red and green clusters represent the regions of Asia and Europe, respectively. Therefore, it is speculated that international partnerships may be influenced by geographical conditions, regional characteristics, language, international relations, political and economic alliances, and so on. In addition to this, it is clear that all the countries are connected to the United States in the network mapping. Therefore, it signifies that the partnering with the United States is conducted with the top 50 countries in terms of volume of the mHealth field research. The triangular-shaped diagram consists of four countries with the United States placed in the center. Shaping the triangle with the United Kingdom, Canada, and Australia. The whole diagram consists of three main clusters, the red cluster containing Asian countries, the green cluster entailed with European countries (Fig. 13).

Considering the top journals in the mHealth field, the journal with the most publication of mHealth related was JMIR mHealth and uHealth. In the range of top mHealth-related journals, 14% of all publications were published in the Canadian Journal of Medical Internet Research and its sister journals JMIR mHealth and uHealth, JMIR Research Protocols, and JMIR Mental Health. There are widespread journals that publish mHealth-related publications. The top 10 most

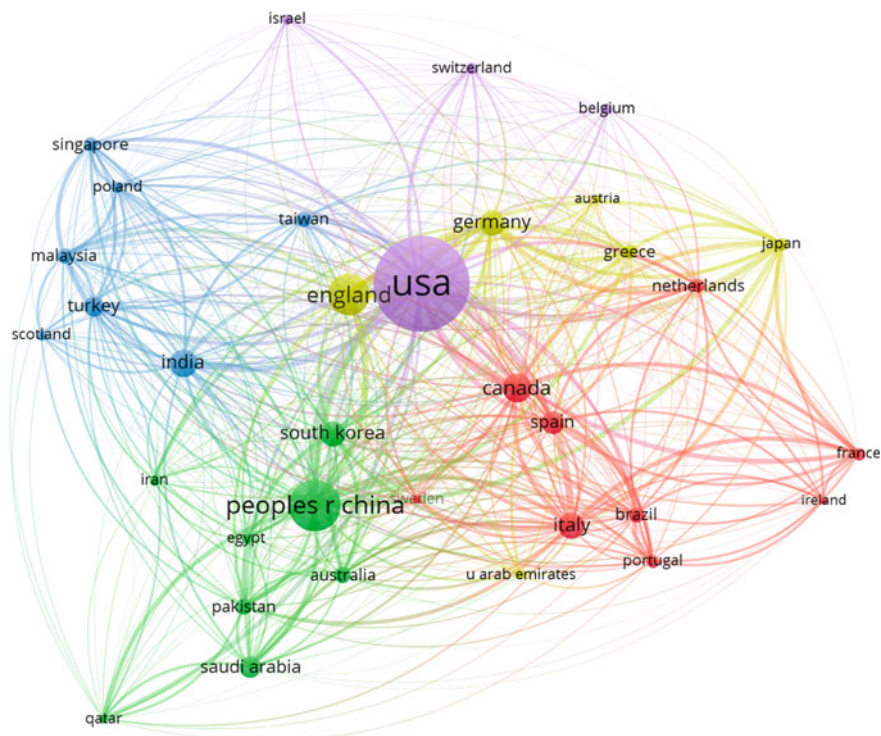


Fig. 12 The co-occurrence network of related countries

publishing mHealth-related journal publications in sum consists of 20.4% in the publication period from 2000 to 2020.

Approaching the author keywords co-occurrence analysis of mHealth publication. While conducting co-occurrence analysis as well as keywords clustering analysis with author keywords have revealed 5 clusters. Within the period of 2000 to 2020, the co-occurring keyword's average year range from 2015.26 to 2017.90. Within this period, the mHealth research field could have formulated its knowledge structure and foundation. The most frequently occurring keyword was mental Health with a number of 449 publications. In addition to this, the top keyword in each cluster is mental health (purple), physical activity (blue), health promotion (green), self-management (red), and HIV (yellow).

The top 15 keywords and the bottom 15 keywords form co-occurrence author keywords of author-provided keywords. The top 15 author keywords' average publication year range is relatively novel compared to the bottom 15 author keywords. On the other hand, the bottom 15 author keywords were used more frequently than the top 15 author keywords with the occurrence number with both maximum and minimum amount. Of the top 15 author-provided keywords, the most keywords consisted of the red cluster with 8 keywords. On contrary, there were 9

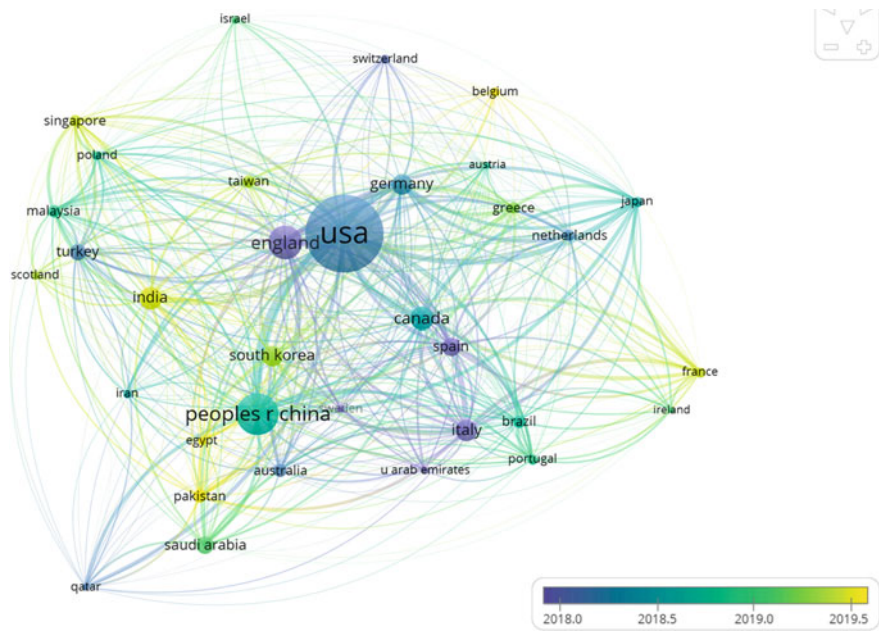


Fig. 13 The co-occurrence network of related countries, average year from 2000–2020

author-provided keywords with a green cluster. Therefore, the red cluster contains relatively higher co-occurrence keywords and on the other hand, the green cluster contains relatively lower co-occurrence keywords.

From the overlay visualization maps of the average publication year of the top 100 author keywords in the mHealth-related publication. From the diagram, there is a shift in the topic of mHealth-related publication from the top of the diagram to the bottom of the diagram while the color changes gradually towards 2018.

The co-occurrence network of the top 100 author provided keywords in the AI-related publications from 2000 to 2020. The top co-occurrence keyword is machine learning, and it is in the center of the co-occurrence network, which implies that the concept of machine learning is holding significance in the AI-related research. The network diagram consists of eight clysters consisting of machine learning and deep learning in the center of the diagram.

Chronological trends of author-provided keyword co-occurrence network appeared according to the average year 2000–2020. The majority of nodes in the network diagram consist of the period before 2019 while centering on machine learning and followed by deep learning and artificial intelligence in the center of the diagram. This could imply that since there is a transformative shift in the AI-related journals from the chronological trends with a network diagram of author-provided keywords co-occurrence.

Chronological Trends of mHealth Publication in countries and Regions. The center of the diagram is the United States, its diagram consists of five clusters.

The greatest number of countries consisting of the red cluster are Canada, Italy, Spain, Netherlands, Brazil, Portugal, Ireland, France, and Sweden. The second largest number contained cluster is the green with Asian countries such as China, South Korea, Australia, Pakistan, Saudi Arabia, Qatar, and Iran. Therefore, the two main research areas of AI-related fields are conducted in the main two clusters consisting of regions.

The co-occurrence network of related countries, average year from 2000 to 2020. There is a transformation shift in the period 2018 to 2019. The United States and England were mainly publishing publications in the year 2018. From the chronological trends with the network diagram, it revealed that there is a new trend of country and regional shift toward Asian countries. India, Pakistan, Singapore, and Taiwan.

This chapter clarifies the latest research trends of mHealth research, research hotspots, and the status of international joint research. As a result, mHealth has shown great potential in all aspects of our lives in recent years, as predicted by previous studies. However, as discussed in this and subsequent chapters, mHealth's development faces challenges such as regulatory policy, the national economy, and personal privacy. Therefore, researchers in this area are encouraged to tackle these challenges to further develop the field of mHealth. We also hope that the results of this book will serve as a valuable guide for future mHealth research.

Acknowledgements We would like to express our gratitude to Ritsumeikan University for providing access to the Web of Science database, which allowed us to access and collect the latest information related to mHealth. We would also like to thank all study participants for their constructive advice and guidance for in this research. This work was supported by the FFJ/Air Liquide Fellowship. The authors gratefully acknowledge the generous support and assistance of the Foundation France-Japon (FFJ) de Ecole des Hautes Etudes en Sciences Sociales (EHESS) and Air Liquide.

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Relationship of Innovation and Regulation on mHealth

Reiko Onodera and Shintaro Sengoku

ABSTRACT

The purpose of this research is to explore the impacts of mHealth on existing health care from the aspect of regulation and innovation. It was investigated through a regulatory transition in the USA. I identified interactive regulators and medical entrepreneurs as potential innovators driving innovative change in mHealth. They have taken on the role of potential innovators after adopting a forward-thinking mindset, allowing innovators to take advantage of new technologies through new regulations and transforming communication between patients and medical doctors. This research provided a deeper understanding of the role of mHealth and clarify the potential factors affecting changes in the healthcare industry.

1 Introduction

1.1 Background of Mobile Health Development

mHealth is a branch of Electronic Health (hereafter eHealth) (Adibi, 2015). The term eHealth is defined as “healthcare practices assisted by communication systems and electronic process.” (Adibi, 2015). The term mHealth is broadly defined as “the use of mobile and wireless devices to improve health outcomes, healthcare services, and health research” (World Health Organization, 2011). The technologies used for mHealth include text messaging, phone call services, mobile tracking

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devices, wearable sensors (which can be used for monitoring and measuring activities), applications (apps), and wireless communications technologies among others. The scope of mHealth extends to acquisitions and transmission of healthcare-related information, telemedicine, electronic record keeping, e-prescribing, and parallel industries such as fitness and wellness (Adibi, 2015). The diffusion of mobile phones and smartphone technologies is making it possible to expand the applicability of mHealth (Perera, 2012). In 2011, US Secretary of Health and Human Services Kathleen Sebelius referred to mHealth as “the biggest technology breakthrough of our time” and maintained that its use would “address our greatest national challenge (Sibelius, 2021).” However, in spite of its significance, very few studies have addressed the dynamics of the mHealth industry from the perspective of innovation management.

In my previous research, I revealed that the current mHealth industry is being shaped, not by incumbents, but by new entrants or start-ups that bring expertise in the field of Information and Communication Technology (ICT) in particular, a minor yet important area of innovation in collaboration with pharmaceutical and medical products companies (Onodera & Sengoku, 2018). I also found significant differences between the characteristics of the companies in the new product development quadrant and the characteristics of the companies in the other two quadrants, market development and diversification of the Ansoff matrix (Onodera & Sengoku, 2018), (Ansoff, 1957). I consider the sharp increase of approvals between 2013 and 2014 to be a turning point in the mHealth market, together with indirect contributions of regulation.

1.2 Innovation in mHealth

Regulations have two sides: one which prevents serious adverse effects to the rights, safety, and lives of citizens (Christensen, 2009; Cooke, 1992), and the other that restricts innovation and causes a chilling effect [9], as well as opportunity loss. The maintenance of an appropriate balance between regulation and industry innovation, and the methods of realizing the purpose of regulations change with the progression of the technology of the age and society. Thus, it is necessary to discuss regulations that reflect the changes in the structure of society and industry (Faulkner, 2009; Kano, 2016; METI, 2021; William et al., 1978). Technological innovation is conventionally seen as outpacing regulation, which usually “lags behind” innovation. There is a need for a new framework to change “Innovation first/regulation after” to “co-development of regulatory arena and novel technology” (Faulkner, 2009; Kano, 2016).

The influence of regulation on corporate innovation is either positive or negative depending on the characteristics of various industries and companies (Dodgson et al., 2008), and on the characteristics of technology (Ashford, 1983). For example, energy technology innovations resulted from policies that stimulate the adoption of widely available, but under-utilized, low-carbon technologies (including both energy efficient and renewable energy technologies and encourage the

development and deployment of new near-term technologies that are close to achieving a market presence (ASE, 1997; Laitner et al., 1998).

In the medical field, as an example of the regulation contributing to the development of the industry, there is the “fast track” program by the FDA for drug approvals. In 1988, the FDA formalized the “fast track” designation, which permitted approval of drugs treating life-threatening or severely debilitating diseases after a single phase 2 study (Darrow et al., 2014). A recent example of a fast-track designation is a vaccine and treatment for COVID-19 (Kesselheim et al., 2020; Mitchel et al., 2021). There was a significant increase of 2.6% per year in the number of expedited review and approval programs granted to each newly approved agent, and a 2.4% increase in the proportion of drugs associated with at least one such program (Kesselheim et al., 2015). Another example is the resolution to disseminate electronic medical records as an economic recovery measure in response to the “Lehman shock,” by the Obama administration (Goldstein & Pewen, 2013). The Obama administration implemented aggressive and expensive plans rooted in the former president’s belief that EHRs are crucial to healthcare modernization and cost containment (Webster, 2010).

1.3 The Objective of This Research

The purpose of this research is to explore the impacts of mHealth on existing health care from the aspect of regulation and innovation. I explore the impact of mobile health-driven innovation in the healthcare system from the perspective of the relationship between innovation and regulation to identify why this situation arose in this research. Along with the emergence of innovation in the regulated industry of medical care, the emergence of mHealth will be examined from various perspectives, focusing on what makes it different from drug and medical device innovations. The relationship between industry innovation and regulation is investigated based on the regulatory transition in the US.

1.4 Theoretical Framework

In this research, I referred to the Paradigm innovation of 4Ps (Product, Process, Position, and Paradigm) of innovation space (Francis & Bessant, 2005) as tools to analyze mHealth innovation and the relationship between the diffusion of innovation in mHealth and regulations. The mixture of the degree of novelty with the 4Ps of innovation resulted in a map of innovation space. Each of their 4Ps of innovation can take place along an axis running from incremental through to radical change; the area indicated by the circle is the potential innovation space within which an organization can operate. We can use the model to look at where the industry currently has innovation, and where it might move in the future. An understanding of mHealth from the perspective of product, process, position, and paradigm is considered to lead to the arrangement of each stakeholder and the understanding

of signs of change and tension. I also consider it a useful perspective to clarify the unique features of mHealth in health care. In this chapter, I focused my research specifically on the paradigm innovation of mHealth.

Paradigm innovation was originally defined as “changes in the underlying mental and business models which frame what the organization does” by Tidd and Bessant (Francis & Bessant, 2005; Joe, 2019; Tidd & Bessant, 2009). This literature advises that paradigm innovation can be triggered by many different sources, from new technologies, the emergence of new markets with different value expectations, and new legal rules of the game, to changes in environmental conditions. It also stated that the point of business model innovation is to explore “how value is created and captured, and by whom” (Joe, 2019).

Rickards (1999) states, “Today the term paradigm” has found its way into the vocabulary of organizational management, in such terms as “paradigm switch” and “paradigm breakthrough.” These expressions are broadly taken to imply that a traditional belief system, the old paradigm, has been replaced by a new way of understanding, a new paradigm” (Rickards, 1999). Thomas Kuhn (1970) introduced the concept of a paradigm shift as a “fundamental change” in the core concepts, values, and practices of a scientific community or discipline (Thomas, 1970). Similarly, paradigm innovation both drives and is informed by a “shift” that may already be happening.

Francis and Bessant (2005) classified paradigm innovation into two types (Francis & Bessant, 2005). One is an inner-directed paradigm, that is, an innovation capability that targets organizational values and people management policies. The other is innovation in outer-directed paradigms (business models), that is, innovations of paradigms related to business models (a system of coherent, comprehensive, explicit and/or implicit constructs used by managers to understand their firm and shape its development). There has been growing attention on how innovation creates and captures value—the so-called “business model innovation” (Casadesus-Gambardella & McGahan, 2010; Masanell & Ricart, 2012; Najmaei, 2013; Tidd & Bessant, 2018; Zott et al., 2011). A business model should be able to link two dimensions of firm activity: value creation and value capture (Tidd & Bessant, 2018). Value creation and capture are linked by what is sometimes called “value delivery” (Casadesus-Masanell & Ricart, 2012). According to Teece (2010), the “business model” defines the way the company creates and delivers value to customers and then captures a portion of this value to make a profit and grow (Teece, 2010). Organizations that pursue this type of innovation develop novel value-creation architectures and original revenue models, more than focusing just on new products or new services.

Tidd (2019) gave these examples of paradigm innovation (Joe, 2019):

- Servitization: the bundling of products and services. For example, AI-connected home automation such as Amazon Echo and Google Home.
- Ownership to rental: for example, music and video streaming platforms such as Spotify, Netflix, and car-sharing clubs.

- Offline to online: internet-enabled substitution of physical encounters with virtual ones. For example, retail shopping and gamification.
- Mass customization, personalization, and co-creation: new technologies and a growing desire for customization enable the creation of not only personalized products and services but also platforms on which users can engage and co-create. For example, from toys (e.g., Lego), to clothing (e.g., Adidas).

I defined paradigm innovation in mHealth as “changes in the underlying mental and business models that frame what the medical system adopts.” Applying paradigm innovation in mHealth can mean influencing the existing business model of the medical system by introducing mHealth. The value of health care provided by each stakeholder varies. For example, physicians provide therapy, hospitals provide medical service, pharmaceutical companies provide medicine for diagnosis and therapy, and medical equipment companies provide medical instruments for diagnosis and therapy. In this research, I examined paradigm innovators in mHealth who improve health care, compared to pharmaceuticals and medical devices, and the impact of mHealth in terms of both inner-directed and outer-directed paradigms in medical systems.

Since the healthcare sector has many stakeholders and complex relationships, there is no clear distinction between inner-directed paradigms and outer-directed paradigms. Rather, these two are interrelated. Based on this premise, I discussed the paradigm of mHealth from two perspectives—inner-directed paradigm and outer-directed paradigm. I defined the inner-directed paradigm as the impact of mHealth on communication between physicians and patients in the healthcare delivery and consumption field, and the outer-directed paradigm as the impact on how mHealth is developed and delivered to patients as a medical service.

With regard to mental models, the original literature of Tidd and Bessant (2009) does not provide a clear definition. The concept of mental models has been explained by theorists in various fields (Kim, 1998), (Rook, 2013). In this study, we used the definition of Senge (1990) of mental models for use in organizational management (Peter, 1990). Senge (1990) describes mental models as assumptions, generalizations, pictures, and images that are deeply rooted in our minds and have the ability to influence how we understand the world and our actions (Peter, 1990). He also states that mental models are important for understanding individual knowledge building and behavior (Peter, 1990). Based on this, I defined the changes in mental models in this study as “How the emergence of mHealth affects medical assumption, and how changes in these assumptions affect the behavior of each stakeholder.”

2 Methods

2.1 Research on Regulations

I investigated regulations related to mHealth in the US using the databases from the FDA, Health IT.gov (the official website of The Office of the National Coordinator for Health Information Technology), and HHS.gov (U.S. Department of Health & Human Service).

3 Results

3.1 Regulatory Transition in the USA

The US government is promoting healthcare ICT to improve the quality of care and reduce costs. These form the core of federal law for healthcare ICT (Health IT.Gov) (Table 1). These laws indicate the need for ICT and information in health care. There is a system of standardization such as Health Level (HL7) for information utilization ahead of ICT adoption. Hospitals and other healthcare provider organizations typically have many different computer systems used for everything, from billing records to patient tracking (Joel, 2010). All these systems should communicate with each other (or “interface”) when they receive new information or when they wish to retrieve information, but not all do so. HL7 and its members provide a framework and related standards for the exchange, integration, sharing, and retrieval of electronic health information. These standards define how information is packaged and communicated from one party to another, setting the language, structure, and data types required for seamless integration between systems. HL7 standards support clinical practice and the management, delivery, and evaluation of health services, and are recognized as the most commonly used in the world (HL 7 international).

As previously mentioned, in 2011, the IMDRF was conceived as a forum to discuss future directions in medical device regulatory harmonization (IMDRF, 2011). FDA was given the approval to forward with regulatory work on medical apps and the FCC approved its MBAN in 2012 (Center for Connected Health Policy). The FDA presented guidance and clarified regulatory targets in 2013 (US Food & Drug Administration, 2013). The IMDRF is a group of 13 or so regulatory bodies that came together to create the “software as a medical device” (SaMD) criteria and framework in 2013. Japan is one of those countries. The IMDRF aims to establish a common and integrated understanding of the principles for clinical evaluation and the demonstration of the safety, efficacy, and performance of SaMD (International Medical Device Regulators Forum).

The FDA launched a Pre-cert pilot program on July 27, 2017, as part of the agency’s Digital Health Innovation Action Plan (US Food and Drug Administration, 2017). The outline of the plan clarifies the provisions of medical software in the Federal Law of 2016 (21st Century Cures) and adds expertise to the digital

Table 1 Core federal law for healthcare ICT in the United States

Year	Name	Summary
1996	The Health Insurance Portability and Accountability Act (HIPAA)	Protects health insurance coverage for workers and their families when they change or lose their jobs, requires the establishment of national standards for electronic healthcare transactions, and requires the establishment of national identifiers for providers, health insurance plans, and employers
2009	The Health Information Technology for Economic and Clinical Health (HITECH) Act	Provides the U.S. Department of Health and Human Services (HHS) with the authority to establish programs to improve healthcare quality, safety, and efficiency through the promotion of health IT, including electronic health records creation, as well as private and secure electronic health information exchange
2010	The Affordable Care Act	Establishes comprehensive healthcare insurance reforms that aim to increase access to health care, improve quality, lower healthcare costs, and provide new consumer protection
2012	Section 618 of the Food and Drug Administration Safety and Innovation Act (FDASIA)	Provides recommendations on an appropriate, risk-based regulatory framework for health IT, including medical mobile applications that promote innovation, protect patient safety, and avoid regulatory duplication. The Health IT Policy Committee formed an FDASIA workgroup and issued recommendations to ONC, FDA, and the FCC
2015	Medicare Access and CHIP Reauthorization Act of 2015 (MACRA)	MACRA is U.S. healthcare legislation that provides a new framework for reimbursing clinicians who successfully demonstrate value over volume in patient care. Under MACRA, the Medicare EHR Incentive Program, commonly referred to as meaningful use, was transitioned to become one of the four components of MIPS, which consolidated multiple, quality programs into a single program to improve care
2016	The 21st Century Cures Act (Cures Act),	Cures Act is designed to help accelerate medical product development and bring new innovations and advances to patients who need them faster and more efficiently

Note Descriptions of selected core federal law for healthcare ICT in the United States. These were signed into law between 1996 and 2012

healthcare sector. The FDA sought to promote digital health innovation while continuing to protect and promote public health by launching a pre-approved pilot program. The pilot participants represented a wide range of digital healthcare companies and technologies, including small startups and large companies, high- and low-risk medical device software products, medical device manufacturers, and software developers (US Food and Drug Administration, 2017). Selected participants are shown in Table 2, and more than 100 companies applied to the program (US Food and Drug Administration, 2017).

The FDA is working to establish a regulatory framework that is equally responsive when issues arise to help ensure consumers continue to have access to safe and effective products. In the Pre-Cert program, the FDA is proposing that software products from pre-certified companies would continue to meet the same safety and effectiveness standard that the agency expects for products that have followed the traditional path to market (Table 2).

The FDA came up with various approaches when they first introduced Proteus Digital Health's ingestible sensor technology. There was no prior category at the FDA for this device. It was innovative. The FDA, on the medical device side, and

Table 2 Company of the software precertification program

Company name	Headquarters	Founded	Categories
Johnson & Johnson	New Brunswick, New Jersey	1886	Health care, Health Diagnostics, and Information Technology
Roche	Basel, Switzerland	1896	Biotechnology, Health Diagnostics, and Pharmaceutical
Samsung Electronics	Seoul, South Korea	1969	Electronics, Hardware, Manufacturing, Mobile, Mobile Devices, and Software
Apple	Cupertino, California	1976	Consumer Electronics, Electronics, Hardware, Mobile Devices, Retail, and Software
Fitbit	San Francisco, California	2007	Cloud Computing, Fitness, Health care, Personal Health, and Wearables
Tidepool	Palo Alto, California	2011	Gamification, Gaming, and Online Games
Pear Therapeutics	Boston, Massachusetts	2013	Biotechnology, mHealth, and Therapeutics
Verily	Mountain View, California	2015	Biotechnology, Data Mining, Health care, Information Technology, and Personal Health
Phosphorus	New York, New York	2016	Biotechnology, Genetics, and Health care

Note Descriptions of selected companies for the software pre-certification program. These pilot participants represent a wide range of companies and technology in the digital health sector, including small startups and large companies, high- and low-risk medical device software products, medical product manufacturers, and software developers. The table was created by the author based on information from the US Food and Drug Administration 2017

the Center for Devices in Radiological (CDRH), under Doctor Gottlieb's leadership at the FDA, work to modernize the approach to approving software. Bakul Patel runs the digital health center of excellence at the FDA and he has done a very good job at bringing software regulation into a more modern context where regulation is lighter and can move at the speed required to have up-to-date products that would run on a patient's mobile phone.

In 2020, FDA launched the Digital Health Center of Excellence within the CDRH (US Food & Drug Administration, 2020). The Digital Health Center of Excellence primarily focuses on helping both internal and external stakeholders achieve their goals of getting high-quality digital health technologies to patients by providing technological advice, coordinating and supporting work being done across the FDA, advancing best practices, and reimagining digital health device oversight. The Center of Excellence for Digital Health participates in Collaborative Communities to build a network of digital health experts to share their knowledge and experience on digital health issues and priorities with FDA staff. The Center of Excellence also initiates strategic initiatives to advance digital health technologies to complement advances in digital health technologies, promotes synergies in regulatory science research in digital health, and facilitates and builds strategic partnerships.

4 Discussion

4.1 Interactive Regulator

Since the healthcare sector has many stakeholders and complex relationships, there is no clear distinction between inner-directed paradigms and outer-directed paradigms. Rather, these two are interrelated. Based on this premise, I examined the paradigm of mHealth from two perspectives—inner-directed paradigm and outer-directed paradigm (Fig. 2). I defined the inner-directed paradigm as the impact of mHealth on communication between physicians and patients in the healthcare delivery and consumption field, and the outer-directed paradigm as the impact on how mHealth is developed and delivered to patients as a medical service.

As an inner-directed paradigm, in the trend of shifting patient care from in-hospital to home, mHealth helps physicians make better decisions and provide effective feedback based on patient data, especially in chronic diseases. Health Level 7 (HL7), an international standard for non-imaging information, enables data exchange between facilities and systems. When I look at the outer-directed paradigm, the occurrence of communication among regulatory authorities, mobile health companies, and pharmaceutical and medical device companies is one feature of the outer-directed paradigm. Particularly, the FDA, as the regulatory authority, is the leader in changing the business model by examining my findings. Commercial barriers in health care are the most critical factors to consider compared to anything else in the industry. On the other side of these barriers, however, are regulations, which are necessary to ensure safety and effectiveness within the health industry.

Assuming paradigm innovation in mHealth, the FDA and medical entrepreneurs are the potential paradigm innovators leading the change.

I define the outer-directed paradigm as the impact on how mHealth is developed and delivered to patients as a medical service. When I look at the business model in terms of how innovation creates and captures value, the FDA, as the regulatory authority, is the leader in changing the business model from examining my findings.

Technological innovation is conventionally seen as outpacing regulation, in other words, regulation usually “lags behind” innovation. This trend is expressed as “Innovation first/regulation after” (Faulkner, 2009). A new framework is needed to change “Innovation first/regulation after” to “co-development of regulatory arena” (Faulkner, 2009; Kano, 2016). Furthermore, it is generally agreed today that regulations ultimately change in reaction to innovators’ success and rarely change to enable disruptive success (Christensen, 2009).

I defined the regulator who led the co-development of the regulatory arena with other stakeholders as an interactive regulator. From examining the findings, the FDA is changing its mental model to promote innovation as an “interactive regulator” in the field of mHealth. In the past, drugs and medical devices were considered to fall under the category of existing drugs or medical devices, requiring a long development period and not requiring any modification of the products after their launch. However, with the advent of mHealth, the FDA changed the approval process by changing its assumptions in anticipation that it would not fall into the category of drug or medical device, and that some modifications to the product after launch would be developed, as with drugs or medical devices, in the short term.

I described the relationship between core federal law for healthcare ICT, regulatory initiatives in the United States, and the number of mHealth products approved by the FDA in Fig. 1. One is a systematic healthcare policy that has been in place since 1996 in the US. The US government developed core federal laws for healthcare ICT between 1996 and 2012. Based on these federal laws, the utilization of ICT in medical care, including EHR, is advancing. The diffusion of mobile phones and smartphone technologies is expanding the possibilities of mHealth. Today, mobile phones and smartphones have become essential components of our lives. Smartphones have been defined as “mobile telephones with computer features that may enable them to interact with computerized systems, send e-mails, and access the web” (Collins 2015). In 2018, the number of mobile phone users was 5.1 billion (McDonald, 2018). In addition, the number of clinical trials using mHealth began increasing after 2010 (Onodera et al., 2016) and the number of clearances for mobile medical apps has been increasing since 2010 and doubled between 2013 and 2014 (Onodera & Sengoku, 2018).

In 2011, the IMDRF started the discussion about SaMD for future directions in medical device regulatory harmonization. The IMDRF captured a trend of ICT, as well as clarified the definition of SaMD and the object of the regulation. The FDA then integrated the SaMD definition and the organization was given approval to go forward with regulatory work on medical apps. In addition to that, in 2012, the

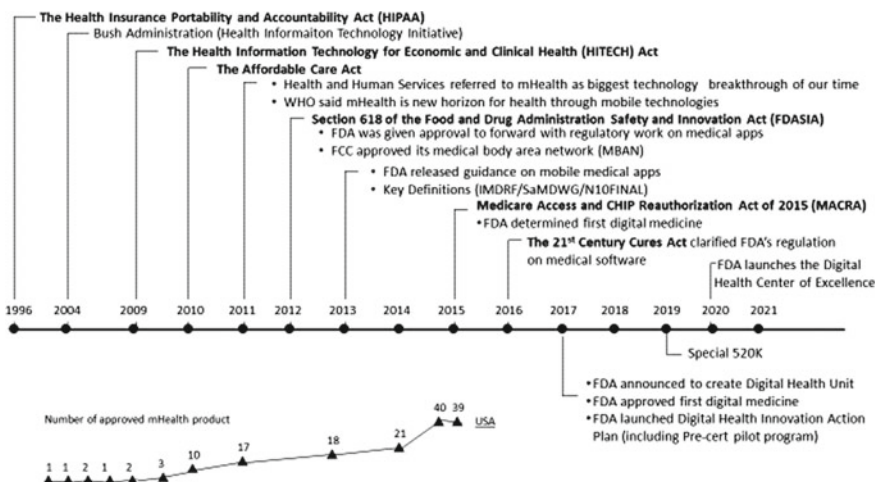


Fig. 1 The relationship between core federal law for healthcare ICT, regulatory initiatives, and the number of mHealth products approved by the FDA in the US. The historical transition of core federal law for healthcare ICT, regulatory initiative in the United States and products approved by FDA from 1997 to 2015 in USA. @@Number of approved mHealth product was based on (Onodera & Sengoku, 2018)

FCC approved its mobile body area network (MBAN). I consider the core federal law to have led to this sequence of events. It is assumed that the FDA captured the ICT trend and predicted the impact of mobile technology in health care based on the US healthcare policy. I believe that these results have contributed to the increase in the number of approvals. It seems that the sharp increase in approvals between 2013 and 2014 became the turning point in the mHealth market.

Furthermore, mHealth has benefitted from pre-cert programs, which now play a vital role. Pre-cert programs aim to streamline the regulatory review process to help encourage the innovation of digital health technologies. The pilot participants represent a wide range of companies and technologies in the digital health sector, including small startups and large companies, high- and low-risk medical device software products, medical product manufacturers, and software developers. It is a case of co-developing regulatory frameworks with small startups, large companies, and regulations. It helps in ensuring that regulation changes to enable disruptive success with innovators. This is a new method to strike a balance between the speed of technological evolution and regulations. The rapid pace of advances in science and technology has important implications for health and medicine. These breakthroughs may come with unintended and unforeseen consequences, with potentially important societal impacts. Policy-makers must work together with other stakeholders, including industry, and academia to promote transparency concerning the use and development of new technologies. According to these results, it is thought that the FDA is an innovator in mHealth.

On the other hand, in Japan, the “Pharmaceutical Affairs Law” was revised to the “Pharmaceuticals and Medical Devices Law” and came into effect in November 2014. In the past, only the software side of the industry was not regulated by the Pharmaceutical Affairs Law. Rather, it was regulated as part of the hardware. However, under the Pharmaceuticals and Medical Devices Law, the software can be distributed as a single unit and is regulated as a “medical device program” (Japan association for the advancement of medical equipment). As of August 2021, the mHealth product in Japan that has been approved as a medical device is “Join” by Allm and “CureApp SC” by Cure App. In 2016, Allm’s service, “Join,” became the first of its kind to be recognized by the Ministry of Health, Welfare, and Labor for coverage within the National Health Insurance. Join is a communication app for medical professionals, designed by doctors for doctors (Allm). In case the ER team needs information fast, Join provides it at the tap of a screen. By enabling connections with PACS (picture archiving and communication systems) and other systems, Join allows professionals to share clinical medical information in order to achieve greater diagnostic precision and better patient care. In 2020, “CureApp SC” was approved and reimbursed as a digital therapeutic for nicotine addiction in Japan. The product consists of three components—a patient app, a doctor app, and a portable CO Checker (CureApp). Details on the patient’s condition obtained from the patient app and the CO Checker will be shared with doctors via the doctor app. The doctor app provides a doctor’s insight into the patient’s response to treatments between checkups.

As rule makers, regulators create regulations and define industry rules; hence, they can play a vital role in paradigm innovations in health care. For example, concerning mHealth, the fact that the FDA and other companies are creating rules to take advantage of new technologies through dialogue is an example of a changing business model (or paradigm innovation). mHealth could be a good opportunity for an “interactive regulator” to take advantage of new technologies. Another paradigm innovation is evident in a new trend where medical entrepreneurs are entering the mHealth sector instead of existing pharmaceutical and medical device companies. These medical-entrepreneurs-led mHealth companies are able to capture data between patients and healthcare professionals that were previously unavailable to major pharmaceutical and medical device manufacturers. However, such data value delivery is not limited to patients and healthcare professionals, it also provides important insights for product development to pharmaceutical and medical device manufacturers. This is a sign of business model changes within healthcare systems.

Figure 2 shows paradigm innovators among stakeholders in the mHealth industry. Stakeholders with orange color are paradigm innovators in mHealth, and the relationships between them, symbolized by red arrows, are important. As an inner-directed paradigm, mHealth helps physicians make better decisions and provide effective feedback based on patient data in the trend of shifting patient care from in-hospital to home, and mHealth company (medical entrepreneur) is a paradigm innovator. In the outer-directed paradigm, the occurrence of communication among regulatory authorities, mobile health companies, and pharmaceutical and medical

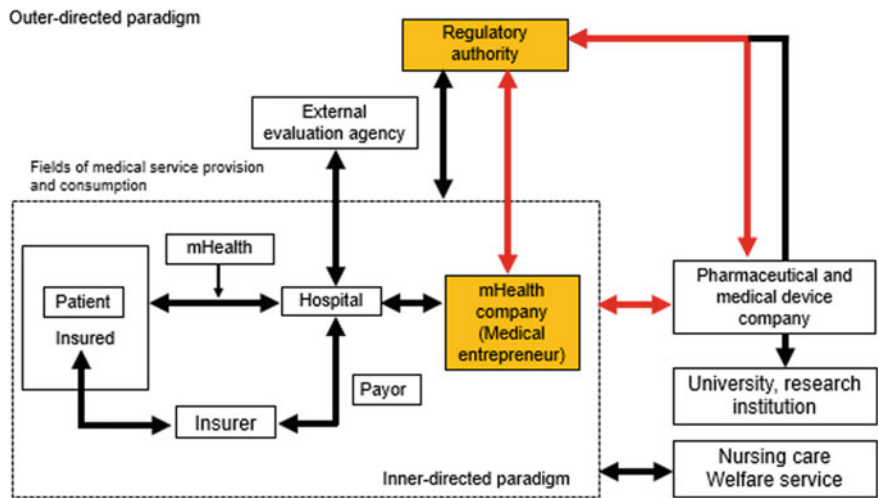


Fig. 2 Potential paradigm innovators in mHealth

device companies is a distinctive point. The FDA is a paradigm innovator leading the change.

4.2 Medical Entrepreneur

The second innovator in mHealth is the medical entrepreneur, a term coined by Hacker (Hacker 2010) for medical doctors that start businesses. In my previous research, Welldoc, Proteus, and GI-Logic, who are developing products classified as radical innovation, are companies founded by medical doctors (Onodera & Sengoku, 2018). These companies, established after 1996, are based in the United States and operate with 18–150 employees. Regarding their common points, apart from the fact that these entrepreneurs are medical doctors that have started mHealth companies, there is nothing common between them in terms of the universities they graduated from or their majors. Although the mHealth industry is still so small that there is no large enough sample size to study, hence I have mentioned only three such samples, it is important to note that new players are entering this market rather than the existing medicines and medical devices sector.

Medical Doctors are said to have great potential as entrepreneurs (Meyers, 2014). I think the reason behind this view is that physicians understand patient’s needs and clinical issues better than anyone else. While the importance of ICT in health care is understood, there are hurdles and barriers to implementing them, and several studies on the difficulty, failures, and challenges of ICT adoption in health care have documented this (Kaplan, 1987; Kaplan & Harris-Salamone, 2009). In the case of electronic health records, the main obstacles reported are costs of deployment, physicians’ low IT literacy, lack of strategic planning for deployment,

and difficulty in recruiting experienced IT personnel (Ford et al., 2009; Anderson, 2007; Ajami & Bagheri-Tadi, 2013). Lack of technical training and support from vendors has also been reported as barriers to physicians' adoption of EMR (Grossman et al., 2007). Because EMR systems were still relatively new to the market at the time of these studies, vendors were not qualified to provide the right services, and concerns arose that they would go out of business and disappear from the market, leading to a lack of technical support and significant losses. In the case of E-Prescribing, barriers to the adoption of technology are said to include previous negative experiences with technology, deployment costs, and changes or increases in the workflow (Halamka et al., 2006). Against this background, it stands to reason those medical entrepreneurs are better positioned to bridge the gap between health care and technology since they understand not only the needs of their patients, but also how they can fit into existing healthcare systems and workflows without increasing their workload.

Consequently, I consider medical entrepreneurs to also represent inner-directed paradigm innovators of mHealth, especially in terms of transforming communication between patients and medical doctors. For instance, since medical doctors capture patients' needs and create value through mHealth, medical entrepreneurs have the potential of being interpreters and filling the gap between patients, other medical doctors, and engineers. They can do this by using insight from their activities as doctors to gain understanding, and communicate this information to the company's engineers. Therefore, these doctors can guarantee the accuracy of products based on their medical expertise and can develop ways to support treatment based on their clinical experiences.

From examining the findings from my research, there are three reasons for this. The first is that investment in digital health in the United States is increasing year by year (Day, 2019; Rockhealth, 2022). In 2021, U.S. digital health startups raised a total of \$29.1 billion in 729 deals, with an average deal size of \$39.9 million. Overall investment nearly doubled the former record of \$149B in 2020 (Rockhealth, 2022). The ICT side of the medical arena has drawn a lot of attention and new entrants because it is a new field. This is because new fields are inherently exciting since they do not have established and dominating incumbents and because of the opportunities they present in terms of innovation and the potential to create something great.

The second is that the US has a good entrepreneurial environment. The Wharton School of the University of Pennsylvania and BAV Group, a unit of global marketing communications company VMLY&R have shown that, through their survey conducted on 80 countries around the world, the U.S. startup environment ranks third after Germany and Japan in 2021 (U.S. News, 2021). This survey considered 9 things: "adventure," "citizenship," "cultural influence," "entrepreneurial spirit," "an inheritance that is inherited," "influential persons," "openness of business," "power," "quality of life," and attributes that are relevant to entrepreneurs.

The third reason is the value of the data collected by mHealth. mHealth is a new modality of therapy following small molecules, biologics, and cell/gene therapies. A mHealth-powered solution can accurately convey data entered by a

patient directly to the doctor. Data can be digitized and stored so that they can be stratified and divided into subgroups, potentially leading to precision medicine. Today, the utilization of digitized data in medical treatment attracts much attention. mHealth is a data entry point and is expected to provide new value in prevention, treatment, and disease management. As the number of stakeholders increases and the need for common rules across countries is anticipated, the findings of mHealth will become important.

4.3 Current Challenges and Future Perspective

Based on a survey of eight physicians in Japan, changes in the mental model of physicians due to mHealth were examined (data not shown). Although mHealth has not been introduced in clinical practice in Japan at present, many physicians responded that they would not hesitate to use mHealth if it is effective and safe, and would employ mHealth, as well as drugs and medical devices, if it were good to do so. In the clinical field, new drugs and medical devices are released daily and it is gradually becoming a matter of course to introduce new drugs and medical devices. Therefore, it was suggested that at this point, mHealth is considered similar to the release of new drugs and medical devices. Since the ultimate goal of drugs and medical devices is to improve patients' lives and treatment experiences, mHealth has a similar purpose. As for its impact on medical care, many respondents said that mHealth is only a support tool for communication between physicians and patients since face-to-face consultation with patients is necessary for medical care. Given this, mHealth is not likely to change the mental model of physicians at this point.

As for changes in patients' mental models, since it was out of the scope of this study, I could not observe changes in patients' perceptions and attitudes about mHealth. However, based on the results of my empirical studies and interviews, mHealth has the potential to strengthen patients' sense of ownership in health care. It is said that although patients are the primary providers of treatment, there is a high tendency for patients to fail to accurately grasp their own symptoms or to leave the treatment to doctors. In this context, mHealth may change the patient's own involvement in treatment by giving them a sense of sharing treatment responsibilities with the physician.

Regulation is also expected to implement various initiatives based on the health-care challenges of each country. Germany enacted a new law called the DVG ("Digitale Versorgung Gesetz"/"digital healthcare act") in 2019. DVG means that around 73 million insured persons in statutory health insurance are now entitled to care involving digital health applications (DiGAs). After digital health apps become approved, they can be prescribed by doctors and psychotherapists and reimbursed by the health insurance company (Naujokaite, 2020; Federal Ministry of Health; Gerke, 2020). In addition, online consultations and electronic prescriptions are being introduced into use, and the use of health data for telemedicine and research purposes is also being promoted (Gerke, 2020).

There is also a need to discuss the data collected through mHealth in the face of growing expectations about the use of data in health care. mHealth companies are able to capture data between patients and healthcare professionals that were previously unavailable to major pharmaceutical and medical device manufacturers. Because of mHealth, data can now be digitized, stored, and then stratified and divided into subgroups, potentially leading to precision medicine. Data captured without time and space constraints, and generated by combining existing medical and mHealth data, will create new value.

Tech giants such as Google, Amazon.com, Facebook, and Apple have been rapidly increasing their presence in health care in recent years. The number of healthcare-related patents filed by these four companies from 2009 to 2017 has been led by Microsoft, with 140 patents, followed by Apple and Google with 40 patents (CB Insights, 2017). Microsoft holds patents for collecting and analyzing electronic medical record data, then sending automatic alerts regarding medication interactions, in addition to patents for predicting disease risks from genomic information (CB Insights, 2017). Apple has published a Research Kit that has increased the usage of iPhones in research (The Verge, 2015), while Google is trying to predict disease risks from unstructured healthcare big data (Harvard business school, 2018). Furthermore, Amazon.com announced in June 2018 that it would acquire the online pharmaceutical seller PillPack (CNBC, 2018). PillPack was founded in the U.S. in 2013. It is a prescription drug delivery service that also provides usage instructions and has a growing number of customers, particularly within the elderly demographic, with over 23 million U.S. customers. With Amazon's acquisitions of PillPack and the launch of its healthcare JV with Berkshire Hathaway and JP Morgan, Amazon was expected to accelerate its entry in to the healthcare industry.

With societal changes and technological changes in medical care, companies entering the field are also changing, and the pace of change is accelerating. For example, Google, Amazon.com, Facebook, and Apple now have wearable devices, smart speakers, and similar products, differing significantly from existing players in the healthcare field given their potential to improve the user experience. Companies newly entering the healthcare field through the progress of these kinds of ICT and the emergence of new platforms are building complementary relationships with various players along the medical value chain.

I consider the possibility that they will eventually gain platform leadership in promoting the evolution of the entire value chain with data. In the healthcare field, the utilization of data, especially personal data, is promising (World Economic Forum, 2019). The use of data in health care has the potential to improve decision-making and address inefficiencies in the healthcare ecosystem. IoT can enable continuous monitoring, irrespective of the presence of healthcare professionals, and even alert them when necessary. Diagnosis, monitoring, and treatment can occur regardless of patient location, enabled by IoT. As the amount of data available through wearable devices and sensor technology increases, pharmaceutical and medical device companies may own drugs and pharmaceutical products, but other companies may own the surrounding information. It is expected that the

time will come when there will be a difference between the owner of the object and the value of the information.

5 Limitations

Although this study focused on the US as the largest mHealth market, observations in other regions are needed, considering that the mHealth market is growing worldwide, and comparisons between the characteristics and environments of each country should be made. For future studies, it would be advantageous to interview more people with diverse jobs including medical entrepreneurs, regulators, payers, and patients, especially to analyze changes in mental models. There is also a need to discuss the data collected by mHealth in the face of growing expectations for the use of data in health care.

6 Conclusion

The previous research examined and addressed the impact of mHealth on the medical industry from the paradigm innovation perspective. I focused on the relationship between regulation and mHealth innovation.

I identified interactive regulators and medical entrepreneurs as potential innovators driving innovative change in mHealth. With regard to regulators, it is generally agreed today that technological innovation is conventionally seen as outpacing regulation. In contrast, the FDA, in the mHealth field, has taken on the role of an “interactive regulator” after adopting a forward-thinking mindset, allowing innovators to take advantage of new technologies through new regulations. In terms of medical entrepreneurs, it has become evident that some medical practitioners are now venturing into the mHealth market, starting their own mHealth companies, instead of joining existing pharmaceutical and medical device companies. A medical entrepreneur has the potential of being a data interpreter, filling the gap between patients, other medical doctors, and engineers. They do this by carefully using their activities as doctors as insight and feeding this data into their mHealth companies and engineers, thereby, guaranteeing the accuracy of products based on their medical expertise. As an overview, rule makers are interactive in driving innovation, and newcomers to healthcare value information through mHealth. Understanding the impact of mHealth on health care is important in predicting future changes in the healthcare industry.

This study presents important knowledge for considering future medical care scenarios with an understanding of the evolution of the marketplace brought about by the introduction of mHealth. Rather than a focus on technology as simply a new modality, it is instead the data created and outcomes achieved by mHealth that will define its value to the medical field and change the way it is evaluated. In each of these scenarios, the significance and meaning of mHealth should be defined as an important factor.

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The Current Situation of Mobile Health in China from the Perspective of Policy, Application, User Acceptance: A Multi-Method Systematic Analysis

Jianfei Cao and Xitong Guo

ABSTRACT

As the most populous country globally, China has continuously faced the challenge of having insufficient medical resources, however, with the rising popularity of smartphones in China, a new medical model based on Internet technology and mobile devices has emerged. Mobile health is valued in China because of its ability to provide users with services anytime and anywhere, remotely detect user health information, and provide personalized health solutions. However, the development of mobile health in China is still in its early stages. This chapter analyzes mobile health development in China from multiple perspectives, including China's mobile health regulations, national policies, social applications of mobile health, and user acceptance. This chapter aims to investigate and clarify the problems encountered in the development of mobile health in China. Finally, we discuss the future of mobile health in China and propose solutions through a multi-method analysis.

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1 Introduction

1.1 The Burden of Disease and the Current State of Health care in China

As the country with the largest population in the world, health care is an essential aspect of China's development. According to the statistical bulletin on the development of health care in China, the total cost of health care in China reached 7,230.64 billion yuan in 2020, representing 7.12% of the country's GDP (). Despite this level of spending, China still bears a huge healthcare burden. As China continues to develop economically and socially, and healthcare standards continue to improve, life expectancy per capita continues to increase. This has led to the aging of the Chinese population, with the population aged 60 and over reaching 264 million, accounting for 18.70% of the total population according to the seventh national census (Chinese Government Website, 2021). In addition to the problems presented by an aging population, China also continues to suffer from the impact of chronic diseases. In 2019, China was reported that chronic diseases caused 88.5% of all deaths (The State Council Information Office of the People's Republic of China, 2020). This percentage will likely increase as life expectancy continues to increase and the survival period of patients with chronic diseases continues to lengthen (The State Council Information Office of the People's Republic of China, 2020). In the face of such a huge demand for health care, the current imbalance between the supply of and demand for medical staff is problematic. Currently, the number of physicians (or physician assistants) and registered nurses per 1,000 people in China is only 2.90 and 3.34, respectively, placing a heavy workload on these health practitioners and affecting the efficiency of medical services received by patients.

1.2 Healthcare Reform in China

With the growth of the global population over recent years, many countries around the world have committed to meeting the growing demand for health care. However, circumstances in various nations often limit the financial resources that can be allocated to health care. Therefore, the rational and efficient use of limited health resources to maximize benefit is a key concern for national health systems.

In the early stages of the development of China's health system (1950–1978), Zhou sought to establish a low-cost and high-coverage public healthcare system to meet the basic health needs of the Chinese people through government investment and unified planning. However, lack of competition and insufficient government funding has limited the development of health care (Zhou et al., 2017). Since China's gradual transition to a socialist market economy in 1978, the government has gradually reduced spending to promote the marketization of health care. A free market incentive health system was introduced in 1984 to control healthcare resources through market allocation. Policies were also relaxed to allow for the

establishment of private for-profit hospitals and the privatization of public hospitals in order to compensate for a lack of government funding (Chai et al., 2020; Daemmrich, 2013; Ryan, 2010; Zhou et al., 2017). However, excessive market competition has led to a gradual weakening of public interest in health care, and the relaxation of policies regulating the price of healthcare services has led to rising drug prices, over-care, and over-prescription. This has led to a rapid increase in the cost of medical care for patients and a widening gap between the levels of care provided in urban and rural settings (Zhou et al., 2017; Chai et al., 2020; Blumenthal & Hsiao, 2015). Despite the introduction of new rural cooperative medical care in 2003, the expansion of financial coverage, and the increase in medical subsidies, there are still problems, such as the rapid increase in medical costs and the wide gap between urban and rural medical standards, and Chinese people have had a strong reaction to this problem (Zhou et al., 2017; Chai et al., 2020). To solve it, China announced a plan to deepen the reform of its healthcare system in 2009, with the government planning to fund 850 billion RMB in the first three years of the plan to carry out key reforms in five areas: the public health service system, the healthcare service system, the healthcare guarantee system, the drug supply guarantee system, and the management and operation system of healthcare institutions. The aim of this reform was to establish a basic health care system for all, covering both urban and rural residents by 2020 (Chinese Government Website¹, 2009; Chinese Government Website², 2009).

In recent years, China has significantly increased government financing for healthcare reform, especially for low-income groups and regions, to provide more subsidies to achieve social equity. However, there are still some limitations. In particular, in terms of healthcare resource allocation, wealthier regions have larger general hospitals with more advanced medical equipment and better trained staff due to the huge disparity in financial capacity between regions. As a result, patients travel across regions to such hospitals in search of high cure rates, even at the cost of time and money (Fan, 2016). This situation not only further exacerbates the existing problems regarding accessibility and costs (Hu & Zhang, 2015; Anand et al., 2008), but also increases the risk of delayed access, leading to adverse outcomes (Wang et al., 2008; Yang et al., 2020).

1.3 Mobile Health

Against this social backdrop, there is a growing demand for mobile health care, also known as “mHealth” in China. mHealth is defined as “medical and public health practices supported by mobile devices such as mobile phones, patient monitoring devices, personal digital assistants, and other wireless devices” (World Health Organization, 2011). There exists a great deal of research confirming the benefits of mHealth in health care. For example, studies on the use of mHealth by older people have shown that mHealth apps help motivate older people to improve their ability to complete daily activities (Knight et al., 2014; Martin et al., 2018; Müller et al., 2016), facilitate faster access to healthcare services (Klimova

et al., 2016), and reduce the potential cost of treatment and care for older people (Maresova & Klimova, 2015). In addition, mHealth continues to receive attention from researchers as an effective intervention for the treatment of chronic diseases (Cao et al., 2021a, b; Peng et al., 2020). Numerous studies have demonstrated that mHealth technology can contribute to better monitoring and management of patients with chronic diseases, such as diabetes and hypertension (Petrella et al., 2014; Yang et al., 2019; Bertonecello et al., 2020; Wang et al., 2019). It has also been shown to have a positive impact on reducing the burden on hospitals and improving patient access to healthcare services (Tu et al., 2018). The demonstrated benefits of mHealth in all aspects of health care make it a key technology that is expected to improve the state of health care in China.

1.4 Objective

The purpose of this study is to systematically analyze the current state of mHealth in China through the lens of policy, application, and user willingness to use and provide valuable suggestions for the proper development of mHealth in China in the future. Although there are several systematic reviews of mHealth in China, most focus on a single perspective. For example, Zhang provided an analysis of policy perspectives on the mHealth market in China (Zhang et al., 2017), and Wang provided a comprehensive evaluation of mHealth technology intervention aspects for the long-term health management of chronic diseases (Sweileh et al., 2017). However, few studies have combined multiple perspectives to provide a comprehensive review. There are two advantages to such an integrated review. The first advantage is that the analysis of different perspectives allows for a clearer view of the links between the different aspects of mHealth development in China, thus providing a more comprehensive picture of the current situation. The second advantage is that this multi-perspective analysis can provide more comprehensive recommendations for the development of mHealth in China.

2 Method

2.1 Data Collection

To gather data on mHealth-related policies, we reviewed key government policies and national industry plans related to the mHealth industry that were published following China's 2009 plan to extend its healthcare system reform.

We also reviewed published articles related to mHealth in China using the Web of Science core database. To narrow our focus to the current state of mHealth, we selected articles published in English between January 1, 2016, and August 31, 2021. We used a multi-step approach to further select articles. First, we collected all articles related to mHealth using two search strategies (strategy 1 and strategy

2). The rationale for using two search strategies has been described in detail in previous articles (Cao et al., 2021a, b; Sweileh et al., 2017). The first strategy yielded 6,524 articles, and the second yielded 5,735 articles. After aggregating the two sets of results and removing 1,118 duplicate items, we were left with 11,141 articles. In the second step, we searched for the keyword “China” within the 11,141 articles, yielding 933 articles related to mHealth in China. In the third step, we searched the 933 articles for studies related to technology adoption in health care (strategy 3) and studies related to technology acceptance (strategy 4) using the Boolean operator “AND.” This resulted in 548 articles related to mHealth applications in China and 78 articles related to mHealth technology acceptance in China. In step 4, the results from step 3 were examined individually by a researcher specialized in the field of mHealth to filter the search results. For studies related to mHealth applications, articles that met one of the following criteria were excluded: (1) not focused on China, (2) not related to mHealth, and (3) not related to mHealth technology applications. For the studies related to mHealth technology acceptance, articles were excluded if they were (1) not focused on China, (2) not related to mHealth, and (3) not related to mHealth users’ willingness to use mHealth technology. Further, only articles that used structural equation modeling (SEM) for model analysis were selected, for statistical ease. As a result, 312 articles on mHealth applications and 26 articles on mHealth technology acceptance were obtained. The data collection process is illustrated in Fig. 1.

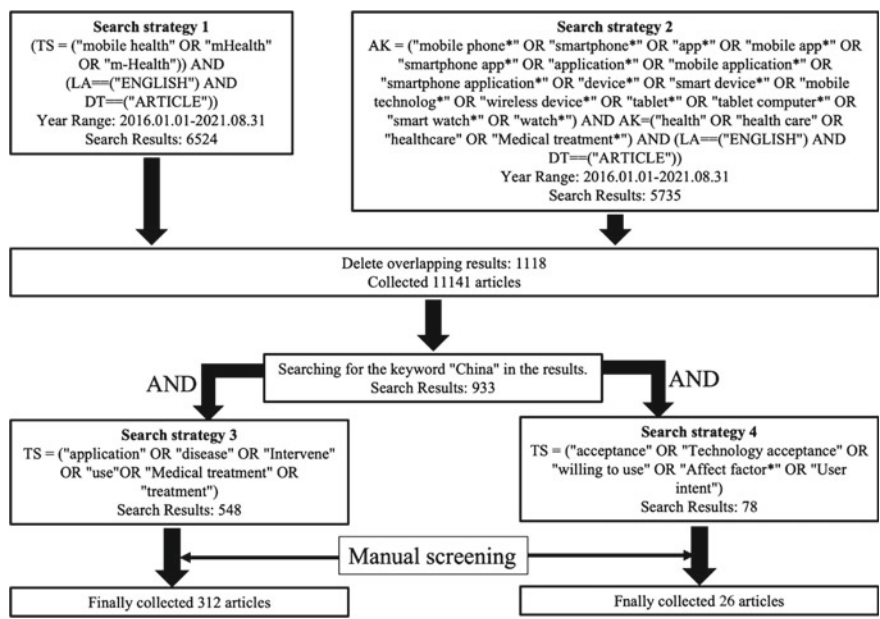


Fig. 1 Data collection process

2.2 Data Analysis

For the policy analysis, a researcher specializing in the field of mHealth conducted a systematic review of the healthcare-related policies introduced in China and extracted the mHealth-related content. The policy context and status of mHealth in China were analyzed by examining the development of policies in different years.

For the application analysis, a co-occurrence analysis of author keywords provided by 312 articles on mHealth applications in China was conducted using the VOSviewer literature analysis tool. The minimum number of keyword co-occurrences was set to five. The keywords used as search strategies were removed from the co-occurrence analysis results. Keywords were categorized according to the purpose of use, mode of use, and target population to identify specific applications of mHealth in China.

In terms of user acceptance, after extracting and analyzing the information from each article, we conducted a meta-analysis of the selected articles. First, we calculated descriptive statistics regarding the articles' titles, journals of publication, publication dates, research objects, and sample sizes. Subsequently, we summarized the theoretical models referenced in these articles and the factors used in the models. Finally, by determining the path coefficients between the factors, and all paths showing significant relationships were counted.

3 Results

3.1 Summary Analysis of China's mHealth Policies

Table 1 provides a summary of China's healthcare policies and the key elements within them that are relevant to mHealth. The summary of the policies related to mHealth that have been announced since the announcement of reform in 2009 shows that healthcare informatization is a key policy focus. The plan for reform focused on five areas: the public health service system, medical service system, medical security system, drug supply security system, and management and operation system of medical and health institutions. The uneven allocation of medical resources is one of the main problems affecting the development of health care in China, thus, initial reforms focused on the establishment of electronic health records and the improvement of the telemedicine systems. However, in the early days of the reform, telemedicine services were very dependent on medical institutions. In China, telemedicine services are clearly defined as medical activities in which one medical institution invites other medical institutions to provide technical support for the treatment of patients in the inviting medical institution by using communication, computer, and information technologies. With the rapid development of Internet technology in China, the content of telemedicine services has been continuously enriched and improved, moving gradually from offline to online. The development of Internet technology has also contributed to the advancement of various medical services, including appointment triage, payment, and the checking of

results. With the rapid spread of smartphones in China, smartphone-based mobile healthcare has become an important complement to the “Internet + healthcare.”

A systematic review of policies related to mHealth services reveals that the government supports the development of mHealth services. It is also actively encouraging third parties outside of medical institutions and patients to join the field and develop innovative healthcare businesses. mHealth services now support a variety of healthcare businesses through appointment booking, online consultation, online prescription writing, online service management, health information inquiry solutions, medical personnel training, online drug purchasing, online payment, and health knowledge popularization. Internet-based mobile medical services are also gradually being standardized, and the prices of “Internet +” medical services are now managed by a unified policy system. Moreover, mHealth services are included in the same scope of medical insurance as traditional medical services.

Overall, government policies have had a positive impact on the development of mHealth in China in order to alleviate the social tensions caused by the uneven development of health care. This has contributed to the rapid development of China’s mHealth market.

3.2 Current Status of Mobile Health Applications in China

Through keyword co-occurrence analysis of the titles and abstracts of 312 articles related to mobile health applications in China, we obtained 113 high-frequency keywords. Of these, 27 keywords that were used as part of the search strategies were omitted on the grounds that they occurred more frequently due to the search strategy and that there were a large number of keywords with similar meanings (e.g., mHealth and mobile health, app, and smartphone app). Removing these keywords allowed the results to be more focused on valuable research topics. The final number of keywords obtained was 86.

The keywords were extracted according to the purpose of mHealth use, the way they were used, and the people who used them. As shown in Table 2, 21 keywords were extracted based on the purpose of use, which can be broadly classified into four main purposes of use: (1) use of mHealth in daily life (keywords: physical activity, quality of life, knowledge, and health care), (2) mHealth use for various diseases, especially chronic diseases (keywords: disease, chronic disease, hypertension, type 2 diabetes, etc.), (3) use of mHealth in mental health (keywords: depression, mental health, and anxiety), (4) mHealth use for specific populations (keywords: smoking cessation and pregnancy). The use of mHealth for physical activity was the most frequent, appearing 27 times. The average publication year range for such keywords was 2018.3–2020.5.

As shown in Table 3, nine types of mHealth use emerged, including self-management, intervention, prevention, secondary prevention, diagnosis, education, treatment, care, and recovery. Various stages of healthcare delivery were also covered. Self-management was the most frequently occurring keyword, appearing 26 times. The average publication year range for such keywords was 2018.5 – 2020.5.

Table 1 Summary of mHealth-related policies in China, 2009–2020

Date	Policy	Relevant content	Source
April 2009	Opinions on deepening the reform of the medical and health system	Medical and health science and technology innovation as the focus of national science and technology development; build rural and community health information network platform; promote hospital information construction; use network information technology to promote cooperation between urban hospitals and community health services; actively develop telemedicine for rural and remote areas	Chinese Government Website ¹ (2009)
April 2011	Guidelines for the construction of an integrated health management information platform (for trial implementation)	Build a comprehensive health management information platform; make construction requirements in terms of the platform's business requirements, data standard system, system architecture, technical architecture, and security system design	Chinese Government Website (2011)

(continued)

Table 1 (continued)

Date	Policy	Relevant content	Source
June 2012	Guiding opinions on strengthening the construction of health information	Build two basic databases and a business network, such as electronic health records and electronic medical records of residents; strengthen the construction of a health information security guarantee system and implement the national information security level protection system; improve the construction of an information security system involving residents' privacy, such as electronic health records and electronic medical records of residents, and implement the simultaneous development of information sharing and privacy protection	National Health Commission of the People's Republic of China (2012)
June 2012	Opinions on the pilot comprehensive reform of county-level public hospitals	Develop remote diagnosis and treatment system for rural grassroots and remote areas; gradually implement remote consultation, remote (pathology) diagnosis, remote education, etc.; build medical health information network	Chinese Government Website ¹ (2012)
October 2012	The Twelfth Five-Year Plan for the Development of Health Services	Build telemedicine systems for tertiary hospitals and county hospitals; actively promote the construction of a regional unified reservation platform, and implement the sharing of electronic medical records across regional medical institutions	Chinese Government Website ² (2012)

(continued)

Table 1 (continued)

Date	Policy	Relevant content	Source
August 2014	Opinions on the promotion of telemedicine services in medical institutions	Incorporate the construction of a telemedicine service system into regional health planning and medical institution setting planning; clarify the content of telemedicine services; improve the process of telemedicine services	Chinese Government Website (2014)
March 2015	National Medical and Health Service System Planning Outline (2015–2020)	Carrying out the Health China Cloud Service Plan, actively applying new technologies such as mobile Internet, Internet of Things, cloud computing, wearable devices, etc.; promoting health information services and smart medical services that benefit all people; promoting the development of remote services and mobile medical care, gradually enriching and improving service contents and methods	Chinese Government Website (2015)

(continued)

Table 1 (continued)

Date	Policy	Relevant content	Source
June 2016	Guiding Opinions on Promoting and Regulating the Application and Development of Big Data in Health and Medical Care	Actively encourage social forces to innovate and develop health care business, and promote the deep integration of health care business and big data technology; develop and promote digital healthcare intelligent equipment; encourage social forces to participate, integrate online and offline resources, standardize the management of medical Internet of things and healthcare applications (APP), and vigorously promote Internet health consultation, online appointment triage, mobile payment, examination, and test results query, and the application of follow up tracking; comprehensive establishment of telemedicine application system; promote healthcare education and training applications; strengthen healthcare data security; implement the national healthcare information technology talent development plan	Chinese Government Website (2016)

(continued)

Table 1 (continued)

Date	Policy	Relevant content	Source
December 2016	“Thirteenth Five-Year” Sanitation and Health Plan	Develop health services for the elderly, promote appropriate technology based on chronic disease management, Chinese medicine, and elderly nutrition and exercise intervention; fully implement the “Internet + healthcare services for people; promote cloud computing, big data, Internet of things, mobile Internet, virtual reality, and other information technology and health services deep integration; encourage the establishment of regional telemedicine business platform, telemedicine services cover more than 50% of the counties (districts, cities)	Chinese Government Website ¹ (2017)
February 2017	“Thirteenth Five-Year” National Population Health Information Development Plan	Build a new model of “Internet + health care” services; promote the clinical and scientific research applications of health care data; strengthen the application of population health information technology and big data risk warning and decision-making; improve the construction of information security systems involving residents’ privacy	Chinese Government Website ² (2017)

(continued)

Table 1 (continued)

Date	Policy	Relevant content	Source
April 2018	Opinions on Promoting the Development of “Internet + Medical Health”	Encourage medical institutions to apply the Internet and other information technology to expand the space and content of medical services; allow the development of Internet hospitals based on medical institutions; support medical, health institutions, and qualified third-party institutions to build Internet information platforms; encourage higher level medical institutions within medical complexes to provide remote consultation, remote electrocardiographic diagnosis, remote image diagnosis and other services for the grassroots with the help of artificial intelligence and other technical means; encourage medical and health institutions and Internet enterprises to cooperate; optimize the “Internet + “ family doctor contracting services, encourage the development of online contracting services for contracted residents to provide online health consultation, appointment referral, chronic disease follow-up, health management, extended prescription services; Internet medical health service platform and other third-party institutions should ensure that the provision of services from third-party organizations (e.g., Internet medical and health service platforms) come from qualified personnel and take responsibility for the services provided	Chinese Government Website (2018)

(continued)

Table 1 (continued)

Date	Policy	Relevant content	Source
July 2018	Internet diagnosis and treatment management measures (for trial implementation); Internet hospital management measures (for trial implementation); telemedicine service management regulations (for trial implementation)	Provides detailed requirements to further regulate the behavior of Internet diagnosis and treatment	National Administration of Traditional Chinese Medicine (2018)
August 2019	Guiding Opinions on Improving “Internet + “ Medical Service Prices and Medical Insurance Payment Policies	Incorporate Internet + medical service prices into the existing unified policy system of medical service prices; According to the principle of fairness online and offline, supporting the medical insurance payment policy for qualified “Internet + “ medical services	National Healthcare Security Administration (2019)
March 2020	Guiding Opinions on Promoting the Development of “Internet + “ Medical Insurance Services During the Period of Prevention and Control of the New Coronary Pneumonia Epidemic	Common diseases, chronic diseases, “Internet + “ follow-up services can be included in the scope of payment of health insurance funds; “Internet + “ medical services, online prescriptions, and drug costs to meet the provisions of the online medical insurance settlement; strengthen the Internet medical insurance services related to data network security work to prevent data leakage	Chinese Government Website (2020a, b)

Table 2 Twenty-one keywords extracted from Chinese mHealth applications based on the purpose of use

Keywords	Frequency of occurrence	Average publication year
Physical-activity	27	2018.8
Disease	19	2018.7
Medication adherence	17	2018.7
COVID-19	15	2020.5
Depression	15	2019.7
Chronic disease	10	2019.3
Hypertension	10	2019.9
Type 2 diabetes	10	2019.3
Cardiovascular-disease	9	2019.2
Quality-of-life	9	2018.3
Knowledge	8	2019.4
Stroke	8	2019.3
Health care	7	2019.4286
Mental health	7	2019.5714
Smoking cessation	7	2018.8333
Anxiety	6	2019.8333
Atrial fibrillation	6	2019.1667
Diabetes	6	2019
HIV	6	2019.3333
Pregnancy	6	2019.6667
Coronary heart disease	5	2019.8

Table 3 Nine keywords extracted from Chinese mobile healthcare applications based on usage patterns

Keywords	Frequency of occurrence	Average publication year
Self-management	26	2019.2
Intervention	19	2019.6
Prevention	14	2019.8
Secondary prevention	11	2018.5
Diagnosis	10	2019.4
Education	8	2019.5
Therapy	8	2019.3
Nursing	5	2020.5
Recovery	5	2019.6

Table 4 Six keywords extracted from Chinese mHealth apps based on the user types

Keywords	Frequency of occurrence	Average publication year
Older-adults	10	2018.7
Adolescents	8	2020.3
Women	7	2018.5
Adults	6	2019.2
Caregivers	5	2017.6
Children	5	2019.6

As shown in Table 4, the study focused on six categories of users: older adults, adolescents, girls, adults, caregivers, and children. Older adults were the main users of mHealth, with a keyword occurrence of 10. The average publication year range for such keywords was 2017.6–2020.3.

3.3 The User Acceptance of Mobile Health in China

As shown in the statistical results in Table 5, the survey participants consisted mainly of people who were directly related to medical care, such as patients with chronic diseases, nursing staff, and mobile medical equipment users in 16 of the articles. Young people were also the focus of some of the surveys (three articles). One article focused on women, and one focused on the users of fitness apps. The remaining five articles did not specifically label the target population, but primarily concentrated on urban residents of China. The sample size for the surveys ranged from 217 to 1,207 participants. The sample sizes of all the articles were 10 times the observation factor, so it can be posited that all surveys had a certain degree of representativeness (Cao et al., 2021a, b; Hair et al., 2014).

As shown in Table 6, 18 theoretical models were used. Most of the articles used the traditional technology acceptance model as their theoretical basis. For example, 11 articles refer to the technology acceptance model (TAM) as a theoretical model. Five articles refer to the Unified Theory of Acceptance and Use of Technology (UTAUT) model. Four articles refer to the elaboration-likelihood model (ELM) based on motivation and ability. Three articles each refer to the protection motivation theory (PMT) model and the theory of planned behavior (TPB) model. In addition, there were 13 articles that used theoretical models used in combination with traditional TAMs, such as the IM and PCT models.

The statistical results showed 107 different predictors. Table 7 lists the ten most common predictors. In the selected articles, perceived usefulness appeared most frequently. Perceived usefulness can be defined as the subjective perception that users use certain technologies to improve their job performance (Davis, 1986). In this study, we altered this definition and replaced work performance with a degree of health improvement. Our review found that perceived usefulness was observed in 11 articles, indicating that perceived usefulness was the most common predictor.

Table 5 Descriptions of the 26 extracted articles

Article Title	Journal	Publication date	Participants	No. of valid samples
The Impact of Gamification-Induced Users' Feelings on the Continued Use of mHealth Apps: A Structural Equation Model With the Self-Determination Theory Approach	<i>Journal of Medical Internet Research</i>	August 2021	Chinese people who have used a mHealth app in the past 3 months	307
Investigating the effects of negative health moods on acceptance of mobile health services	<i>Journal of Electronic Commerce Research</i>	August 2021	Residents of Shanghai, China	270
Examining Protection Motivation and Network Externality Perspective Regarding the Continued Intention to Use M-Health Apps	<i>International Journal of Environmental Research and Public Health</i>	June 2021	Chinese people who were recruited across the country via the Internet	368
Determinants of the behavioral intention to use a mobile nursing application by nurses in China	<i>BMC Health Services Research</i>	March 2021	Chinese nurses (96.2% female)	1,207
Implementation of Online Hospitals and Factors Influencing the Adoption of Mobile Medical Services in China: Cross-Sectional Survey Study	<i>JMIR mHealth and uHealth</i>	February 2021	Young and middle-aged people	407
Understanding sustained usage of health and fitness apps: Incorporating the technology acceptance model with the investment model	<i>Technology in Society</i>	November 2020	Health/fitness app users	346

(continued)

Table 5 (continued)

Article Title	Journal	Publication date	Participants	No. of valid samples
Determinants of Patients' Intention to Use the Online Inquiry Services Provided by Internet Hospitals: Empirical Evidence From China	<i>Journal of Medical Internet Research</i>	October 2020	Patients with chronic diseases	638
Healthcare at Your Fingertips: The Acceptance and Adoption of Mobile Medical Treatment Services among Chinese Users	<i>International Journal of Environmental Research and Public Health</i>	September 2020	Mobile medical treatment service users	303
Understanding consumer acceptance of healthcare wearable devices: An integrated model of UTAUT and TTF	<i>International Journal of Medical Informatics</i>	July 2020	Chinese people from tier cities in China	406
Exploring Patients' Intentions for Continuous Usage of mHealth Services: Elaboration-Likelihood Perspective Study	<i>JMIR mHealth and uHealth</i>	April 2020	Users of mHealth management apps	255
Adoption intention and usage behavior of mHealth services in Bangladesh and China A cross-country analysis	<i>International Journal of Pharmaceutical and Healthcare Marketing</i>	December 16, 2019	Young consumers	250
What Motivates Chinese Young Adults to Use mHealth?	<i>Healthcare</i>	December 2019	Young adults	486
Mobile health service adoption in China Integration of the theory of planned behavior, protection motivation theory and personal health differences	<i>Online Information Review</i>	August 2019	People or their relatives who suffer from the disease	494

(continued)

Table 5 (continued)

Article Title	Journal	Publication date	Participants	No. of valid samples
Factors Influencing Patients' Intentions to Use Diabetes Management Apps Based on an Extended Unified Theory of Acceptance and Use of Technology Model: Web-Based Survey	<i>Journal of Medical Internet Research</i>	August 2019	Adult patients with diabetes who were familiar with diabetes management apps	746
The routine use of mobile health services in the presence of health consciousness	<i>Electronic Commerce Research and Applications</i>	May–June 2019	Citizens at a community event in Shanghai, China	270
Understanding mobile health service use: An investigation of routine and emergency use intentions	<i>International Journal of Information Management</i>	April 2019	Chinese community residents	241
Investigating the Adoption of Mobile Health Services by Elderly Users: Trust Transfer Model and Survey Study	<i>JMIR mHealth and uHealth</i>	January 2019	Hospital visitors	395
Effects of mobile information-seeking on the intention to obtain reproductive cancer screening among Chinese women: testing an integrative model	<i>Chinese Journal of Communication</i>	January 2019	Females from Nanjing, China	1065
Central or peripheral? Cognition elaboration cues' effect on users' continuance intention of mobile health applications in the developing markets	<i>International Journal of Medical Informatics</i>	August 2018	Users of mHealth management apps	284
What Predicts Patients' Adoption Intention Toward mHealth Services in China: Empirical Study	<i>JMIR mHealth and uHealth</i>	August 2018	Patients and their caregivers	388

(continued)

Table 5 (continued)

Article Title	Journal	Publication date	Participants	No. of valid samples
Exploring mHealth monitoring service acceptance from a service characteristics perspective	<i>Electronic Commerce Research and Applications</i>	July–August 2018	The customers of a large company providing health services in Harbin, China	217
Moderating factors influencing the adoption of a mobile chronic disease management system in China	<i>Informatics For Health & Social Care</i>	2018	Hospital visitors	279
Factors that influence users' adoption intention of mobile health: a structural equation modeling approach	<i>International Journal of Production Research</i>	2017	Chronic disease patients between the ages of 40 and 60 at various hospitals in Shanghai	519
User acceptance of mobile health services from users' perspectives: The role of self-efficacy and response-efficacy in technology acceptance	<i>Informatics for Health & Social Care</i>	2017	Users of a company providing mHealth services in Harbin, China	650
Examining individuals' adoption of healthcare wearable devices: An empirical study from a privacy calculus perspective	<i>International Journal of Medical Informatics</i>	April 2016	Users of healthcare wearable devices	333
The privacy-personalization paradox in mHealth services acceptance of different age groups	<i>Electronic Commerce Research and Applications</i>	March–April 2016	Users of a company providing mHealth services in Harbin, China	650

Behavioral intentions were the second most common predictor, as it was observed in 9 articles. Behavioral intention refers to the goal or plan for an individual to perform a characteristic behavior (Chao, 2019). In the context of mobile medicine, behavioral intention can be defined as a goal or plan to use mHealth technology. In the existing theoretical models, behavioral intentions provide direct evidence of users' willingness to use new technologies, thus, behavioral intentions are usually treated as a direct influencing factor of actual behavior (Hoque, 2016; Alam et al., 2020; Dwivedi et al., 2016). In addition, we found that most of the ten most common predictors were derived from traditional TAMs, such as the TAM, the UTAUT model, and the UTAUT2 model. It is worth noting that health consciousness is not

Table 6 Use of theoretical models in selected articles

Theoretical Model	Frequency of occurrence
Technology acceptance model (TAM)	11
the Unified Theory of Acceptance and Use of Technology (UTAUT) model	5
Elaboration-Likelihood model (ELM)	4
Protection motivation theory (PMT) model	3
Theory of planned behavior (TPB) model	3
Expectation confirmation model of information system continuance (ECM-ISC)	1
Self-determination theory (SDT) model	1
Motivational model (MM)	1
Network Externalities model	1
Investment Model (IM)	1
Task-Technology Fit (TTF) model	1
Motivation theory model	1
Trust Transfer model	1
Trust in Mobile Health Services model	1
Health Belief model (HBM)	1
Social cognitive theory (SCT) model	1
Privacy calculus theory (PCT) model	1
Privacy–personalization paradox model	1

a predictor in any traditional technology model. This shows that mobile medical technology is unique, and that people's subjective awareness of improving health is also an important predictor.

Table 7 Most frequently occurring factors

Variable	Frequency of occurrence
Perceived usefulness	11
Behavioral intention	9
Perceived ease of use	8
Adoption intention	6
Performance expectancy	5
Effort expectancy	5
Social influence	5
Facilitating conditions	5
Health consciousness	5
Attitude	5

A total of 161 paths showing significant relationships were verified in the 26 articles reviewed in this study. Table 8 lists the path relationships between the predictors that were proven more than two times (18 paths). As shown in Table 8 and Fig. 2, the greatest number of paths point to behavioral intentions (6 paths). Notably, adoption intention and behavioral intention have similar attributes, thus, there were three paths that pointed to adoption intention. Perceived usefulness and trust were both key links in the relationships between factors. The direct impact of performance expectations on behavioral intentions was the most frequently verified path, with five articles verifying its significance.

Table 8 The most frequently occurring paths showing significant relationships

Relationship	Frequency of occurrence
Performance expectancy → Behavioral intention	5
Social influence → Behavioral intention	4
Facilitating conditions → Behavioral intention	4
Perceived ease of use → Perceived usefulness	4
Perceived usefulness → Adoption intention	4
Perceived usefulness → Continuance intention	3
Effort expectancy → Behavioral intention	3
Perceived ease of use → Adoption intention	3
Perceived usefulness → Satisfaction	2
Self-efficacy → Attitude	2
Response efficacy → Attitude	2
Self-efficacy → Behavioral intention	2
Attitude → Behavioral intention	2
Privacy concerns → Trust	2
Perceived personalization → Trust	2
Effort expectancy → Performance expectancy	2
Trust → Adoption intention	2
Perceived informativeness → Perceived benefit	2

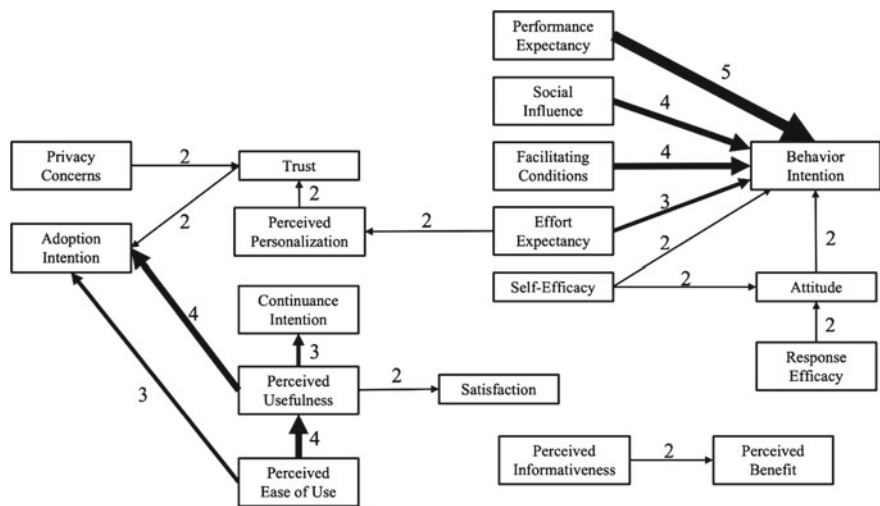


Fig. 2 A summary diagram of the path relationships that were verified more than two times

4 Discussion

4.1 Policy Support and National Conditions

By extracting and analyzing authors' keywords from 312 papers, we found that China's application of mHealth technology has three primary characteristics: (1) it has a wide range of applications, mainly in the medical field; (2) it covers everything from disease prevention to post-diagnosis care recovery, etc.; and (3) the various stages of medical services have a wide audience, covering all age groups from children to the elderly. China's emphasis on mHealth technology is evident. This finding may be closely related to the various national conditions in China. First, the patient-provider ratios in China are imbalanced; thus, the key goal of medical reform in China is solving this staff shortage. The emergence of mHealth is an adaptation to the current social needs of China that allows more people to have access to medical services, alleviating the current imbalance between the supply and demand of medical services. Second, the uneven distribution of medical resources remains a serious issue within China's medical system. The ability to obtain medical services online allows spatial limitations to be alleviated which also allows people living in remote areas to have the opportunity to receive the same medical services as those living in major cities. Additionally, due to the popularization of China's logistics system and the rise of mobile technology, mobile payment systems, interactive online systems, and other technologies (Xu et al., 2020; Ye et al., 2021; Sleiman et al., 2021; Ni et al. 2020; Gao et al., 2020) are indispensable components of a user-friendly healthcare system.

4.2 Factors that Affect the Use of Mobile Health Technology

Based on the results presented, we found that traditional technology acceptance models such as the TAM and the UTAUT model are equally applicable for surveys on the acceptance of mobile medical technology. The path relationships that were proven more than two times are shown in Fig. 2. Performance expectations, social influence, promotion conditions, effort expectations, self-efficacy, and attitudes are direct factors that were shown to affect behavioral intentions. Trust, perceived usefulness, and perceived ease of use were shown to directly affect adoption intentions. However, some of the terms used by the researchers refer to similar structures (e.g., adoption intentions and behavioral intentions, perceived usefulness and performance expectations, perceived ease of use and effort expectations, etc.). Taking into account the similarities between terms, it appears the perceived value of mHealth is the most critical factor affecting people's acceptance of mHealth. Therefore, technology developers should pay more attention to the functionality and practicality of mHealth. Ease of use for mHealth technology is also key to people's acceptance of mobile health. The basic requirement for using mobile health is a mobile device that can connect to the Internet, and smartphones are expanding at an unprecedented rate in China. However, although older adults are a key group in need of medical resources, the proportion of older adults using smartphones is still very low (Qi et al., 2021). Therefore, decision-makers should consider how to lower the barriers to the use of mobile devices.

mHealth covers a wide range of fields, such as medical care and information technology. Therefore, when exploring people's technological acceptance of mHealth, in addition to using traditional TAMs, researchers have also tried to combine technological acceptance models with other models, such as the health belief model (HBM) (Meng et al., 2019) and the privacy–personalization paradox model (Guo et al., 2016). In addition, the significance of the path, such as privacy personalization, has a direct impact on perceived usefulness and perceived ease of use (Guo et al., 2016). However, further research is required to verify this conclusion. Therefore, we recommend that future research include other special factors of mHealth, such as health awareness and privacy issues, in addition to the traditional technology acceptance model.

4.3 Policy Recommendations

The results of China's development in the field of mHealth are remarkable at a global level. It is inconceivable that in just 10 years, China has built a comprehensive healthcare information technology system around Internet technology. Significant state funding and strong policy support played key roles in this process. However, there are drawbacks to the rapid development of mobile health care based on Internet technology. This rapid development of technology could easily lead to policy planning that cannot keep pace with the speed of technological development despite the need to introduce new policies to improve and plan for

new issues arising from this development. For example, privacy policies related to mHealth appear in almost every policy plan. In the early days of healthcare reform, healthcare providers focused on policies aimed at protecting patient privacy. As the state has encouraged the involvement of third-party social forces, the management of residents' privacy is no longer limited to medical institutions. The complexity of Internet technology has also put patient privacy more at risk. In recent national-level policy planning, the protection of patient privacy has remained a key focus in the development of mHealth. Now that mHealth has entered every aspect of healthcare-related business, the government, as the leader and stakeholder of the entire healthcare industry, should strengthen the regulation of mHealth devices and app manufacturers to clearly regulate the scope of use of patient information by healthcare institutions and third parties.

5 Limitations

This study had several limitations. First, although this study provides a systematic review of policies related to mHealth in China, due to regional differences in financial status and demand for health care, there are regional differences in terms of the policies issued to implement the national policy. For example, in Wuhan, where the COVID-19 outbreak was more severe, all drugs and items required for the treatment of patients and suspected patients with new cases of pneumonia in Wuhan were included in the medical insurance settlement before the national-level policy was released. Therefore, the impact of regional differences on the policy should be analyzed more systematically in future studies.

Second, this study used Web of Science as a data source in terms of mHealth applications and mHealth user acceptance. Web of Science has a sufficiently large database and maintains a degree of assurance of the quality of the articles provided; however, there likely exist some articles that were not on Web of Science (but instead on databases such as Scopus and PubMed) that may have impacted our findings.

Third, only articles published in international journals in English were retrieved for this study. Although high-quality articles are usually published in English, many articles related to mHealth in China have been published in Chinese journals. As a result, our analysis of Chinese mHealth applications and mHealth user acceptance may not be comprehensive. Future studies could be supplemented by including articles published in Chinese journals.

6 Conclusion

As one of the key components in the development of healthcare informatics in China, mHealth is considered a good solution to address the shortage of healthcare resources and the uneven distribution of healthcare resources faced by traditional

healthcare services. This study systematically analyses the current status and various dimensions of the development of mHealth technology in China from three perspectives: policy, application, and user acceptance. By joining these results together, we can find some connections in them. As described in the previous section, China's national context dictates that China has to pay sufficient attention to how it addresses the issue of healthcare resources. China's policy of vigorously developing healthcare information technology at the national level since the healthcare reform has also been a major driving force behind the development of mHealth. With this social need, users are more concerned about the practicality of mHealth products. In addition, as the healthcare issues faced in China are multifaceted, mHealth in China provides healthcare services beyond health monitoring, but at all stages of healthcare services, from consultation to care. There is no doubt that the results of the rapid development of mHealth in China, supported by various policies, are evident. This also proves the effectiveness of policy first in driving innovative new technologies. Therefore, this study will provide an important reference for the development of mHealth in other countries.

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Digital Healthcare Development and mHealth in South Korea

Yeong Joo Lim and Tack Joong Kim

ABSTRACT

With an increase in life expectancy, rising healthcare costs have burdened public finances. While some illnesses progress rapidly, others can be controlled by improving the quality of daily life. This chapter outlines an analysis of digital healthcare development in South Korea. Given the aging population, the healthcare industry has been expanding to support people in the pre-patient stage. Notable among them is the mHealth industry that involves the use of mobile devices. The present discussion of social issues, policies, regulations, and case studies facilitates an understanding of the industry's formation and potential. A case study examines the utilization of the mobile healthcare services provided by public health centers in South Korea as the base model and the use of mHealth during COVID-19. The chapter concludes with a discussion of the potential of the government's mHealth model.

1 Introduction

Reflecting the rising social challenge of healthcare, South Korea's healthcare expenditure as a proportion of Gross Domestic Product (GDP) increased by 1.5% over 5 years, from 6.5% in 2014 to 8.0% in 2019, the most significant increase among Organization for Economic Cooperation and Development (OECD) countries and it is considered as a social challenge (Hyun et al., 2016). In

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comparison, during the same period, the United States (US) healthcare expenditure had increased by 0.6% from 16.4% to 17.0%, Japanese healthcare expenditure had been increased by 0.3% from 10.8% to 11.1%, and the OECD average percentile had been increased by 0.1% from 8.7% to 8.8% (OECD, 2020). According to an OECD report, the healthcare spending growth is expected to outpace GDP growth in almost all OECD countries in the next 15 years, with per capita healthcare spending rising by 2.7% annually on average in OECD countries, from 8.8% of GDP in 2018 to 10.2% of GDP by 2030 (OECD, 2019).

The report states, “On average across OECD countries, a person born today can expect to live almost 81 years. But life expectancy gains have slowed recently across most OECD countries, especially in the United States, France, and the Netherlands. The causes are multifaceted. Rising levels of obesity and diabetes have made it difficult to maintain previous progress in cutting deaths from heart disease and stroke. Heart attacks, stroke, and other circulatory disorders caused about one in three deaths across the OECD, and one in four deaths were related to cancer. Better prevention and health care could have averted almost 3 million premature deaths” (OECD, 2019). This suggests that maintaining a healthier lifestyle is crucial. However, there is a limit to the traditional way of providing health care with the expansion of healthcare spending by the government. Therefore, the change from treatment/hospital-centered healthcare to prevention/consumer-centered healthcare is required (Moon & Choi, 2018).

Societal changes such as demographic changes, increasing healthcare spending, and the proliferation of smart devices have triggered patients or consumers to demand digital healthcare. In addition, the development of artificial intelligence (AI) has established the technology for the integration of AI and healthcare (Shi et al., 2020). The Canadian AI platform was the first to recognize the risk of COVID-19 and has raised the possibilities and expectations for the integration of Information Communication Technology (ICT) and health care.

Digital health care is “interactive media (the Internet and the World Wide Web) and associated applications used to access those media (portals, browsers, specialized Web-based applications) will result in a substantial, positive, and measurable impact on medical care faster than any previous information technology or communications tool” (Frank, 2000). The World Health Organization (WHO) has also stated that the use of digital technologies is essential to achieving universal health coverage. Ultimately, digital technology is a crucial tool for health promotion, global security assurance, and protection of vulnerable groups (WHO, 2019).

The size of the digital healthcare industry, which is preventive and consumer-centric rather than curative and hospital-centric, has been growing continuously. It was estimated at \$206 billion in financial year (FY) 2020, up 20% year over year (YoY), with a compound annual growth rate (CAGR) of 21%. In line with the growth of the healthcare industry, the scale of digital healthcare industry investment is also expanding, reaching a record high of \$14.6 billion, an increase of \$3 billion YoY on an FY2018 basis in line with the Korean National IT Industry Promotion Agency (NIPA). According to the study conducted by the Statista,

wireless health care¹ accounted for the largest share of the FY2020 base digital healthcare market size breakdown at \$110 billion, up to \$21 billion YoY, or 53% of the total digital healthcare industry (National IT Industry Promotion Agency, 2019). mHealth² accounted for \$46 billion, while Telehealth³ and Electronic Medical Record (EMR)/ Electronic Health Record (EHR)⁴ accounted for \$26 billion and \$24 billion, respectively. mHealth saw the highest growth, with a CAGR of 41% during the 2015–2020 period. Statista also estimates that mHealth will grow sustainably, growing to \$332.7 billion by 2025 at a CAGR of 59% and as high as \$311.9 billion by 2027.

2 Healthcare Industry for the Aging Population in South Korea

It is predicted that in 2050, South Korea's older adult population (65 years old and above) ratio will be 35.9%. Following the Japanese older adult population with the percentile of 40.1%. According to the OECD, South Korea's aging population will accelerate and be considered super-aged (Kowal et al., 2016; OECD, 2019). Figure 1 shows the trends of the population aged over 80 years, 1990–2050. The population aged 80 and above is projected to reach 15.1% by 2050. In South Korea, social problems caused by the aging population include an aging workforce, a shortage of workers, and an increase in social safety net expenditures such as pensions and medical guarantees. Already, South Korea's national health insurance program is running at a deficit, and this is due to the rising cost of medical care for the older adults.

The government faces a challenge in terms of the rapidly increasing medical expenses due to the aging population, rise of chronic diseases, and growing interest and demand for well-being. The “healthcare” industry related to proactive prevention and health management has swiftly grown because of the development of ICT. The paradigm shift from treatment to the 4Ps (Preventive, Predictive, Personalized, and Participatory) is already underway. In comparison to conventional medical care, which focused on treatment in hospitals under a system in which the medical system was built to provide treatment in hospitals and the government covered the cost through health insurance. Recent medical care has undergone a consumer-centered preventive initiative. The healthcare industry is attracting attention as a countermeasure that can improve the quality of healthcare services and

¹ Wireless health care: Healthcare devices and services to which wireless technology has been adapted. This is a different concept from mHealth because not all wireless services are used on mobile devices.

² mHealth(Mobile healthcare): A healthcare service that utilizes mobile devices. It is a different concept from wireless healthcare in that all mobile devices are not wirelessly connected.

³ Telehealth(Telemedicine): To provide patients with medical and health-related services and information through the internet.

⁴ EMR/EHR: A patient management system that records patient health data on a digital platform.

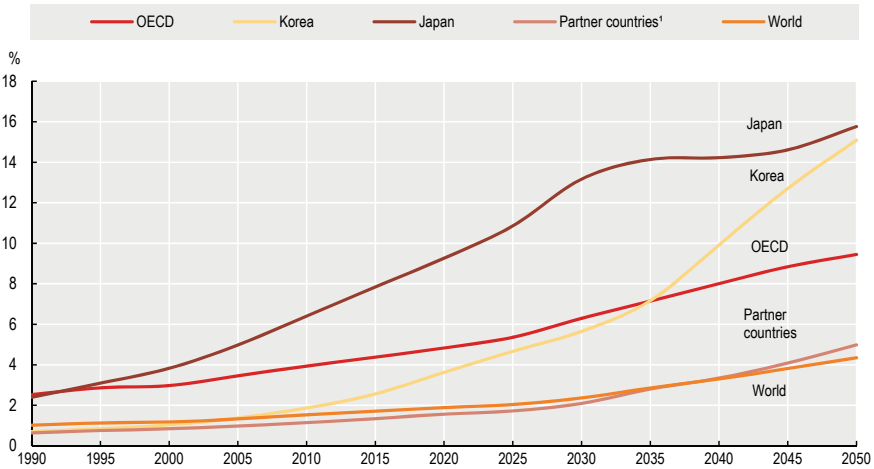


Fig. 1 Trends in the share of the population aged over 80 years, 1990–2050. *Source* (OECD, 2019). *Note* Partner countries include Brazil, China, Colombia, Costa Rica, India, Indonesia, the Russian Federation, and South Africa

reduce healthcare costs, decrease socioeconomic costs, create jobs, and impact economic growth (Hardin & Kotz, 2021). In addition, COVID-19, which has been ongoing since 2020, has raised awareness of healthcare and expectations regarding the digital and non-face-to-face healthcare industry. As a result, the South Korean government has announced in a national policy for the post-Corona society that it will intensively invest in the non-face-to-face digital-based sector, medical and biotechnology industries.

Digital health care is a methodology that uses ICT to improve human health. By integrating digital technology and health care, medical services are being improved depending on local and national conditions (Darwish et al., 2019). Through the development and integration of technology, as well as the collection and management of patient information, it will be possible to remotely prevent, diagnose, and treat diseases “anytime, anywhere.” In addition, services that can provide necessary information for health care have been expanded and developed as “Telehealth,” “E-health,” “U-health,” “Smart healthcare,” and “IT-healthcare (Crico et al., 2018; Gajarawala & Pelkowski, 2021; Iwaya et al., 2020; Jones et al., 2014; Papa et al., 2020).” Table 1 shows the development of health care and its service contents, suppliers, users, systems, and based on communication technologies.

Table 4.1 shows the development of healthcare and its service contents, suppliers, users, and systems, based on communication technologies.

“Telehealth” aims to increase the operational efficiency of hospitals. In addition to the intranet built from “Telehealth,” “E-health” seeks to improve the hospital’s operational efficiency by effectively sharing patients’ information. In addition to the intranet built from “Telehealth,” “E-health” uses information technology to

Table 1 Trends and Characteristics of Healthcare Service and Communication Technology

Service Contents	Telehealth	E-health	U-healthcare	Smart-Healthcare	IT-Healthcare
	In-hospital treatment	Treatment and information provision, medical informatization	Treatment and prevention management, E-health + telemedicine, management of patients with chronic diseases	Treatment, prevention, management, welfare, safety, U-health + healthy lifestyle management such as physical activity and diet	Smart health, personalized health management, preventive information, self-management
Suppliers	Hospitals	Hospitals	Hospitals, ICT companies	Hospitals, ICT companies, insurance companies, sports companies, service companies, etc	Hospitals, ICT companies, Insurance companies, Service companies, and other stakeholders
Users	Medical Providers	Medical Providers, Patients	Medical Providers, Patients, General Population	Medical Providers, Patients, General Population, Business Companies	Medical Providers, Patients, General Population, Business Companies, Government
Systems	Hospital information systems (HIS), Picture Archiving and Communication System (PACS)	Electronic Medical Record (EMR)	Electronic Health Record (EHR)	Personal Health Record (PHR)-based personalized system	IoT-based PHR, Cloud Big Data, AI
Fundamental Communication Technologies	Internet	High-speed Internet	Wireless Internet	Smart devices, wearable devices, mobile devices Appstore	Smart devices, wearable devices, mobile devices

Source (Cho & Kim, 2013; MOTIE, 2015; Park, 2015)

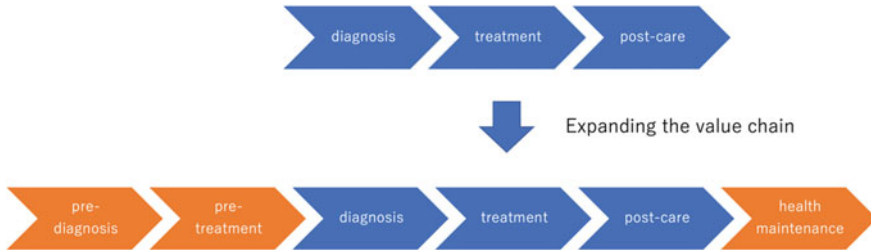


Fig. 2 Changing value chains in digital health care. *Source* Park & Shim (2018)

connect medical institutions to the system server, thereby improving the transmission of medical records. “U-healthcare” similarly provides medical information as well as knowledge, and services to medical institutions, patients, and individuals, allowing users to monitor their own health (Park, 2015).

“U-healthcare” has enabled users to monitor their own health status. Currently, “Smart-healthcare,” which aims to provide 4P medical care, is increasingly serving an important role in services to the aged community. In addition, there are expectations that “IT-Healthcare” will integrate AI and other technologies from “Smart-healthcare.” The content of digital healthcare services, suppliers, and users is broadening from the existing concept of health care. Technological developments, deregulation, and changes in suppliers and users have altered the value chain of the healthcare industry (Lee & Lee, 2021). Figure 2 illustrates how the healthcare industry is adding Pre-Diagnosis and Pre-Treatment (orange) before the standard Diagnosis, Treatment, and Post-Care (blue) as well as extending the process to Health Maintenance (orange).

The digital healthcare market in South Korea can be divided into five main areas: health IT, healthcare big data, blockchain-based healthcare technologies, telemedicine, and consumer health electronics (Intralink, 2019). Significant developments have been made in health-related IT and big data sectors with the intention of enhancing medical data exchange, improving nationwide healthcare delivery, and establishing an initial precision medicine foundation. Blockchain-based healthcare technologies and consumer health electronics have become focus areas of new policy initiatives for the main drivers of smart healthcare technology. Although currently limited to pilot projects, with anticipated deregulation, the implementation of telemedicine programs is also expected, opening a new digital healthcare industry for South Korea (Department for International Trade, 2019).

3 Healthcare-Related Policies in the US and European Union (EU)

To ensure the competitiveness of the fast-growing digital healthcare sector, the government is promoting the “supply competitiveness policy” to support the development of healthcare devices and services such as mobile and wearable devices. The “social demand enhancement policy” promotes initial demand through subsidies and improves awareness through public education (Choi & Whang, 2016). It has also introduced deregulation strategies, such as exemption and simplification of approval processes, ensuring medical information exchange. Medical information security requirements have also been eased, to support new technologies and services active within the healthcare ecosystem (Park et al., 2018). Table 2 shows the trends in US and European Union (EU) policies. In the US, policies are focused on building EHR systems and establishing Food and Drug Administration (FDA) guidelines, medical information sharing, and approval processes. The EU focuses on establishing guidelines for smart health care, building a platform, and building big data, while the US and EU are promoting policies in different directions and have not established international standards.

Figure 3 shows an infrastructure conceptual diagram of digital healthcare regulation. Digital healthcare-related policies and regulations are based on the three concepts: (1) medical device regulation, efficiency, and clarification; (2) standardization of medical and health records; (3) security of medical and health records to build the infrastructure.

3.1 US Policy

The US has pioneered various medical innovation policies in health care. From a relatively early stage, the private sector and the government have shared roles, with the government providing clear guidelines and the private sector developing according to them. They introduced Pre-Cert, which allows early introduction and monitoring in the market (Lee & Kesselheim, 2018). In addition, deregulation has created the platform infrastructure necessary for building big data. These policies have played a role in encouraging the construction and activation of the healthcare ecosystem. In particular, the Precision Medicine Initiative (PMI) was announced in 2015: (1) \$130 million was invested in the NIH for all of the US research programs to collect and utilize big data; (2) \$70 million was invested in data-based research to identify cancer genomic factors and establish treatments, led by the National Cancer Institute (NCI); (3) \$10 million was invested in a platform for sharing research materials, led by the FDA, to build a platform; (4) In data infrastructure research, \$5 million to establish a standard system for inter-system data sharing under the jurisdiction of the ONC (Office for the Coordination of Health Information Technology) (National Institute of Health, 2015). ONC Health Information Technology (HIT) will be established to build a standard system; (5)

Table 2 Key Policies and Institutions for Smart Health Care in US and EU

	Policy	Major contents
US	– Announcement of five major strategies under the National Bioeconomy Blueprint and promoted policies to support the healthcare industry, including the 21st Century Cures Act of 2015 and the Precision Medicine Initiative – Promotion of the Patient Protection and Affordable Care Act (PPACA), a bill to expand health insurance to provide coverage for clinical and preventive services in areas that are essential for improving national health through the National Health Insurance Exchange (NHIE), and to provide services such as personalized prevention plans – Announcement of personalized treatment and prevention plans through the Precision Medicine Initiative – Presentation of the 2015 Mobile Health (Wellness/Medical Device Category) Guidelines – Guidelines for mobile medical device accessories presented in 2015 – 2015 Revision of Medical Device Data System (MDDS) and software-related regulations – FDA approval of direct-to-consumer genetic analysis in 2015 – In 2016, the NIH allocated 60% of the Precision Medicine Initiative (PMI) program budget to the All of Us Research Program – In 2017, the FDA established a new Digital Health Unit and Digital Health Program at CDRH – In 2017, the FDA established a new Digital Health Unit at CDRH. It also approved the Digital Health Innovation Action Plan with guidelines for the 21st Century Cures Act	– Establishment of the EHR system – Establishment of guidelines for mobile application medical device regulation by the FDA – Official approval of mobile applications that can be linked to medical devices in 2015 – Automatic transfer of patient medical records from medical institutions to e-mails and healthcare applications in digital form, and transmission of medical records between medical institutions – Establishment of a professional review and approval system for medical devices and management and supervision of digital healthcare, including cooperation with developers, patients, and hospitals for the development of digital healthcare products and services – Introduction of Pre-Cert in software – Introduction of Pre-Cert for software · Pre-marketing declaration exemption for some medical devices – Expediting the approval process through the Breakthrough Devices Priority Review Program
EU	– e-Health Action Plan 2012–2020 – The EU Executive Committee announced Horizon 2020 to support research on the development of mobile healthcare applications and tools – In 2014, the United Kingdom (UK) FDA issued guidelines on medical software – General Data Protection Regulation (GDPR) to strengthen personal data rights – France’s Genomic Medicine 2025 and Finland’s FinnGen launched national genome projects – EHDEN project promotion (2018–2024)	– Building Smart Healthcare Guidelines and Platforms from an EU Perspective – Germany invested \$23.82 million in 13 projects to develop services for older adults – The UK aimed to reach 3 million users of the telemedicine system by 2017 – Promote genomic data collection – Establish Common Data Model (CDM) – Support for building medical-related big data

Source (Choi & Whang, 2016; Park, Shim & Lee, 2018; Moon,Yoon & Sun, 2019; Resource Research Team of KDI Economic Information Center, 2021)

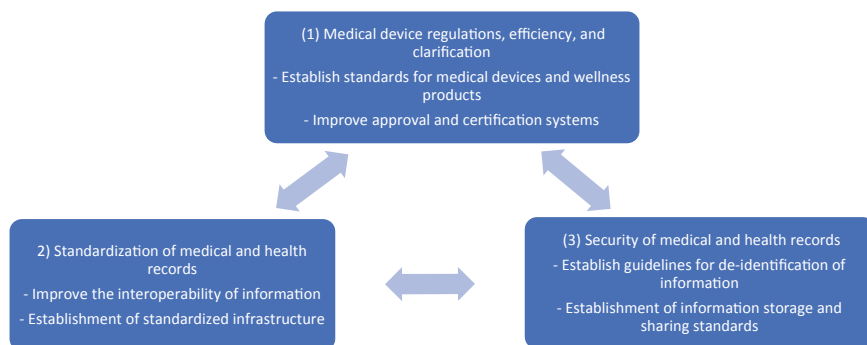


Fig. 3 Infrastructure conceptual diagram of digital healthcare regulation. *Source* (Park et al., 2018)

To build a platform, \$10 million was invested in a platform for sharing research materials, led by the FDA, to build a platform.

The 21st Century Cures Act, drafted in December 2016, made several deregulatory changes, dividing medical devices into three Classes and exempting Class 1 and Class 2 devices that do not directly affect health and safety from pre-marketing declarations. The priority review program for medical devices introduced a fast-track approval process for medical devices that treat and diagnose diseases more effectively. Such policies are regarded as the most innovative since the PMI plan in 2015. The policies of the July 2017 Digital Health Innovation Action Plan are summarized in Table 3 as follows: (1) Issuing new guidance implementing legislation; (2) Reimagining digital health product oversight, and (3) Growing our expertise (FDA, 2017). According to this policy, nine companies including Apple; Samsung, Fitbit, and others, were selected in September 2017 to obtain the Pre-Cert process to develop the product: in March 2020. Pear Therapeutics' Somryst was the first software medical device to be approved (Resource Research Team of KDI Economic Information Center, 2021).

Such U.S. healthcare policy aims at deregulation to activate private ecosystems and build government-led big data for the PMI to achieve personalized treatment and prevention.

3.2 EU Policy

The EU's e-Health Action Plan 2012–2020 aims to improve the efficiency of ICT-based healthcare, with the following main goals: (1) improving the interoperability between e-Health services; (2) increasing innovative research and development activities; (3) improving the health literacy of patients and healthcare professionals; (4) improving data transparency and legal clarity of mobile applications. Health literacy of patients and health professionals; (5) improving data transparency and legal clarity of mobile applications. In January 2014, the EU launched the Horizon

Table 3 Digital Health Innovation Action Plan and Contents

	Contents
(1) Issuing new guidance implementing legislation	· New draft guidance with draft interpretations of several of the medical software provisions in the 21st Century Cures Act, explaining their effect on pre-existing FDA policy, including policy · New draft guidance that delineates the clinical decision support software that is no longer under FDA’s jurisdiction · Draft guidance on FDA oversight of products with both software functions that fall under FDA’s medical device oversight and software functions that do not · Finalizing guidance on Deciding When to Submit a 510(k) for a software change to an existing device · Finalizing the International Medical Device Regulators Forum approach to clinically evaluating SaMD
(2) Reimagining digital health product oversight	· Reimagining its approach to digital health medical devices – Developing a precertification program that could replace the need for a premarket submission for certain products and allow for decreased submission content and/or faster review of the marketing submission for other products – “Pre-cert” status could collect real-world data postmarket that might be used
(3) Growing our expertise	· Building a cadre of experts with a deep understanding and experience with software development and its application to medical devices · Entrepreneurs in Residence program this fall to take advantage of input from thought leaders and others with real experience in software development to build and structure the digital health function within CDRH

Source FDA (2017)

2020 project, which aims to improve the health (European Commission, 2014). The Horizon 2020 plan, designated health, demographic change, and well-being as the social challenge (SC), and the EU decided to establish and support the strategy as shown in Table 4.

The European Commission (EC) has announced that Horizon 2020 will include: (1) Big data against childhood obesity; (2) Collective wisdom driving public health policies; (3) Evidence-based management of hearing impairments: Public health policy-making based on fusing big data analytics and simulation; (4) Integration

Table 4 Horizon 2020 social challenge: Better health care, economic growth, and sustainable health systems

	Main priorities	Support size
1	Personalized medicine	7.7 billion euros
2	Innovative health care industry	
3	Infectious diseases and improving global health	
4	Innovative health and care systems—Integration of care	
5	Decoding the role of the environment, including climate change, for health and well-being	
6	Supporting the digital transformation of health care	

Source European Commission (2014)

and analysis of heterogeneous big data for precision medicine and suggested treatments for different types of patients; (5) Meaningful Integration of Data, Analytics, and Services; (6) Participatory urban living for sustainable environments, which will build up the big data and reflect it in the policymaking (European Commission, 2014).

In addition, the EU is promoting genome projects by Genomic Medicine 2025 in France and Finn Gen in Finland. EU is building a Common Data Model (CDM) for medical data through the 2018 EHDEN project. The EU aims to establish a data-based healthcare infrastructure to implement policies for data collection, utilization, integration, and sharing, and to standardize data so that it can be used in research for the prevention of diseases and the development of treatment methods.

4 Digital Healthcare Policy and Development in South Korea

The activation of the smart healthcare industry in South Korea has been relatively slow due to regulations and conflicts of interest. With the introduction of the National Health Insurance System (NHIS), the introduction of the electronic digital interchange (EDI), and online charting system (OCS), the digitization of medical information, which is essential for digital health care, was done at an early stage. Hospitals based on EDI and OCS have actively introduced EMR, which has become the foundation for the growth of digital healthcare. Even though South Korea’s smart healthcare industry has secured a certain degree of competitiveness, it is difficult to say that the ecosystem is sufficient due to the limitations of social acceptability, such as laws and systems.

4.1 EMR as the Foundation of Healthcare—Introduction of EMR in South Korea

The digitalization of medical care in South Korea was brought about by the implementation of the medical insurance system for all citizens in the late 1970s. In the 1980s, the billing method of medical fee points for medical insurance evolved from paper-based billing to disk-based billing and then to EDI. Since the mid-1990s, EDI has been implemented to digitize the business processes of health insurance medical-fee billing, review payment between medical institutions such as Health Insurance Review and assessment of the service as a medical-fee review organization. It has contributed significantly to the proliferation of medical information technology in South Korea.

EDI for medical insurance billing has also brought about many changes in internal informatization in medical institutions. The hospital information systems (HIS) in South Korea were established between the mid-1990s to the early 2000s, and hospitals aimed at automating insurance billing. This initiative resulted in the development of an order communication system (OCS) to be introduced before the EMR, unlike any other history of healthcare systems in the world. In spite of the development of digitization, there were legal restrictions at the time that required various records stored in digital form to be printed out, signed, and stored, which caused inefficiencies in the process. As a result of the revision of the Medical Service Act, EMRs were rapidly introduced in 2003. Since the middle of 2000, EMRs have been introduced mainly in major hospitals in South Korea. In 2010, 77.3% of 44 medical institutions in South Korea introduced EMRs (Chae et al., 2010). The government and the private sector cooperated to improve the quality of medical services, reduce administrative costs through digitization, and reduce medical and laboratory costs by preventing duplicate testing. They are supporting EMR adoption, standardization, and information exchange, with the goal of exceeding 90% by the year 2020.

However, most of the South Korean medical institutions are in the private sector, and EMRs are developed by each medical institution and company, which poses challenges for exchanges and standardization. To solve these issues, the government revised the Medical Service Act in 2017 to standardize EMRs and establish a legal infrastructure for sharing medical records among medical institutions. In addition, a pilot project has been conducted since August 2018 to examine the effectiveness of EMRs in improving field efficiency, accelerating information sharing, and adapting EMR standards to the field.

4.2 Healthcare-Related Policies in South Korea

The introduction of EMRs has enabled the digitization of medical records and sharing of information among medical institutions. The integration of ICT and medical technology will lead to digital healthcare and IT-healthcare development. As a result, this is expected to contribute to the revitalization of the economy by

effectively addressing the economic and social challenges associated with health services to the aging population and the increase in lifestyle-related diseases.

In the year of 2014, the government introduced the “Medical Device Items Strategy.” In the same year, South Korea revised the “Regulations on Medical Device Items and Grading by Item” and “Regulations on Medical Device License Declaration Examination.” To ensure the competitiveness and revitalization of the healthcare industry, South Korea announced the “Smart HealthCare Industry Revitalization Plan” and the “Health Industry Development Direction” in 2015. It also released the “Criteria for Medical Devices and Personal (Wellness) Products” and the “Regulations on Medical Device Software Licensing, Declaration, Examination” to establish legal standards and regulatory systems for digital healthcare-related technology and information. In 2016, it continued to promote the “Health Industry Comprehensive Development Strategy for Entering the Seven Biohealth Powerhouses” and other plans to foster the healthcare industry.

It has been pointed out that the administration has changed the direction of policy, resulting in inefficient management and inconsistency (Lim, 2016). To solve these problems and improve the consistency of information sharing and policy management among organizations, three organizations were established in 2005: the Ministry of Health and Welfare (MOHW), the Ministry of Science and ICT (MSIT), and the Ministry of Trade, Industry and Energy (MOTIE). To improve consistency in health and policy management, these three government departments have collaborated to hold the Digital Healthcare Global Strategy Forum in November 2017 to discuss digital healthcare.

In the “Health Industry Comprehensive Development Strategy for Entering the Seven Bio health Powerhouses” promoted in 2016, the MOHW set the goals of overseas expansion of the ICT-based medical industry and attraction of foreign patients, analyzed regional demand, promoted personalized medical packages including medical systems, pharmaceuticals, and medical IT. They focused on the following prioritized issues including overseas expansion of digital health: the creation of ICT-integrated essential medical services; revitalization of the precision, regenerative medicine industries; support for the development of advanced medical devices. As a medium- to long-term policy, the Growth Engine Project was planned and promoted to contribute to the expansion of the economy’s future growth potential and job creation. Many healthcare-related policies were included in the 2016–2020 Future Growth Engine⁵ Project and the 2018–2022 Innovative Growth Engine Project.

The Korea Institute for Advancement of Technology (KIAT) selected 20 promising industries to support the medium- to the long-term strategy of industrial technology to support future growth-driven businesses, including mobile devices, medical imaging, and diagnostic equipment, and IT health care. These include

⁵ Growth engine: Core technologies, products (materials, parts, equipment, facilities), and services that, if discovered and nurtured through government and national strategic choices and support over the medium to long term, are expected to create new markets, develop into new industries, and contribute significantly to value-added and job creation over the long term.

mobile devices, medical imaging and diagnostic equipment, and IT health care. The core and strategic products of the mobile device industry included small wearable devices and healthcare devices. MOTIE and the Ministry of Science, ICT and Future Planning (MSIP) jointly launched the “Wearable Smart Device Project” as a representative project of the Future Growth Engine Project. The project was implemented for five years from 2016 to 2020 through MSIP, which announced a total budget investment of 127 billion won for the five years from 2016 to 2020. In this project, the government actively invested in developing the wearable device industry, which was in the early stage of market formation. In addition, the “2016 Comprehensive Implementation Plan for Future Growth Dynamics (Draft)” lists 5G communication technology, wearable smart devices, smart bio-production systems, personalized wellness care, AIoT (AI + IoT), and big data. Moreover, the government has been actively invested in the area including 5G communication technology, wearable devices, and AIoT grouped under the private sector initiative, personalized wellness care under the public–private sector joint promotion, and a smart bio-production system under the government initiative.

The Innovation and Growth Dynamics Project from 2018 to 2022 has announced 13 innovation and growth dynamics areas. In the “Current Status and Plan for Promoting Innovation and Growth,” digital healthcare-related areas such as personalized health care, big data, AI, VR, robotics, and new drugs were selected. Digital health care was given priority in the policy management of the healthcare sector. The government released the “Direction for Promoting Government Regulatory Reform” for technology industrialization and commercialization in 2017 and the “Biotech Healthcare Regulatory Improvement Plan” in 2020.

The National Informatization Basic Plan (2018–2022) announced plans to promote the development of legal systems to strengthen industries in the digital health sector, including the development and strengthening of legal infrastructure for the safe use of medical information and healthcare big data services. The expansion of the use of AI in medical devices, medical services, new drugs, and biotechnology was also promoted. According to the National Informatization Basic Plan, the government has revised three laws: the Personal Information Protection Act, the Information and Communication Act, and the Credit Information Act. To build a foundation for information sharing and to support the development and commercialization of wearable smart devices as well as its commercialization process (product design, development and startup support, and overseas expansion support) for small and medium-sized venture companies, the Wearable Smart Device Commercialization Support Center was established with a budget of 16.1 billion won in the year of 2018.

Figure 4 shows South Korea’s policies and deregulation. The South Korean government supports the development of the healthcare industry through strategic policies and deregulation.

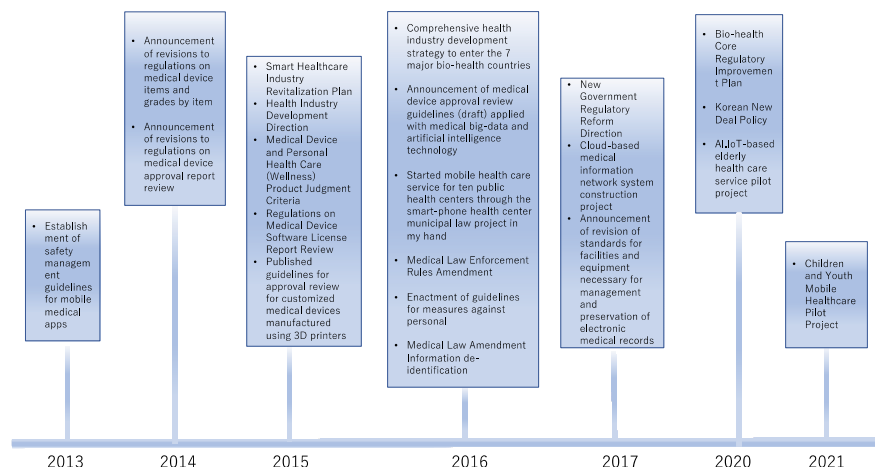


Fig. 4 Timeline diagram for policy and deregulation in South Korea

5 mHealth in South Korea

The adoption of mobile health care reduces healthcare costs in developed countries and increases access to basic health care in developing countries (European Commission, 2014). 54.3% of South Korean adults have chronic diseases due to aging and an irregular lifestyle. Moreover, hypertension or diabetes rate among people aged above 30 years old is expected to reach 42.8% by 2030 (Yoon, 2013). Health insurance treatment costs attributable to chronic diseases are increasing annually, and accounted for 83.7% of total treatment costs in 2018 (KDCPA, 2020). The economic cost of chronic diseases from 2010 to 2030 is as high as \$1 trillion (Bloom et al., 2020). Sustainable monitoring of chronic diseases is complex; however, proactive prevention is the most critical to reducing their incidence and impact. Many people ignore their health status and do not continue treatment or exercise if their health status improves temporarily. Moreover, many people are not interested in their health status, making it difficult to monitor their health on a sustainable basis. In response to this situation, South Korea promotes ICT-based public goods health management projects through public health centers. However, these projects are yet to be implemented widely. Also, the need for the system to be operated sustainably as well as for the development of ICT public goods make such projects difficult to realize.

mHealth is defined as a “medical and public health practice supported by mobile devices, such as mobile phones, patient-monitoring devices, personal digital assistants (PDAs), and other wireless devices” (GSMA. PwC, 2012). It is not limited to mobile devices (medical devices and sensors). It includes applications linked to devices such as short message services (SMS) for health management, telemedicine-provided personal guidance systems, medication reminders, and so on (European Commission, 2014). The term “mHealth” encompasses hardware

such as devices and sensors and software (S/W) such as applications that provide information. With the widespread use of smartphones, we are constantly connected to the Internet, Bluetooth, Near Field Communication (NFC), and WLAN, which allow us to link our cell phones to smart devices, share the information obtained, and promote the management of our health.

Mobile-based interventions are more beneficial than traditional face-to-face consultations because they provide more frequent and ongoing access to individualized health information and management (Patrick et al., 2008). The interventions that send SMS will help consumers achieve their behavioral goals by providing information on lifestyle changes such as healthy eating and exercise, self-management, motivation, educational materials, and supportive messages (Schoeppe et al., 2016). As medical devices such as blood glucose meters and electrocardiographs are also linked to smartphones, the use of mHealth makes it possible to measure, record, and analyze the blood glucose levels and electrocardiographs of patients with chronic diseases, and notify medical institutions when abnormalities are found. Therefore, it can increase efficiency and convenience and improve the effectiveness of medical care compared to the use of offline forms (Lee, 2015).

The mHealth industry is composed of services that integrate hardware (H/W) and S/W, and the primary strategy is to build an ecosystem and platform through inter-industry integration and cooperation. mHealth consists of mobile devices that collect data from H/W and transmit the collected information and applications that utilize the transmitted data. Three components are essential: mobile devices that collect data from H/W and transmit it and applications that use the transmitted data to employ various services in the ecosystem. The mHealth applications include applications related to activity tracking, physical index monitoring, diet and weight loss, exercise methods, medical health information, campaign applications for medical professionals, and patient management. With the development and proliferation of wearable devices that enable activity trackers, the focus is on fitness and health management.

6 Status of mHealth Business in South Korea

The global mHealth market is growing rapidly, especially in the wearable device market. However, South Korea's technological development in wearable smart devices still has room for development. Table 5 shows the technical gap between developed countries and South Korea. According to the results of this study, South Korea's technical gap compared to developed countries has been assessed to be up to a factor of 3.9 (Lee, 2017).

In terms of technical gaps in the mHealth field of South Korea, the US was 1.0 times behind the EU and Japan in bio-signal measurement technology, but 1.5 times, 2.0 times, 3.0 times, and 3.9 times behind in wearable devices, physical activity measurement technology, biofeedback, and health management services, respectively.

Table 5 Technology technical gap

Category	Field	Relative level of technology technical gap				Technical gap
		US	EU	JAPAN	South Korea	
H/W	Wearable device	100	90	90	85	1.5
S/W	Bio-signal measurement technology	100	90	90	90	1.0
	Physical activity measurement technology	100	90	80	80	2.0
	Biofeedback technology	100	85	80	70	3.0
Services	Health management services	100	90.6	90	79.2	3.9

Source Lee (2017)

The South Korean government has decided that an aggressive policy strategy is needed to narrow this technical gap. To enhance the competitiveness of H/W, S/W, and services, the Wearable Smart Device Commercialization Support Center was established in 2018 to support the commercialization of wearable devices and promote their development and overseas expansion. In addition, to encourage technology development and services through deregulation, the New Government Regulatory Reform Promotion Direction (2017) and the bio-health Core Regulatory Improvement Direction (2020) have been issued. Although the South Korean government has implemented policies to support the development of the healthcare industry through support and deregulation regarding new technologies, deregulation is still insufficient.

Against this backdrop, South Korea has divided the roles of the private and public sectors in the “2016 Comprehensive Action Plan for Future Growth Dynamics (Draft).” The private sector will lead 5G communication technology, wearable devices, and AIoT(AI + IoT). The public and private sectors will jointly promote personalized wellness care, and the government-led plan supports a smart bio-production system. This kind of cooperation was practically implemented in the form of mHealth, a comprehensive healthcare service “mobile healthcare service provided by public health centers,” with the private sector providing the Activity Tracker technology and the government producing and managing the network of health centers and operating a comprehensive platform. Samsung and other private companies have offered wellness services using Activity Tracker technology through Samsung Health and other services. Although they struggled initially to expand the wellness market, with the government’s cooperation, the wellness market scaled in a short time.

Along with government policy and deregulation, public interest in post-COVID health care has also increased. Deregulation has made it possible to offer new

services that previously could not be offered because of legal restrictions on the handling of personal information. Insurance companies are developing and offering products with new healthcare services. Korean insurance companies have begun to develop new services by sharing customer data with collaborating institutions. Table 6 shows the mHealth services of Korean insurance companies.

This type of service can now be developed because of the deregulation of the exchange of information, which was previously not possible due to regulations.

To further promote the development of new services, a mobile healthcare support center was opened in March 2021 in the Gangwon Digital Healthcare Regulatory Free Zone. It is one of the three regulatory sandboxes that have been exempted from regulations for 48 months from August 2019 to August 2023 and is a region specializing in digital health care. In the regulatory sandbox, three systems

Table 6 Healthcare services provided by insurance companies

Company	Service name	Contents
Samsung Fire&Marine Insurance	ANYFIT	– Health management service application – Providing points for achieving walking and acupuncturist goals – Psychological status check service for osteoporosis, health risk analysis, stress, depression, etc. in collaboration with specialized companies
Kyobo Life Insurance	KARE	– Integrated customer service platform – Health promotion, health forecasting, health examination record inquiry, and monitoring of changes – Insurance coverage inquiries (including other companies) – Medical record inquiries with partner hospitals (40 hospitals) to file insurance claims without the need for proof documents – Mental care services
Shinhan Life Insurance	HOW-FIT	– Healthcare platform services – Using a smartphone-mounted camera, the system senses movement when exercising. If you cannot exercise in the correct posture, it will not be counted. Equipped with a feedback function from the trainer – Subscription model
AIA Group	AIA Vitality	– Healthcare and Wellness Platform – Subscription Model – Health status is monitored and discounts on premiums are applied – Use of wearable devices from partner companies

Source Electronic Times Internet (2021)

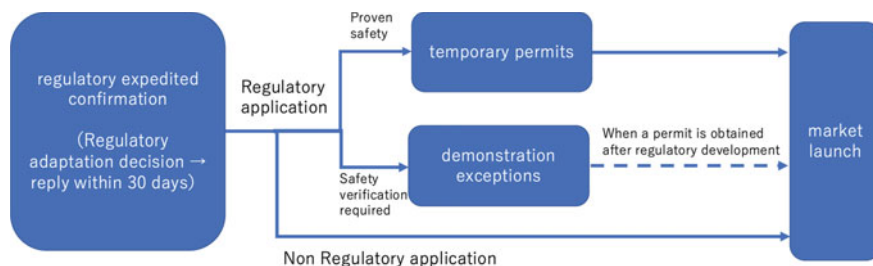


Fig. 5 What is a special regulation-free zone? *Source* Ministry of SMEs and Startups Korea (MSS, 2022)

will apply: regulatory expedited confirmation, temporary permits, and demonstration exceptions. The regulatory expedited confirmation system is a system that provides a prompt response within 30 days when there is an inquiry regarding regulatory compliance, and if no response is received within 30 days, the regulation is deemed to be nonexistent. The temporary permit system is one under which a temporary permit is issued, and the product can then be sold if the safety of the product has been ensured in the case of regulatory application. The demonstration exception system strengthens the verification and safety (demonstration) of new services and products in the absence of regulations. Figure 5 shows the flow of regulatory expedited confirmation, temporary permits, and demonstration exceptions.

The Gangwon Digital Healthcare Regulatory Free Zone attempts to encourage innovation by temporarily allowing products that are difficult to commercialize or validate due to regulations. In fact, a patch-type electrocardiogram device is being piloted for COVID-19 vaccinators and home care patients to monitor physical information (heart rate, epidermal temperature, etc.). Another product is a portable X-ray imaging service to assist diagnosis by transferring the resulting images to a medical facility.

The Gangwon Digital Healthcare Regulatory Free Zone saw an 8.8-fold increase in sales from approximately 4.8 billion won in 2019 to 42 billion won in 2021, and a fourfold increase in new job creation from 44 in 2019 to 166 in 2021. The startup ecosystem is ongoing, with 41 companies operating in the region by 2021, compared to the initial 8, with grants investments totaling 36.5 billion won and 43.1 billion won, respectively (Breaknews website, 2021).

6.1 mHealth through Public–Private Partnership (PPP)

mHealth requires H/W devices to measure and analyze the data and S/W to analyze the collected data. Deregulation, time, and funding as well as other measures will be necessary for new technologies to launch and to be of practical use. In South Korea, the government is developing mHealth through PPP to resolve social

challenges. The government invests public funds through subsidies to promote development and encourages startup companies to participate in the ecosystem of mHealth development. This is by the way of the government opening APIs.

7 Mobile Healthcare Service Provided by Public Health Centers

The health center's mobile healthcare project aims to provide personalized health counseling to health center professionals (doctors, nurses, nutritionists, exercise specialists) anywhere at any time. This is by way of a mobile application to assist people identified as having health risks. This project aims to realize wellness and well-being through personalized preventive health management and services. These are provided at health centers using ICT and big data. Following the pilot mHealth services being implemented in 10 public health centers in 2016, 139 public health centers then provided the service in 2020. The service targets those who are not patients, but following test results, are known to be at risk, because of blood pressure, glucose levels, or obesity. Measurements of blood pressure, neutral fat, blood glucose levels on an empty stomach, waist size, and HDL-Cholesterol are used as decision indicators. If one or more of these five indices is outside the normal range, the patient is considered to be diagnosed at risk (MOHW, 2021).

For a private hospital or company to develop a mHealth business, the process of developing and approving the H/W and S/W requires a considerable amount of time and money. Various regulations, restrictions on information sharing, and clinical trials for approval increase the uncertainty of the business. This makes it risky for individual hospitals and companies, especially start-ups, to operate platforms. For this reason, the healthcare industry is in a position of being relatively easy to commercialize, without violating medical laws, if limited to health monitoring using wearable devices.

In South Korea, public health centers have been established and operated to promote the health of local residents, as stipulated in the Community Health Act. Health centers supplement the functions of diagnosis, treatment, and insurance administration and are operated nationwide. Using health centers, mHealth can, therefore, deliver services to people over a wide area. In addition, as the operating entity is the national government, it can be operated on a common platform. This system can be expected to bring economies of scale to the companies that provide H/W. As a national policy, the South Korean government has thus expanded the scope of its mobile Healthcare program to include older adults and youth.

The base model of mHealth service public health centers was designed to provide healthy lifestyle monitoring (including self-monitoring) and counseling through a mobile app over 24 weeks. After receiving an explanation about the service from a public health coordinator, the mHealth IG installed the public health center mHealth app on participants' smartphones and registered them for membership. Activity monitors were provided to all participants, along with sphygmomanometers, glucometers, and body composition measuring devices,

(depending on the health risk of each participant). As part of the self-management service, the participants were instructed to sync their activity monitor with the app at least five times per week, update an exercise journal at least once per week, and upload a picture of their meals once every four weeks. This was in addition to the baseline, mid-term (12 weeks), and final (24 weeks) examinations and consultation at public health centers. These services were provided by professional health management teams comprising physicians, nurses, nutritionists, and physical activity experts who monitored health information online in real time. According to records, monthly reports were provided to motivate participants to continue practicing healthy lifestyle behaviors. In particular, nutritionists at the public health centers conducted intensive nutritional consultations by assessing the participants' meals based on the uploaded pictures and providing advice on balanced dietary intake. In addition, online communities for each public health center were created on the app, which facilitated consultations regarding the practice of a healthy lifestyle and the management of health risk factors (Kim et al., 2019).

7.1 Mobile Healthcare Service Provided by Public Health Centers for High-risk Individuals

These operate as described in Sect. 7. Shows the health risk factors and decision criteria (Table 7).

The aim is to improve lifestyle and monitor health status from the stage of the pre-patients stage (based on health checks) as preventive medicine. Figure 6 shows the processes involved in mobile healthcare services.

First, people in the pre-patient's stage are screened through physical examinations and interviews, and people in the pre-patient's stage are registered on a priority basis. The enrollees visit the health center, are consulted, monitored, and advised by a team of experts, and receive regular diagnosis and guidance. Monitoring is discontinued if a person becomes chronically ill and receives medication or treatment during this process.

Table 8 shows the composition and roles of the expert team described in Sect. 7.

Figure 7 shows a schematic diagram of the mHealth service platform. The wearable device provided by the health center operates as described in Sect. 7.

By September 2019, mobile healthcare services were provided to 26,029 people at public health centers. Of the enrollees, 44.6% were male and 55.4% woman. In terms of participants' age, 6.1% were in their 20 s, 60.7% were in their 30–40 s, and 33.2% were in their 50 s or older. After completing the entire 24-week program, 57.7% ($n = 12,354$) of the participants improved their lifestyles (Fig. 8). In addition, five health index values were also improved (Fig. 9) (Korean Society of Insurance Administration, 2019).

In South Korea, the use of mHealth has proved successful by continuously monitoring and providing information to people in the pre-patient stage. This result serves as a model for the growth and dissemination of mHealth as a policy (Table 9).

Table 7 Health risk factors and decision criteria

Health risk factors		Criteria for judging risk groups	Classification of risk groups	Criteria for judging patients
Blood pressure	Blood pressure systolic blood pressure	130 mm Hg or more	Pre-hypertension	140 mm Hg or more
	Diastolic blood pressure	85 mmHg or higher	Pre-hypertension	90 mmHg or higher
Blood glucose level on an empty stomach		100 mg/dL or more	Fasting blood sugar disorder, Disorder of glucose tolerance	126 mg/dL or more
Waist size	Men	over 90 cm	Dangerous	–
	Women	over 85 cm	Dangerous	–
Neutral fat		150 mg/dL or more	Borderline triglycerides	200 mg/dL or more
HDL-Cholesterol	Men	less than 40 mg/dL	Dangerous	–
	Women	less than 50 mg/dL	Dangerous	–

Source KHPI WEBSITE <https://www.khealth.or.kr/board?menuId=MENU00864&siteId=null>

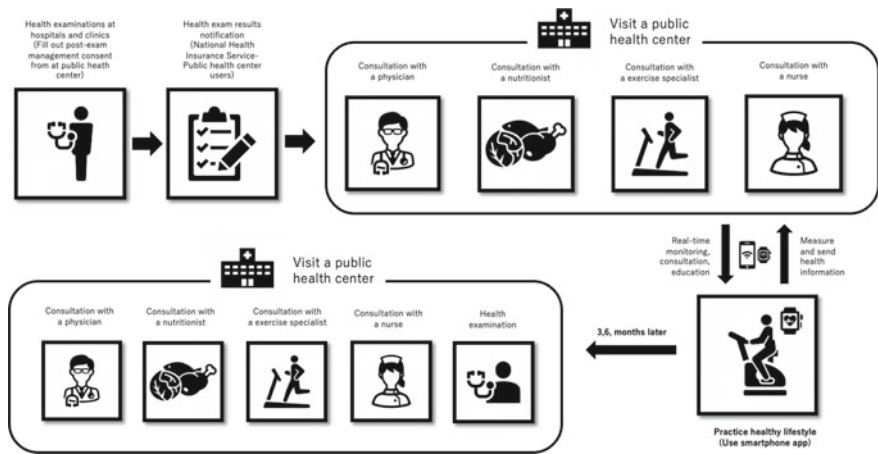


Fig. 6 The process of the mHealth service provided by the public health centers. *Source* (Kim et al., 2019)

Table 8 Expert team and duties

Expert	Duties
Coordinator	– General management and coordination of services – Registration, management of checkups, and service schedule for the user – Information on service contents, schedule, and usage – Current management of wearable device distribution and collection – Coordination of services within and outside the health center as necessary
Doctor	– Consultation on test results and decide on service participation – The setting of health risk factors and health habit management goals – In case of chronic diseases, cooperation with medical institutions
Nurse	– Health counseling and management goal setting through collected health information and service utilization confirmation – Monitoring of abnormal health values
Nutritionist	– Individual dietary diagnosis and management goal setting through collected health information – Online nutrition counseling, education, and information provision
Exercise expert	– Diagnosis and management of individual physical activity status and goal setting through collected health information – Online physical activity consultation, education, and information provision – Wearable device activity meter monitoring

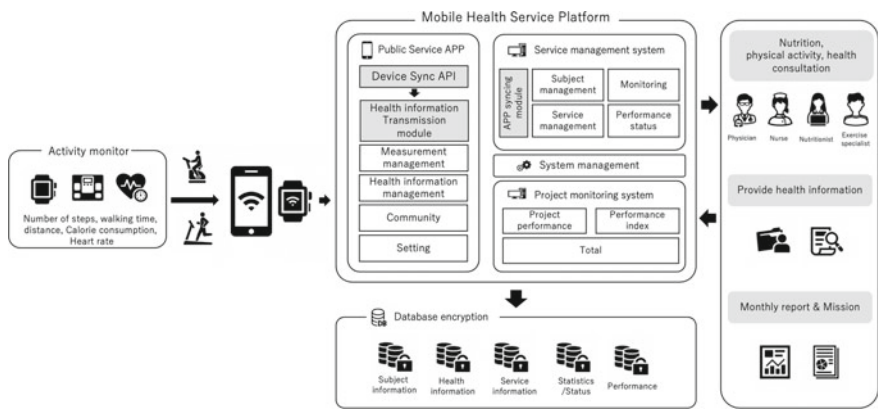


Fig. 7 A schematic diagram of the mHealth service platform. *Source* Kim et al. (2019)

7.2 Mobile Healthcare Services Provided by Public Health Centers for Older Adults

Mobile healthcare services provided by public health centers have shown positive effects on national health management through the use of mHealth. Therefore, in 2020 the government began a pilot project of non-face-to-face health management services to older adults using AI and IoT. They aimed to prevent the trend of chronic diseases. The project began with 24 health centers and expanded to 80

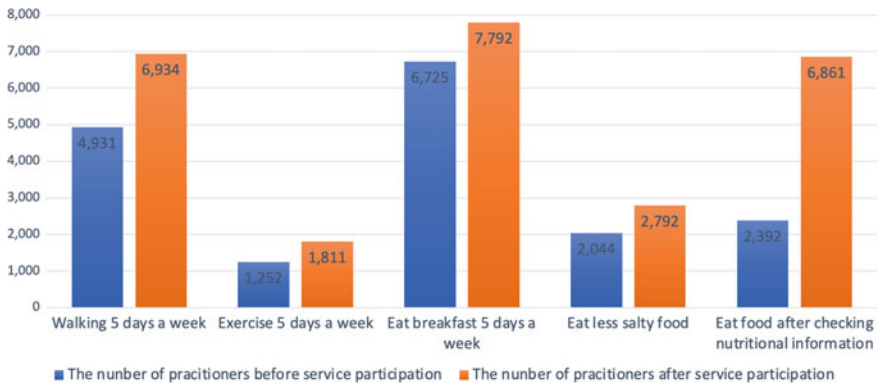


Fig. 8 Number of people with changed living behavior. *Source* (Korean Society of Insurance Administration, 2019)

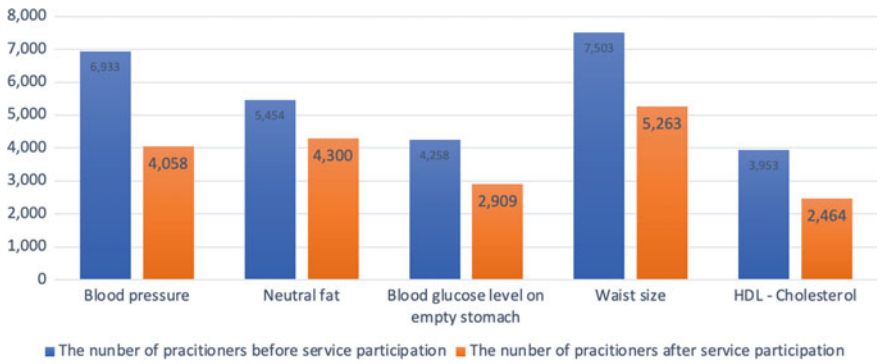


Fig. 9 Number of improved health. *Source* (Korean Society of Insurance Administration, 2019)

Table 9 Mobile healthcare service provided by public health centers for older adults’ devices

Device	Target
Activity meter	All participants
Bluetooth scale	
Blood pressure meter	Distributed according to health screening results
Blood glucose meter	
AI speaker	Priority distributed to older adults living alone or judged to be socially weak

Source KHPI (2021a)

Table 10 Expert team for mobile healthcare service provided by public health centers for older adults

Expert	Duties
Nurse	– Health condition monitoring, management goal setting, health management service provision, and outcome measurement
Nutritionist, Exercise expert, physiotherapist, dental hygienist	– Mission proposal for health form issues – Non-face-to-face health consultation through app and phone communication
Administrative staff	– Guidance on application use and devices – Administrative support and support services

Source KHPI (2021a)

public health centers in 2021. The goal is to provide the service at all health centers in South Korea by 2025. The project will target people aged 65 years and above who need chronic disease management and health status improvement. They will be provided services through registration.

Participants were offered a 6-month program based on the mobile healthcare service provided by the public health centers for older adults. In the first phase, participants registered for the service in the second phase, they completed an in-person pre-health screening and were categorized into health groups; in the third phase, they were provided with devices and applications to install and configure. In the fourth stage, participants participated in a mission that is delivered through the application for six months, with non-face-to-face expert consultation and health information provided through messages. In the fifth stage, they had a face-to-face post-program health screening to decide whether to rejoin or exit the program. After completing the -6-month program, participants received a predetermined reward if their health improved. As of February 2021, 11,496 people were enrolled in this service, with a given mission accomplishment rate of 48.6%.

The program based on the mobile healthcare services provided by public health centers targeted pre-patients who were at risk of developing diseases. Often, the team of specialists included a coordinator to liaise between the doctors and the outside world. However, in mobile healthcare services provided by public health centers for older adults, the composition of the expert team was different because the focus was on monitoring health status. From the aspect of healthcare for older adults, the expert team was composed as shown in Table 10.

7.3 Mobile Healthcare Services Provided by Public Health Centers for Youth

South Korea has established a similar platform in 2021 for mHealth services targeting young people with high health risks through the deployment of health centers.

Table 11 Expert team for mobile healthcare services provided by public health centers for youth

Expert	Duties
Coordinator	– General management and coordination of services – Registration, management of checkups, and service schedule for the user – Information on service contents, schedule, and usage – Current management of wearable device distribution and collection – Coordination of services within and outside the health center as necessary
Doctor	– Participation will be determined based on exceptional circumstances such as high obesity – In case of chronic diseases, cooperation with medical institutions
nurse	– Monitoring of abnormal health values
Nutritionist	– Individual dietary diagnosis and management goal setting through collected health information – Online nutrition counseling, education, and information provision
Exercise expert	– Diagnosis and management of individual physical activity status and goal setting through collected health information – Online physical activity consultation, education, and information provision – Wearable device activity meter monitoring

Source KHPI (2021b)

This project was launched as a 1-year pilot project (intended to begin in 2020 but postponed because of COVID-19).

It is believed that healthy lifestyle habits developed at a young age can endure into adulthood and beyond, reaping huge health benefits. In addition, through continuous monitoring, the implementation of the cycle of prevention, early detection, and post-event management is expected to have a high economic impact in lowering health services costs.

Mobile healthcare services for youth were also provided through a similar program based on the mobile healthcare services as described in Sect. 7. The only difference was that doctors were selected for participation based on exceptional patient circumstances such as severe obesity. Table 11 shows the expert team for mobile healthcare services provided by public health centers for youth.

The technological innovation of mHealth has progressed gradually, as one be observed from the above table. The results of the mHealth development in South Korea have contributed to the suppression of the global pandemic as well as better management of the virus spread. These mHealth technologies and well-established medical centers and institutions, together with the cooperation of the South Korean people, have achieved this while improving overall health outcomes.

8 COVID-19 and mHealth in South Korea

The global pandemic known as COVID-19 has dramatically changed our lives and mobility patterns worldwide. As a result, countries worldwide implemented

lockdowns and other restrictions, including measures to block face-to-face contact. Rather than mobilizing its security forces to lock down entire cities and cut off nearly all forms of in-person contact, South Korea focused on rapid and widespread testing, as well as close tracking of all contact between people exposed to the virus. These two pillars, testing and tracking, along with the utilization of mHealth, allowed South Korea to lessen the exponential spread of the virus without having to halt all internal movement and access between its cities for COVID-19 while utilizing mHealth in South Korea (Park et al., 2020).

8.1 Immigration Management

In the early stage of COVID-19, South Korea did not set any restrictions on entry from abroad. However, the situation shifted soon after the declaration of COVID-19 as a pandemic. The reason for the 2-week self-isolation measure was that there were no isolation facilities for international visitors. South Korea demonstrated that it could operate strong self-isolation using mHealth, minimize social and economic losses, and take countermeasures against infectious diseases.

The MOHW developed an application to monitor patients with possible COVID-19 symptoms and has made it mandatory for all travelers or returnees entering the country from abroad to install it. This was done so that they could self-report their health status and symptoms for 14 days after entry. In case of fever or respiratory problems, users needed to report their health status and contact Korea Centers for Disease Control and Preventions (KCDC) for testing.

While enforcing this mobility restriction using the application's GPS tracking feature, at the same time, there was also the threat of severe legal penalties (Lee & Lee, 2020). At the time of installation, nationality, travel history, and contact information were logged. The app linked self-diagnosis questions, clinic locations, and direct chat help channels. During the self-quarantine period, four self-assessment questions were asked every day regarding fever, cough, sore throat, and difficulty in breathing. Through these measures, mHealth was able to properly monitor people entering the country from abroad. In the absence of infrastructure to manage a large number of arrivals, South Korea's strategy of using mHealth to rapidly respond has been credited with helping to curb the rapid spread of COVID-19.

8.2 Self-Quarantine Monitoring Application

The Ministry of Interior and Safety (MOIS) has developed an application to monitor self-quarantine and self-monitoring of people's health conditions. People who confirmed that they were exposed to the trajectory of a known coronavirus patient were requested to contact KCDC to be monitored for 14 days. They received diagnostic testing free of charge; otherwise, they self-quarantined and regularly responded to monitoring queries. The application also used the GPS sensor to detect whether the user violated the self-quarantine boundary. This was intended

to help local governments monitor a large pool of potential patients with minimal labor and cost (Lee & Lee, 2020).

8.3 Management of COVID-19-Positive Individuals

Patients with a positive COVID-19 real-time polymerase chain reaction (RT-PCR) test but no or mild symptoms were eligible for admission to LTSC. Once the disease was confirmed, a group of experts from the public sector triaged the patients and determining treatment options based on the severity of symptoms. Patients with severe symptoms were admitted to the hospital and treated in a negative-pressure isolation ward, while those with mild and asymptomatic symptoms were designated for admission to LTSC. Patients were initially admitted to the LTSC from self-isolation at home or transferred from other community hospitals (Bae et al., 2020).

Figure 10 shows the overall flow of ICT operations according to the patient’s journey. When a patient was transferred to the hospital, the cloud system was used to share medical images immediately. Patients self-reported their vital signs and subjective symptoms using a mobile app. These data were automatically linked to a semi-structured EHR template for patients with mild COVID-19, which was new to the HIS and allowed medical staff to obtain patient-reported data conveniently and accurately. In addition, vital signs were transmitted to the HIS in real time in some rooms equipped with wearable devices. Through the mobile app, medical staff could notify and alert individual patients and communicate with them as needed (Bae et al., 2020).

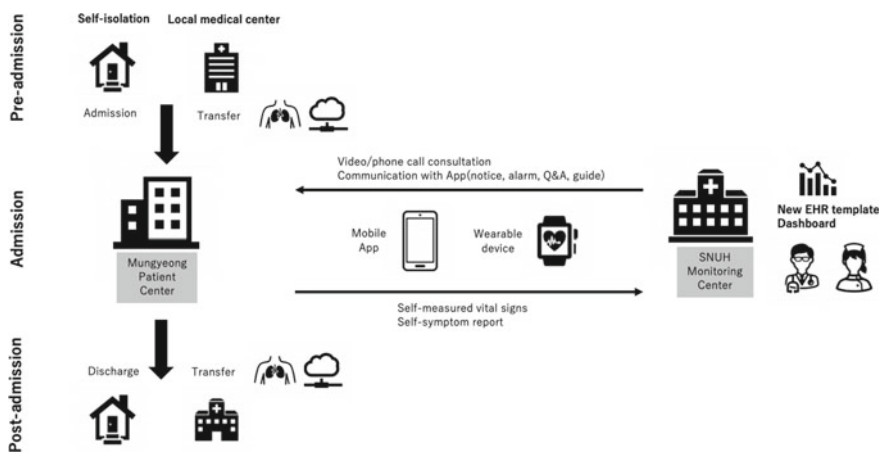


Fig. 10 Overall ICT operation flow according to the patient’s journey. *Source* (Bae et al., 2020) EHR: electronic health record. ICT: information and communications technology. Q&A: question and answer. SNUH: Seoul National University Hospital

9 The South Korea Government-Driven mHealth Model

The widespread adoption of mHealth can potentially improve health communication and health outcomes. mHealth apps are available in large numbers. Business models for mHealth include free, freemium, and premium models. However, most mHealth apps are only used by innovators and early adopters and have not been generally popular.

Major companies such as Samsung are trying to build an ecosystem around their smartphones, but they are limited to measuring physical activity using the activity tracking function and ECG using sensors. In addition, medical institutions cannot use the information obtained from the wearable device to make a diagnosis, so the patient must undergo another examination. In addition, the collected data can be monitored by the user, but no other services have been provided. There is no professional consulting or other services, although there is a function to notify one via messages according to a certain level of values. This situation is occurring because mHealth providers are not always able to provide expert resources such as doctors and nurses as a service. In addition, the approval of medical devices requires strict regulations and time for data collection. Private hospitals use their own core systems, leading to issues regarding versatility with devices such as wearable devices also exist.

To further unlock the potential of mHealth, a platform is needed where the information can be shared and operated beyond the mobile and wearable devices that collect the data. A platform is defined as a company that creates significant value by attracting, brokering, and connecting two or more groups of customers so that they can trade with one other (Reillier & Reillier, 2017). The following challenges exist for companies to provide a platform for running mHealth.

- (1) Legal regulation of information sharing between private hospitals.
- (2) Regulations for the use of wearable devices in medical practice.
- (3) Limitations of the functionality of non-medical wearable devices.
- (4) Absence of a mechanism for information sharing between wearable device providers and hospitals.
- (5) Inability to provide professional knowledge due to the lack of an information-sharing mechanism.
- (6) Lack of medical staff.

mHealth is more effective in targeting patients who can reduce disease incidence through lifestyle improvement than those who need immediate treatment. The healthcare industry has been transitioning from diagnosis and cure of affected to well-being and care as wellness. Against this background, the South Korean government's mobile healthcare service offers public health centers as a model that utilize state-run health centers, provides a platform for the government to integrate existing infrastructure, and connects companies that provide information through HW and SW to people who manage their health through mHealth.

The rapid progression of the COVID-19 pandemic severely impacted the world's economic development. The spread of the infection brought factories and logistics to a standstill. As for the government's response, it was challenging to build new infrastructure in a short period. Simultaneously, a challenge arose regarding the worldwide shortage of medical equipment. Efficient utilization of limited resources was key. Fortunately, the severity of pandemics such as COVID-19 can be controlled to an extent with proper management. However, some patients can develop severe symptoms rapidly, and continuous monitoring is necessary to save lives. Traditional face-to-face and person-to-person practice cannot monitor the rapidly increasing number of patients. In addition, the constraints on medical care are apparent. The adoption of mobile devices to provide mHealth services presented huge potential to deliver healthcare services effectively (Zapata et al., 2015). Its use allowed for effective monitoring and management of patients, PCR testing, and early isolation. As a result, South Korea's pandemic efforts were recognized worldwide.

In South Korea, we used PCR testing was used to generate a list of close contacts and monitor their health status through mHealth. Patients who showed abnormalities during the monitoring were centrally managed, making efforts to prevent deaths. Regular monitoring of at-risk patients and prompt action in case of abnormalities formed the basis of mHealth. The COVID-19 pandemic has allowed the exploration of the possibilities of healthcare using entirely new technologies.

The speed of mHealth service using AI and big data can be accelerated with the development of extensive data collection platforms. Amid many regulations and challenges, the strategy of considering platforms as public goods is one of the factors that can speed up the spread of mHealth. In addition, in areas of depopulation or with limited medical infrastructure, the appropriate use of mHealth can enable effective activities of medical resources.

10 Conclusions

The increase in average life expectancy and the associated burden of rising medical costs is currently a challenge and leads to economic losses for society. The medical model is shifting from the traditional "diagnosis, treatment, and post-care" model to include a "pre-diagnosis, pre-treatment phase followed by a "health maintenance" phase. Such a shift in the medical model requires the provision of 4P medical care. Against this backdrop, the smart healthcare industry is one of the fastest-growing industries globally, and its ecosystem is strengthening collaboration beyond existing business domains. To achieve the development of a smart healthcare industry, it is necessary to digitize medical records, deregulate, and establish S/W and H/W.

In South Korea, deregulation and other national policy projects have encouraged the growth of the smart healthcare industry. However, although the case of the

Gangwon Digital Healthcare Regulatory Free Zone shows that deregulation and other measures may promote innovation, this is not sufficient.

Some progress has been achieved in improving national health by providing policy directions and developing services through PPP. This was demonstrated by the fact that during the COVID-19 pandemic, the active use of mHealth enabled the effective use of limited medical resources. For further development of mHealth, it is necessary to establish the following three infrastructures and build an open innovation service model in which companies and governments can collaborate to develop an ecosystem.

- (1) Streamlining and clarifying medical device regulations.
- (2) Standardization of medical and health records.
- (3) Security structure for medical and health records.

mHealth is a new industry that integrates new technologies into the existing healthcare system. Rather than building a new ecosystem, it is better to utilize the existing vertical players who have already begun developing healthcare systems. The key to success is an ecosystem of horizontal relationships and cooperation. It is necessary to create and share rules—including deregulation—to achieve mHealth implementation.

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Regulations and the Status of Social Implementation of Services on mHealth in Japan

Makoto Niwa and Yasushi Hara

ABSTRACT

Existing typical applications of mHealth include behavioral change through remote intervention, information and data collection and integration, logistical support, service substitution and efficiency of healthcare workers, management and settlement of healthcare costs, and support for healthcare institution management. Some concrete examples of each of these types are provided, and their current status and development prospects in Japan are described. The status of mHealth applications as regulated medical devices, the meaning of health promotion applications in the Japanese context, and the investigation of the funding of Japanese mHealth start-ups are described.

1 Introduction

Japan has a high level of medical, scientific, and data transmission technologies. However, Japanese mHealth research and development has not received much attention in the academic literature. For example, according to the bibliometric analysis of Cao et al. (2021), there were only 175 academic papers on mHealth published in Japan between 2000 and 2020, which represents a meager 1% of the total number of publications worldwide, ranking Japan 22nd in the world.

The mHealth applications that appear in the literature include asthma (Harada et al., 2020; Iio et al., 2020), diabetes (Yamaguchi et al., 2017, 2019), large vessel occlusion (Komatsu et al., 2021), depression (Furukawa et al., 2018; Kageyama

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et al., 2021; Kato et al., 2020), COVID-19 tracking (Yamamoto et al., 2020), influenza tracking (Fujibayashi et al., 2018), eating habits (Watanabe-Ito, Kishi, & Shimizu, 2020), neck/shoulder pain/stiffness and low back pain (Anan et al., 2021), emergency medical services (Yamada, Inoue, & Sakamoto, 2015), physical activity (Miyaji et al., 2020; Murakami et al., 2019), nicotine dependence (Masaki et al., 2019), carpal tunnel syndrome (Fujita, Watanabe, & Kuroiwa, 2019; Koyama et al., 2021), and the distance stethoscope system (Hirosawa et al., 2021).

This chapter provides an overview of the state of mHealth in Japan, taking into account the limitations of approaching it from the academic literature, with emphasis on the status of regulation and social adoption. Specifically, the position of mHealth in the healthcare system is confirmed, and the status of pharmaceutical regulations related to mHealth in Japan and the status of health promotion recommendations by the Japanese government are presented. The chapter then introduces mHealth case studies collected by expanding the scope of the search beyond the literature. Next, the attitudes of Japanese pharmaceutical companies toward mHealth are examined. A study on the status of start-up businesses in Japan is also presented.

2 Types of Existing mHealth Applications and Examples

mHealth is a medical and health system supported by mobile devices such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices (European Commission, 2014). It also includes smartphone applications, such as lifestyle and well-being applications that may connect to medical devices or sensors (e.g., smartwatches or bracelets), smartphone-based personal guidance systems, health information, and medication reminders.

Six typical application types of mHealth with examples raised in the published literature are listed below (Iribarren et al., 2017). However, these examples were based on the Global Health Learning Center mHealth Basics, USAID (as of the year 2014), (Global Health eLearning Center, 2013) and the mHealth Compendium (as of the year 2015; Levine et al., 2015), and eHealth and mHealth may have been grouped together.

2.1 Behavior Change Communication

Behavior change communication application provides health information and behavior change messages directly to clients or the general public and helps link people with services. Message content may enhance individuals' knowledge or influence their attitudes and behaviors. Examples include medical appointment reminders, support for medication adherence, promotion of healthy behavior (e.g., smoking cessation), community mobilization, awareness-raising, health education, and supporting self-management.

Typical example is Eboratxt, a text messaging system for mobile phones implemented from 2014 to 2015 in Sierra Leone, Mali, Ghana, Uganda, and Malawi to enable awareness-raising, social mobilization, and reporting on the Ebola outbreak (Levine et al., 2015). Specifically, this system sends information on risk factors of Ebola infection and the way of improving hygiene, one of the best ways to fight the virus, as there is currently limited treatment. Infection reporting can be sent from mobile phones, and this system helped to construct political countermeasures against the Ebola outbreak.

2.2 Information Systems/Data Collection

Information systems/data collection application utilizes electronic methods to collect data and dispatch information to various levels of the health system (district, state, national) for quicker analysis compared to paper-based systems. In this application, a mobile device is a component of an information system. Examples include collection and reporting of patient health and service provision, electronic health records (EHR), registries, vital event tracking, surveillance, and household surveys.

One example is collecting data on an indoor residual spraying project to fight against malaria in Angola in 2013 (Levine et al., 2015). Spray data was collected via smartphones held by operators, and manual data collection hubs used for the paper-based system were eliminated.

Other examples of the existing mHealth include remote monitoring devices for blood pressure and other conditions (CardioMEMS/Abbott, approved in the US), and smoking cessation apps (CureApp/CureApp, approved in Japan, described in this section). Both collect data on day-to-day patients' conditions and provide them to practitioners and aim to improve treatment practices.

2.3 Logistics/Supply Management

Logistics/supply management application helps track and manage commodities, prevents stock-outs, and facilitates equipment maintenance. This also transmits information from a lower level to a higher level health facility. Examples of activities are ensuring that medicines and basic supplies are in stock.

A specific example is a family product supply system implemented in Senegal in 2013. This system uses tablets for logistics professionals assigned per region, and logistic professionals actively manage the delivery (informed push model) (Levine et al., 2015). The system was developed under the initiative of a non-profit organization IntraHealth International (US). Experience from this activity revealed that a small number of trained logistic professionals can serve a large number of supply depots. This activity was able to free health providers from logistics and improved their service quality.

2.4 Service Delivery

Service delivery application supports health worker performance related to diagnosis, treatment, disease management, and referrals. This includes preventive services and decision support for the patients. Examples of electronic tools are medical decision support systems, point-of-care tools, checklists, diagnostic tools, and treatment algorithms provided electronically. Examples of communication tools are electronic notification of test results or follow-up visits, used by healthcare providers, or between healthcare providers and patients.

A specific example is an International Quality Short Messaging System providing comprehensive anti-Acquired immune deficiency syndrome (AIDS) services including delivery of human immune-deficiency virus (HIV) testing kits and medicines, and collecting information such as test results (Levine et al., 2015). Analysis of collected information identified infants who were not tested for HIV. The use of this system reduced the number of infants lost to follow-up.

2.5 Financial Transactions and Incentives

This application improves access to health services, expedites payments to healthcare providers and health services, and reduces cash-based operating costs. Examples of activities include loading/transferring/withdrawing money, savings accounts, and insurance. Activities also include transactions related to performance-based incentives or vouchers for services (e.g., family planning and antenatal services).

A typical example is a Heartfile Health Financing system implemented in Pakistan in 2010 (Levine et al., 2015). Heartfile is a fund-based purchasing system supported by various donors, such as individual philanthropy, bilateral and multilateral agencies, and institutional donors. Requests from pre-registered hospitals arrive as short message services (SMSs), which trigger the system, and automated alerts go to patients and doctors in local vernacular to gauge a patient's eligibility for assistance. The use of SMS (and not using more sophisticated smartphone features) is based on the intention to avoid compatibility issues which were of concern at the time of the introduction of this system. Automated SMS-based decisions are conveyed to patients and doctors, followed by SMS-based purchase orders to suppliers and pre-registered hospitals ordering supplies and/or procedures for a particular patient. By using such a system, financial risk protection for the poor in the informal sector was achieved. The features and controls built into the system help protect against abuse, improve efficiency, and achieve value for money.

2.6 Workforce Development and Support at Healthcare Facilities

This application facilitates training and education, provider work planning and scheduling, supportive supervision, and human resource management. Examples of activities include training and retaining healthcare workers and providing education.

A typical example is an mHERO system implemented in Liberia in 2014. mHERO consists of an open-source health workforce information system and health information inter-operability architecture. The information provided by the system includes verifying active health workers, identifying inactive workers to re-engage them, and determining health facility status through SMS exchange. The platform can also be used to quickly disseminate critical information, collect data on key health services delivery indicators, support continuing professional development, or provide a technical resource for frontline health workers.

3 Healthcare System of Japan

3.1 Overview of the Japanese Healthcare System

As a country, Japan has moderate to rich healthcare resources, characterized by 12.8 hospital beds, 2.5 physicians, and 11.8 nurses per 1,000 population (OECD, 2021). Health spending is 4691 USD per capita based on purchasing power parities. Access to health care is generally good, having 100% population eligible for core services.

A significant feature of Japan's healthcare system is that it is a universal healthcare system, and all citizens are covered by public health insurance. In other words, all citizens are enrolled in some kind of public health insurance, although there are different management entities depending on the employment status of the insured, such as National Health Insurance, Employee's Insurance, and the Japan Health Insurance Association (Digital Agency e-Gov, 2021a, c). The current social insurance system was established in 1961 (Ministry of Health, Labor & Welfare, 2011). Medical services are provided by hospitals or clinics, and patients choose which hospital or clinic to visit and receive medical treatment (Ministry of Health, Labor and Welfare, 2021a, b, c). A portion of the medical fee (10–30%) is paid by the patient, and the rest is covered by insurance.

Some of the mHealth covered in this book will be incorporated into this healthcare system as it relates to this type of medical care. On the other hand, those related to health and wellness improvements that do not involve hospitals and clinics exist outside the framework of such a healthcare system.

3.2 The Pharmaceutical Affairs Law

Pharmaceuticals and medical devices used as a means of medical intervention are governed by the Pharmaceutical Affairs Law of Japan. The Japanese name of this law refers to the law concerning the quality, efficacy, and safety of drugs and medical devices (Digital Agency e-gov, [2021d](#)). The current regulatory system was enacted in 1970 with the primary objective of regulating pharmaceuticals, and after numerous revisions, the current Japanese name was adopted in 2014 to include medical devices.

As described below, under this law, mHealth used in medical treatment can be either a drug (when combined with a drug) or a medical device. In Japan, the manufacture and sale of pharmaceutical products or medical devices must be licensed by the Ministry of Health, Labor, and Welfare as a business entity. When a new drug or medical device is developed, it can be manufactured and sold only after obtaining manufacturing and sales authorization for each product. To obtain this license, both drugs and medical devices require the submission of test results from clinical trials, and various tests, including clinical trials, must be conducted in accordance with the standards of reliability set by the MHLW, such as GXP.

3.3 Status of the Consideration of Medical Insurance System Reform in Japan

Japan's total national healthcare expenditure is 43 trillion yen (\$39 billion) (2018), accounting for 8% of Japan's GDP and increasing by approximately 1% every year (Ministry of Health, Labor & Welfare, [2020](#)). Factors contributing to the increase in medical costs include increased hospitalization costs, increased medical costs for the elderly, and increased medical costs due to the advancement of medical care (especially the advancement of cancer treatment), (Ministry of Health, Labor & Welfare, [2015](#)). Under these circumstances, in order to maintain universal health insurance, the optimization of medical costs has become an issue (Japanese Government, [2011](#)). As a concrete measure, medical insurance system reforms are being considered with an awareness of the following points: optimization of hospitalization, promotion of community-based comprehensive care that does not depend on hospitalization, promotion of disease prevention and health promotion, and utilization of ICT. These social issues are closely related to the state of mHealth development in Japan, which are discussed next.

4 Status of mHealth Development and Approval as Medical Devices in Japan

4.1 Current Regulatory Framework

In 2014, the Pharmaceutical Affairs Law was amended and “programs” were added to categories of medical devices (Japan Association for the Advancement of Medical Equipment, 2021). Through this amendment, the pathway for stand-alone programs to become medical devices was clarified. In addition, acts to strengthen regulatory frameworks, such as encouraging developer–regulator communication, are implemented to promote the practical application of programmed medical devices (Ministry of Health, Labor & Welfare, 2021a, b, c).

4.2 Regulatory Approvals of Stand-Alone Programs as Regulated Medical Devices

A search of the package insert of regulated medical devices in the public database for “category: programs” resulted in 144 cases as of March 31, 2021. Most of these were treatment planning programs (e.g., radiotherapy planning), data processing programs (non-portable), and operation programs for equipment such as diagnostic imaging, as an evolution of conventional technology. A review of these search results led to only 12 mobile or telecommunicating applications. The applications are listed in Table 1.

There could be cases where a product is approved under a category other than “program” even though its main function is as a program or a smartphone application (e.g., mHealth). For example, a smoking cessation system’s core component is a program, but the actual approval is for a “device for testing visceral functions: system for assisting smoking cessation treatment: CureAppSC nicotine dependence treatment app and CO checker” (CureApp Inc.), which is regulated as a “device for testing visceral functions.”

The ECG application for the Apple Watch is described as an “irregular heart-beat notification program” and is regulated as a program. This was the latest approval, and the item was not included in the search results described above. The application was positioned as a “home-use” application, with a package insert emphasizing that it was for assistance with medical treatment, and it is not intended to be used as the basis for medical decisions (Ministry of Health, Labor & Welfare, 2021a, b, c). Whether this management approach will become an established method for regulating mHealth medicines in Japan would be of interest.

The recently approved innovative cloud-based communication tool to be used by medical staff, called “Join,” developed by Allm Inc., is described as a “program for general-purpose diagnostic imaging system workstation” and legally regulated in a group of viewer programs for radiologists (this is not included in above search results neither). The innovative feature of Join is that it enables the communication between medical experts using text messages, verbal communications, and image

Table 1 Mobile or telecommunicating program applications approved as stand-alone regulated medical devices in Japan

Purpose/Function	Brand name	Vendor	Notes
Program supporting device for respiratory systems	EncoreAnywhere	Philips	Sleep apnea syndrome, remote monitoring
	EncorePro2		
	Care orchestrator		
Program for heart activity recorder during seizures	EventScope 2	Microport CRM Japan	Remote data receiving
Program for data recorders for long time ECG	EasyScope		
	CineScope		
Program for data recorders for long time ECG	CardioTrakAnalyzer	San-Ei Medisys	Remote data receiving
Program for holter ECG	Duranta analysis	Durantis	Remote data receiving and transmission
	Marquette Mars PC Ambulatory ECG holter system	GE healthcare	
	QP-550 Series	Nihon Kohden	
Program for management of insertable cardiac monitors	Reveal LINQ mobile manager	Medtronic	App-based device management
Program for tele-transmitting ECG data	CareLink express mobile application		App-based data monitoring

viewing on smartphones (Takashita, 2021). This feature allows specialists who cannot immediately assemble at a medical institution to participate in treatment decisions from a distance.

5 Political and Social Initiatives for Health Promotion in Japan

This section describes the policy and social approaches to health promotion in Japan. Health promotion is an approach to health from a different perspective from that of disease treatment, and is based on the concept of preventing disease by improving health. In Japan, the Health Promotion Act was enacted in 2002 in response to the Japanese government's 2001 concept of extending healthy life expectancy and controlling medical costs in an aging society by actively promoting health and preventing diseases (Digital Agency e-Gov, 2021b). Under this law, health insurance unions, employers, and local governments are supposed to conduct health promotion projects.

On the other hand, health insurance societies, which are responsible for 70–90% of medical costs, have also begun to implement health promotion programs to improve their own financial health (Techfirm, 2021). Health promotion using smartphone applications is being explored as a means of doing so.

6 Examples of mHealth Used for Health Promotion in Japan

6.1 Overview of Health Promotion Apps

To outline the status of mHealth used for health promotion in Japan, the mHealth app appeared on Google Play searches (Google, 2021) using “health” in Japanese (i.e., “kenko”) as a keyword (October 30, 2021). International apps were included in the search, provided that the language used in the apps was Japanese. Apps with more than 500,000 downloads are listed in Table 2.

Most of the apps were pedometers, activity data handlers connected with wearable devices, or physical condition recorders. Some were diet recorders intended for weight control. Some apps are internationally provided, while others are

Table 2 Health promotion apps with 500,000+ downloads available from Google Play in Japan

App name	Vendor	User ratings	Function
Rhythm care	dot-i studio	4.4	Recording physical data
Pacer	Pacer Health	4.2	Pedometer
Asken	Asken, Inc	4.2	Recording diet data
Kenko Daiichi	QOLeap	4.1	Pedometer, handling activity data
Withings health mate	Withings	4.0	Recording physical data
Sync health	H2 Inc.	4.0	Recording physical data
Huawei health	Huawei	3.9	Pedometer, handling activity data
FiNC	FiNC	3.9	Recording diet data
OMRON connect	Omron	3.7	Recording physical data
Health & fitness tracker	Droid Infinity	3.7	Recording physical data
d healthcare	NTT DOCOMO	3.6	Pedometer, recording physical data
Health planet	Tanita	3.5	Pedometer, recording physical data
S health	Samsung	3.3	Pedometer, handling activity data
Google fit	Google	3.0	Handling activity data
Noom	Noom Inc	2.8	Body weight management program

developed domestically by local vendors. Vendors included two body scale manufacturers (i.e., Tanita and Omron), which provide highly functional body scales (body weight and body fat) and manometers that communicate with smartphones.

6.2 Example of Broader Use of Health Promotion mHealth—Combination with Life Insurance

This section describes a case of the use of a mHealth app in a life insurance product that incorporates health promotion activities that are being marketed in Japan.

(1) Outline of life insurance products that incorporate health promotion activities

The life insurance product that incorporates health promotion activities is called “Vitality” developed by Discovery Ltd. of South Africa, which has 8.4 million members in 17 countries and regions around the world as of 2018. In Japan, Vitality was launched as an add-on program to life insurance policies by Sumitomo Life in 2018 through a partnership between Discovery Ltd. and Sumitomo Life. The program monitors daily health promotion activities, and based on the results, changes insurance premiums and provides rewards. The program requires a monthly fee of JPY 800.

The design of this program was based on behavioral economics (Kitamura, 2019). Specifically, the program commences with a discount on the first-year premium based on the concept of hyperbolic discounting. The next step is to avoid optimism bias and status quo bias by objectively assessing health status. Furthermore, from the perspective of loss aversion, health promotion activities are reinforced by the desire to avoid premium increases.

The health promotion initiative consists of the following three steps. The first step is an online self-check to assess the current state of health. This includes weight, physical activity, cholesterol levels, eating habits, mental wellness, and alcohol consumption. This will reveal what kinds of health risks exist in people’s lifestyles. At the same time, it is expected to contribute to the improvement of literacy about effective activities and their importance in health promotion. The second step is to conduct activities to improve health status. By increasing the number of steps walked and participating in sporting events, the member status class will improve, which is expected to reduce the premium for the next year. The third step is to provide rewards, such as beverages and travel discounts, which are intended to motivate members to continue their health promotion activities.

There are two incentives to promote health: premium changes and rewards. Premiums start at 85% of the normal premium in the first year of the policy. Thereafter, premiums can vary from −2% to +2% annually, depending on the level of health promotion efforts. The range of premium fluctuation ranges from 70 to 110%. This mechanism of premium fluctuation results in the formation of a subpopulation of good character, with improved mortality and morbidity motivated

As the structure of the ecosystem, including the Vitality program, is complex, a causal loop diagram displaying elements is shown in Fig. 1. A causal loop diagram was used for a comprehensive understanding of complex systems (Littlejohns et al., 2018). From Fig. 1, one can understand the carefully designed mechanism for behavioral change in the insured person. Health promotion is reinforced by reinforcing loops, including incentives and rewards, while avoiding optimism bias and status quo bias. On the other hand, insurance companies' financial risks possibly raised by this new program are reduced by a balancing loop that includes a higher premium for a low-activity group. In addition, the reduction in financial risk can be reinforced by the formation of a health subgroup.

The diagram illustrates the mHealth-based insurance premium adjustment mechanism, showing the flow of information and incentives between four main entities: Insurance Company, Insured Person, Partner Companies, and Society.

- Insurance Company:**
 - Starts with **Expected Excess Capital** and **Expected Better Premium Payment Balance**.
 - Offers a **Higher Premium for Low Activity** and a **Lower Premium for Activity on Health Promotion**.
 - Engages in **Efforts to Seek Partners** to **Establishing Partnership** with **Partner Companies**.
 - Implements a **Rewards Program** for the **Formation of Healthy Subgroup**.
- Insured Person:**
 - Can **Join the Program** and **Self Check**.
 - Engages in **Promoting Health**, influenced by **hyperbolic discounting**, **loss aversion**, **incentive**, **communication by mHealth**, and **optimism bias status quo bias**.
 - Leads to **Prolonged Healthy Lifetime** and **Economic Activity** in the **Society**.
- Partner Companies:**
 - Involved in **Establishing Partnership** and **Customer Relationship**.
 - Contributes to the **Rewards Program**.
- Society:**
 - Experiences **Prolonged Healthy Lifetime** and **Economic Activity**.

The diagram uses arrows to show the flow of information and incentives, with positive (+) and negative (-) signs indicating the direction of the effect. Circular arrows (B, R) indicate feedback loops within the Insurance Company and Insured Person respectively.

Fig. 1 Causal loop diagrams of factors related to the SUMITOMO LIFE Vitality program. *Source* Newly produced from the information appeared in Kitamura (2019) *Note* R indicates reinforcing loops and B indicate a balancing loop

(2) Use of mHealth in life insurance products that incorporate health promotion activities

Smartphones (Apple Healthcare, Google Fit, S Health, Withings Health Mate) or wearable devices are expected to help measure the number of steps walked in this program (as of November 2021). The wearable device can add the heart rate to the program.

This program allows life insurance companies to collect member data. These data could be used to advise members of health promotion activities. For this purpose, company examined whether the number of steps taken in the first three months of health promotion activities would predict membership status, which is the result of behavioral change over one year (Tachibana, 2021). Logistic regression showed an accuracy of 80.1%, a precision of 86.3%, a recall rate of 77.3%, and an area under curve (AUC) of 88.3%; LightGBM showed 83.0% accuracy, 86.9% precision, 81.8% recall rate, and 91.0% AUC. In both cases, the initial behavior explained membership status. In other words, it seems realistic to use mHealth to provide individualized advice targeting member status linked to premiums, depending on the member's initial behavior.

An effort was made to evaluate this program as a whole through a survey and analysis of the membership data. In the questionnaire, 93% of respondents said they were more health conscious than before joining the program, and 84% said their quality of life had improved. Analysis of the accumulated data ($n = 51,316$) showed that the actual number of steps taken increased by approximately 17%, and of the participants whose blood pressure was outside the appropriate range (systolic blood pressure of 140 mmHg or higher), 48% had a decrease in blood pressure by at least 10 mmHg compared to the time they joined (Sumitomo Life, 2019).

These initial evaluation results suggest the potential for behavioral change with this program and the possibility of developing a more effective program.

7 Responses of Japanese Pharmaceutical Companies to mHealth

Japanese pharmaceutical companies have shown interest in mHealth. These can be categorized into several types, as presented below.

7.1 Better Control on Medication: Sensors Embedded in Tablets (Medication Control) Connected to Smartphones

Abilify MyCite (Otsuka Pharmaceutical Co., Ltd., 2017a, b), marketed in the US by Otsuka Pharmaceutical (approved in 2017), is a schizophrenia treatment system with a sensor embedded in the pharmaceutical tablet, originally developed by

Proteus. After administration, the sensor sends out a signal when it comes into contact with gastric juice, which is detected by a patch-type detector attached to the abdomen and sent to the patient's smartphone via Bluetooth. This signal indicates that the tablet disintegrates in the stomach of the patient. This allows patients, caregivers, and healthcare professionals to obtain information on medication. Otsuka says this is the world's first digital medicine, meaning that it integrates medicine (i.e., drug) and digital medical equipment.

7.2 Development of mHealth Business as a Treatment Option Complementing Treatments by Chemical Drugs

Otsuka Pharmaceutical (and Otsuka America, Inc.) signed an agreement with Click Therapeutics, Inc. to co-develop CT-152, a digital treatment application for major depressive disorder (Otsuka Pharmaceutical Co., Ltd., 2017a, b). The product was targeted for approval by the FDA as a medical device.

Dainippon Sumitomo Pharma interprets the future of the healthcare field as "an era in which it will be difficult to achieve the 'required health' through pharmaceuticals alone," and plans to commercialize comprehensive multidisciplinary healthcare systems. Under this business strategy, Dainippon Sumitomo Pharma co-developed a mobile application for type 2 diabetes management guidance, created by Save Medical (Sumitomo Dainippon Pharma, 2020).

Shionogi & Co., Ltd. is planning to transform itself from a pharmaceutical company providing only innovative prescription drugs to a company creatively providing "Healthcare as a Service (HaaS)." Its current intention is to provide original value to society through interdisciplinary comprehensive solutions to the problems faced by patients and society. Digital therapeutics, including mHealth, are considered an important component of such solutions (Shionogi & Co. Ltd., 2020a, b). In 2019, Shionogi acquired the right to develop and market two treatment apps originally developed by Akili Interactive Labs, Inc. (Massachusetts, US) in Japan and Taiwan. These apps are AKL-T01, a pediatric ADHD treatment app, and AKL-T02, an autism spectrum disorder (ASD) treatment app (Shionogi & Co. Ltd., 2019).

7.3 mHealth Use in Clinical Trials and Clinical Research in the Area of Commercial Interest from Pharmaceutical Business's Perspective

Takeda Pharmaceutical began a collaborative clinical research partnership in 2018 (mHealth Watch, 2019) with Verily (a subsidiary of Alphabet Inc., US) using Verily's wearable device Study Watch®, which enables continuous monitoring and analysis of vital signs and motor symptoms in Parkinson's disease patients. Takeda expects to gain new insights into the clinical features of the disease from exhaustively collected data. In addition, Takeda is collaborating with Integrity Healthcare

(Tokyo, Japan) to initiate a clinical study to validate a societal network system composed of online medical examinations, including home monitoring and online prescription guidance for Parkinson's disease patients (Integrity Healthcare, 2020). Further, based on an agreement with Kanagawa Prefecture, Takeda is working to support Parkinson's disease patients and their families through online medical treatment and medication guidance, and further, Takeda is planning to conduct clinical research on monitoring technology of symptoms (tremor, dyskinesia, etc.) using wearable devices and dedicated applications. The aim of this activity is to decrease the burden on Parkinson's patients, in the sense that motor symptoms prevent patients from visiting hospitals (Takeda Pharmaceutical Company Limited, 2020).

7.4 mHealth as Part of Comprehensive Healthcare Services Proposed by Pharmaceutical Companies in the Fields Where Companies Have Been Providing Pharmaceutical

This class of activities could be hypothetically interpreted as corralling of the market, and mHealth and related systems used are not necessarily provided as medical devices.

Takeda Pharmaceuticals, mentioned in the previous section, are working on a comprehensive service to support Parkinson's disease patients and their families through online medical treatment and online medication guidance, including home monitoring. In 2021, the company started offering a nonmedical device app for this purpose (Takeda Pharmaceutical Company Limited, 2021).

Similarly, Shionogi & Co. Ltd. proposed home-based online influenza diagnosis and drug administration guidance using video communication to the national government, and signed a partnership agreement with Yabu City in Hyogo Prefecture to improve community health care incorporating this system (Shionogi & Co., Ltd., 2020a, b). These activities possess the element of comprehensiveness stressed in this section.

Eisai aims to establish a comprehensive ecosystem for treating dementia, which is the prioritized business field of the company. Eisai's focus areas are neurology, including dementia and oncology. Eisai formed a business alliance with Cogstate of Australia in 2019 to develop and commercialize a cognitive function test created by a company in Japan (non-medical device) (Eisai Co., Ltd., 2020a). Eisai and ALM (Tokyo, Japan) will work together to provide information to patients and healthcare professionals, and develop and provide digital health solutions for regional healthcare coordination and comprehensive regional care by utilizing ALM's medical and nursing care ICT systems (Eisai Co., Ltd., 2019). This is a component of the dementia ecosystem that Eisai is building and will create new patient value in the fourth industrial revolution, bringing new benefits to people with dementia and their families.

In addition, Eisai has formed a business alliance with DeSC Healthcare, a subsidiary of IT company DeNA, to provide the nonmedical application "Easiit" to

prepare for dementia in 2020 (Eisai Co., Ltd., 2020b). Eisai plans to use this as a foundation for building a “dementia ecosystem” described earlier, which delivers new benefits to patients through cross-industry collaboration.

7.5 Investigation of the Presence or Absence of a Shift of Interest from Pharmaceuticals to Medical Devices Among Major Japanese Pharmaceutical Companies

In the context of mHealth being classified as a medical device under regulatory control, we investigated whether Japanese pharmaceutical companies have already shifted their focus to the medical device business by examining public reviews and reexamination reports to see if they have been approved for sale.

Out of 264 marketing authorization review reports (including follow-up reviews) for the 11-year period from 2010 to 2020, only 4 medical devices were marketed by the top 10 Japanese pharmaceutical companies. Of these, three were three prosthetic materials for promoting embolization in the central circulatory system (two in 2013 and one in 2018, Astellas and Eisai), and one was a genetic analysis program (2018, Chugai). In other words, there have been no notable moves to position themselves as manufacturers and distributors in the medical device field.

8 Status of Readiness to Utilize Public Healthcare Big Data

In Japan, the government’s ministries and agencies are positive about the use of medical big data, but multiple ministries and agencies tend to work separately on their own. For example, there are three guidelines for data security in electronic handling issued by three ministries. They are “Guidelines for the Safety Management of Medical Information Systems,” (Ministry of Health, Labour and Welfare) “Guidelines for the Safety Management of Information Processors Who Manage Medical Information on Consignment,” (Ministry of Economy, Trade and Industry) and “Guidelines for Safety Management of Medical Information by Cloud Service Providers” (Ministry of Internal Affairs and Communications). As is common in the Japanese administration, when handling medical information, it is necessary to adapt to all of these guidelines, whichever is appropriate.

Personal health records (PHRs) in Japan have advanced with the mindset of distinguishing between medical information and health (healthcare) information (Ministry of Health, Labor & Welfare, 2019). As for the relationship between electronic health records (EHRs) and PHRs, the Ministry of Health, Labor and Welfare (MHLW) has been working to expand the system that allows therapists to access medical records of particular patients nationwide, establishing an electronic prescription system. The intention of MHLW seems to organize these systems into EHR and to develop this EHR to “lifetime EHR,” which can be utilized as rich secondary data in medical research (Yakuji Nippo, 2020). On the other hand, as

a PHR system, the Japan Medical Association is promoting the digitization of the currently used “pocket notebook for general practitioners’ cooperation,” which is a paper-based medical history note managed by patients, to create a system that safeguards the sanctity of policy handling personal information (Ministry of Internal Affairs & Communications, 2019). In addition, PHR systems are also being considered for the refined use of personal vaccination information and school medical checkups (Ministry of Health, Labor & Welfare, 2019).

In general, the promotion of PHRs has not yet made substantial progress, but it is being considered a priority policy issue by the Japanese government, and the utilization of PHRs by the private sector is being fully considered (Ministry of Health, Labor & Welfare, 2019). In other words, the utilization of PHR-derived health information is expected to stimulate the development of health promotion mHealth.

9 The State of Japanese Startups in the mHealth Industry

To understand the status of mHealth-related startups, we used a database of startups in Japan to provide an overview. In this case, we used Startup DB (for Startups, Inc., 2021). This database contains information on about 12,000 startups in Japan. Information on about 200 companies related to mHealth was extracted based on the categorization by the database.

Figure 2 shows the year of establishment of the mHealth companies extracted from the Startup DB. Most companies were founded between 2016 and 2018.

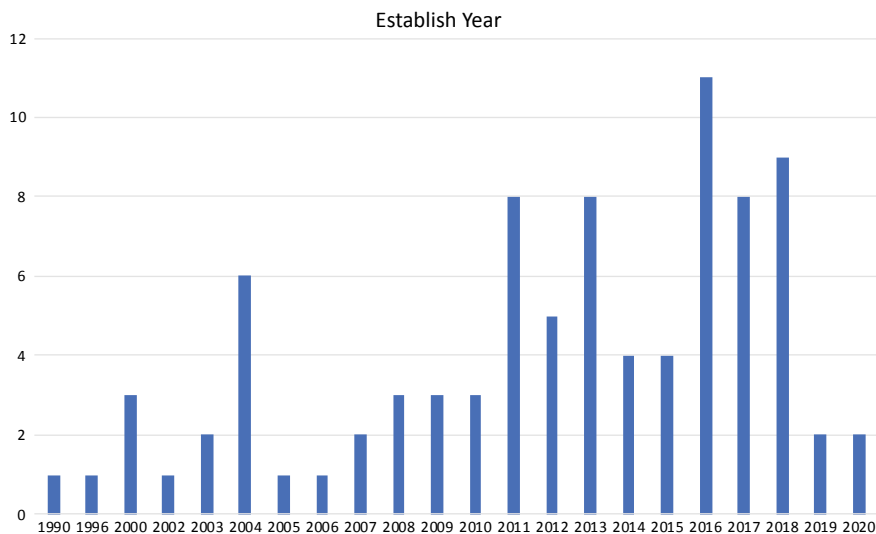


Fig. 2 Establishment year of mHealth firms. *Source* Startup DB

Figure 3 shows the number of employees; for just under 70 companies, the number of employees is unknown. Many companies have fewer than 50 employees. As mentioned above, mHealth companies and their products in Japan are mainly led by large companies, not start-ups. In addition, the average age of the workforce was 33.73 years. As indicated in 6.8, legislation on mHealth spans across the three ministries. Coordination between the ministries requires skilled personnel in the public policy sector, which is difficult to obtain from the Japanese labor market. Hence, in inverse proportion to the investment situation described below, this is the main reason why products are unlikely to emerge from Japanese mHealth start-ups.

Figure 4 shows the headquarters location of mHealth start-ups. Like most start-ups in Japan, they are concentrated in Tokyo. There are 71 companies in Tokyo, six in Osaka, and two in Aichi Prefecture and Hokkaido.

Funding from mHealth start-ups in Japan is on the rise, even if their role is limited. Figure 5 shows the total amount of funding raised, with 45 companies having an unknown status and 7 having zero funding, indicating that many start-ups are still in their nascent stages. On the other hand, there are about 30 companies that have received more than 100 million yen in investment.

This situation can be seen in Fig. 6 as well, which shows that investment in the mHealth sector has increased rapidly since 2015.

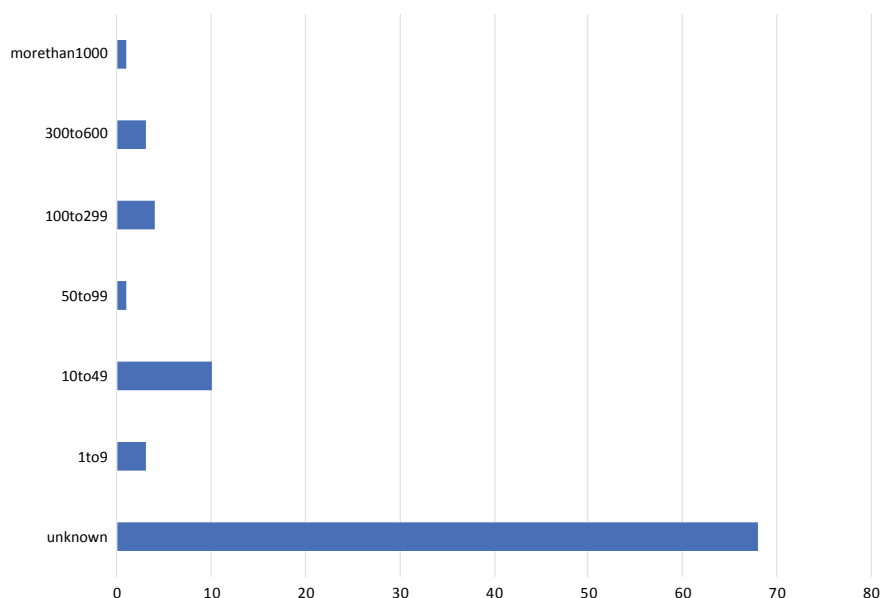


Fig. 3 Number of employees of mHealth firms. *Source* Startup DB

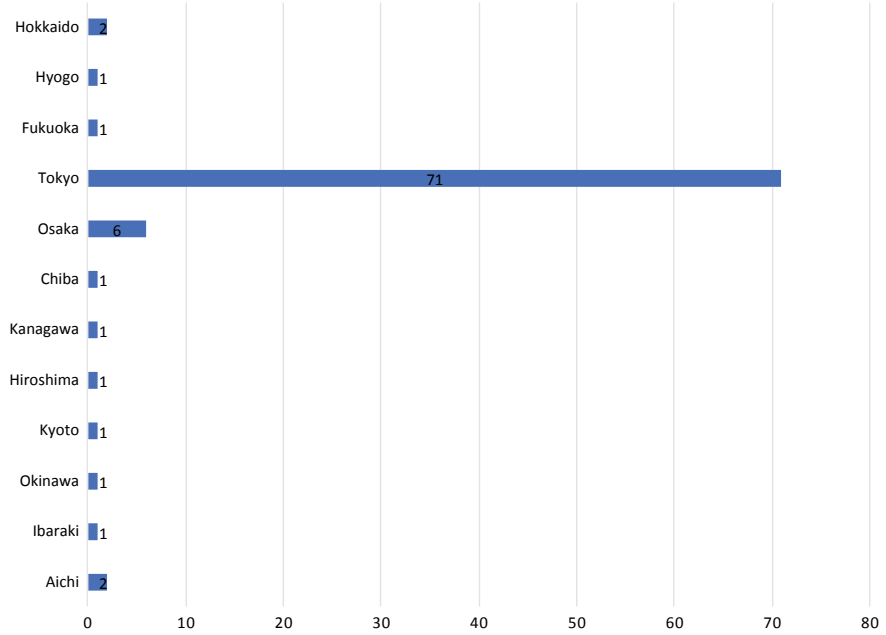


Fig. 4 Headquarters location of mHealth firms. *Source* Startup DB

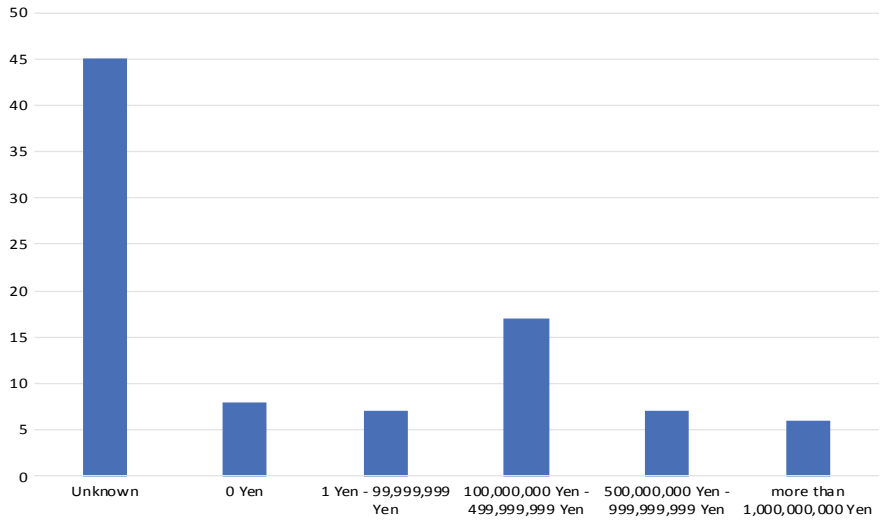


Fig. 5 Amount of total fund raise of mHealth firms. *Source* Startup DB

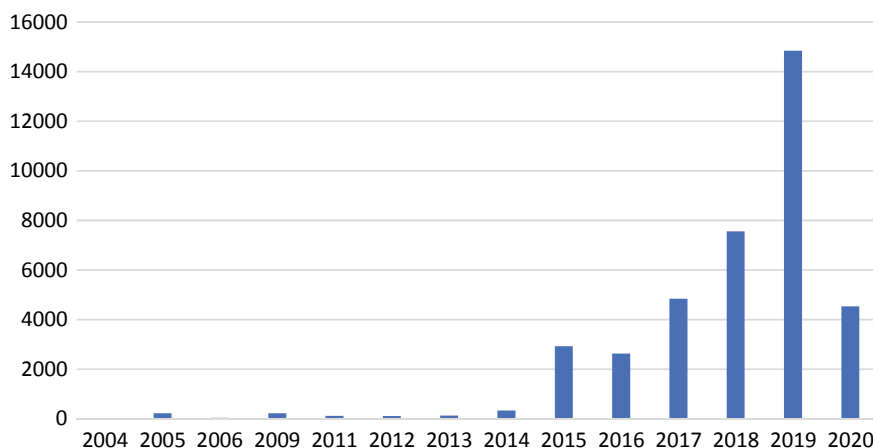


Fig. 6 Total fund raising in the sector. *Source* Startup DB. *Note* yearly; in million Yen

Which organizations and institutions are investing in mHealth companies? Table 3 categorizes the sources of investment by year based on the investment information available in Startup DB. Also, this table classifies investments into firms, VC (venture capital), CVC (corporate venture capital), Angel (investor), GVC (governmental venture capital), and banks. It can be seen that prior to 2015, when the amount of investment was relatively small, the investments were mainly made by angel investors and companies. However, since 2015, when the amount of investment has increased dramatically, the investment in startups by firms, venture capitalists, and corporate venture capitalists has increased.

10 Conclusion

In Japan, medical device approval for stand-alone programs has been possible since 2014, and obstacles to medical device regulations have been resolved. The number of approvals has not noticeably increased yet, and the government has been taking steps to promote development.

Health promotion using smartphone applications is being explored to avoid unnecessary increases in health care costs. Concretely, avoiding lifestyle-related diseases (diabetes, dyslipidemia, hypertension, or hyperuricemia) may be of interest. As of 2021, most of the apps that appear in Google Play Store, accessible from Japan, are pedometers, activity data handlers connected with wearable devices, or physical condition recorders. Some were diet recorders intended for weight control. Among them, Apple Healthcare, Google Fit, S Health, and Withings Health Mate in combination with wearable devices are applied to health promotion programs provided by life insurance companies.

Table 3 Sources of investment by year

Type of funder	Firm	VC	CVC	Angel	GVC	Bank
<2004	3	3		2		
2004				1		
2005		8				
2009				7		
2010		1		9		
2011	2	2		1	1	
2012	1		1			
2013	4	1				
2014	4	2		2		1
2015	15	7		7	2	1
2016	8	3	1			
2017	15	21	1	3	2	
2018	25	15	3	3		3
2019	41	29	2	8	1	
2020	10	4	1			
Total	128	96	9	43	6	5

Source Startup DB

Although Japanese pharmaceutical companies have shown a certain interest in mHealth, they tend to regard it as a component of an integrated healthcare system in the area of existing products and existing applications and are not necessarily focused on medical devices. In addition, the startup ecosystem surrounding eHealth is still in a nascent stage. Only a few firms could achieve huge investments by firms, VC, and CVCs.

As for the utilization of public medical data, PHRs are regarded as an important issue for the government. The Ministry of Internal Affairs and Communications (MIC), the Ministry of Health, Labor and Welfare (MHLW), and the Ministry of Economy, Trade and Industry (METI) are working to create a framework to promote the use of PHRs, but no significant results have been observed yet.

As described above, the status of mHealth and related social structure development in Japan is still in the development stage in terms of regulations, industry, and social infrastructure.

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Precision Public Health and the Role of mHealth: The Use of Smartphone Applications Worldwide in Mitigating the COVID-19 Pandemic and Their Integration as Components of Public Health Policies. A Focus on the French Example

Lefèvre Thomas and Guez Sabine

ABSTRACT

The COVID-19 pandemic was an opportunity to observe how, in practice, the means of precision public health could materialize, be mobilized, and with what results. Among the various measures required to control the pandemic, we can highlight the use of smartphones and applications, in particular, contact tracing applications. Their deployment has been almost synchronous all over the world, and their use called for by the public sector as well as the private sector. It is an innovation that has not encountered major problems in terms of regulation, in part due to exceptional regimes justified by the pandemic, such as a state of a health emergency. However, privacy issues do exist, as do issues relating to the social implementation of these services. Here, we examine in several countries what has been the place of the use of smartphones in the context of the COVID-19 pandemic, and what seems to have been the use of it as a prototype on a global scale of a precision public health tool. A particular focus is made on Europe and France more specifically.

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1 Public Health, Individual Health, One Health, and Precision Public Health

Public health is both a collective project and a field straddling the science of the state of health of populations—how to define it, measure it, research its determinants—and the means of action to maintain and prevent the degradation if not improve the state of health of the populations, political means included (WHO). In this first introductory part, we see the main and characteristic features of public health and individual health—their articulation. It is possible to examine these two types of health according to different models of representations, which will condition the type of knowledge and action that can be mobilized. Closer in time to us, we then discuss how the concepts of public health and individual health seem to be able to integrate certain technological innovations essentially, through precision public health and P4 medicine, respectively (Fröhlich et al., 2018). Finally, we briefly illustrate all of these elements through an archetypal example in health and medicine, that of communicable diseases. We also understand that both through predominant knowledge models and through the structuring of nations and contemporary policies, a certain conception of health is no longer reduced to either individual health or the health of populations, but extends beyond the human person and their societies, to encompass all the dimensions of their conditions of existence: we are talking about the concept of One health (Evans & Leighton, 2014).

1.1 Individual Health and the Health of Populations

Since a population is made up of individuals, there are necessarily intersections between the state of health of a population and the state of health of individuals: to a certain extent, by preventing degradation, maintaining or improving the state of health of individuals, individuals can prevent, maintain, and improve the state of health of populations—to a certain extent only, since this would amount to considering that a population is only the sum of individuals independent of each other, without direct interaction or indirect between them, or with their common environment. Indeed, in particular with constant and limited resources, favoring the state of health of certain individuals can have the consequences of degrading that of others, by competition for access to resources for example, or by degradation of the environmental conditions of other individuals.

1.2 The Articulation Between Individual and Population Level

Also, how does the health of populations and individual health fit together? In terms of knowledge and in terms of means of action? Part of the answer lies in models of health representation, and what they say about it; we tackle them soon after. However, another part of the answer also lies in a specific “place”

of meeting between individuals and the implementation of collective means for health: the health system. Public health, within the scope of its domain, includes the organization of the health system, both the training of health actors (medical, paramedical, administrative agents, executives, etc.), and the conditions of access to care (system health insurance, or social security more broadly), or the functional and geographical structure of places where we provide information or care (Didier, 2004). Finally, the organization of the health system is also linked to the regulation of this system and its various components: regulation of tariffs and fees, regulation of types of acts, regulation of diplomas, and regulation of innovation.

The health system is, therefore, this “place,” in the broad sense, where both individual demand and collective response meet: we try to orchestrate access to individual resources, while aiming at collective health objectives. Health policies are thus an essential social element in the articulation between the individual and the population level.

1.3 Biomedical and Biopsychosocial Models of Health: Individual, Environmental, and Social Determinants of Health

Historically, there are two main models of health representation: the biomedical or biological model (Yuill et al., 2010) and the biopsychosocial model (Engel, 1977). There are others—variations, mainly, of the first two statements—but we will consider here only these two main models in the sense that they clearly shed light on the majority type of scientific production concerning health in all its dimensions (prevention, therapy, etc.), as well as the means of action thought out and put in place.

The biomedical model intends to define health on the basis of individual health, this health itself being defined and determined by the biology of the individual, at different scales: genetics at the most basic scale today, molecular scale, cellular scale, histological and anatomical scale, etc. This individual-centered representation is supplemented, to take into account everything that is not the individual, by the notion of the environment. To refer to health as a whole, we then speak of a gene x environment interaction model. It is, therefore, an initially both deeply reductionist and materialist representation.

Another model proposed in the 1970s by Engel is the biopsychosocial model. As its name seems to indicate, it defines individual health by taking into account at least three complementary dimensions: the biological, psychological, and social dimensions. Note that if this model, at least in these dimensions, differs significantly from the biomedical model, these two models are nonetheless models of individual health, taking into account differently, on the one hand, the environment, and on the other hand, the social contributions to individual health.

It is important to know which model we are referring mainly to, because the dimensions defining individual health being different depending on the model, this means that what we will seek to identify as mechanisms and causes of good or

bad health of an individual, regardless of the methodological means implemented, will not necessarily be the same from one model to another, nor considered to be able to interact together. Thus, in the biomedical model, the cognitive and psychological dimension is seen as a consequence of biology, even if we do not know precisely through what means. It is not foreseen, initially, an autonomy of an object which would be the psychological life of the individual, which could maintain links starting from psychology to biology, for example. Psychological state, therefore, cannot be a determinant of health in general, nor a determinant of biological health. The same is true of the social determinants of health: possibly, in the biomedical model, the social can be absorbed in the environment, but does not benefit from a specific autonomy, nor from the status of an intrinsic component of health. individual.

If the determinants sought are different, then the means of action deriving from them will also be. This has immediate repercussions in terms of health policies and regulations. Take, for example, the opposition between the biomedical view where individuals are independent of each other, and the biopsychosocial view, where individuals are by nature defined by social interactions. In the first case, one can tend more easily to policies that place a large part of the responsibility for the state of individual health on the individual himself: beyond genetic chance, the responsibility of which can, however, be transferred. For the parents, the individual is responsible for all the so-called modifiable factors contributing to his or her good or bad health, independently of the behavior of other individuals. Thus, if we recognize that smoking is bad for health, and that no one is supposed to ignore it, then contract a pathology that we can estimate with great certainty that would be linked to the fact of having smoked, and may be attributable to the sole responsibility of the individual (Bourjolay, 2003). This responsibility means that it no longer seems legitimate for the individual to benefit from collective and joint responsibility for the consequences of his pathology: the costs of care will be his sole responsibility. In contrast, in a model where the social component is an essential component of individual health, it is no longer possible to immediately release collective responsibility for the deterioration of a person's state of health.

From the moment when the recognized determinants are not the same, and some relate to the social or the environment, this implies that the policies to be put in place can no longer target only the individual, or even the health sector is taken into account. In a classic sense, but will necessarily concern, virtually, all dimensions of life in society: thus, the development of laws concerning housing, agriculture, the installation of certain activities, etc.

At the same time as this movement to broaden policies that we could qualify as participating in public health, we can see the desire to make more targeted, precise, or individualized definitions and means of action relating to population and individual health, essentially with a view to improving efficiency.

1.4 The Concept of Precision Public Health Versus that of P4 Medicine

The past 20 years have seen the emergence of concepts on the one hand of precision public health (CDC) and on the other hand of P4 medicine (Seeking precision in public health, 2019)—this is mainly in parallel with the development of clinical genetics and IT and digital means: digitization, storage capacities, and calculation, accessibility of algorithms.

P4 medicine, for participatory, personalized, predictive, and preventive, reflects fairly well the consideration of developments mainly technological rather than theoretical, by the biomedical model. It remains self-centered, and aims, through the use of new tools at its disposal, to be more effective in its means of action through increased relevance at the individual level. The participatory dimension is not a consideration of the social dimension per se, but above all, a propensity to request greater participation from the individual in their health, passively (collection of personal data) or actively (education therapy, response to questionnaires, etc.); this goes in the direction of greater individual responsibility, as seen previously, even if these two evolutions are not necessary for each other (Syrett, 2021). P4 medicine is particularly based on the now almost ubiquitous nature of digital technology, whether in terms of data collection (via internet browsing, or simply the use of smartphones), storage and computing capacities (especially for data genome sequencing in clinical routine) or in terms of development and use of algorithms. It updates an old idea and desire, to have means of action that are more specific, more targeted, and more suited to a given pathology and person.

Indeed, whether it is antibiotics or anti-cancer drugs, the general principle remains to flood the entire organism with an active principle, and that part of this principle can reach the places where it must actually act—knowing that the treatment will not be active only on the targeted site, but will have a wider impact, and with more or less so-called adverse events—but not for all that random, because well explained by the mechanism of action of the principle on the different tissues or cells. The ideal would be to take only the principle most effective on the target, at the most accurate dose, acting only on the target, and respecting the physiological peculiarities of a given person (Bashraheel et al., 2020). This is what P4 medicine is aiming for through the analysis of big data and the use of artificial intelligence. The very use of algorithms raises at least two questions within the scope of what interests us here: what is the status of the algorithm (is it a medical device, subject to the same regulation? How do we establish the different responsibilities between the doctor who uses the algorithm, the algorithm itself, the designers of the algorithm, the seller of the algorithm, etc. in the event of a problem?) and what does the fact that this algorithm and what it induces as an action, is “personalized”? (He et al., 2019).

The concept of precision public health is somewhat newer than that of P4 medicine. It is also largely based on the development and increased accessibility of technological means, mainly digital, with the aim here too of being more relevant and more effective in its prescribed actions. Precision can refer here to at least two

quite different elements (Olstad and McIntyre, 2019). The most obvious here is to refer again to the individual. For example, health information, communication, and education follow the same paths as advertising and marketing. Advertising first used (and still does) what is called broadcast: a message is broadcast almost independently of the place, time, and characteristics of those who will be exposed to it. This is not quite correct, if we consider that we are going to choose one channel (medium) rather than another, or one type of location or time slot rather than another: to pass an advertisement in a newspaper of a supposed political tendency, in winter and full page, or place an advertisement in the middle of the super bowl half-time. Marketing quickly tried to segment the populations to be addressed, in particular, to target certain characteristics: adjusting products, their price position, or the audience to be targeted by advertising. Segmenting simply means stratifying the population into “homogeneous” groups—here in terms of tastes, needs, and financial means—on the basis of certain characteristics (Lefevre et al., 2014). Its translation into health is that of risk factors, which stratifies populations into groups more or less at risk of a pathology. Digital technology has seen the emergence of a new way of advertising, as practiced primarily by Google, but also Facebook to limit itself to these two examples. From broadcasting, or one-to-all, we have moved on to so-called targeted—or “personalized” advertising. How? or what? By segmenting more or less finely the populations exposed to advertisements, for example, on the basis of their internet browsing data or their expressed social links. Everyone using Google or Facebook is no longer uniformly exposed to the same ads at the same time, but virtually everyone is exposed to a “personalized” selection of ads.

Public health messages have always faced the same limitations as advertising: how do you reach people who you think should be the first recipients of the message? Precision public health has or will have in its tools this *a priori* possibility of better targeting its prevention messages.

The second element covered by the notion of precision refers to precision in terms of scale, notably spatial, but also temporal. It has now been known for a long time by epidemiologists that ecological indicators can be dangerous, in the sense that they can show inverse links to those which might actually be observed at the individual level. Roughly speaking, it is as much a question of documenting certain measures and certain links between exposure and health event other than through an excessively imprecise average effect. An example is that of the birth and death indicators in certain African regions: an overall measurement can indicate an improvement in these indicators over time, while a measurement at a finer geographical scale, and more respectful of territorial heterogeneities or inequalities, can show a very different reality: the worsening of these indicators over time for a whole section of the population, and an improvement affecting only a minority (Richard, 2018). Of course, the same phenomenon can be observed by varying the time scale of observation.

1.5 *The Specific Place of Communicable Diseases—An Archetype for Reasoning and Decision-Making and Evolution Toward the One Health Model*

Historically, whether in individual health or in population health, there is an archetypal model for reasoning and the development of means of action, it is that of the communicable disease, in particular, the infectious disease gives rise to a more or less important and serious epidemic. Why is this an archetype? (Masquelet, 2006) From the point of view of individual health, it is an initial model satisfying intellectually and from the point of view of action, because it allows to think and isolate the simplest causality in medicine: a pathogen A is responsible for pathology B. Remove A, and B disappears. Ideally, if B is not observed, then A cannot be found either. This is obviously not perfectly true, and this “pure” model very quickly finds its limits, the consequences of which are far from trivial. For example, the concept of a healthy carrier: we know that in general, at least 1% of a population will carry A without expressing either mild symptoms or pathology B—and can nevertheless be contagious for other individuals with regard to B. By taking the scale of A, we can study its mechanisms of action which cause disease B to start. By knowing these mechanisms, or quite simply, by knowing the weaknesses of A, one can design interventions, treatments that will make it possible to get rid of A, at the level of the individual (for example, an antibiotic). At the level of population health, the reasoning will be based on the modes of contagion and propagation of A. If we know how A is transmitted, according to what environment and under what conditions, again, in a complementary manner, we can take more or less targeted and differentiated measures to reduce or prevent transmission: one can think of isolation, such as quarantine, or vaccination. This model would therefore tell us that a transmissible pathology can be controlled using at least two approaches, one perfectly individual, by neutralizing the pathogen, the other more collective and population-based, hampering the spread of the agent. So here we are again on this articulation between the individual and the population, both in terms of knowledge and in terms of the means of action that can be mobilized.

At this stage, both P4 medicine and precision public health can be called upon in order to develop knowledge and means of action in terms of transmissible pathologies, in parallel with changes in the archetypal model of this type of pathology.

P4 medicine can look for the individual variations that will make one person rather than another be asymptomatic or severely affected by the pathology when exposed to the pathogen, but also the type of treatment most suitable for a person, its constitution, or stage of the disease. Precision public health will be able to support traditional means of communication and information (broadcast) by using more targeted media, such as smartphones, but will also be able to rely on existing tools, at various spatial and temporal scales to monitor, anticipate, and intervene in population movements, population concentrations, and pathogen transmission opportunities.

If we change the initial model of infectious pathology, then we very quickly go beyond the purely biomedical model in particular. For example, it is estimated that about 60% of human transmissible pathologies have an animal origin—and this is only a question of the origin, not the role of the animal in the evolution of existing pathologies (Taylor et al., 2001). Also, how can we only consider the pathology by restricting ourselves to the individual and his immediate surroundings, without taking the animal into account? However, the animal lives in interaction with other animals, and more broadly, within one or more ecosystems, the very definition of which is the opposite of a reductionist definition—an ecosystem is based on complex interactions between the different constituent elements; any subtraction of an element is likely to radically change the physiognomy of the ecosystem. The animal, its habitat, and its feeding conditions are linked to human activities, directly or indirectly—for example, agriculture and animal husbandry. We could still expand to other dimensions, including flora, or quite simply the different human activities: the principle remains the same, which the concept of One health tries to encompass, namely that we can consider health human in isolation. The direct consequence in terms of means of action is that policies aimed at maintaining or improving the state of health can operate in a multitude of areas that do not initially fall under health.

In this context, we understand that health interventions, individual or population, are based less and less exclusively on the use of undifferentiated information and classic therapy, both responding to an established public health code and known market and health system regulation laws. Innovation is taking an increasing place as a candidate for enriching the tools, not so numerous, that can be mobilized to control variations in the state of health of populations. The question of the regulation of innovation is central: we must be able not to ignore a new means that is individually and socially acceptable, and effective in terms of service provided to health, while refusing that these developments occur in all anarchy and without any regulation guaranteeing individual and social freedoms, and the proper functioning of society.

2 Guarantee the Conditions of Individual Health and the Health of Populations

We have just seen that different representations of health can lead to the development of different knowledge, and different means of action aimed at preserving the state of individual or population health. The overflow of the sphere historically identified as relating to health towards other fields of activity, this form of sanitization of society, means that policies, in particular regulatory policies concerning health, also go beyond the initial health field. The main challenge is to guarantee the conditions for both the health of individuals and the health of populations. There is a distinction to be made between policies of public health and public policies of health. In addition, this development is accompanied by another phenomenon, which again follows the technical means at our disposal,

that of insurance companies, companies based on perception, quantification, and the desire to control risk, including risk. sanitary. Finally, the third important element is the entanglement between the public and the private sector in health policy, particularly with regard to the regulation of innovation.

2.1 Public Policies of Health or Policies of Public Health?

The public health code of a country defines everything that regulates health at the national level: its organization, its financing, rights and duties... (French Public Health Code) Part of it may relate in particular to the law of health products. It is historically centered on a classic definition of health, oscillating between the biomedical model and a little biopsychosocial.

In a context where there is a sanitization of society, that is to say, a vision through the prism of health, of different social dimensions, or an extension to other social dimensions than that of health, health-related concerns, we are witnessing a sort of transitional regime between public health policies, in the classical sense of the public health code, and public health policies, which do not necessarily say their name (Pelchat et al., 2006). Thus, one cannot claim that the application of laws to different sectors of activity, be it real estate, industry, energy, telecommunications, agriculture, etc. which aim to control the impact of social and environmental determinants of health, does not help shape these sectors of activity. Mechanically, if the actions taken have a real effect, they have an impact on the activity concerned. Also, we are witnessing the emergence of more and more public policies, targeting different activities distinct from the health, but targeting public health.

However, whether we position ourselves from the point of view of public health, or preventive or corrective health measures via public policies applying to other sectors of activity, there is at least one principle common, operational and predominant: the principle of risk and insurance against the materialization of this risk.

2.2 Society of Insurance, Risk-Based Society, and Sanitization of Society

Knowledge of public health is mainly based on epidemiology, one of the ultimate goals of which is knowledge of the causes of pathologies (Last, 2001). However, in the vast majority of cases, the cause is difficult to reach, is rarely unique, and independent of other factors, and we essentially identify risk factors, which are a statistical concept—in fact, inseparable from the statistical technique. Our means of action are then alienated by our means of knowing, and the technologies available to do so, here statistics. There are thus at least two distinct stages in terms of health: that of the declared pathology, and that of the potentiality of the pathology. We want to develop prevention—to prevent individuals from getting sick—and we

are seeking to acquire the means to carry out this prevention. The central tool is the risk factor.

Insurance companies, whatever the field, know this tool perfectly, since it is at the center of their business: assess the risk, segment the population to be insured against this higher or lower risk according to the profile of the insured and associate a premium with it via the quantification of this risk and the estimation of the costs that would be generated by the materialization of this risk, in relation to the numbers of similar policyholders over a given period (Kaelin et al., 1992). The methods of assessing and quantifying risk, especially in the health sector where companies do not have access to the detailed medical information on people to be insured, have changed little over time. The most accurate and precise information, potentially the most complete, is a central research for insurance companies, in order to estimate as accurately as possible the premiums and margins they can generate from their activity. It's easy to see how there is now a plethora of insurances for almost every activity, every purchase, and mainly for frequent, low-risk activities.

The sanitization of society, associated with a risk, health and risk society sharing a common tool that is a risk, reinforces the race for information, individual, massive, and perhaps represents the most concrete form to date. Preventive measure in terms of health: above all, we prevent the financial risk, which may result from the occurrence of an individual's (or collective) health risk.

The context is thus very conducive to the use of big data, in the sense of departmentalization and cross-checking of information of various kinds concerning individual activities, both from the point of view of health and insurance. The question of data is of course accompanied by the processing and the measures that can be taken from it—hence the question of innovation in terms of data capture and processing, and communication. Regulation of the insurance sector, in particular, in the health sector, is one of the most restrictive, hardly compatible with the speed of development of other sectors, such as the digital giants, which have been given the freedom to build their capacities. Data-centric logistics.

2.3 Places of Industry, the Private Sector, and the Concept of Innovation in Health Policies

We have mentioned it several times previously: current developments are strongly linked to technological developments, in particular digital. The public sector does not have specific digital innovation or production capacities. Nor does it have its own production units for drugs, conventional or more innovative. Historically, if regulation falls to the public sector, as well as the obligation to guarantee the state of health of its population and the conditions to maintain this state of health, the means of action are mainly produced by the private sector, via industry, in particular the pharmaceutical industry. Regulation, in particular in terms of tariffs, but also in terms of authorization to market therapeutics, exists from this moment

that the private sector offers products for health purposes. However, innovation in this area is relatively slow, which is structurally linked to the operation of this industry, and therefore reasonably foreseeable, or constitutes innovation within a field or type of product whose regulation is well established, and therefore not required to change substantially.

The overflow of health toward other areas of activity and life, the sanitization of society, and finally the development of a risk society have the consequence that private actors are likely to play a major role in the provision of the means of action to preserve health are no longer the same, and above all, do not originate in the field of health. Better or even worse, digital companies even have the particularity of having based their success in part on the very principle of innovation, with development and growth in countries where regulation is or was relatively unconstrained *a priori*. This is particularly the case of the GAFAMS (Google, Apple, Facebook, Amazon, Microsoft, and Samsung). The general context is, therefore, that of a competition around access to data that would be relevant in terms of individual health and public health, between historical players in health and insurance, and new digital players, knowing that it is recognized that an important part of the determinants of individual health is behavioral determinants (Islam, 2019). This behavioral data is in reality often absent from medical or medico-administrative databases, but can be retrieved or inferred via other means and fields, in particular via connected objects and the use of digital services. The regulations in place are under major tension: those relating to health and insurance are among the most restrictive, while those relating to digital platforms have yet to be determined and made operational, along a transnational basis.

Then in 2020, a global health and social crisis arises, generating exceptional reactions. How did these exceptional reactions redistribute the cards between actors?

3 Example of the COVID-19 Pandemic

3.1 Historical and General Context

At the beginning of 2020, after apparently a start that passed under the radar in China, and possibly in other countries of the world, a health and social crisis began, affecting the whole world very quickly. The discovery of pathology due to a coronavirus, of significant contagiousness and a lethality greater than that of a seasonal viral infection among certain profiles (elderly men with chronic comorbidities) leads to more or less similar reactions in the patients in majority of countries in the world.

We are interested here in this crisis because it is an archetype of medicine—a communicable disease—occurring in the particular context of competition around classic and innovative tools, between historical players and new players. We examine the measures taken in this context, how much information systems useful for decision-making have been used, and how digital technology and innovation have

been mobilized. We will take the French example as a common thread for us, placing it in the European or global context as the case may be.

3.2 Beginning and Development of the Pandemic

For the record, we briefly resume here the chronology of the development of the epidemic then pandemic to COVID-19 as can be found in [23]:

- January 9—WHO Announces Mysterious Coronavirus-Related Pneumonia in Wuhan, China
- January 21—CDC Confirms First US Coronavirus Case
- January 21—Chinese Scientist Confirms COVID-19 Human Transmission
- January 23—Wuhan Now Under Quarantine
- January 31—WHO Issues Global Health Emergency
- February 2—Global Air Travel Is Restricted
- February 3—US Declares Public Health Emergency
- February 25—CDC Says COVID-19 Is Heading Toward Pandemic Status
- March 11—WHO Declares COVID-19 a Pandemic
- June 18—WHO Ends Study Into Hydroxychloroquine
- June 22—Study Suggests 80% of Cases in March Went Undetected
- June 29—Gilead Sets Price for Remdesivir at \$3120
- July 7—US Surpasses 3 Million Infections, Begins WHO Withdrawal
- July 9—WHO Announces COVID-19 Can Be Airborne

3.3 First Public Health Measures Taken

To deal with this epidemic, initially highly localized in specific regions of a handful of countries, such as China, Italy, or France, the first measures were taken were classic and historical measures, undifferentiated and radical: isolation, in different forms (Leplâtre, 2020; Verdier, 2020; Les, 2020). The isolation of the sick, but also and more broadly, the confinement of the population likely to be contaminated, according to a spatially determined logic—a city and a region. This logic of isolation was able to continue through increased control of trade with other countries, including the reestablishment of border controls within the European free trade economic area, or quite simply, the ban on travel to Europe and within a country or between countries. What interests us in these first public health decisions taken, is their massive nature—they concern entire populations, even though very strongly contrasting risk profiles were quickly established, without differentiation or targeting according to specific characteristics such as age, gender, or existence of co-morbidities. At the start of the pandemic, we are therefore in an almost archaic public health situation, far removed from the intentions of precise public health.

4 How Were the Information and Decision-Making Systems in Place Before the Pandemic, in Terms of Decision Support?

An information system can have at least two modes of operation and use: use of robust and reliable recording making it possible to follow measurements of more or less stable and regular phenomena in space and time, to monitor a situation and adapt action measures, or emergency use, where the need to have information of which we control the quality, in a reactive way and adapted to the time of crisis, is central for decision-making. Here we are mainly interested in the system for registering deaths and causes of death.

4.1 The Count of Deaths, Identification of the Medical Causes of Death, and the Associated Determinants

The historical statistics were the registration—the counting—of births and deaths, within a circumscribed territory. The development and deployment of the socio-technical device dedicated to this enumeration do not actually go without saying, even if it seems to us in our time to be something elementary. From this type of recording, the information systems evolved and diversified, and we wanted to extend the surveillance to other dimensions, beyond the birth rate and mortality, which were above all the responsibility of civil status. Thus, we were able to witness the development of cohorts in different countries, centered on the surveillance and identification of the causes of more or less varied pathologies, and the constitution of morbidity registers: recording as exhaustively as possible, on a well-defined territory or population, the number of cases of a specific pathology. The same goes for deaths: beyond the simple count of the number of deaths over a given period, we wanted to enrich the associated data. Age at death, sex, place of death, socio-professional characteristics... and health data, in particular, the estimated cause of death, its mechanism, and associated comorbidities.

In France, this role falls to two distinct public institutions: Insee and CépiDc (CepiDc). The former is in charge of the majority of statistics for the state, and regularly conducts studies on the population. The second is a small team hitherto reporting to Inserm, that is to say, the public research body dedicated to medical research. The CépiDc collects and analyzes all the causes of death in France. There were known operating difficulties of CépiDc, cumulative difficulties encountered throughout the collection chain (quality of the information provided by doctors on the death certificate, completeness of information, the predominant use of the paper medium for certificates, slow transmission of certificates, the undersized team at CépiDc to manage all certificates quickly and at the appropriate level of quality, etc.); these difficulties were exacerbated in times of crisis (Borowczyk, 2020), when this information system was in demand on the front line, and rightly so: how many deaths in the week, where, and what share attributable to COVID-19? What associated profiles? In short, a need for information in order to take the preventive

and corrective measures most suited to the situation, and where appropriate, to avoid measures that are either inappropriate or completely undifferentiated.

In this case, under steady-state conditions, the CépiDc is capable of delivering consolidated data in terms of causes of death with an 18-month lag between the death and the availability of the data. This delay is roughly the length of time between the onset of the crisis and the time of writing this chapter.

5 States of Emergency: The Parallel Between the Existing and Ad Hoc Information Systems, and Usual and Ad Hoc Policy Measures

Several countries, considering that the usual legal framework did not allow them to react appropriately to the challenges of the pandemic, have declared a state of emergency—for example, in France, a state of health emergency was declared on March 17, 2020 ([Vie publique](#)), then extended several times and is still active at the end of 2021. It is therefore a state of exception, defining the legality and the terms of a set of measures dedicated to crisis management. The usual framework was therefore deemed insufficient or unsuitable. However, still in France, this state of health emergency has not changed anything in terms of the regulation of innovation.

At the same time, countries including France, have over the past two decades equipped themselves with information systems in various fields of interest, including health and demography. These systems, in the light of the pandemic and its management by states, have often shown their limits or their inadequacy in emergency or crisis situations. Thus, while many channels, often of high quality and proven, were routinely available and relatively controlled, allowing information to be collected, were in place, these were partially or totally bypassed in several cases. This was the case in France for the census of deaths and cases of COVID-19, where several systems, at first very rudimentary—of the Excel file type fed manually every day—have been installed on the sidelines of the classic system for which constant efforts have been made. been invested by the State, in particular over the past 5 years (development of the SNDS, the Health Data Hub, etc. (Tuppin et al., 2017; Goldberg and Zinz 2021)): SI-VIC, SI-DEP for example, whose history has also shown the particular vulnerability and the relatively blurred boundaries in terms of respecting medical confidentiality (French ministry of Solidarities & Health, 2020; Lefèvre, 2021).

In a somewhat paradoxical way, therefore, the framework for regulating innovation, called for by the international community in the face of a situation where we were destitute in terms of treatment or measures less radical than the confinement of populations, has not evolved even though states of emergency were being declared making exceptional public health and sanitary police actions lawful; similarly, the available conventional tools have been overwhelmed, and others have been hastily created dedicated to the crisis, which will have to be successfully absorbed once the crisis over.

6 Contact Tracing Applications and Policy Measures for Pandemic Control

After having considered the concepts of individual and collective health, the means of action that can result from them, and having explained that both knowledge and these means of action are strongly structured by available techniques and technologies, including digital technology, we have discussed the context of the health and social crisis represented by the COVID-19 pandemic. We discussed the fact that this context was the opportunity to trigger states of emergency and a priori exceptional regimes. In this section, we see more specifically what these exceptional measures were, as well as the role and place of digital innovation played in them. We will focus on the use of smartphones as a tool within the framework of public health policies and part of a set of measures.

From April 2020, with the support of the EHESS (School for advanced studies in the social sciences, France), we undertook to identify data concerning the projects, then the launches of various smartphone applications presented as “contact tracing” applications, or more generally, applications allowing to play a role as one of the tools in the service of epidemic control. We collected information about 40 different countries at first. We then imagined that these applications would change little or little, or that their role would remain defined by their initial role, when they were made available. This was without taking into account that the pandemic, or at least its consideration and management by nations, would continue to spread over time, even at the time of this writing (November 2021). Also, the situation of several of these applications may have changed over time, depending on the country, and we have refocused our attention on 17 of these 40 countries listed, with an update in the summer of 2021 of several information concerning, in particular, the role of these applications in relation to all the tools and measures for managing the epidemic, in particular, if these roles may have changed. Table 1 presents the 40 countries selected first, as well as the main characteristics, and the 17 countries selected for follow-up in summer 2021. The characteristics are mainly taken from publicly available sources, so it is probably more optimistic than pessimistic estimates, especially regarding estimates of application adoption rates, or policies relating to the privacy and security of such applications. The list of sources is given in additional material (supplementary table).

6.1 A Call for the Use of Smartphones from Several Countries and Several Communities

The idea that smartphones, which are considered to be of almost universal adoption in the world for several years now, and multi-daily use, deemed almost unsubstituted, is the connected device par excellence, pivot between data capture and vector of individual action, is not new. The smartphone has precisely the advantage over any other connected device that has the potential to have imposed itself massively, to have integrated into the daily lives of billions of people—therefore,

to be accepted and used (Statista^c). It is also a vector of information and a means of communication, both broadcast and peer-to-peer.

It seems natural that the idea of using smartphones in one way or another has emerged quickly in different communities and places around the world (Bengio and Moayed, 2020). Without listing the different uses that have been proposed, we can list a few that are significantly different.

6.2 Use of Smartphones and Network Data—Mobility Data

Several countries have proposed to work with telephone operators in order to collect information on population flows at more or less fine geographic scales, and with more or less fine temporal resolution. In Italy or France (L'Express, 2020; Pepe et al., 2020), for example, in particular, following the introduction of a measure to restrict individual inter-regional travel, research teams were able to access aggregated data from base stations in order to have an idea of the flows. Population has passed from one region to another between two dates.

6.3 Use of Smartphones for Personal Information

After all, classic use of smartphones is that dedicated to information, general or individualized, concerning a given area. Thus, applications have been developed, offering users more or less specific information concerning the virus, the associated pathology, or the risks of contagion.

6.4 Using Smartphones for Contact Tracing

One suggested use, at the intersection of uses for documenting the spatial and temporal flows of people and individual information, is that which will be understood as contact tracing. A central problem in the knowledge of a transmissible process is to be able to document, on an individual scale and at suitable time resolutions, the contacts. A proxy imagined to document these contacts is to say that an individual is associated with a smartphone, which he is likely to carry with him regularly enough (Almalki & Giannicchi, 2021). If we assume that the majority of individuals carry a switched-on and operational smartphone with them, we can rely on them and the exchanges they may have with the community or directly peer to peer to estimate the existence of probable contact between two or more people at some point. The underlying technical implementation may then vary, but the principle remains the same. From this detection, several actions can be generated, whether toward the user himself or a third-party user, or a public body responsible for monitoring, studying the phenomenon, or providing information.

What is important to note here is that different actors, on sometimes complementary aspects, quickly positioned themselves in favor and with concrete

proposals, of the use of smartphones, and that the use of them should not be thought of as an end-to-end solution to the management of the pandemic, but as an innovative tool that fits into a set of public health measures, which can go as far as health policing and population control through a government, in the context of an exceptional regime.

Thus, consortia were able to emerge to specify and standardize the technical aspect making contact tracing possible, whatever the precise use (PEPP-PT), (Google Apple exposure notification system). Well placed to design, promote and benefit from this situation, several digital giants have also offered the use of their proprietary solution, such as Google or Apple. Finally, countries were able to opt for specific solutions designed in-house.

Let's see what measures have been adopted by many countries and into which the use of smartphones can be integrated.

7 What Political Measures Have Been Deployed? A Typology

Several public health measures have been proposed, rarely by a single country, but on the contrary simultaneously or rapidly shared, transposed with or without variants, between many countries. The majority of these measures are remarkable in that they are not at all innovative or take advantage of technological innovations or increased or updated knowledge about the disease and its mechanisms of spread and action (WHO). They are based on general and fundamental considerations, first and foremost the fact that in order to transmit a pathogen, special spatial conditions are needed: places where people will be in sufficient contact to transmit the pathogen.

7.1 Closure of Certain Stores/Public Places

This is the case with certain places of frequent frequentation and repeated daily intermixing and concerning the entire population: shops, or public places bringing together a large number of people, for a time increasing the probability of transmission. Obviously, businesses providing vital services, such as the sale of food, are difficult to close. On the other hand, several countries established lists of businesses that it was not considered imperative to keep open, in the sense that temporarily it was quite possible to do without their service. This was the case, for example, for businesses selling clothes, bookstores, etc.

Likewise, gathering places, like cultural venues, were considered both at risk of promoting spread, and dispensable while the epidemic was brought under control: museums, concert halls, cinemas, etc.

7.2 Closure of Schools

Among the measures recommended by the WHO, the closure of schools and universities, first in a rather undifferentiated manner again—that is to say, regardless of the age of the people attending school—then with differences according to the age: universities, in particular, have been subject to measures similar to those concerning places of professional practice. Elementary schools, for their part, in a second were kept open as much as possible. As this is a virus that during at least the entire first part of its spread mainly affected adults, and even adults over 50 or 60 years old, and mainly killed adults over 65 years old, with co-morbidities, The logic of an undifferentiated closure of these places can be questionable.

7.3 Isolation, Quarantine, and Confinement

The classic measures to control an epidemic with significant contagiousness and worrying lethality were undertaken very quickly: isolating populations “at risk” in the general sense, that is to say, not only at risk of contracting the disease or “die from it, but the population likely to be carriers of the virus, whatever its symptomatic status or its supposed contagiousness. The isolation of people carrying the virus, in particular asymptomatic, paucisymptomatic, or simply in the phase preceding the onset of the disease, has been made difficult for two main reasons: the first, classic, is that there is a period when the person she herself is not necessarily aware of being a carrier or contagious, the second is technical and logistical, with the prolonged unavailability of reliable tests to establish the diagnosis.

7.4 Regional, National, and International Travel Restrictions

Isolation and confinement can take place within a spatially defined population, but also in its exchanges with other populations, especially foreign ones. Travel restrictions were thus able to be decided, within a region or a country, in particular when in its early phases, the epidemic was quite strongly geographically circumscribed, or between countries, for example, with the establishment of lists of “at risk” countries, for which people coming from them could be refused entry into the territory, or quarantine for varying periods of time.

7.5 The Tools Used for These Measures, the Use of Technology

We have seen a fairly new use of technology as a tool in its own right and linked to other public health measures in the management of the epidemic. In particular, the use of smartphones, or telecoms in general. In fact, we have been able to use data from mobile networks to estimate the mobility of populations between different

regions of a country, or between countries, at an often macro level, that is to say, without individual or identifying data.. This is a use of network data which does not presume the type of telephone used.

More specifically, we have been able to use smartphones, in the sense that they allow the installation and use of more or fewer complex applications and take advantage of the functionalities of these phones: geolocation among others, but also communication technologies. between objects, such as Bluetooth. Finally, in some cases, smartphones, via these apps, have also been able to take the place of a pass, in the sense of the passport, in connection with the status of a person carrying the virus or not, vaccinated, or “cured.”

8 A Panorama of Applications in Several Countries

Our intention was, therefore, to provide an overview of contact tracing applications in different countries of the world, in particular by researching what was publicly available on these applications, through official government announcements or communications in the general press. Thus, out of the 40 countries listed, all the applications were launched between February (China) and September 2020 (Portugal), the majority having been launched between March and May 2020, which testifies to the development and deployment capabilities of these countries relatively fast, considering that we began to consider the spread of the virus internationally from the first quarter of 2020 and that these were new tools, from a technical point of view but also from a legal point of view as to the scale of their use and the nature of their use.

Several specificities were then combined: the supposedly highly contagious nature of the virus and affecting all age groups of the general population, its significant lethality, the context of globalization of product exchanges and circulation of populations, and the absence of preventive treatment or curative known to counter the virus, healthcare capacities in particular which have evolved in many countries towards a decrease, the adoption of unprecedented digital tools, in particular smartphones, by the general population, an interest and increasing accessibility for algorithms applied to health data, a legal framework regulating the use of personal and health data which is evolving in many countries (in particular, in Europe, with the adoption of GDPR—General Data Protection Regulation). On paper, the use of smartphones and digital technology in general to complete the toolbox of measures to control the epidemic seemed to be necessary. This recourse can be seen as a classic problem in the design and use of a digital tool for public health purposes, at the individual level. So, as a problem of regulating precision public health innovation, in a specific context of a pandemic. The classic questions arise:

- Who designs, who operates the tool?
- What is the status of the tool and its use with regard to the law: how is data collected, what data is it, who has access to it, and for what type of processing? Are there any guarantees regarding the duration of data storage and use of apps?

- Is the use of these apps for a single, well-defined purpose, or can it evolve more or less vaguely?
- Are there rights and duties attached to this use case: Are the people whose data is collected identifiable? Can they ask to access their data and have it modified in the event of an error? Is transparency ensured as regards the storage of data and the source code of the algorithms used?

In the following sections, we review the main characteristics of these applications, depending on the country.

8.1 Main Initial Intended Uses of the Applications

We have identified the main information of apps in 40 countries that allow us to characterize their starting point: their name, the players involved in their design and operation, the estimated number of users/penetration rate of the general population, the rate of penetration targeted by the country, the type of technology used for the app, whether the country has opted for compulsory use of the app or not by its citizens and finally, whether the use of the app was initially planned in a narrow and well-defined goal, by a limited if not a single number of actors. These data are reported in Table 1.

We will repeat it later for other characteristics, but a first remark is the relatively large number of data not made public, or partial/imprecise—or simply perhaps not known by the countries. This can question the ability or the willingness of countries to be transparent about their objectives and the compliance of these apps with the legal framework when they are put in place.

In terms of designers and operators, we notice the vast majority of operators are of a state nature, which seems natural, whether it is the government directly, or one of its ministries: mainly health or interior ministries. Just as frequently, we note the use of private companies, either old or start-ups for the design and deployment, and outsourcing in the operation of apps.

The penetration rate is inconstantly available, although this is a critical piece of information on the prerequisites for the effectiveness of the tool. When it is available and estimated, it exceptionally exceeds 30 to 40%. The highest rates communicated (i.e., above 80%) correspond to countries where the use of the app was made compulsory. The target penetration rates are exceptionally available and are remarkable in two other respects: they are very variable and mostly do not correspond to what we have read in the scientific literature (they are lower, and it is difficult to understand what this objective corresponds to), and none is achieved.

As for the technology chosen for the apps, a large majority have used Bluetooth, either alone or in conjunction with other technologies, mainly tracking technologies such as GPS. The use of joint Google/Apple technology is ultimately quite widespread.

The app was compulsory for citizens to use, at least partially, for 8 of the 40 countries surveyed, making it a minority, but still 20% of cases. Finally, a majority

of countries announced when their app was set up that it would be of limited use, and the data collected, of restricted access.

8.2 Main Characteristics of These Applications Depending on the Country

We have used the same generic term “contact tracing” to use all the apps listed. This means that overall, these applications have a similar basic operation: for a person who is positive on a Covid test or diagnosed with Covid, to be registered as such. From this postulate, several variants can be considered: the applications can make it possible to estimate the spatial and temporal interactions between people who have installed the app and trigger different actions according to the status with respect to the Covid infection of these persons, or to provide information adapted to their status.

This says little about the individual, but especially collective, use, which could initially be expected by countries when designing and deploying these applications. We have seen, upstream of the specification of a particular use of the app to its deployment, that not all countries have restricted themselves to reserving these apps for a single and well-defined use, with a known deadline, but that several have left the field open to an evolution of the role of these apps over time and according to estimated needs.

However, we have tried to identify the main uses, but also users, depending on the country. Complementary results to those reported in Table 1 are reported in Table 2.

8.3 Changes in the Use of Applications Over Time

Many applications were initially intended to help detect interactions between a person carrying the virus and a “healthy” person, in order to identify situations at risk for the spread of the virus. Some of these apps could be accompanied by contextual alerts, or more or less generic or personalized advice concerning the virus, the risk factors, and the measures to guard against it.

However, many of these apps have served as a medium for broadening purposes or uses. We can thus note the use in the professional space, for example, to regulate work on-site or remotely, in telework.

More generally, we have seen a widening of the initial use of apps through their use as digital health passes in several countries. Often, the use of a smartphone is not explicitly required, as a QR code is usually at the heart of the device and can be printed on paper. In practice, everything is done to encourage the use of smartphones rather than paper. The principle of the health pass is similar to that of the laissez-passer or passport, so that its holder can access a set of places or services, the scope of which varies over time and according to the countries or regions of the same country: restaurants, hospitals, concerts ...

9 Contact Tracing Applications Seen as Innovations in Health, the Case of France

We are discussing here more specifically in the case of France, concerning the use of smartphones and contact tracing apps in the context of the COVID-19 pandemic. We see how the “StopCovid” initiative (INRIA, 2021) is part of a global movement, and how it has concretely been implemented in the French ecosystem. We are interested in the relationship between the innovation in mHealth represented by the development of this app, the needs of public health, and the legal frameworks.

9.1 *Precision Applications and Public Health—A Synchronous Prototype on a Global Scale?*

The massive use of smartphones to detect and manage cases of infection and contact with these cases has been almost unanimous, all over the world, and almost synchronous. The idea for this remedy seems to have been put forward by civil society, health and IT researchers, private companies, and even governments. This, in itself, is certainly the first example of innovation developed in the context of a health crisis, and part of a precise public health approach. Until then, the concept of precision public health relied on mostly theoretical, prospective, and a handful of limited concrete examples. In a matter of months, the whole world shifted naturally to the very real possibility of global precision public health.

Like any idea that must pass the stage of its concrete realization, of its implementation, the development of these apps had to confront, in an accelerated manner, the difficult course of innovations in health, let alone in digital health. It is about confronting the idea with reality on the ground.

9.2 Public or Private?

In order to make the app idea real, two very specific questions arose. We are used to private contacts and the regulations that go with them when it comes to developing drugs, vaccines, or medical devices. The private sector overwhelmingly develops and industrializes products, subject to known regulations, notably allowing products to be placed on the market and the setting of their prices. Who was responsible for developing and then operating digital public health tools? Public actors or private actors?

In France, for example, the response was far from being different from usual, with no specific *modus operandi* for an innovation. Thus a “StopCovid project-team” (StopCovid is the first name of the app, rebranded “TousAntiCovid” a second time (<https://bonjour.tousanticovid.gouv.fr/>)) was set up, bringing together the research organization Inria (specializing in automation and robotics), the strategic consulting firm usually mandated by the government Capgemini, the historic

but private mobile operator, Orange, the aircraft manufacturer Dassault via its subsidiary Dassault Systems, two start-ups specializing in the development of mobile applications and connected objects (Lunabee Studio and Withings), and finally 3 public institutions: Inserm (health and medical research institute), ANSSI (cybersecurity) and Santé publique France (the public institution in charge of public health in France, besides the ministry of health). This partnership has not been the subject of any public tender or competitive bidding for companies or consulting firms with regard to specifications. With the exception of Withings and Lunabee Studio, the partnership only brings together old players, with no specific contribution in terms of innovation in health. It is specified that the participation of private actors in the project team, in the prototyping phase, is not invoiced (French ministry of economy). However, it should be understood in this declaration, that anything that will go beyond the framework of prototyping will be all the more heavily billed, under fairly opaque conditions: for example, the maintenance of availability of the infrastructure, quantified in hundreds of thousands of dollars, euros per month, even if the system is not adopted very much, and the effective number of contacts, infinitesimal (Berger, 2020). The usual regulatory mechanisms in terms of contract award, and choice of service providers, do not seem to have been respected, and the entire project was conducted with a certain opacity.

9.3 What Regulations Have the Applications Had to Comply with?

The development of StopCovid, like that of other apps in other countries, has not been able to ignore the regulatory framework for both personal data and health. The recent and current framework is that of the GDPR, and its translations into national law in each country of the European Union. In France, the body in charge of granting authorizations for the collection, storage, and processing of data is the CNIL (CNIL). This organization revised its texts, increased them, in order to take up the GDPR passages almost to the letter.

Also, the deployment and use of StopCovid had to receive approval from the CNIL (CNIL, 2020), and was the subject of an opinion from the National Ethics Council (CCNE, 2020). The CNIL underlined various points of attention and expressed concerns about the respect for the privacy of users. The government responded to the CNIL in the sense that everything was planned for compliance with the GDPR. It didn't take long for information to leak that the app was collecting and storing information it was not supposed to collect and record (Le Monde, 2020). This kind of breach of regulatory texts and regulations seems systematic, whether the actor is public or private. It is therefore noteworthy that the regulatory body has few means to ensure compliance with its injunctions, let alone the government.

Thus, an innovation such as these contact tracing apps, in France but in a similar way around the world, has developed in a permissive context, where little or

no effective regulation has been applied, on the pretext of a state of a health emergency. However, the regulatory mechanisms exist precisely to guarantee a certain number of rights, in particular against so-called exceptional situations. The technical skills to develop these apps, a fortiori within a globally supported and shared effort, are not disruptive techniques. It is the use of these apps that makes it so innovative. As it stands, this innovation has not been the subject of any regulation in relation to its innovation status—StopCovid is not even considered a health device. However, it also has a role in prevention and in guiding the management of cases and contact cases.

9.4 Evaluate a Priori the Actual Benefit of the Applications

An important dimension in terms of innovation in health and the regulation of health products, particularly in France and in Europe, is that of evaluating the actual benefit (the therapeutic value or added value) of these products. Their authorization, and especially their reimbursement by national solidarity, depend on this therapeutic value. These apps have a role to play in controlling the epidemic, they are precision public health tools, and in themselves constitute an intervention in the population, with significant socio-economic and health implications. They should, therefore, be subject to evaluation: pre-, peri-, and post-deployment.

9.5 Necessary Coverage, Equipment Rate of Target Populations

The initial idea of contact tracing apps is to be able to detect, and then somehow “track,” interactions between people, especially people with the virus and people without. Obviously, and by analogy with vaccines, for any intervention based on these detections to have a chance of being effective, it is necessary to have a sufficiently large adoption or coverage of the population, otherwise, we miss the majority of potentially contaminating interactions and contacts.

It has been estimated that to be effective, these apps need to be adopted and actually used by at least 60% of the population (Ferretti et al., 2020). This, therefore, means, among other things: having an operational smartphone, having installed the app, that this app works and works all the time, keeping your smartphone with you at least when traveling, and therefore that at least 60% of the population general or in this configuration. Depending on the country, the rate of smartphone equipment can vary significantly, and within a given country, this rate of equipment can vary significantly by age group, regardless of any consideration in terms of digital literacy.

In France, the rate of smartphone equipment, that is to say, the proportion of people who have bought a smartphone at one time, is estimated at 77% in 2019 (Statista^a). In addition, the rate of equipment for the segment population most at risk (people over 70 years old), drops to around 44% in 2019 (Statista^b). Presumably, a pre-deployment evaluation would have been unfavorable as to the use of

the app given the mathematical impossibility, and of far, to approach the estimated threshold prerequisite for the effectiveness of measures based on the use of these apps.

9.6 Determinants of Intent to Use Applications

The pre-deployment assessment can also be based on measuring the intended use of these apps by the target population. A few studies have taken an interest in this fairly quickly, knowing that measures of intention can be weakly correlated with actions actually observed, as can be seen in electoral matters. Thus, we were able to estimate the following determinants of intention to use the app, in 5 different countries (the USA, the UK, Italy, France, and Germany): overall, there seems to be a reasonable acceptance of the principle of apps for the epidemic management (Altmann et al., 2020). However, there are variations between countries, and depending on several factors: the youngest (18–30 years) are in favor, but nothing can be said about the older age groups, which is embarrassing, given that the older ones, young people are the least at risk. People living in Germany or the USA are the most resistant to the idea of such an app, in particular in connection with a limited confidence in public institutions and the government, in particular with regard to questions of management of data, surveillance, and privacy. People reporting co-morbidities were also more likely to adopt these apps. On the other hand, there was no link with the number of deaths due to COVID-19. This initial information, quickly available in early 2020 at the start of health crisis management, therefore indicated at least 3 important elements: i) the people most at risk were not those who were most in favor of using apps, except those with co-morbidities, ii) around 68% of respondents said they intended to install the app from their country, which appears both in line with the possibility of achieving the minimum coverage necessary on first reading, and on second reading, this objective of minimal coverage is unrealistic: it is about intention, and about the prerequisite of having a smartphone; it is therefore 68% of people equipped, which reduces real adoption by as much, iii) adoption intentions are strongly linked to trust in institutions, and therefore in part to the existence, reliability, and application of a regulation of these apps.

9.7 Determinants of Application Use

The measurement of usage intentions, if we considered that it was reasonable to deploy these apps in the context of a pandemic, logically should have been followed by research into the determinants of the effective use of apps by the target population, to estimate the potential effectiveness of metrics based on app usage.

To our knowledge, no interventional, pilot study has been carried out to estimate these determinants, and therefore the chances of the tool's effectiveness.

Conversely, we are aware of the refusal of such evaluations by the French government, proposed by independent consortia of the StopCovid project-team, despite excellent expert reports supporting the funding of these evaluations, even though the application was not yet deployed; these evaluations could have best guided the adequacy of the prototype to the reality on the ground. A few researchers have looked at the determinants of adoption and use of apps, once they are deployed, for example, researchers from the Digital Global Health & Humanitarianism Lab (Putric et al., 2021). They were interested in 5 countries (Iceland, Cyprus, Ireland, Scotland, and South Africa). Eight types of determinants were identified according to them: Perceptions of Data Collection and Management, Sense of Community, Communications and Misinformation, Accessibility & Inclusion, Trust in Public/Private institutions, Policy and Governance, Response Infrastructure, and Digital Capability.

Some are therefore more of the order of the individual determinant, while others relate to the institutional or societal scale. The way in which regulation applies to these apps, in terms of policies, communication, trust in public and private institutions, and finally in terms of data collection and processing, represents half of these determinants. Thus, the regulation, in the broad sense, of this type of innovation does not appear only as a legal tool reserved for specialists, but as a practical societal necessity, conditioning the effectiveness of the measures taken to manage the epidemic.

9.8 State of Exception, Exception Status for Applications?

As outlined earlier, we have seen the establishment in several countries of states of emergency, authorizing governments to adopt emergency measures to manage the pandemic. These states of emergency, to our knowledge, have not impacted the regulatory frameworks for innovation, which is nevertheless highly anticipated to supplement or relay conventional public health measures.

The development of contact tracing apps, or more specifically, the innovation consisting in establishing an unprecedented use of smartphones for precision public health purposes, occurred in this context of an exceptional state, with an untouched regulatory framework.

Apart from the effort at least in principle to comply with national or international regulations concerning personal data or health data, the development, deployment, and use of contact tracing apps have been carried out in practice without any consideration for any framework. evaluation and regulation, and even independently of any preliminary data making it possible to estimate the real contribution, or to evaluate the first risk–benefit balance.

9.9 Innovation, Precision Public Health, and Societies

The management of innovation by the public authorities, and its regulation, is not easy: it is a question of not hindering the creation and production of potentially useful products or services if not disruptive, while guaranteeing sufficient rights to people and society. In health, the problem of regulating innovation is no less complicated, and the acuteness of the questions it raises is redoubled in the event of a perceived or real emergency. There is, however, a fairly well-developed arsenal in health to provide a framework for therapeutic innovation, in particular in its medicinal form, medical devices benefiting to date from less comprehensive regulation, but which have been evolving over the past ten years. Digital health, in these different forms, whether it is the use of connected objects, personal data, or AI algorithms, once again redoubles these regulatory questions, because its tools do not currently have perfectly clear statutes—one possible path being that of assimilation into the category of medical devices. However, there is a broader legal framework concerning digital technology, and in particular, transactions relating to personal data.

Here we are interested in a prototypical and archetypal situation, in the conjunction of several conditions: a global health crisis, linked to a contagious pathology, the emergence until then more theoretical than the concrete of precise public health, and the development and installation of digital technology—its technical means and its uses—unprecedented among the general population. Innovation has emerged in this context of global scope: the use of smartphones as a precision public health tool.

We summarize below what we retain from this conjunction of elements.

9.10 A First Attempt that May Cause Concern: Innovate with Old Things, and Ignoring Known Good Practices

To our knowledge, there is no antecedent directly similar to the one we are experiencing on the occasion of the COVID-19 pandemic, from the point of view of the elements mentioned: global crisis, digital development, and the emergence of health public precision. The decision to use smartphones and contact tracing apps seems to have arisen almost synchronously and very quickly, in different parts of the world and from different socio-economic backgrounds. The ground, therefore, had to be ready to host this first test.

One way of looking at it is this. The necessary tools, the technologies to make this remedy possible, were already available, or at hand, requiring only relatively marginal adjustment or articulation. The culture and habits of many people around the world make the idea of an app easily understandable in concrete terms, regardless of the possible consequences of its actual use. The issue of digital health is a current issue, the legal framework of which has been refined for several years. The regulation of medical products is well defined in all countries and even internationally. Also, the innovation essentially consisted of a customary innovation:

resorting to digital technology, massively on the scale of the entire population and on an individual basis, to manage a public health problem declared urgent. A parallel can be drawn with the search for therapies and vaccines against COVID-19: overall, all the players concerned felt bound by the need to play the game of regulation, even at a forced march, certainly with excess, frauds, but which are not necessarily specific to the crisis. The products have been tested, evaluated, followed closely, communication has taken place, scientific controversies have taken place, authorizations have been issued and withdrawn.

Contact tracing apps, placed as a public health tool, collecting and allowing the processing of health data, are only marginally included in this framework: simple or detailed communication has been more an exception than the rule; no pre-, peri- or post-epidemiological evaluation has been carried out as it should for a population intervention, a fortiori of this magnitude and also prototypical, probably posing as a precedent that lays the foundations for the future. We even have an example of the government's refusal to entrust qualified independent teams with the proper evaluation of these apps. It can hardly be a question of cost: even if this type of evaluation is in itself expensive, of the order of a million euros, this cost is perfectly marginal compared to the expenses incurred in the health sector, dedicated to fight the COVID-19.

Using personal data, the apps had to be part of a process of compliance with the regulations governing the use of this data. Although they have changed in recent years, these regulations are still very heterogeneous from one country to another. In Europe, the GDPR has been put to the test in this context. In France, in particular, the public body in charge of data and individual freedoms (CNIL) was able to issue an opinion on the government's app proposal, deeming it insufficient in terms of guarantees on several points. The government's promises of transparency and compliance were flawed in the first few weeks after the app was set up.

Finally, although no rigorous evaluation has been carried out on the population, several rapid studies have been carried out either on declarations of intention to use apps, or on the determinants of their actual use. These available elements, in addition to the fact that they pointed to a very likely ineffectiveness of apps, particularly due to very insufficient population coverage, indicated an important role for regulatory mechanisms and their consequences in societal terms. Transparency, communication, respect for individual data and digital rights, and trust in public institutions and the private sector would have favored app membership. The absence of a real or effective regulation and of the elements which relate to it, appear as strongly to the detriment of innovation in this context, contrary to what can be said in other contexts, for example, that too many regulations slows down or prevents innovation.

9.11 Different Political Regimes, But Few Differences in the Use of Applications?

Trust in public institutions appears to be a major determinant of membership in apps—or in any case, of downloading these apps, because this is essentially the indicator available and make it possible to estimate very imperfectly the possible subscription to the use of apps. It is known that downloading an app says very little about its actual use, and its continuity of use over time. The type of political regime could therefore be associated with different estimated memberships.

It is clear, on our working sample, that this is only imperfectly the case, or with significant and different variations to be taken into account. App penetration rates are mostly below 30–40%, with the exception of countries whose political regimes are usually seen as rather paternalistic or authoritarian when it comes to public policies, or Asian countries—but not all either. More specifically, the highest penetration rates were directly related to the constraining use of apps, that is, the obligation to use them for activities of daily living. In practice, beyond this measurement, it does not tell us about the actual use of apps in these countries.

9.12 Applications as an Example of the Use of Technology as a Neutral, Non-Scientific Mediator of Biopolitical Actions

Finally, we can consider that the use of apps is an example of using a preferred medium, consistent with Western political dogmas at least. The recourse to technology, after recourse to the knowledgeable and to the experts, who were able to show that they were often in disagreement with each other—which is, in fact, an intrinsic necessity in the scientific process, where controversy is necessary—appears as a non-human third party, supposedly politically or ideologically uncolored, “neutral,” and individual or even individualistic. It takes on aspects of democracy: it gives citizens the possibility but also the responsibility to participate in the management of their health and that of the population, and beyond that in life in society. It is also an attempt that has overtones of admission of helplessness, in a situation where unusual remedies are being attempted, for lack of an obvious and effective solution, immediately available. The use of apps could thus be seen as an intermediary supposedly neutral, and impartial, between state will and individual wills. In other words, if this example provides an exemplary illustration of precision public health innovation, it also provides an example of tools that can be mobilized in the context of governance of living beings, that is to say, of biopolitics.

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Summary of the First Half and the Possibilities and Problems Related to mHealth in the Later Chapters

Kota Kodama

ABSTRACT

This book consists of the first half, which analyzes and compares the regulations, product development status, and acceptance status of mHealth in developed countries, and the second half, which explains the details of mHealth applications, including those in fields other than medicine. In this section, we will review and organize the first half of the book, discuss the overall structure of the book, and consider the significance of the book. Particularly, we will discuss the possibility of a paradigm shift in the medical social system by mHealth and the problems for social implementation.

1 Summary of the First Half Chapter of the Book

1.1 Challenges and Possibilities Faced by Implementation of mHealth

Interest in applications of machine learning and deep learning technologies, known as artificial intelligence (AI), continues to grow worldwide, especially in the healthcare field. With the increasing ease of collecting consumer and patient data from smartphones and other devices, there is growing interest in using these technologies to evaluate the effects and side effects of pharmaceuticals and to improve the accuracy and adaptability of medical devices. However, products in the medical field have traditionally been developed under very strict regulations because of their direct impact on human health and life.

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As introduced in this book, mHealth, which is a medical system that utilizes mobile wireless devices, enables a form of approaching patients without the intervention of a medical professional, and the AI algorithm used for that judgment is due to its nature, algorithms are continually updated based on the existence of new datasets, and many countries have not yet determined a regulatory method to deal with the fact that old management methods cannot handle it. For instance, research has shown that within 300 most frequently rated apps both iOS and Android app has only 30.5% with privacy policies. Compared to the conventional medical testing which patients were asked to visit the hospitals were removed to a real time testing (Kumar et al., 2013). However, without a profound regulation to follow, it is still making it difficult for newcomers to adapt to the regulations. At present, we believe that this situation is the main factor hindering innovation in this field.

To overcome this challenge, governments have already started working on special legislative systems for AI-based medicine. The intention is to clarify the distinction between types that should truly be treated as medical devices and those that do not require regulation and to eliminate the inhibition of innovation caused by unclearness.

1.2 International Trends and Development of mHealth Research

In the mid of these trends, we first analyzed the trends of the last 20 years by analyzing the research trends on mHealth from 2000 to 2020 using Bibliometrics in chapter “[Introduction of the Concept of AI in the Field of mHealth While Discovering the Trends in mHealth Research Field](#)” of this book. Previous research has also conducted research in AI and found out the hotspot as recent most searched topics (Yu et al., 2018). As a result, mHealth research and development has increased exponentially in the past few years, and social implementation is expected to advance in developed countries in the next few years. With the characteristics of mHealth of fast penetration rate of mHealth with wireless access to an Internet as well as new coming apps with features (Davis et al., 2016). Although the focus of R&D is still on the US, R&D in East Asia, especially China, is becoming more active, and the market is large, so future trends will be very interesting. It was also suggested that the disease areas where mHealth is expected to be most adapted in the future are mental health areas such as dementia, bipolar affective disorder, schizophrenia, and mainly depression.

According to the World Health Organization (WHO), depression alone affects at least 300 million people worldwide, generating hundreds of billions of dollars in economic losses in the US every year (WHO, 2017). Despite the availability of treatments and social services, many people with mental illness tend to avoid seeing a doctor for fear of losing their social reputation. The study on patients with mental health concerns revealed that the improvements with sleep and exercise (Lipschitz et al., 2019). Another research also shown that the endorsement by the professionals at the mental illness were the most effective for the patients to be

interested in the app. It is crucial for researchers to further analyze the implementation of mHealth while providing safety with the privacy concerns. Therefore, it is important to assess with further research to see the utilizing pattern of a mHealth application for mental health to develop effective management program (Baumel et al., 2019).

1.3 Healthcare Entrepreneurship with the Development of Policy and Regulations

Mobile applications have also been developed to support these mentally ill patients by providing therapeutic interventions while maintaining patient privacy. They are highly dependent on machine learning, deep learning, etc., which has raised concerns among regulators in terms of the aforementioned potential for continuous change and the delicacy of the value provided.

In this analysis, it was suggested that the center of mHealth development is still in the US, so the analysis was conducted in chapter “[Relationship of Innovation and Regulation on mHealth](#)”, focusing on examples of US innovations in mHealth and the regulations related to them. As Mergel (2014), stated that US government are currently working on implementation of mHealth through reusing the open data so-called [Challenge.gov](#). The results suggest that, as we expected, the driving force of mHealth innovation in the US is the regulatory authorities, mainly the FDA, and the medical entrepreneurs who responded to their measures. As for regulators, today it is generally believed that technological innovation has traditionally outpaced regulation. Therefore, it is important to expand the knowledge to consider with privacy concern through the implementation of mHealth for users and developer as well as policy makers (Bol et al., 2018). Also, as Cortez et al. (2014) mentioned that it is quite a process to maintain a good balance through simultaneously monitor and innovate. Zhang et al. (2017), mentioned that the government is holding a significant role when it comes to developing regulation of privacy policies for private institution to follow. In contrast, with respect to the mHealth field, it is suggested that the FDA, after adopting a progressive mindset, is playing the role of an “interactive regulator,” encouraging innovators to take advantage of new technologies through new regulations.

Healthcare entrepreneurs have the potential to become data interpreters, bridging the gap between patients, other healthcare professionals, and engineers. They do this by carefully using their activities as medical professionals as insights and providing this data to mHealth companies and engineers to ensure the accuracy of their products based on their medical expertise. Thus, rule makers are interactive in driving innovation and are new entrants to healthcare value information via mHealth. As Stefan et al. (2014), stated that it is important to release their information of privacy protection methodology as standardized comments of an app prior to downloading them developer for users. Understanding the impact of mHealth on health care will be important in predicting future changes in the healthcare industry.

1.4 mHealth Research Trends and Policy Regulations in China

Next, in chapter “[The Current Situation of Mobile Health in China from the Perspective of Policy, Application, and User Acceptance: A Multi-Method Systematic Analysis](#)”, we focused our analysis on China, the world’s second largest economy and with the world’s largest population base. Despite the fact that the total cost of health care in China will reach 7.12% of GDP in 2020, China still bears a heavy burden of health care. Even with the results of the trend analysis in chapter “[Introduction of the Concept of AI in the Field of mHealth While Discovering the Trends in mHealth Research Field](#)”, we are or will soon be in the second group after the US in the global trend of mHealth development. As Bhuyan et al. (2017) mentioned that it is significant for us to look into the data encoding technologies to minimize the data leakage for growth of mHealth with primary aspects of trust. In addition, the development of mHealth in China is different compared to other developed countries due to personal information is highly centralized and is a very important matter. According to Chen et al. (2018), China faces a burden that “inequitable distribution of healthcare resources among different regions”. To overcome this, China has conducted healthcare reform to deliver healthcare for all. Therefore, we focused our analysis on the relevant regulations, applications, and user willingness to use in China, although there are fewer products that have already been implemented in society than in the US. According to Kasperbauer and Wright (2020), in the US the FDA are currently not focusing on the non-medical application which includes health and wellness app. The guaranteeing the safety and its effectiveness of users are very unstable. For, instance google play and Apple are making the progress by taking a gatekeeping role (Kasperbauer and Wright, 2020). However, the cross-sectional survey has found that the accuracy and safety of the data were trusted by the majority of the users (Krebs and Duncan, 2015). Also, research conducted for over a year has revealed that there were a privacy policy in a different language from the actual app and the privacy policy were existed with 404 error web pages. Such circumstance is threads for user’s privacy and security (Papageoriou et al., 2018). As a result, in China, as in the US, regulators are driving innovation in mHealth, and Internet-based mobile medical services are gradually becoming standardized. It was suggested that the price of “Internet +” medical services is now governed by a unified policy system. Moreover, they are included in the same scope of medical insurance as traditional medical services were acknowledged. However, due to the rapid development of this field in China and the complexity of Internet technology, it has been difficult to predict the negative aspects of mHealth, such as patient privacy. As Armontrout et al. (2016) stated that since the individual private corporations have different guidelines for privacy policies and processes to take care of the patient’s personal health related data and information. Even in China where the centralization of personal information is most advanced.

1.5 mHealth Trends and Advancements in Korea from the Perspectives of Policy and Regulations

In chapter “[Digital Healthcare Development and mHealth in South Korea](#)”, we analyzed the trends in digital health and mHealth, focusing on South Korea, which is both the second most aged society after Japan and one of the countries with the highest smartphone penetration in the world. Specifically, we analyzed social issues, policies, and regulations in Korea, as well as case studies of mHealth in Korea. Particularly, we used the mobile healthcare service provided by the Center for Public Health as a base model to investigate a Korean case study of the application of mHealth to COVID-19.

In the very early stages of the COVID-19 epidemic around April 2020, the Korean government mandated GPS tracking applications and strict legal penalties for COVID-19 cases, close contacts, and all long-term residents returning from abroad. In addition, in South Korea, which seems to operate more democratically in terms of privacy than China, the effective use of personal information based on trust between citizens and the government can also be a reference for social implementation in other developed countries. As previous study has identified the importance on developing a national standard for data handling as well as provide clear and transparent information on how the data were used and shared (Michie et al., 2017).

1.6 Trends and Development of mHealth in Japan

In chapter “[Regulations and the Status of Social Implementation of Services on mHealth in Japan](#)”, we focused our analysis on Japan, which is currently the most aged country in the world. Japan has the lowest smartphone penetration rate compared to other developed countries, and as pointed out in the analysis in chapter “[Introduction of the Concept of AI in the Field of mHealth While Discovering the Trends in mHealth Research Field](#)”, Japan has made the least progress in mHealth adoption among other developed countries. As in other chapters, we have analyzed the relevant regulations, products, and the companies that develop them in Japan. As a result, most of the mHealth products that have been socially implemented in Japan were introduced in the US, and domestic startups have finally obtained medical device approval for mHealth. However, the insurance reimbursement is the same as that for conventional medical devices, suggesting that the development of follow-on products is not very active at present. According to Zhao et al. (2016) stated that it is important to see the effectiveness of mHealth carefully based on the number of subjects and theory since some apps does not perform their effectiveness which must be considered.

Several existing pharmaceutical companies have been seen entering this area, but they seem to be moving more slowly than startups, perhaps because they are bound by the traditional behavioral principles of the pharmaceutical industry. In addition, there is no doubt that the government’s efforts are very weak compared

to the other regions discussed in this book. The government's active promotion of mHealth and support for startups to develop it will be necessary. For example, studies have already been reporting a significant effect of mHealth for increased physical activities (Cadmus-Bertram et al., 2015). Therefore, it is important to further analyze the implementation for elderly in Japan. Since, it is recognized as a country of longevity, there is a need to improve its healthy life expectancy.

1.7 Connection Between Public Health and mHealth During the Pandemic in France

Chapter “[Precision Public Health and the Role of mHealth: The Use of Smartphone Applications Worldwide in Mitigating the Covid19 Pandemic and Their Integration as Components of Public Health Policies. A Focus on the French Example](#)” presented a case study of an analysis focused on the EU, another center of mHealth development. This chapter provided an analysis of where smartphones were used in the context of the COVID-19 pandemic and their utility as a global prototype of a precision public health tool, with a particular focus on Europe and France. As previous literature stated that COVID-19 is difficult to be traced since the virus become infections before 1-2 day of experiencing the symptoms and it will take 3-4 days to show the symptoms (Altmann et al. 2020). With such unique development of mHealth application to COVID-19 was essential. Moreover, this application of mHealth applications to COVID-19 prevention was the first of its kind to be adapted for most citizens worldwide. As a result, it has provided evidence on many aspects, both positive and negative, of its ethical, political, policy, and public health aspects.

This chapter is analyzing decision-making in each of these aspects, focusing on the French case. We have also pointed out the importance of the political system of the region and the trust relationship with the government in terms of decision-making factors regarding the acceptance of the application in each region, a view similar to some of the previous chapters.

2 Coordinating the Challenges and Solutions for the Development of mHealth Implementation Worldwide

In the previous chapters, we mainly focused on the relevant regulations, applications, and user willingness to use in each region in developed countries where social implementation of mHealth has progressed. As a result, mHealth has the potential to cause a paradigm shift in the entire healthcare system, unlike existing drugs and medical devices. Therefore, it is necessary for regulators to implement promotion measures and regulation reforms that are appropriate for each region while taking into account the cost-effectiveness of the entire healthcare system. According to the research, the hedonic value was significantly affecting at the

developed nation and in developing country waiting time was significantly effecting for adoption of innovation (Dwivedi et al., 2016). Also, a successful personal data protection was able to be achieved while allowing the users to select functions to build trust between individual level and institutional level (Pool et al., 2020). In parallel with this, it can be seen that for its smooth social implementation, it is also important to build an ecosystem that encourages the entry of startups other than the existing players like pharmaceutical companies. In this sense, the pandemic caused by COVID-19 may serve as a catalyst to force social implementation in regions like Japan, where the adoption of mHealth has lagged behind. In any case, the analysis of each region suggested that a paradigm shift in the entire healthcare system due to mHealth is imminent. According to the research which analyzed the adoption process in the Bangladesh for elderly, the results shown that performance expectancy was the most effective factor which led people to adopt mHealth (Hoque and Sorwar, 2017). Comparing the adoption patterns in different countries will allow us to understand the needs for optimal implementation plan. In the chapters that follow, more specific applications of mHealth will be introduced, including applications to non-medical practices.

3 Possibilities of the Development and Future Perspectives in mHealth

Chapter “mHealth as a Component of Next Generation Healthcare” analyzes the potential future use of mHealth, which is expected to be central to the next generation of health care, in terms of various aspects such as possible services and technological developments at present, providers expected to offer them, and cost-effectiveness. For instance, research which conducted systematic review and meta-analysis has found that for utilizing a wearable activity tracker has significant effect on increase with daily steps (Brickwood et al., 2019). Specifically, (1) the future prospects of EHR/PHR and its relationship with health care in terms of big data utilization, (2) the current status and expected development of wearable devices, (3) the way VR can be used in mHealth, (4) the current use of AI/ML in mHealth, (5) the needs of telemedicine interventions and their future prospects, (6) the current status of mHealth providers and the prospects of new participants to join in the future, (7) the current status and expected development of early detection technologies for diseases, and (8) the future prospects of cost-effectiveness of mHealth have been discussed in this chapter.

As discussed in the previous chapters, the mHealth technology has already been implemented in society for the diagnosis of diseases and prevention in a broad sense, including COVID-19 contact confirmation applications. This trend is expected to accelerate in the future, and although the monetization issue has not been resolved at this point, it is expected to spread to the treatment of diseases that require medical intervention other than diagnoses, such as telemedicine and mental health treatment. According to Iribarren et al. (2017), the systematic

review of economic evaluations has revealed a consistent positive economic outcome through calculation of costs-effectiveness with mHealth. Also, the funding system for movie clinics which utilize mobile health are also facing a struggle to maintain the annual operations (Attipoe-Dorcoo et al., 2020). Through these analyses in this chapter, we were able to highlight the expected future uses of mHealth.

3.1 Possibility and Developments of Labor Management with the Implementation of mHealth

In chapter “[mHealth’s Potential for Measuring Work Attitudes in Psychological and Physical Factors](#)”, we will introduce research on predicting labor productivity and occupational safety from workers’ Psychological and Physical Factors as a new possibility for mHealth. A feature of wearable devices is that they can collect the user’s heartbeat and the amount of physical activity obtained from the device’s 3-axis accelerometer for a relatively long period of time. This is an interesting case study of a demonstration experiment in the construction industry, a labor-intensive industry that takes advantage of this feature. For companies that employ a large number of workers, ensuring that they have the necessary labor without sacrificing their health and safety is a critical challenge. Since this trend is expected to continue and grow stronger in today’s aging society, it is hoped that this kind of service will not be limited to demonstration experiments but will be implemented in society. For instance, previous research has conducted systematic review on the accuracy of Fitbit devices and the results of steps of walking were 50% accurate depending on whether walking or jogging and which part of the body you wear a device either wrist or torso (Feehan et al., 2018). In this chapter, the empirical experiment and its analysis were conducted on blue-collar workers who are engaged in physical labor such as carrying heavy objects. However, since it is known that psychological stress can be predicted by heart rate and physical activity, it is possible to adapt the system to all workers, for example, those engaged in desk work. This seems to be a good example of the great potential for deployment of mHealth.

3.2 Expansion of Value Distribution Range with mHealth from the Entertainment Perspective

In chapter “[mHealth Beyond Healthcare-Fusion Approach Towards Better Wellness-](#)”, we extend the discussion beyond health care to the realm of wellness, discussing the significance and benefits of mHealth as well as its challenges and prospects. In the mobile field, the market has been largely shaped by the entertainment sector, such as music, games, and e-books, rather than mHealth. There is no doubt that these entertainments enrich the lives of human beings. According to

Pai and Alathur (2019), they stated that it is important to utilize gamification and rewording system to introduce attractiveness of mHealth to many people.

This chapter discusses the impact of these mobile entertainments on wellness and considers their potential to reduce the burden on the general public and transform sick care into health care by providing an affordable, quality, and preemptive approach. Specifically, we have utilized PokémonGO, a location-based game application for smartphones, as a case study and analyzed it by using the innovation process proposed by Rogers (2003) and other methods. According to Althoff et al. (2016), Pokémon GO is a mobile game which integrate the Pokémon world and augmented reality to create opportunity for people to exercise in the real world. We investigated the potential of mHealth, described the prospects for future innovation, and discussed the importance of developing advanced technologies and integrating different disciplines.

3.3 MHealth Development of the Perspectives from Preventive Medicine

Chapter “[Mobile Health for Preventive Healthcare](#)” discusses the potential of mobile health in preventive medicine. At present, some mHealth for preventive medicine for hypertension and diabetes have been socially implemented and proven effective, but the effectiveness of mHealth for rheumatic and musculoskeletal diseases is unknown, and it is important to develop new back casting technologies to meet such unmet needs of patients. In addition, although it has not been pointed out much in this chapter, insurance coverage in medical practice basically does not include the concept of prevention. Moreover, as pointed out in chapter “[Overall Summary](#)”, in all of the mHealth discussed in the previous chapters, the end product is software, not hardware such as drugs or medical devices. Therefore, even in the medical field, the reimbursement price is too low compared to those development costs, and there remains the problem that the development of new mHealth products is not active. In addition, for non-medical products, the user must bear all payments at this time. Therefore, the situation where the product price is not commensurate with the high level of guarantee of the quality is more remarkable than mHealth in the medical field. We hope that the development of mHealth will solve this problem by blending the fields that are currently regarded as different categories, such as diagnosis and treatment, prevention, health management, and wellness, and by bringing about new and unknown innovations.

4 Implication of the Book

The healthcare industry, not just mHealth, is a knowledge-intensive industry based on science. In addition, the direct customers of these related products are not patients who benefit from medical care and medical treatment under medical insurance, but medical professionals, mainly doctors, who perform these services, and

thus have different market principles from general consumer goods. As a result, end consumers, who are the patients who benefit from medical treatment and medical care, consume products without knowing the price, value, and problems of the products they use and consume in detail. According to Mohr et al. (2017), with the number of different technologies available therefore user must not only consider which information to reveal but to consider how, who, for what reason and how long the information will be stored. From the policy maker view, it is important to continue research to compare the international regulations to improve regulations by benchmarking other regions regulations (Moshi et al., 2019). The mHealth technology has the characteristic of shifting the direct customers from medical professionals, who are the direct customers in the healthcare business at the moment, to the end consumers, and thus it will promote a paradigm shift in the entire healthcare system and the social system that supports it. As this was discussed in the first part of this book, the speed of social implementation of mHealth is likely to be influenced by the existing healthcare system and supporting social systems in the region. However, there is no doubt that the increase in medical expenses will continue in the future, coupled with the aging of developed countries. For this reason, to make the healthcare system sustainable, technologies that promote automation such as mHealth will be implemented in society as a result of market-wide pressure, whether fast or slow, as shown by the examples of driverless cars and unmanned stores in other industries.

At this time, the question then becomes how to deepen the literacy of end consumers about these products without involving professional medical personnel. While consumer goods in other fields, such as automobiles and home appliances, are easy for consumers to understand in terms of their external appearance and functions, the differences in products and services in the healthcare field are very difficult to understand without specialized knowledge. In addition, there is a large gap between the price consciousness of consumers and the market price because consumers are basically covered by medical insurance for most of their costs. This is a major barrier to entry for non-Medicare healthcare products and services. We think it will be necessary, especially in the mHealth sector, to foster literacy, including price awareness, in the healthcare industry among end consumers, as well as to build a medical insurance system that adapts to the automation of the healthcare sector.

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Discussion of mHealth Development with Case Studies



mHealth as a Component of Next-Generation Health Care

Makoto Niwa

ABSTRACT

Advances in data science have highlighted the potential, for example, for an early detection of a disease, of large-scale data to contribute to health care. In addition, attempts can be made to ensure patient safety through the rapid detection of signs of seizures based on combinatorial data. The potential of mobile health (mHealth) as a concrete implementation of these approaches is discussed with examples in this chapter. Specifically, this chapter presents a review of the prospects of (1) electronic health records/patient health records (EHRs/PHRs), (2) wearable devices, (3) virtual reality, (4) artificial intelligence/machine learning, (5) medical interventions from a distance, (6) trends of mHealth providers, (7) technology for early detection of diseases, and (8) cost-effectiveness of mHealth. The aim of this discussion is to obtain an overview of the future prospects of mHealth in health care. In the future, sooner or later, the elderly population will increase in every country, extending healthy life expectancy by preventing diseases. In this condition, maintaining the productivity of the entire society by ensuring the activity of the elderly people, and improving the efficiency of medical care will become a challenge. Various types of mHealth solutions are significant for these issues.

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1 Relationship Between Future Social Issues and Mobile Health (mHealth)

The world will soon have more older people than children and more people at an extremely old age than ever before (WHO, 2011). Under these circumstances, to maintain a healthy society, it is important to (1) reduce the burden on medical personnel and caregivers, which will increase as the population ages, (2) ensure the health of children with declining fertility, and (3) extend healthy life expectancy through early detection of diseases. mHealth is considered to be a technology that can make these possible. Furthermore, the outbreak of the new coronavirus infections in 2019 showed that new infectious diseases can be a risk factor placing a large burden on social systems. Based on this background, this chapter discusses the prospects of solving social issues using big data, artificial intelligence (AI)/machine learning (ML), wearable devices, and early disease detection methods as new technologies that can be incorporated into mHealth.

2 Societal Conditions for the Use of Medical/health Big Data

2.1 Societal Conditions and Prospects of Electronic Health Records (EHRs)

EHRs are a systematic collection of longitudinal health information collected electronically (Roehrs et al., 2017). Currently, the use of AI to analyze the diverse data of EHRs has attracted attention. For data analysis, conventional ML or recurrent neural networks are being used, and extracting meaningful information from ultra-sparse data of EHRs has been a technical challenge (Wang & Preininger, 2019). Another challenge is to utilize unstructured information, such as free text, in EHRs. The existence of different EHR systems worldwide requires developing interoperative AI systems or standardizing EHR formats. For example, Observational Health Data Sciences and Informatics (OHDSI) is an international collaborative effort to standardize the EHR.

At present, the standardization of the EHR format is not very advanced. To facilitate the use of data, it is desirable to standardize the data format or introduce a sophisticated language analysis technology.

2.2 Prospects of Personal Health Records (PHRs)

The PHR is a lifetime personal health record maintained by each patient (Roehrs et al., 2017). The purpose of PHR is to encourage patients to engage with their own health care (Zhou, DeAlmeida, & Parmanto, 2019). Nevertheless, most PHR systems available in the market have been workstation-based (not smartphone

app-based) and have mainly been created by hospitals and EHR vendors, thus limiting patient engagement. Recently, several studies have investigated the concept of patient-centric mobile apps linked to PHRs. For example, Zhou et al. (2019) explored and tested the concept of a mobile PHR app through questionnaires and usability testing of prototype apps. The desired features of the mobile apps include medical record management (test results, medication, immunization, and medical history) and tracking daily-life activities (nutrition, physical activity, and health activity). The desired health issue to be controlled was body weight. As another application studied, Yamamoto et al. (2020) re-purposed the mobile PHR app “K-note” developed by the Healthtech Laboratory Inc., a Kyoto University-originated venture company, for COVID-19 symptom tracking. In this case, the K-note is intended to be used for health data sharing between potential patients and regional health officers.

2.3 Future Use of EHR/PHR and mHealth

Real-world clinical big data can be extremely useful for developing and improving diagnostic algorithms. These big data can be beneficial for the development of diagnostic mHealth. Suggestions for personalized health-promoting behaviors based on patients’ lifetime data (PHR) can also be beneficial for improving individual health. In the future, EHR/PHR as the real-world data and PHR as a means of promoting individual health are expected to develop in collaboration with mHealth.

Currently, challenges for big data analytics are recognized. One challenge is the shortness of existing evidence for its usefulness. This is a complex issue, and one aspect shown in cardiology field is that merely identifying higher risk patients will not lead to better outcomes or improved cost-effectiveness (Rumsfeld, Joynt, & Maddox, 2016). This suggests that merely using more information intending “appropriately” to use traditional outpatient care would not produce much additional value in certain areas. Big data is just a basis of analytics, and the value should come from some innovative approaches, for example, individualized medical services “on demand”. An example of medical services on demand is immediate intervention after seizure detection. mHealth can be a connection between patient health monitoring and individualized medical services on demand. Such consideration highlights the importance of wearable devices, and their use combined with “on demand” intervention.

3 Established Wearable Devices (in Market) and Their Reliability

Nowadays, wearable devices measuring body energy consumption, heart rate, and step count are very common. For studying the reliability and validity, Fuller et al. performed a systematic review of the literature examining the performance of such items under brands, such as Apple, Fitbit, Garmin, Mio, Misfit, Polar, Samsung,

Withings, and Xiaomi (Fuller et al., 2020). This systematic review, reported in 2020, concluded that they are generally accurate but vary according to the manufacturer and device type. It is safe to say that these basic functional devices were sufficiently accurate at the time of this review.

Meanwhile, Verdu et al. reported an overview of seizure detection devices for refractory epilepsy (Verdu & Van Paesschen, 2020). These devices varied in function, using accelerometry, surface electromyography, and electroencephalography. Verdu et al. reported two uncultivated areas (in the field of refractory epilepsy seizure detection) in this study. One is the combined use of multiple bio-signals for seizure detection, and the other is the lack of standards for the desired function. The authors also reported that the business-to-business model is desirable as a business model in comparison to the currently proposed business-to-consumer model, considering the central role of neurologists in this field.

Based on the above findings, it can be concluded that currently, the commercially available wearable devices for the general public are reliable for their purpose (such as weight control), and multiple bio-signals are being used in uncultivated areas for more complex purposes, such as seizure detection, for which, the business-to-business model is important.

3.1 Research Trends of Wearable Devices in Health Care

The research trend of wearable devices for health care has been investigated. Literature search in the Web of Science (Clarivate Analytics) was performed using the queries “Wearable $\times$ Health,” “Wearable $\times$ Health $\times$ Systems,” “Wearable $\times$ Health $\times$ Sensor,” and “Wearable $\times$ Health $\times$ Flexible.” All search results showed an exponential growth in publications in this decade (Fig. 1).

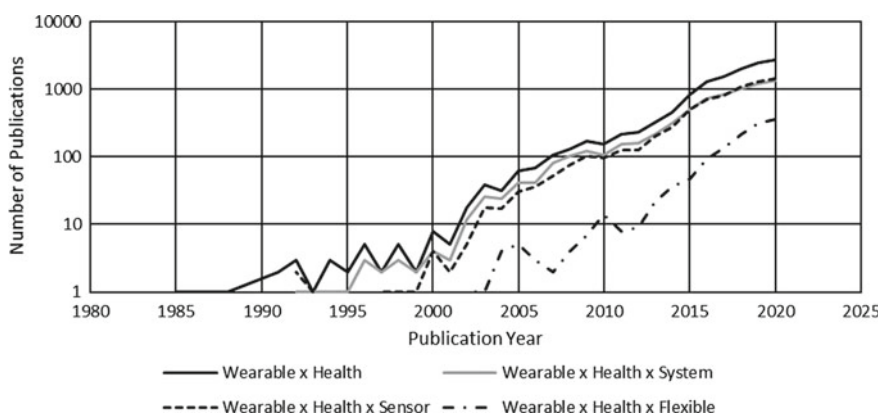


Fig. 1 Publication trends related to wearable devices. *Note* The numbers of publications collected through queries “Wearable $\times$ Health,” “Wearable $\times$ Health $\times$ Systems,” “Wearable $\times$ Health $\times$ Sensor,” and “Wearable $\times$ Health $\times$ Flexible” from Web of Science are shown

The major potential application of wearable devices in the context of health care is remote health monitoring (Majumder et al., 2017). This application comes under the definition of mHealth (Rowland et al., 2020; Silva et al., 2015).

According to the literature, remote health monitoring, based on non-invasive and wearable sensors, actuators, and modern communication and information technologies, is considered an efficient and cost-effective solution that allows the elderly to continue living in their comfortable home environment, instead of expensive healthcare facilities. These systems also allow healthcare personnel to monitor important physiological signs of their patients in real time, assess health conditions, and provide feedback from distant facilities (Majumder et al., 2017).

Interestingly, several researchers state that organic semiconductor technology and nanotechnology play a crucial role in wearable sensors or electronics. Chow, Someya, and Someya (2020) argued that next-generation wearable electronics will need to be mechanically flexible and stretchable, such that they can be conformally attached to the human body. This applies not only to conductors but also to photodetectors, which are typically crystalline and have limited mechanical flexibility in existing technology. A more frequent use of organic photodetectors is expected. Liu et al. (2017) pointed out that conventional rigid electronics is one of the causes of motion artifacts and mismatches in mechanical properties. Thus, it is important to use reliable elastic and flexible materials in devices. Technologies reported by Liu et al. include using extremely thin polymeric, metallic, and semiconducting materials to fabricate active electronic devices. More concretely, such materials are single-crystalline silicon nanomembranes with thicknesses of 100–200 nm, which can be transferred from silicon-on-insulator (SOI) wafers onto thin-polymer substrates. Parrilla et al. (2019) reported that relevant wearable ion sensors have emerged for sensing devices during the last decade, and material preference is clearly in favor of conducting polymers and carbon (nano) materials.

3.2 Example of Physically Flexible Wearable Devices

Highly flexible wearable devices are a cutting-edge technology, and there are only a few examples of commercially successful devices (Lovett, 2020), even though the concept is promising (Gu et al., 2019).

As commercially available products, Nanowear (New York City, US) obtained a Food and Drug Administration (FDA) clearance for SimpliECG, a remote cardiac-monitoring undergarment in 2016 (Comstock, 2016). Chronolife (Paris, France) launched a CE-marked and machine-washable smart T-shirt Nexkin that monitors physiological indicators (heart rate, abdominal and thoracic breathing, body temperature, physical activity, and pulmonary impedance) (Posteinicu, 2019). Data are sent through Bluetooth to the user's smartphone and integrated to generate actionable insights that can then be reviewed by health professionals. Thus, this product contributes to various risk reduction and prevention programs.

Tufts University has developed an experimental-level flexible sensor patch that can be sewn into clothing, and it is designed to analyze the wearer's sweat (Lovett,

2020). The researcher at Tufts University aims to construct a thread-based system to build smart garments at a level of thread (Terse-Thakoor et al., 2020).

3.3 Future of Wearable Devices as mHealth Components

Wearable devices, as sensors, are essential components of mHealth for monitoring purposes (applications that do not fit into this category are behavior change apps, messaging apps, and informational apps). Flexible devices can avoid signal reading errors and improper fitting, which help improve the reliability of monitor-based mHealth.

One typical application that appeared in literature is the use of e wearable strain sensor using the MXene/polyaniline fiber. This strain detection can be used to capture various human movements (Chao et al., 2020). Integration of such sensor devices into optimized noncontact human–computer interaction system is discussed (Ma et al., 2021). Combination of wireless Bluetooth communication, and real-time monitoring of human signals can be utilized.

4 Prospects of Using Virtual Reality (VR)

Rey, a US-based mental health and wellness startup, has launched a virtual mental wellness platform, integrating immersive tools and digital interventions with teletherapy, in 2021. The platform is powered by OxfordVR, a spin-out of Oxford University (Eddy, 2021). The service combines individualized care with VR tools and offers customized therapy sessions designed to trigger the same psychological and physiological reactions as those in real-life situations. The goal is to determine what patients learn from VR and stay with them in the real world.

As reported in the literature, VR can be used not only for assessment, understanding, and treatment of mental health disorders (Freeman et al., 2017) but also for rehabilitation and physical function in older adults (Dermody et al., 2020) or for pain management (Ahmadpour et al., 2019). In addition, VR can be used to train health professionals (Chen et al., 2020; Khan et al., 2018). These elements are readily used in mHealth, as the coverage of mHealth includes workforce development and support from healthcare facilities (Iribarren et al., 2017).

As shown in these examples and the literature, VR can be an attractive component of health care, particularly in the field of mental health. The VR tools that can be used at home can be operated in the context of mHealth.

5 Prospects of Artificial Intelligence (AI) and Machine Learning (ML)

5.1 Use of AI/ML as Technological Components

AI, including ML as a component and using big data, is considered to be a breakthrough in health care (Khan & Alotaibi, 2020). With the current availability of AI for the improved capabilities of smartphones, the use of AI technology in mHealth is inevitable. However, it is difficult to eliminate the risk of mislearning in AI/ML, which is a self-learning technology, and we should be cautious about the use of unchecked AI/ML as that can lead to a possible bias in the outcome (Brault & Saxena, 2021; Dzobo et al., 2020).

Furthermore, the advantage of AI/ML includes identifying relationships that remain unnoticed by human (US Food and Drug Administration, 2021b), which seems to be the present and future role of AI/ML. The findings should be implemented in a useful form after confirming that they are not based on mislearning. In this context, the role of mHealth is to collect large-scale data and intervene via established useful form in the implementation phase.

5.2 Use of AI/ML in Regulated Circumstances

AI and ML are important parts of data processing in various fields. According to the US FDA (US Food and Drug Administration, 2021a, 2021b), 343 medical devices use AI/ML as of September 22, 2021. Several listed medical devices come under the definitions of mHealth. This indicates that AI/ML is already used in regulated circumstances and is not a special item in inappropriate regulated circumstances. A broader use of AI/ML is expected under both non-regulated and regulated conditions.

6 Consideration on Medical Intervention from a Distance

6.1 Effect of New Infectious Diseases on Medical Intervention from a Distance or Control of Epidemic

(1) COVID-19 pandemic and its implications on mHealth research

COVID-19 is a new infectious disease that emerged in 2019, has become a pandemic, and is not under control to date (the time of writing this manuscript).

Owing to the high infectivity of COVID-19 and the silent transmission from non-symptomatic virus carriers, infection control through contact-tracing applications is expected, and various remote communications are required throughout society.

For an overview of the research activities on COVID-19 and mHealth, a literature search using the search term “COVID-19 AND mHealth” was carried out in the Web of Science (Clarivate Analytics) (April 18, 2021). The top-ranked topics included “health care sciences services,” “medical informatics,” and “public and environmental occupational health,” indicating a high level of research on telehealth care, remote information acquisition, and public health responses against COVID-19. These three areas accounted for more than 28 % of the total number of research papers. Less than 8 % of the studies were on specific disease categories, such as psychiatry, cardiovascular diseases, infectious diseases, and psychology. Mental health management, cardiovascular disease management, and routine vaccination (for conventional infectious diseases such as poliomyelitis) management during a pandemic were identified as challenges.

The research papers reported the role of mHealth in the control of new infectious diseases, including COVID-19, and included disease surveillance (situational awareness), screening and isolation, triage according to disease status (Owoyemi et al., 2021), support for decision-making with infection diagnostic kits at home and diagnosis with CT at medical facilities, remote monitoring, and contact tracing (Alwashmi, 2020).

The need for such surveillance, triage, and remote response may be important not only in the COVID-19 context but also in the future in case of the emergence of new infectious diseases with similar transmission profiles.

(2) Condition of anti-COVID-19 apps developed to date

The important functions of the anti-COVID-19 apps in use mainly include providing symptom-based advice for virus testing or medical services, educating about preventive behavior against the spread of infection, contact tracing, infection reporting, and home monitoring (Ming et al., 2020). In particular, apps supported by national health authorities have the functions of contact tracing, infection reporting, and home monitoring. The quality of apps is overall good, as many of them are related to health authorities. The evaluation of the 13 apps created by the health authorities (only the English version was evaluated) showed a very high grade of performance (Salehinejad et al., 2021).

In the Netherlands, an observational study on an app designed for educating about diseases, screening functions for early symptoms, and reporting on interactive maps showed that the app resulted in high satisfaction among users and effective communication with healthcare providers, demonstrating practical usefulness (Timmers et al., 2020).

These reviews show that the development of contact tracing, infection reporting and home monitoring apps have reached a satisfactory level to date.

(3) Issues with the installation of tracing/reporting apps

Although contact tracing is expected to be an important function in controlling diseases spread through silent transmission, there are issues in the implementation

of this type of app. This is due to the nature of tracing/tracking, which benefits the entire society but does not necessarily trace individuals. For example, individuals traced as the personnel having contact with patients disadvantageously get isolated, even though they were not actually infected. This condition demonstrates that the tracing apps do not necessarily benefit each individual in a reasonable manner.

To understand this issue from another point of view, some studies exploring candidate factors for installation preferences have been reviewed.

Altman et al. (2020) investigated the level of acceptance of COVID-19 tracing apps through a survey and found that younger people and people who more frequently touch their phones have a higher tendency to install. This finding can be interpreted as an issue of accessibility.

Another finding was that people with high levels of trust in the government are more likely to install. This is an interesting finding of this study, portraying the trust in the government in this issue.

Blom et al. (2021) investigated the effects of access, ability, and willingness to install warning apps using a web-based survey. The results indicated that access and ability have moderate effects, but willingness have a larger influence on the installation of the app. This study implied a pessimistic view that aged and vulnerable populations are under limited access, and persons with the highest potential to spread the virus (i.e., with frequent social and work contacts) are not willing to install the apps.

Garrett et al. (2021) surveyed the reasons for downloading or not downloading the apps. The major reasons for not downloading in the future would be privacy concerns, battery usage, non-effectiveness, and lack of trust in the government, while those for not downloading in the past were the considered pros and cons and dependence on others.

In spite of the general fear of privacy exploitation, analysis of Google/Apple store reviews on existing apps suggests that data protection strategies and abilities are well understood by users (Rekanar et al., 2021).

Jonker, de Bekker-Grob, and Veldwijk (2020) investigated the factors influencing the use of apps using a discrete choice experiment. The study showed that factors, from the most important to least important to the users, are gaining financial incentives, allowance to attend gatherings (with 10 people) using apps, and virus testing applied to not only the symptomatic cases but also those receiving contact warnings. This study highlighted how users' benefits are important for the apps to be implemented.

Chan and Saqib (2021) investigated the effect of salient disease concerns on the unwillingness to install and use contact-tracing apps. After an online psychological experiment, the authors concluded that the hypothesis that disease concerns increase the unwillingness to download and use apps, owing to social conservatism and increased privacy concerns, was supported.

From the studies reviewed herein, the basis and challenges of tracing apps under current conditions can be summarized as follows. The basic features include (a) tracing apps may be useful in the future for new infectious diseases with silent transmitting features and (b) the privacy data protection ability of current apps is

well understood by users. The challenges include (c) functions that benefit each user should be explored and (d) a privacy protection strategy under improved function (as described above) should be presented to potential users to avoid installation evasion.

- (4) Importance of continuing the tracing, reporting, and education apps against novel respiratory virus diseases

The difficulty in controlling the spread of COVID-19 largely lies in its silent transmitting nature (Moghades et al., 2020). Diseases that are contagious during the late stage of infection, when infected people are very sick and cannot move, have limited opportunities for spreading. On the contrary, diseases that are contagious prior to symptom development, such as COVID-19, have larger spreading opportunities as infected individuals are able to conduct their daily activities (Center of Health Security Johns Hopkins Bloomberg School of Public Health, 2018).

Because this is true across pathogen types, the issue of silent transmission needs to be solved for humans in the future, considering the possibility of new emerging pathogens, even after the COVID-19 pandemic ends. Thus, the importance of tracing, reporting, and education apps remains the same considering newly emerging pathogens.

- (5) Importance of distant health care emerged due to COVID-19 pandemic

There has been frequent discussion that COVID-19 has increased the importance of mHealth in the management of diabetes, cardiovascular diseases (Neubeck et al., 2020), AIDS, exercise habits, mental health (Zhou et al., 2020), and commonly administered immunizations (such as polio or tuberculosis), (Chandir et al., 2020; Chen & Saqib, 2021). However, there is a concern that the effectiveness of mental health apps is uncertain, and this should be clarified through randomized controlled trials (RCTs) that require several years to complete (Marshall, Dunstan, & Bartik, 2020). Furthermore, there is a belief that current knowledge on the effectiveness of mHealth is not sufficient, and increasing information through the accumulation of single case reports may be important in the meantime (Marshall et al., 2020). In addition, the lack of a clear privacy policy for some apps is an obstacle to the use of mHealth, particularly in the mental health field, where considerable contributions are expected and further improvement is desired.

6.2 Prospects of the Control of Mental Diseases from a Distance

The usefulness of mHealth in the mental health field needs further research, with some systematic reviews being positive (Rathbone & Prescott, 2017) and others being unclear (Grist, Porter, & Stallard, 2017). In recent years, not only traditional interventions, such as text messaging and web-based information provision, but

also the improvement of treatment through information acquisition, such as e-diaries, have been included as the components of mHealth (Koch, Moukhtarian, & Skirrow, 2021), and this is expected to contribute to treatment.

7 Trends of mHealth Providers as Regulated Medical Devices—Example in the US

The recent trend of mHealth providers as medical devices was investigated considering the US FDA clearances, according to the viewpoint of a preceding study by Onodera and Sengoku (2018).

A previous study clarified that there are 189 mHealth products using the information from the MobiHealthNews (2013) and US FDA 510(k) databases (US Food & Drug Administration, 2021a). Among these, only 30 companies have multiple applications, which sums up to 106 applications. This indicates that a small number of companies have applied for multiple products, while others have applied for only one product. Thus, 83 applications were made by 83 applicants, suggesting the contribution of many emerging companies.

A similar investigation was conducted to examine the recent trends. Because of the absence of literature or databases of the US FDA-cleared mHealth in recent years, web news reported by MobiHealthNews was manually collected from 2017 to 2019 (Lagasse, 2017; MobiHealthNews, 2017, 2019; Muoio, 2018; Muoio & Lovett, 2019). Using an approach similar to that in the preceding study, the mHealth clearances reported by MobiHealthNews were referred to the US FDA databases for the identification of 510(k) mHealth products. This search resulted in the identification of 140 510(k) mHealth products cleared in these three years. They were applied by 81 applicants (companies). Among the 30 companies that appeared in the preceding study as applicants with multiple applications from 1997 to 2016, only 14 companies applied from 2017 to 2019. These 14 companies are Abbott Diabetes Care, Airstrip Technologies, AliveCor, Andon health, Carestream Health, EarlySense, Gauss Surgical, Glooko, Lifewatch Technologies, Reciprocal Labs, Sotera Wireless, Vital Connect, Welch Allyn, and WellDoc. In addition, reviewing the applicants' profiles revealed that as many as 51 applicants appearing in these three years are new to mHealth.

These profiles imply that many mHealth providers are emerging, while only a small number of companies produce new products continuously. This profile seems to have been maintained for a long time, and this trend will probably last for some time.

8 Early Detection of Diseases from the Data-Science Aspect

8.1 Prospects of Early Detection of Seizures

(1) Arrhythmia (atrial fibrillation)

Giebel and Gissel (2019) discussed the accuracy of mHealth devices for atrial fibrillation screening through a systematic review of the scientific literature. Devices that were reported in the scientific literature were in the form of smartphone apps, wrist-worn devices, small plates such as AliveCor, or rod-like devices. These devices mostly use electrocardiography (ECG) or photoplethysmography (PPG). The currently available devices utilize established detection technologies and downsized traditional devices. A more common technology is PPG, which allows the detection of atrial fibrillation with high accuracy. The most effective method is to combine ECG and PPG, and this technology requires the use of wrist-worn devices.

The ability of the Apple watch to detect irregular pulses was studied by Stanford University (Apple Heart Study) (Perino et al., 2021). The Apple watch irregular pulse detection algorithm was found to have a positive predictive value of 0.84 for the identification of atrial fibrillation. In addition, it was found that 40 % of the participants who received notifications from the Apple Watch for possibly having arrhythmia, but had no arterial fibrillation revealed through follow-up tests using a medical grade ECG, had other types of arrhythmia (mainly premature arterial contraction and premature ventricular contraction). This implies that the Apple watch has the intrinsic ability to collect and detect irregular movements of the heartbeat.

Several newly proposed technologies with an emphasis on AI are described below. Cardio Intelligence Inc. (Tokyo, Japan) (Cardio intelligence) has developed an AI system predicting atrial fibrillation seizure based on baseline data and is developing a system under the medical devices development promotion project of the Japan Agency of Medical Research and Development.

(2) Epilepsy

The number of projects developing epilepsy seizure detection system seems increasing.

Traditionally, electroencephalography (EEG) plays the central role in analyzing the condition of patients potentially having epilepsy. Nevertheless, non-EEG-based devices that emphasize seizure “detection” utilizing biological (such as electrodermal activity or heart rate) or physical (such as body movement) data, rather than “analyzing” what is occurring inside the body, are becoming common.

For example, the Embrace seizure monitoring system, the FDA 510(k) premarket notification-cleared device (traditional class II device) developed by Empatica, has accelerometers and electrodermal activity, temperature, and gyroscope sensors.

(Regalia et al., 2019) Physiological signals are obtained from a wristband-type device to identify the abnormal physiological activity that may be associated with seizures. Although the algorithm for data processing progressively utilizes ML, this device is intended for seizure detection and not for seizure prediction (Regalia et al., 2019).

Approaches for seizure prediction utilizing common biological data are under investigation. Quadlytics (Kyoto, Japan) (Quadlytics Inc.) is in the process of commercializing an epilepsy prediction system using only heart rate data, and the clinical evaluation of the system is in progress (representative organization for the clinical evaluation: Nagoya University).

Tharayil et al. (2017) investigated the predictive value of the mixed-effect model using big data; however, this type of approach should be investigated further.

(3) Cerebral apoplexy

Cerebral apoplexy is caused by trouble in vessels in the cerebrum and is clinically detected as various disabilities related to talking or moving or from falling down of patients. The time elapsed between the stroke and medical intervention is important for patient prognosis.

A wearable headband with EEG, developed by Zeit Medical (<https://www.zeitmedical.com/>), can detect stroke through EEG, even when patients are sleeping, and reduces the time from stroke to hospitalization. This device was designated as a breakthrough device by the US FDA, and clinical trials are ongoing as of October 2021.

8.2 Early Detection of COVID-19

Mishra et al. (2020) analyzed physiological and activity data from 32 individuals infected with COVID-19, identified from a cohort of nearly 5,300 participants. They found that 26 of the infected individuals (81%) had alterations in their heart rate, daily step count, or time asleep. It is to be noted that 22 of the individuals had some physiological alterations as symptom information before (or at) symptom onset, with four cases having alterations detected at least nine days earlier. Using retrospective smartwatch data, 63% of the COVID-19 cases could have been detected before symptom onset. A typical finding was the occurrence of extreme elevations in the resting heart rate relative to the individual baseline. These findings suggest that activity tracking and health monitoring through consumer wearable devices may be used for the detection of respiratory infections, often pre-symptomatically.

Wong et al. (2020) presented a protocol for a clinical trial investigating the possibility of early detection of COVID-19. This study utilized a wearable biosensor and collected body temperature, blood pressure, heart rate, oxygen saturation, and body movement data. Data and condition forecast predicted through multivariate

analysis are remotely transmitted to the physicians. The time to detect COVID-19 infection is tested against the control group. The collected physiological data are simultaneously used to enhance the prediction model for COVID-19 infection using ML technology.

The DETECT (Digital Engagement & Tracking for Early Control & Treatment) Study, headed by the Scripps Research Translational Institute, uses combined heart rate, activity, and sleep data collected through a range of devices, such as Fit-bits, Apple Watches, Garmins, Oura Rings, or any others that can share data with Google Fit or Apple HealthKit, and pairs it with participant-submitted symptom reports. Through this approach, more individualized approaches to health care using person-specific vital-sign readings can be established.

The TemPredict Study, conducted by the University of California San Francisco, invites Oura Ring users to provide their device-collected physiological data and complete daily surveys on their condition. It also aims to identify patterns that can predict the onset, progression, and recovery in future cases of COVID-19 (Muoio, 2020).

Therefore, the comprehensive use of multiple physiological data is developing, and the power of ML in this field seems promising.

8.3 Early Detection of Other Infectious Diseases

Grzesiak et al. (2021) evaluated the ability of wrist-worn devices to detect the H1N1 and rhinovirus infections in the early phase. The data collected through wearables included accelerometer movement, resting heart rate, and body temperature. The heartbeat data were analyzed in terms of seven features: median resting heart rate, mean heart rate variability, median heart rate variability, root mean square (RMS) of successive RR intervals (intervals between QRS wave), number of successive RR intervals that differ by more than 50 ms, percent of NN intervals (intervals between normal R-peaks) differing by more than 50 ms, and the standard deviation of the NN intervals. The diagnosis model was built as a random forest classifier and validated using leave-one-person-out validation trees. This model was able to distinguish between infection and non-infection with accuracies of up to 92 and 88% for H1N1 and rhinovirus, respectively.

8.4 Future Prospects of Early Detection

The examples discussed in the above sections show that attempts are being made to acquire multiple physiological data from easy-to-wear devices, such as wristbands, and predict using the latest data science methods utilizing the big data.

From another point of view, the power of AI and ML is already being unleashed at the smartphone level (Alwashmi, 2020). Thus, smartphone data handling will be utilized further in the near future.

In particular, the RCT of the COVID-19 early detection in this context is under process (Wong et al., 2020). The outcome may clarify the usefulness of such approaches.

9 Consideration of Unmet Medical Needs and Cost-Effectiveness of mHealth

(1) Considerations in view of CardioMEMS: the importance of early detection for improved treatment outcomes

An example of simple remote monitoring is CardioMEMS HF, a heart failure prediction system using CardioMEMS, an implantable remote pulmonary artery blood pressure monitor already developed by Abbott. It has shown excellent cost-effectiveness in improving quality-adjusted life years (QALYs). This improvement is achieved through improved monitoring and management, despite the cost of implantation and the risk of complications associated with the implantation (Schmier et al., 2017). A breakdown of this cost-effectiveness analysis shows that the main contribution is made by a reduction in hospitalization rates for heart failure, possibly because of an early detection of symptoms.

The implication of this case is that the cost-effectiveness of telemonitoring is not necessarily achieved by the reduction in monitoring costs (by reducing visits), instead, it is achieved by better control of patients' conditions (resulting in reduced total treatment costs). To improve treatment outcomes (and reduce total treatment costs), it is important that monitoring is directly linked to medically meaningful endpoints, and the overall process of diagnosis to treatment is improved.

(2) Consideration in terms of AliveCor: benefit from ease of use

In their systematic review article, Giebel and Gissel (2019) discussed that AliveCor, an FDA-approved wearable ECG system, has the advantage of ease of use. AliveCor is found to be cost-effective in detecting atrial fibrillation and screening patients.

(3) Considerations in terms of preventing sudden death (epilepsy)

Sudden unexpected death in epilepsy (SUDEP) or death by accident associated with epileptic seizures may be avoided by early detection and prediction of seizures using wearable devices (Regalia et al., 2019). Although no comprehensive cost-effectiveness studies have been conducted in this field, it is expected to be cost-effective, based on the circumstance that an unexpected death has a large impact on life years for the young population.

Table 1 Portray of cost-effectiveness mHealth

Factors increasing costs	Factors decreasing costs
Development cost of apps	Increase in Quality Adjusted Life-Years (QALY) by early detection or adequate diagnosis of diseases
Medical intervention costs related to mHealth	Decrease in visit to hospital
Data transmission costs	Decrease in labor costs of medical staff in monitoring

(4) Discussion on cost-effectiveness of mHealth

Based on the example reviewed above, factors related to the cost-effectiveness of mHealth are presented in Table 1. Although one major expectation from mHealth is decreasing the labor costs of medical staff, it seems that the current major factor for decreasing costs is the increase in QALY. At present, no factors have been observed to change this tendency. From another point of view, the development cost of apps may decrease by employing a shared platform across several medications. In addition, data transmission costs will decrease with the evolution of data transmission technology.

(5) Another perspective—scope economy and use of existing platforms

The above analysis was based on a case study considering a standalone mHealth device. We are now in a situation where local public health indicators and disease epidemics are being examined using data acquired through Fitbit (Radin et al., 2020) and Apple Watch (Perez et al., 2019; Perino et al., 2021). Furthermore, the development of seizure prediction systems using large-scale data can also be achieved using these data. Therefore, there is a possibility of a scope economy effect for vendors, in which devices that originally penetrated the market for different purposes, such as improving convenience in daily life or managing exercise intensity as a leisure activity, can also be used to detect diseases. The effects of the scope economy have not been observed in the similar technology of electronic payments (Adams, Bauer, & Sickles, 2004), and there is a slight evidence of a scope economy in the area of health care-related data (Höcük et al., 2021). However, considering the limited scale of beneficiaries for individual disease control measures and the fact that public health care is the first choice, it is unlikely that the penetration of disease-related mHealth will proceed directly and easily in a scale economy. Thus, there is a possibility that the scope economy will be involved in the penetration of mHealth.

In addition, the use of existing platforms through diversion, utilization, and partnerships will be effective in reducing implementation costs. The aforementioned examples of Fitbit and Apple watch are the result of collaboration between existing platform vendors and research institutions, and similar activities will possibly

be carried out for commercialization. As another example, all of the COVID-19 contact tracking applications developed by the national health authorities use smartphones, and many of them use anonymizing technology by Apple or Google (Elkhodr et al., 2021). This is a good example of the device pre-penetration and externalization of elemental technologies.

10 Conclusion

This chapter describes the potential future use of mHealth as a component of next-generation health care and the societal, technical, and economic basis of such usage.

Specifically, (1) the future prospects of EHR/PHR and its relationship with health care in terms of big data utilization, (2) the current status and expected development of wearable devices, (3) the way VR can be used in mHealth; (4) the current use of AI/ML in mHealth, (5) the needs of telemedicine interventions and their future prospects, (6) the current status of mHealth providers and the prospects of new participants to join in the future, (7) the current status and expected development of early detection technologies for diseases, and (8) the future prospects of cost-effectiveness of mHealth have been discussed in this chapter. I believe that this narrative review has been able to highlight the expected use of mHealth in the future.

A society with a large number of elderly people is currently a social issue for developed countries and will eventually become a social issue worldwide. At that time, it will be extremely important to prevent diseases that reduce the activity of the elderly people, to detect diseases at an early stage to reduce the aftereffects, and to realize efficient medical care. Thus, the need for mHealth is expected to increase in the future.

Several basic items are under maturation, and several new approaches to health care with the use of mHealth are expected to emerge in the near future.

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mHealth's Potential for Measuring Work Attitudes in Psychological and Physical Factors

Nobuki Hashiguchi

ABSTRACT

Owing to technological advances in implantable biosensors (e.g., heart rate sensors and skin temperature sensors), wearable health devices are now sufficiently powerful to monitor the health status and physical load of workers using digital solutions such as mHealth. Today's wearable devices, such as wristbands, watches, and underwear, are lightweight and comfortable to wear in physical activities and are extremely useful in monitoring a large number of people using the cloud and databases through smartphones without interfering with the progress of work and for visualizing the participants' biometric information. In this chapter, the potential for quantitative labor management of employees through mHealth based on the case of construction workers is described. Because the physical and psychological risks faced by workers are increasing owing to the increasing sophistication and complexity of technology, the quantification of work attitudes and workloads for the psychological and physical factors of workers in labor-intensive environments are discussed. For companies that employ a large number of workers, ensuring that they have the necessary labor without sacrificing their health and safety is a critical challenge.

The original version of this chapter was published as an Open Access article in Vol 9, Issue 9 of Sensors, MDPI, 2020, under the terms and conditions of the Creative Commons Attribution (CC BY) license (<http://creativecommons.org/licenses/by/4.0/>), <https://doi.org/10.3390/s20133786>.

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1 Introduction

1.1 Workplace Health Environment After a Pandemic

Individual risks and issues exist in every workplace, which can negatively affect the health of workers and reduce their labor productivity by leading to injuries and accidents. Even if those risks are latent factors, timely identification and remediation have important implications for the health, safety, motivation, and overall productivity of workers (Hashiguchi et al., 2021). Therefore, corporate employers should focus on technologies that monitor, manage, and optimize workplace resources (e.g., tools, machines, inventory, safety equipment, assistive technologies, and workers).

The use of mHealth (biometric devices, mobile devices, body-worn accessories, personal protective equipment tools, etc.) in the workplace enables the tracking of the work activity, physical behavior, and health status of individual workers. They are rapidly expanding in almost every industry, with many niche applications emerging for each solution (Patel et al., 2021). The applications extend beyond medical professionals, patients, and office workers and are beginning to be used for detecting awkward work postures, heavy lifting, vibrations, physical and mental fatigue, mood and emotions, safety compliance behaviors, and rest periods, as observed in blue-collar workers (Schall et al., 2018; Xue et al., 2019; Okhifun, 2019). By building a smart and connected workplace, workers today are better equipped with situational awareness, site visibility, and remote monitoring (Richter et al., 2020; Porter et al., 2014). Ensuring the safety, health, and productivity of workers will be crucial for addressing the challenges companies face after the COVID-19 pandemic—the severe shortage of skilled workers, supply chain management burden, global inflation, and rising healthcare costs. In solving these challenges, intelligent systems (deployable sensors and analytics) play a key role in facilitating total worker health (TWH) through the continuous monitoring, management, and prediction of workplace risks and organizational assets.

Human performance (biomechanical functions, physical activities, physiological signals, etc.), such as situational awareness, risk management, efficient workflow, healthy behaviors, and cognitive habits, can now be monitored using many devices. In contrast, new intelligent systems are being introduced to proactively monitor and manage mental health, such as stress, emotions, and state of mind, using EEG sensing, biofeedback, and human-in-the-loop models (Patel et al., 2021). Because these systems can identify different occupational risk scenarios and have predictive capabilities for timely intervention, there is ample room for mHealth device manufacturers to further expand their customer needs.

1.2 Background of Mobile Health Measurement

The increasing sophistication and complexity of technology has increased the physical risks and psychological stress faced by workers. For companies that

employ workers, it is critical to ensure that they have the workforce they need for their production activities without sacrificing their health and safety. This chapter targets the psychological and physical factors of workers in labor-intensive work environments. It also discusses the quantification of the relationship between work attitudes and productivity and the relationship between workload and physical factors.

The working conditions of construction workers were monitored, and the workload was quantified to determine health risks. A practical method for estimating workload was discussed based on the physical activity and environmental information of construction workers. Data was collected using a wearable device equipped with a heart rate sensor and a 3-axis accelerometer, and a measurement system with a wireless IoT device. Additionally, a model was devised that can easily estimate the health risk due to workload from the worker's age, physical activity, and the heat index (WBGT) of the working environment. When the health risk was judged from the measurement results of construction workers, the correct discrimination of the model was 89.2%, indicating that the health risk of workers can be judged with high probability in an environment where it is difficult to measure users' heart rate in advance. The results of this study are the first to determine the health risk due to workload from the worker's age, physical activity, and WBGT without using heart rate.

In the discussion, the possibility of visualizing the workforce in labor-management by quantitatively recognizing the productivity workload and health risks of workers in different age groups according to their psychological and physical factors are described. The results of this study can contribute to the understanding of workers' health risks, work motivation, and work attitudes in labor-intensive projects as well as in the construction sector, suggesting that monitoring workers' health status can be useful in managing the workforce.

1.3 Heart Rate Measurement and Measurement Methods

Many measurement devices are available for measuring heart rate, and they can be classified according to the intensity of the user's physical activity and the measurement period, as shown in Fig. 1. The 12-lead electrocardiogram records the potential difference between two points on the body surface and is called 12-lead because there are a total of 12 different positions for attaching the electrodes (the direction in which the flow of electricity is observed): six for the limb leads and six for the chest leads. When cardiac muscle cells are excited and contract, a minute electric current is generated, and this electric phenomenon is recorded by an electrocardiograph, which is called an electrocardiogram. An electrocardiogram (ECG) is a medical device used in cardiovascular treatment because it can be performed easily without subjecting the patient to any pain. Electrical activity was conducted in the following order: (1) sinus node, (2) atrioventricular node, (3) his bundle, (4) right and left legs, (5) Purkinje fibers, and (6) ventricular muscles, and it was measured as a single electrocardiogram. To record the ECG correctly, it is important

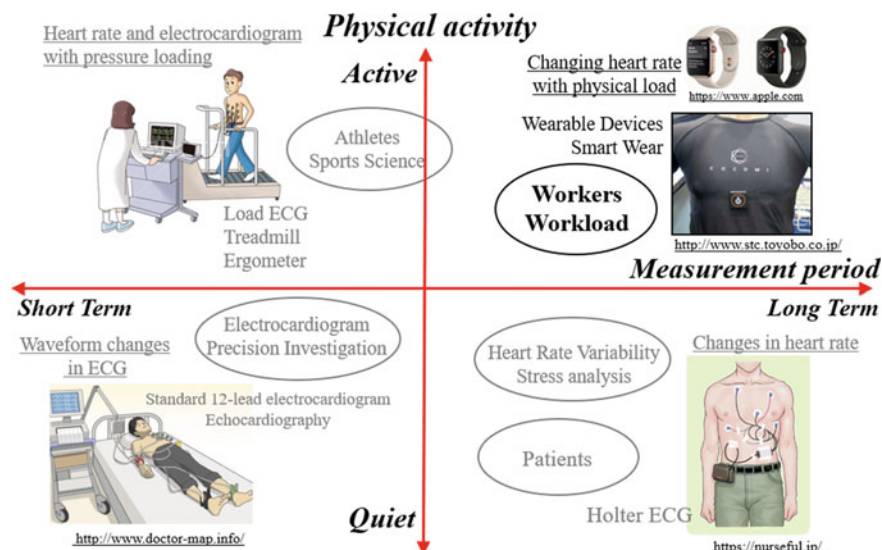


Fig. 1 Means of measuring heart rate information and measurement tools

to attach the electrodes in the correct position. If the electrode position attached to the body is incorrect, the results of the recorded standard 12-lead ECG will not be useful. Although it is a promising method for accurate heart rate measurement, it is difficult to apply it to heart rate measurements in an intense working environment.

A Holter electrocardiograph records the heartbeat by attaching several electrodes to the chest. By recording ECG waveforms over a long period of time (approximately 24 h, including sleep) with a portable electrocardiograph, the presence of arrhythmia and angina pectoris (unstable angina pectoris and exertional angina pectoris) that cause palpitations and chest pain can be checked. The purpose of the ECG is to determine the heart rate variability in daily life, and it is not suitable for measuring strenuous physical activities that involve sweating.

Load electrocardiographs or treadmills are used to measure heart rate in athletes in the rehabilitation phase. In this test, the participant is asked to climb stairs or walk on a motorized conveyor belt to load the heart and examine the ECG changes. This test is useful in determining the suitability of rehabilitation for ischemic heart disease and recovery from heart disease, which cannot be determined at rest by applying an external load. A dedicated 12-lead electrocardiograph is often used for heart rate measurement, which is relatively resistant to vibration caused by exercise and can record a highly accurate electrocardiogram. Recently, a type that uses wireless communication and does not require incidental cables has been released.

A wearable device is a heart rate measurement tool used for health management. Most of them are non-medical devices, and many of them are watches that monitor the pulse rate of the wearer's arm using an optical system, such as the Apple Watch. This type includes EPSON's PULSESENSE, Fitbit's Charge, and

Fig. 2 Smart wear being developed at the College of Sports and Health Sciences, Ritsumeikan University.

Source <http://www.ritsumei.ac.jp/tanq/302140/> retrieved on September 1, 2021



Polar's A360, released in 2016, which can record activity and sleep times in addition to heart rate. Fitbit's Charge3, released in 2016, has a relative SpO2 sensor that can detect sleep apnea.

Figure 2 shows a garment-type sensor in the form of underwear with an embedded heart rate sensor, which is called smart wear. It was jointly developed by the College of Sports and Health Sciences of Ritsumeikan University and TOYOBO Co. and is marketed under the product name COCOMI®. It can measure heart rate, respiratory rate, and electrocardiogram because it can easily measure physical biometric data.

For the measurements in this study, this smart wear was used to measure fluctuations in the participants' heart rates. Underwear-type wear has elasticity in the fabric, and electrodes for measuring the heart rate are printed on the wear itself. The electrodes of the Holter electrocardiograph, which is often used in long-term electrocardiographic examinations, may cause itching and redness on the user's skin because of its invasive nature, because an adhesive sticker or the like, which integrates conductive gel and electrodes of the heart rate sensor, is applied to the skin, as shown in Fig. 3.

However, the electrodes for the heart rate measurement sensor printed on the fabric of the smart wear come in contact with the skin of the user but do not adhere to the skin using adhesive gel. Therefore, there is less discomfort when wearing the smart wear, and redness and itching are less likely to occur. It is also expected to reduce constraints and discomfort when worn during physical activities. The smart wear is also washable and thus can be kept clean.

In electrocardiogram testing using smart wear, noise (artifacts) during measurement due to body movement has been reported, and there are some issues that need to be resolved for clinical medical diagnosis and use in medical devices; however, it is possible to capture fluctuations and sudden changes in heart rate, and it has been reported that the R wave and R-R wave interval (Fig. 4) can be stably detected not only at rest but also during walking and running (von Scheidt et al., 2019).



Fig. 3 Example of Holter ECG electrodes for testing. *Source* iMedex, Inc. Retrieved September 1, 2021, from <https://www.imedex.co.jp/products.html>

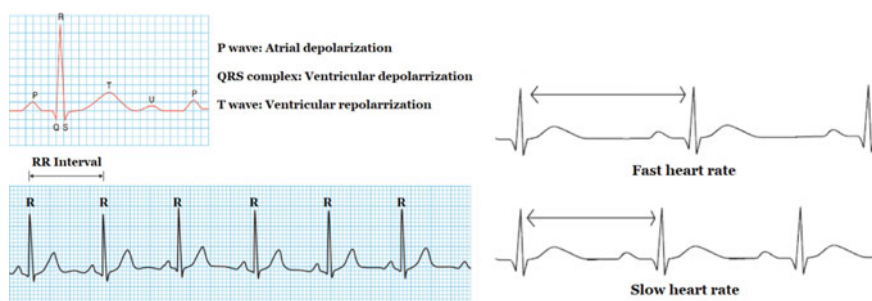


Fig. 4 ECG R wave and R-R wave interval

1.4 Construction Environment for Workers

For mHealth devices that quantitatively monitor the activity status of workers, the use of sensing technologies that allow accurate recording of their heart rate is important. Advances in embedded biosensor systems (such as heart rate and skin temperature sensors) have led to the development of mobile devices that can measure the effects of physical workload (Adibi, 2015; Wang et al., 2019). These wearable health devices are commercially available in the form of lightweight wristbands at affordable prices, and they provide comfortable contact with the skin. In these smartwatches, sensors measure the acceleration caused by the user's physical activity, electrical signals capture the electrocardiogram (ECG), and photodiodes and light-emitting diodes facilitate photoelectric volumetric pulse wave (PPG) probes (Bambang et al. 2020). Although the measurement accuracy and resolution of these devices are currently inferior to those of ordinary medical devices,

they can help monitor heart rate and collect various biological information such as ECG and arterial blood oxygen saturation (SpO₂).

Compared to chest straps with heart rate sensors, which are uncomfortable and tight for the body, wearable heart rate sensors can collect continuous heart rate variability without causing discomfort to the worker. Therefore, the author conducted a case study to investigate the potential of wearable devices in workers by capturing changes in the load applied to the body of construction workers over time. Specifically, heart rate was measured using smart wear to study the factors affecting the body owing to the load on the body, and changes in workload based on heart rate reserve (%HRR) were studied to continuously monitor the workload of individual workers. This analysis also included individual physical information (age, height, weight, and BMI) and activity patterns (direct work, indirect work such as preparation and cleaning and 3-axis accelerometer). Continuous measurements throughout the day can be important in revealing differences among multiple workers with different individual skills and task responsibilities.

1.5 Objective of This Research

The research objectives of this study were two-fold. As the first objective, in order to clarify the relationship between heart rate and workload during work, the developed wearable device and IoT system were used to collect and analyze data on the heart rate and physical activity of workers. The second research objective of this study was to investigate a practical measurement method without the burden of prior preparation. A method to estimate the workload with a high rate of correct answers by logistic regression analysis was developed, and its validity was evaluated. In this research objective, the psychological and physical factors related to worker productivity were analyzed together, and the second objective was to propose labor management by monitoring workload.

The research question for this study was: How much of the workload can be practically measured from the information of workers' age, physical information, information on their activities during work, and information on the work environment?

2 Measurement Methods Using Mobile Tools

2.1 Devices and Systems Used for the Measurements

The list of mobile health measurement devices and infrastructure used in this study are shown in Table 1. In this study, temperature, relative humidity, and WBGT were measured to evaluate the type of work environment; acceleration (ACC), which changes in relation to these factors, was measured along with HRR and ECG to determine the workload. In Table 1, the data acquisition device synchronized the

Table 1 Measurement devices used to measure the working environment

Measurements	Devices (Manufacturing company)	Measuring accuracy	Resolution	Interval	Note
Air temperature	AD-5696 (A&D Co., Ltd.)	$\pm 1\text{ }^{\circ}\text{C}$	$0.1\text{ }^{\circ}\text{C}$	10 min	Thermistor
Relative humidity		$\pm 5\% \text{ Rh}$	$0.1\% \text{ Rh}$	10 min	Capacitance
WBGT		—	$0.1\text{ }^{\circ}\text{C}$	10 min	—
ECG (smart clothing)	COCOMI ^a (TOYOBO Co., Ltd.)	—	0.3 mm^c	—	Stretchable conductive film
Heart rate sensor	WHS-2 ^d (Union Tool Co., Ltd.)	—	1 kHz^e	Per beat	Analysis of R-R interval
3-axis acceleration		—	31.25 Hz^e	Per beat	Capacitive sense
Time of data acquisition	CC2650 ^f and ThinkPad (Texas Instruments and Lenovo co., Ltd.)	—	1 ms	Per beat	Synchronize time with whole system
Data transmission	Raspberry Pi Zero W (Raspberry Pi Foundation)	—	—	—	IEEE802.11 b/g/n and Bluetooth low-energy

Note ^a Fig. 1b; ^b Sheet resistance of smart wear; ^c Approximate thickness; ^d Fig. 1a; ^e Sampling in frequency; ^f Fig. 1c

time data so that there would be no difference in the data acquisition time among the workers.

As shown in Fig. 1a, workers' heart rate and physical activity were measured based on the ECG acquired by the smart wear, which was a vest with a built-in biometric sensor (to detect the heart rate; Axisa et al., 2005; Lin et al., 2018) and a 3-axis accelerometer. The smart wear was made of stretchable fabric and had stretchable ECG electrodes embedded in the hardware to measure the heart rate (TOBYO Co. Ltd.). The heart rate is detected by detecting the R-R interval of the ECG signal, and then the HRR under load and at rest is obtained by converting the detected R-R interval. A small heart rate sensor device (WHS-2) was attached to the smart wear, and the participant's physical activity was measured by a 3-axis accelerometer, and the heart rate and physical activity were observed simultaneously (Shiozawa et al., 2015). The heart rate and triaxial acceleration data were transmitted to a data acquisition device (CS2650, Texas Instruments, Inc., Texas, United States) used by the worker using a Bluetooth low-energy device. The data from the data collection device were then transmitted to a server located on the network through a wireless access point (data transfer device) installed at the work site for recording. Figure 1b shows the measurement devices used and overall system configuration.

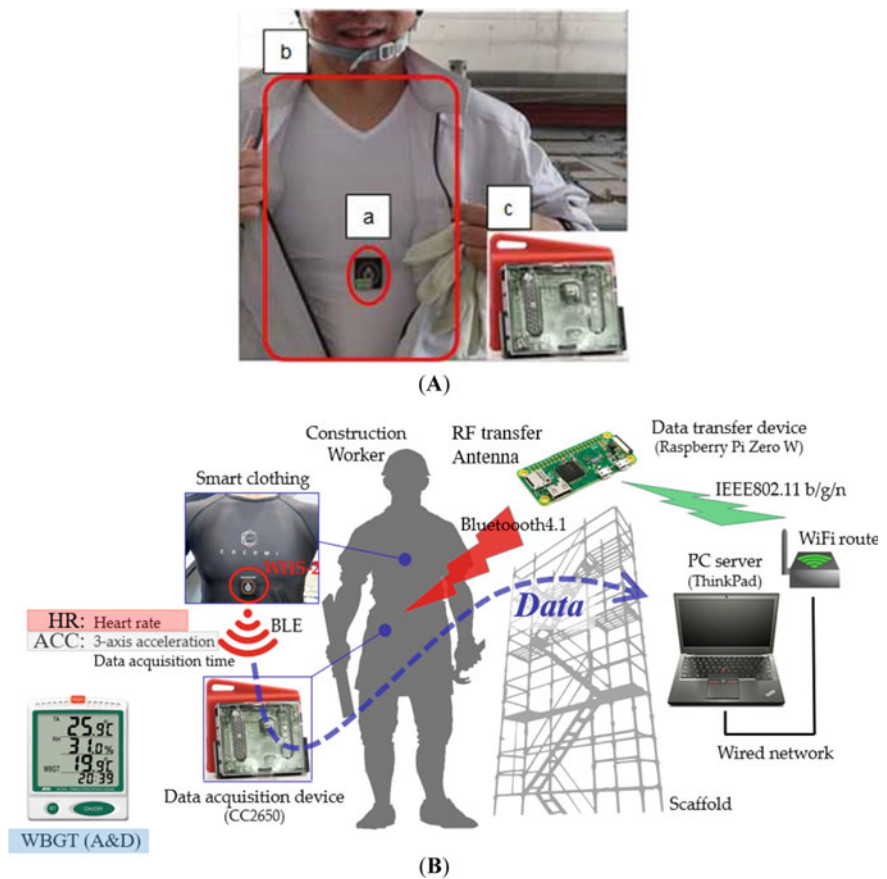


Fig. 5 Devices used for physiological measurements. *Note* **A** a: Heart rate and 3-axis accelerometer (WHS-2), b: smart wear (COCOMI), c: data acquisition device (CC2650); **B** Overall system configuration for physiological measurements

BMI was calculated based on the height, weight, and age data provided by the workers, and the WBGT was calculated for the working hours. WBGT in the work environment was also measured at 5-min intervals to determine the temperature and relative humidity (Fig. 5).

2.2 Participating Workers

The data shown here were obtained in 2018 at a drainage pump construction site for a construction company (Kumagai Gumi Co., Ltd., Tokyo, Japan). The time period in which the study was conducted was determined from an ethical point

of view in order to avoid as much as possible the extreme temperatures and the mental and physical burden on the participants caused by the measurements. The participants were in charge of dismantling the steel scaffolding. Specifically, eight steeplejack workers performed repetitive tasks (related to dismantling), and four assistant workers performed indirect tasks such as preparation work. These 12 participants were selected by the company as participants for the experiment.

2.3 Measurement Parameters

The measurement parameters and methods are presented in Table 2. Because the participants work for a construction company that routinely takes body measurements, it was expected that they would be aware of their own body measurements. The participants were asked questions about their age, height, and weight, and their BMI was calculated based on their answers. A study of an East Asian cohort (Zheng et al., 2011) showed that those with a BMI between 22.6 and 27.5 had the lowest risk of death, while those with a higher BMI tended to have a higher risk of death from cancer, cardiovascular disease, and other causes. In this study, BMI was added as an explanatory variable to examine the health risks of workers.

The heart rate during work (HR_{working}) was determined by measuring the heart rate of each worker every 5 min and averaging them. Thus, the heart rate during work represents an average value over 5 min. These data were corrected by removing invalid data and outliers (Porges & Byrne, 1992; Caballero et al., 2020). Accurate measurement of HR_{max} is not suitable for construction workers, who are often not in a fixed workplace for long periods of time. Therefore, Tanaka's equation to predict HR_{max} (Tanaka et al., 2001) was used. To check the stability of the resting heart rate, the resting heart rate was measured at least three times at 5-min intervals, and the lowest average heart rate was used as HR_{resting} .

Furthermore, the physical activity level of the participants was evaluated by continuous monitoring using a 3-axis accelerometer to obtain the ACC (De Bruin et al., 2007) of the three axes (vertical axis: X, horizontal axis: Y, vertical axis: Z); the ACC, which is the amount of physical activity, was calculated by the average value generated at 5-min intervals. The intensity level of physical activity has

Table 2 Measurement parameters for model development

Measurement parameter	Calculation methodology	Unit
BMI	$\text{weight}/(\text{height})^2$	kg/m^2
HR_{working}	average heart rate in 5 min during the workday	beats/min
HR_{resting}	average heart rate in 5 min during the rest period	beats/min
HR_{max}	$208 - 0.7 \times \text{age}$	beats/min
%HRR	$\%HRR = \frac{HR_{\text{working}} - HR_{\text{resting}}}{HR_{\text{max}} - HR_{\text{resting}}} \times 100$	%
ACC	$\sqrt{Kx^2 \cdot \text{Acc}(t)_x^2 + Ky^2 \cdot \text{Acc}(t)_y^2 + Kz^2 \cdot \text{Acc}(t)_z^2}$	mG

been shown to be a predictor of health status (Menai et al., 2017). The triaxial acceleration method was used to observe the overall intensity of movement of each worker during working hours. Unlike office workers, construction workers can provide more detailed motion data than can be obtained from the measured parameters. These data may include their ability to lift loads on the stairs. This method captures the intensity of a worker's movements during work activities (e.g., walking, standing, and squatting) performed during working hours.

2.4 Study Protocol

Prior to data collection, the potential risks and discomfort to the participants, as well as privacy issues due to data collection, were examined. It was confirmed that the mHealth device used in this study would not interfere with the progress of the construction because it is a non-invasive device. In accordance with the Declaration of Helsinki, the human genome, and the Universal Declaration of Human Rights, the data collection protocol, including heart rate, physical activity, and participant privacy conditions, was approved by Ritsumeikan University Research Ethics Review Number: BKC-2017-071-1. The approved protocol and informed consent form distributed to all participants prior to data collection included a statement of participant's rights and ensured confidentiality of the data. To protect privacy and minimize the risk of workers' personal information being compromised, workers' names were not used, and personal identification codes (identifiers) were used for data collection and analysis.

2.5 Data Acquisition

The data acquisition date, participant's age, work content, physical measurements, data collection time, rest time, work content, and each participant are shown in Table 3. The measurement time was from 8:30 am to 5:00 pm. Data were collected at 5-min intervals for the entire work period or for half of the work period. All participants were male and were asked to provide information about their age, occupation, body size, and weight via a questionnaire. Because the cardiopulmonary function was intended to exclude unhealthy participants from the measurement, participants were also asked about their history of cardiovascular disease and their current health status (e.g., whether they suffered from chronic cardiovascular disease). Of the initially planned 13 participants, one participant with arrhythmia did not participate in the experiment. Excluding the preparation time for data collection, 882 datasets were collected from the 12 participants.

In this experiment, the Hawthorne effect (Adair, 1984) was confirmed. Rather than directly monitoring the activities of the participants, the author waited for a short distance away from the work area and recorded and photographed their work using two cameras installed in the work area. In general, each manual laborer who performed high-load work had their own health concerns, and they paid attention

Table 3 Description of the obtained data of the participants

ID	Age (Years)	Main job task	Height (cm)	Weight (kg)	Duration of data collection (min.)	Scheduled resting (min.)	Number of data ^a (Sets)
S1	20	Scaffolder	159.0	57.0	450	90	90
S2	39	Scaffolder	179.0	74.0	300	90	60
S3	32	Scaffolder	177.0	93.0	450	90	90
S4	25	Scaffolder	182.0	82.0	450	90	90
S5	41	Scaffolder	176.0	70.0	510	90	102
S6	40	Scaffolder	176.0	75.0	510	90	102
S7	36	Scaffolder	170.0	68.0	510	90	102
S8	22	Scaffolder	165.0	55.0	510	90	102
L1	43	Worker	168.0	70.0	210	60	42
L2	50	Worker	174.5	87.5	210	60	42
L3	27	Worker	170.5	62.5	150	60	30
L4	59	Worker	169.0	76.0	150	60	30

Note ^a The data was averaged over a time interval of 5 min

to the physical load caused by their daily work. Therefore, before starting the measurements, the participants were instructed not to deviate from their normal work patterns and were also informed that the intention of this study was to measure physical workload, not worker skills.

2.6 Risk Model and Validity of Variables

Binomial logistic regression was used to analyze the health risks determined by the %HRR level. Logistic regression modeling analysis is widely used in the study of physiological medicine as well as biology, engineering, ecology, health policy, linguistics, and business and finance (Agresti, 2018; Hosmer & Lemeshow, 2000). The regression analysis has become an integral element of data analysis to describe the relationship between the independent variables and one or more of the explanatory variables.

The independent variables were age, BMI, amount of physical activity during labor, and WBGT in the work field. A prediction model that considers the parameters of these independent variables improves the accuracy of risk detection, and a strong correlation between risk factors was observed. Therefore, it is important to consider the possibility of multicollinearity when conducting the statistical analysis. In developing the statistical model, the Pearson's correlation coefficient and variance inflation factors (VIF) were calculated to determine the physical activity of ACC, BMI, and AGE of the participants and WBGT in the work environment.

Table 4 Descriptive statistics and correlation matrix regarding the analytical model for workers' risk

Variables	ACC	BMI	AGE	WBGT	VIF
ACC	1.00				1.17
BMI	0.021	1.00			1.48
AGE	− 0.333 ***	0.415 ***	1.00		1.43
WBGT	− 0.067 *	− 0.387 ***	− 0.048 *	1.00	1.20

Note *** indicates $p < 0.001$ and * indicates $p < 0.05$

The results regarding the correlation coefficients between the independent variables and VIF are shown in Table 4. A weak negative correlation coefficient (−0.333) was found between physical activity ACC and AGE, while no correlation was found between BMI and WBGT. BMI also showed a slight positive correlation (0.415) with AGE and a weak correlation (−0.387) with WBGT. Furthermore, the AGE of the participants was found to be poorly correlated with WBGT, the VIF was used as a criterion to check for multicollinearity, and values for all independent variables showed a range of values 1 – 2. This indicates that the possibility of multicollinearity is low (Daoud, 2017).

3 Results of Worker Measurements Measured by the mHealth Device

3.1 Characteristics of the Measured Participants

Concerning S1–S8 scaffold workers and L1–L4 construction assistants, Table 5 shows the measurements associated with the heart rate, physical activity ACC, and the correlation coefficient $r_{\text{ACC-\%HRR}}$ between ACC and %HRR. The average and standard deviations of the data on the effect of the amount of physical activity on the heart rate were determined during the data collection spanning all working hours, including the break time.

Scaffold workers S1–S8 were compared with L1–L4 assistants, whose average and standard deviations between the ACC and the %HRR were large and their workload in the scaffold dismantling was found to be relatively high. The average %HRR of S5 and S7 was more than 40%, implying that they were exposed to a high physical workload. Among the other workers, the %HRR of several workers exceeded 40% frequently, implying that the workers were exposed to safety and health hazards. S2 was assigned to the foreman responsible for monitoring the progress work at the construction site. On the day of the experiment, S2 participated twice in the meeting spanning approximately 30 min, and S2 was not exposed to a heavy physical workload; therefore, S2's heart rate and physical activity were not affected.

Table 5 Overview of participants' physical workload measurement

ID	Estimated HR _{max} (beats/min)	Estimated HR _{resting} (beats/min)	HR _{working} Ave. ± SD (beats/min)	%HRR Ave. ± SD (%)	ACC Ave. ± SD (mG)	r _{ACC} -%HRR
S1-S8	185.8 ± 5.6	75.8 ± 2.5	115.0 ± 20.2	35.8 ± 18.5	152.1 ± 67.0	—
S1 ^b	194.0	77	117.9 ± 21.4	35.0 ± 18.3	195.6 ± 86.3	0.808
S2 ^c	180.7	79	106.6 ± 16.0	27.2 ± 15.8	113.9 ± 35.7	0.755
S3 ^b	185.6	76	112.7 ± 21.9	33.4 ± 20.0	158.8 ± 55.7	0.810
S4	190.5	75	105.0 ± 15.8	26.0 ± 13.7	188.0 ± 86.9	0.800
S5 ^a	179.3	75	119.1 ± 17.6	42.3 ± 16.9	138.6 ± 47.1	0.801
S6 ^b	180.0	72	111.5 ± 22.4	36.5 ± 20.7	149.2 ± 64.4	0.863
S7 ^a	182.8	80	125.7 ± 19.4	44.5 ± 18.9	139.9 ± 43.4	0.895
S8 ^b	192.6	74	117.2 ± 17.4	36.4 ± 14.7	127.4 ± 55.5	0.697
L1-L4	176.5 ± 7.6	77.0 ± 2.0	95.0 ± 10.7	18.4 ± 10.2	106.7 ± 47.4	—
L1	174.4	76	90.4 ± 5.4	14.2 ± 5.3	99.1 ± 39.5	0.770
L2	173.0	80	106.4 ± 11.2	28.3 ± 11.9	108.2 ± 41.2	0.917
L3	189.1	75	89.8 ± 6.9	13.0 ± 6.1	147.8 ± 57.6	0.788
L4	166.7	76	90.4 ± 5.5	15.9 ± 6.1	74.2 ± 14.8	0.814
Total Ave. ± SD	182.4 ± 8.4	76.3 ± 2.4	111.7 ± 20.4	32.9 ± 18.6	144.7 ± 60.3	—

Note ^a Heart rate ≥ 40% HRR occurring all day; ^b ≥ 30% HRR occurring frequently all day; ^c Foreman of scaffold

While the amount of physical activity of S5–S8 was relatively small, their %HRR was slightly higher at 36–45%. On the day of data collection, they were engaged in manual labor for a long time at the scaffold tower. Some of the participants were engaged in removing the steel scaffolding materials and placing them under the scaffold stairs; this work entailed a continuous exchange of steel materials among the participants. Although this physical activity did not involve a lot of movement, it was laborious to dismantle the steel materials; hence, a high heart rate was recorded for these subjects.

3.1.1 Analysis of Relationship Between ACC and %HRR by Workers

Figure 6 shows the results of the %HRR for the ACC measured in each participant. The relationship between the ACC and the %HRR is shown in linear approximation; Table 5 describes the correlation coefficient r_{L1-L4} of L1–L4 and the correlation coefficient r_{S1-S8} of S1–S8. In all the participants, the %HRR increased according to the increase in the ACC, and the correlation coefficient r of the ACC and the %HRR was approximately 0.7–0.9. When compared to assistant workers, the higher heart trend of the scaffold workers shows their exposure to a high physical workload. During the break time, the workers' ACC and %HRR were relatively low, and their physical activity and heart rate at rest time were stable.

Figure 6 also shows that, despite an increase in ACC from S5 to S8, the %HRR tends to be relatively large. S1 recorded the highest ACC among all participants because S1 not only placed the dismantled steel materials under the scaffold stairs but also carried them to the collection location. It is presumed that there was an increase in the transportation task between the unloading location of the scaffold stairs and the collection location, which led to an increase in both %HRR and

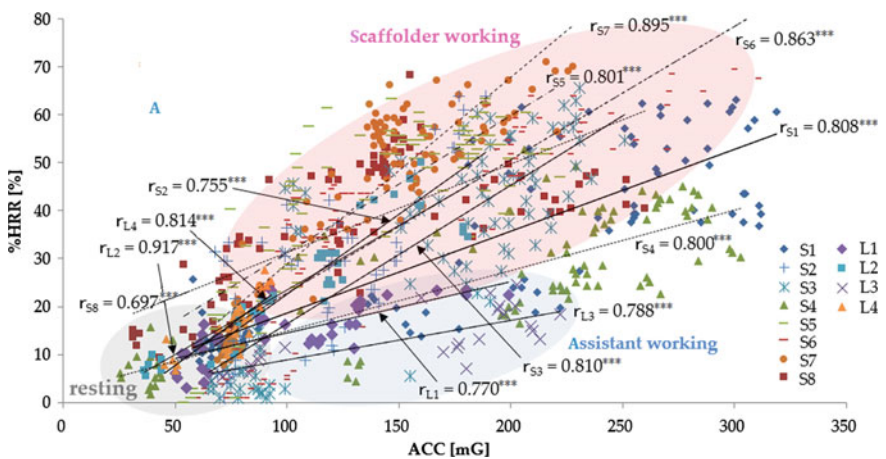


Fig. 6 Relationship between acceleration (ACC) and heart rate reserve (%HRR) (Scaffolder_{S1–S8}, Labor_{L1–L4}). Note r_{S1-S8} denotes the correlation coefficient of the relationship between ACC and %HRR for S1–S8, and r_{L1-L4} is the correlation coefficient of the relationship between ACC and %HRR for L1–L4

ACC. S1 is the youngest among the participants; as HR_{max} increased by the calculation based on age, there is a possibility that even the same $HR_{working}$ is no longer conspicuous when compared to the other participants. Conversely, although relatively high-age assistant members, such as L3, had a relatively low ACC without a large movement behavior, L3's %HRR was higher than that of the other assistant workers. This can be attributed to the fact that the HR_{max} obtained for L3's age is lower than that for the other participants.

3.1.2 Analysis of Relationship Between ACC and %HRR by Workers' Age

Concerning the younger and older age groups, Table 6 shows the number of participant data, the average and standard deviations regarding the age, ACC, %HRR, and the correlation $r_{ACC\text{-}\%HRR}$. The workers were divided into two age groups: 20–39 years and 40–59 years. In the younger age group (20–39 years old), %HRR was relatively low, while the amount of physical activity was the highest, when compared to the relationship between the ACC and the %HRR in the older age groups. Data on the ACC and %HRR were significantly different between $AGE_{younger}$ and AGE_{older} patients.

For the two age groups, Fig. 7 shows the relationship between the ACC and the %HRR in linear approximation and describes the correlation coefficient r of each participant in the two age groups. The correlation coefficient between the two age groups is separated by 20–39 years and 40–59 years of age, as indicated by $r_{younger}$ and r_{older} . The correlation coefficient of 0.588 was seen to have a moderately strong correlation in the young age group; the correlation coefficient r of the relationship between the ACC and the %HRR increased with an increase in age, and the correlation tended to be stronger. Figure 7 shows an increase in the change in %HRR against the ACC in the older age group (40–59 years old), compared to the younger age groups. This relationship suggests that the %HRR increased with an increase in workers' physical activity and age.

Table 6 Overview of workers' age and relationship between ACC and %HRR

Age groups (Years)	Number of data (Sets)	AGE Average $\pm$ SD (Years)	ACC average $\pm$ SD (mG)	%HRR Average $\pm$ SD (beats/min.)	$r_{ACC\text{-}\%HRR}$
$AGE_{younger}$	562	28.7 ± 7.2	154.7 ± 69.8	33.3 ± 18.3	0.588
AGE_{older}	310	46.6 ± 8.0	127.1 ± 55.7	32.3 ± 19.1	0.836
$p\text{-value}_{younger\text{-}older}^*$			< 0.001	0.049	—

Note $AGE_{younger}$ and AGE_{older} denote the group of workers aged 20–39 years and 30–39 years, respectively. *: The p -value is obtained from multiple comparisons between $AGE_{younger}$ and AGE_{older} , using the Mann–Whitney U test

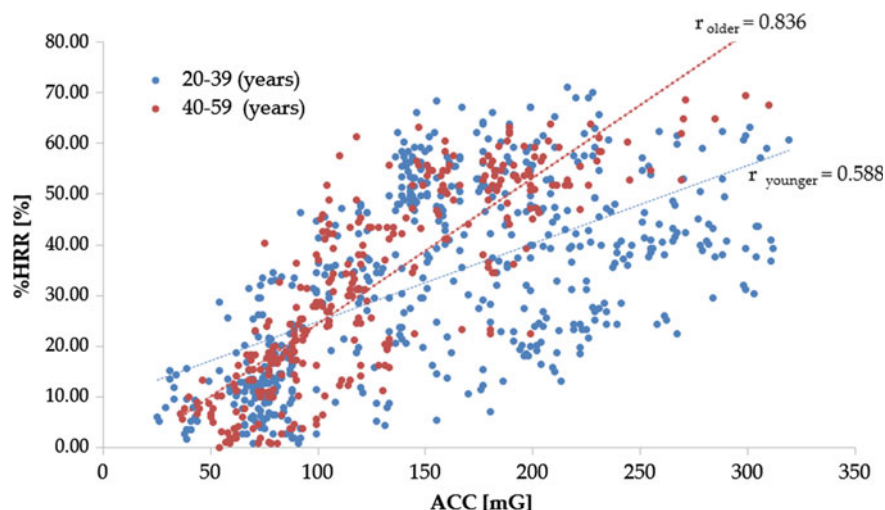


Fig. 7 Relationship between ACC and %HRR (workers' age levels are 20–39 years old and 40–59 years old). *Note* r_{20-39} and r_{40-59} are the correlation coefficients of the relationship between ACC and %HRR for 20–39 years old and 40–59 years old, respectively

3.1.3 Analysis of Relationship Between ACC and %HRR by Workers' BMI

For each BMI group of workers, Table 7 shows the number of participant data, average, and standard deviations with regard to the ACC, %HRR, and correlation. The BMI groups are divided into three layers— $\leq 22.5 \text{ kg/m}^2$, $22.6\text{--}27.5 \text{ kg/m}^2$, and $\geq 27.6 \text{ kg/m}^2$ (Zheng et al., 2011). Regardless of BMI, a large difference was not found between the values of %HRR and ACC. The data on the ACC and the %HRR were non-significant among BMI groups, except for the relationship between BMI_{middle} and BMI_{high} with regard to ACC.

For each BMI group, Fig. 8 shows the relationship between the ACC and the %HRR in linear approximation and describes the correlation coefficient r for each age group of participants. The correlation coefficients of each BMI group are shown as r_{low} , r_{middle} , and r_{high} , respectively. All correlation coefficients were between 0.6 and 0.8, approximately, in any BMI group; the relationship between the ACC and the %HRR showed a moderately strong correlation. Although the correlation coefficient r tended to be greater in the groups with higher BMI participants, a significant change in %HRR for the ACC due to BMI was not observed. This relationship suggests that the workers' BMI is not affected when there is an increase in the %HRR due to an increase in physical activity.

3.1.4 Analysis of Relationship Between ACC and %HRR by Workers' WBGT

Table 8 shows the number of participant data, the average, and standard deviations regarding the WBGT, %HRR, ACC, and correlation coefficient r between %HRR

Table 7 Overview of workers' BMI and relationship between ACC and %HRR

BMI groups (kg/m ²)	Number of data (Sets)	BMI Average ± SD (kg/m ²)	%HRR Average ± SD (beats/min.)	ACC Average ± SD (mG)	r _{ACC, %HRR}
BMI _{low}	222	21.3 ± 1.07	32.6 ± 17.3	157.8 ± 76.6	0.610
BMI _{middle}	528	23.9 ± 1.02	33.6 ± 19.3	139.7 ± 63.3	0.767
BMI _{high}	132	29.4 ± 0.46	31.8 ± 17.9	142.8 ± 56.6	0.810
<i>p</i> -value * _{low-middle}			n.s	0.011	—
<i>p</i> -value * _{middle-high}			n.s	0.316	—
<i>p</i> -value * _{low-high}			n.s	0.334	—

Note BMI_{low}, BMI_{middle}, and BMI_{high} denote ≤ 22.5 kg/m², 22.6–27.5 kg/m², and ≥ 27.6 kg/m², respectively. *: The *p*-value is obtained from multiple comparisons among BMI groups by using the Kruskal–Wallis test; n.s.: non-significant

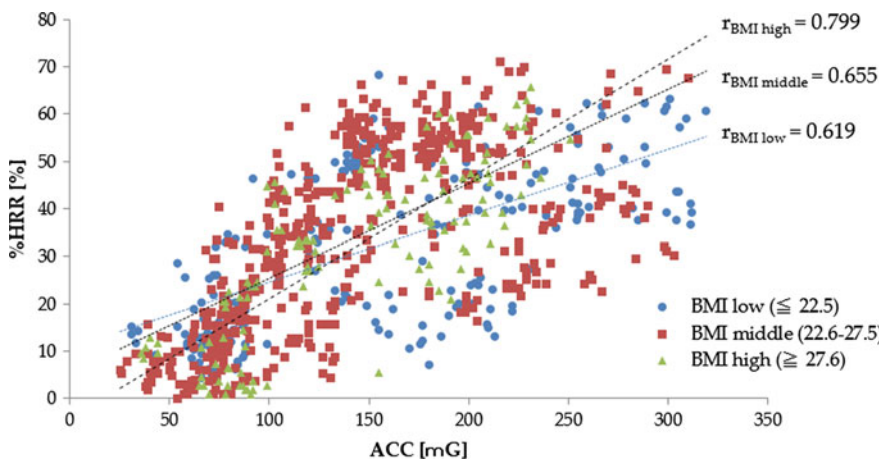


Fig. 8 Relationship between ACC and %HRR. *Note* Workers' BMI levels are ≤ 22.5 kg/m², 22.5–27.5 kg/m², and ≥ 27.6 kg/m². *r*_{low}, *r*_{middle}, and *r*_{high} are the correlation coefficients of the relationship between ACC and %HRR, for ≤ 22.5 kg/m², 22.6–27.5 kg/m², and ≥ 27.6 kg/m²

and ACC. At the time of measurement, the time participants spent on heavy work accounted for 75% of the total working hours, and the rest of the quarter was the rest time. Based on the limit of WBGT of ISO7243 (Indoor Environments; Parsons, 2006), the WBGT was divided into two groups: low and high—at 25.9 °C. The ACC and %HRR data were significantly different between WBGT_{low} and WBGT_{high}. Regardless of the BMI group, at high WBGT, a large difference was not significant for %HRR and ACC. Figure 9 shows the relationship between the ACC and the %HRR per WBGT group in a linear approximation and describes the correlation coefficient *r* for each age group of the participants. The correlation coefficient was *r*_{<25.9} and *r*_{≥25.9}. The correlation coefficient *r* became *r*_{<25.9} =

Table 8 Overview of wet bulb globe temperature (WBGT) and the relationship between ACC and %HRR

WBGT groups (°C)	Number of data (Sets)	WBGT Average ± SD (°C)	%HRR Average ± SD (beats/min)	ACC Average ± SD (mG)	r _{ACC-%HRR}
WBGT low	552	16.3 ± 2.75	30.7 ± 17.6	168.6 ± 77.4	0.703
WBGT high	330	27.6 ± 0.21	34.3 ± 19.1	130.5 ± 53.9	0.750
p-value * low–high			0.005	< 0.001	—

Note WBGT_{low} and WBGT_{high} are < 25.9 °C and ≥ 25.9 °C on WBGT, respectively. *: The *p*-value is obtained from multiple comparisons between WBGT_{low} and WBGT_{high} using the Mann–Whitney U test

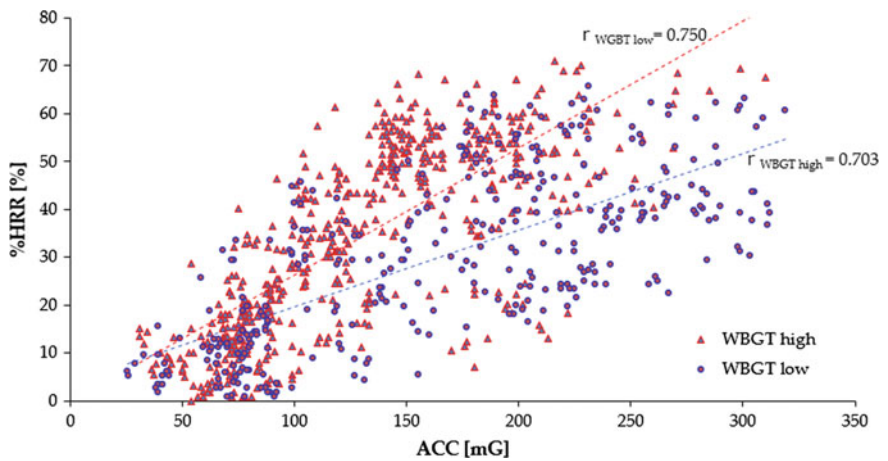


Fig. 9 Relationship between ACC and %HRR (WBGT levels are ≤ 25.8 °C and ≥ 25.9 °C). $r_{WBGT\ high}$, $r_{WBGT\ low}$ are the correlation coefficients of the relationships between ACC and %HRR for ≤ 25.8 °C, ≥ 25.9 °C

0.703 and $r_{\geq 25.9} = 0.750$ in any WBGT group; a strong correlation between the ACC and %HRR is observed. As WBGT increased, the change in %HRR, which was larger than ACC, led to an increase in the heart rate. This relationship suggests that the %HRR increased with an increase in workers’ physical activity and WBGT.

3.2 Logistic Regression Model for Workers’ Health Risk

Logistic regression analysis was performed using the statistically significant ($p < 0.05$) independent variables in Table 4. The logistic model formula used in this

study is as follows:

$$\begin{aligned} &\text{Workers' health risk } (\geq \text{HRR } 40\% : 1, < \text{HRR } 40\% : 0) \\ &= f(\text{ACC}, \text{AGE}, \text{BMI}, \text{WBGT}) \end{aligned} \quad (1)$$

where the objective variable is 1 for the worker's health risk ($\geq \text{HRR } 40\%$) and 0 for no health risk ($< \text{HRR } 40\%$).

The independent variables were physical activity ACC, AGE of participants, BMI calculated from height and weight, and WBGT in the work environment. Using the HR_{max} and $\text{HR}_{\text{resting}}$ of each participant and calculating their %HRR, the independent variable was estimated as $\text{HRR} \geq 40\%$.

Table 9 shows the estimation results of the model on the health risks of the workers examined in this study. In Model 1, ACC, AGE, BMI, and WBGT were independent variables. The ACC, AGE, and WBGT of the participants in the work environment were statistically significant, but the BMI of workers was not significant. Wald χ^2 shows the contribution of each variable to the model, and it indicates that the larger the value, the higher its importance (Onder & Mutle, 2017). In Model 1, compared to AGE and WBGT, the contribution of the ACC was relatively high. The odds ratio in the logistic regression was used to determine the influence of the dependent variable. It is indicated that the independent variable increases because of an increase in the odds ratio when $\text{OR} > 1$; hence, the odds ratio can be a measure of the likelihood of a decline in the independent variable with an increase in the odds when $\text{OR} < 1$ (Agresti, 2018; Hosmer & Lemeshow, 2000; Onder et al., 2014). When the odds ratio is larger than 1, while the lower limit of the confidence interval (CI) is not less than 1, the ACC, AGE of workers, and WBGT in the work environment are independent variables. However, the BMI of workers is an independent variable whose odds ratio is less than 1; the lower limit does not exceed 1. Using the results, without BMI, Model 2 examined a model based on the independent variables ACC, AGE, and WBGT. The statistical significance of the three independent variables, AGE, ACC, and WBGT, may be high to show the health risks of workers, which are important parameters for the model. Furthermore, according to the odds ratio, the influence of WBGT on the health of workers was the largest.

Concerning the estimation results of the model, Table 10 shows the suitability index of the model owing to its goodness of fit (GoF). The positive discrimination rate by the estimation of Model 1 was 88.9%; the positive discrimination rate by the estimation of Model 2, except for the BMI that did not have statistically significant results, increased to 89.2%. Three indicators were used to test the significance of the GoF model. Akaike's information criteria ($\text{AIC} = -2\log L + 2k$) were defined, and the AIC was considered as indicative of the model fit (Uh et al., 2007; Friedman, 2001). Here, k denotes the number of parameters in the model, the first term model represents the true goodness of AIC, and the second term represents the penalty due to an increase in the variable. The AIC values were small. According to the obtained AIC, the adaptation of Model 2 was slightly better than that of Model 1. The Cox-Snell R^2 corresponds to determining the coefficients

Table 9 Estimation by the logistic regression model

Model	Independent variables	Coefficient	Standard error	Wald χ^2	<i>p</i> -value	Odds ratio	95% CI for odds
Model 1	Constant	−25.6	3.40	61.3	<0.001	0.000	—
	ACC	0.041	0.003	183	<0.001	1.042	1.036–1.048
	AGE	0.074	0.020	14.0	<0.001	1.077	1.036–1.120
	BMI	−0.035	0.058	0.361	0.548	0.966	0.862–1.082
	WBGT	0.705	0.095	54.6	<0.001	2.023	1.678–2.438
Model 2	Constant	−28.1	2.35	142	<0.001	0.000	—
	ACC	0.041	0.003	181	<0.001	1.042	1.036–1.048
	AGE	0.066	0.014	23.1	<0.001	1.068	1.040–1.097
	WBGT	0.742	0.074	101	<0.001	2.100	1.817–2.427

Table 10 Overview of health risk of participants

Model (Independent variables)	Predicted risk percentage				Goodness of fit		
	Observed	0	1	(%)	AIC	Cox–Snell R^2	Nagelkerke R^2
Model 1 (ACC, AGE, BMI, WBGT)	Risk 0	487	53	90.2	57.5	0.435	0.590
	1	45	297	86.8			
	Overall			88.5			
Model 2 (ACC, AGE, WBGT)	Risk 0	486	54	90.0	59.5	0.434	0.589
	1	40	302	88.3			
	Overall			89.2			

of a linear regression analysis R^2 , referred to as pseudo- R^2 . The fit of the model becomes better as the Cox–Snell R^2 becomes larger; the Cox–Snell R^2 s of Models 1 and 2 are only 0.4–0.5, while the fit of the independent variable for the dependent variable was not very high (Bewick et al., 2005; Smith & McKenna, 2013). However, when Nagelkerke R^2 approaches 0.51, the fit becomes higher (Nagelkerke, 1991; Mbachu et al., 2012; Guo et al., 2017). The fit of the independent variable for the dependent variable of Model 1 was 0.590, and that of Model 2 was 0.589. Both of them were high. Both the fit of Model 1 and Model 2 were good, based on these results.

4 Discussion

4.1 Construction Workers' Health Risk

This study shows that a continuous measurement of the physical load of construction workers can change work conditions and increase the understanding of

their health conditions. It measures the load fluctuation of the workers by using data collected from the smart wear; this fluctuation corresponds to workers' age, the temperature of the working environment, and working conditions (e.g., foreman and real workers, and the difference between the assistants and the scaffold workers). In line with the results of previous studies, this study shows that the physical demands differ for each worker; hence, the results seen in previous studies on wearable devices (wristband-type devices) correspond (Guo et al., 2017; Lee et al., 2017) in this study.

Based on the work patterns (dismantling, transportation task, and the percentage of work activities, including preparation work), the physical demands of the workers vary even on the same construction site. To understand the health risks of workers, there is a need to continuously measure work in progress.

When measuring the participants, it was observed that the physical demands should not be sustained for a long time. Specific guidelines were created for the workplace and physical demands (i.e., work activities that increase the %HRR beyond 40% should be limited to 30–60 min; Matsuura et al., 2019). Based on these guidelines, as shown in participants S5 and S7 (Table 5 and Fig. 6), there were several workers with more than 40%HRR who continued to work throughout the day. Therefore, to reduce the high physical demands of these workers, some interventions must be implemented. This study provides insights into the appropriate interventions required to manage excessive physical requirements.

Most studies determine %HRR based on typical activity patterns and experimental environments, and there are very few cases that consider an actual construction site. Concerning the application of methods for determining the %HRR of construction workers, it is difficult to measure HR_{max} and $HR_{resting}$ (Garet et al., 2005; Lounana et al., 2007; She et al., 2015) in advance for workers, and it is likely that %HRR will interfere with actual use as indicators.

The value of this study's important finding is that the use of covariates in logistic regression instead of %HRR rate has revealed hypotheses about the effects of physical workload on workers. The relationships among these covariates influence the heart rate of workers (Buller et al., 2008; Miller 2007; Al-Bouwarthan et al., 2020). WBGT has the largest odds ratio among all covariates, and the impact on workers' %HRR was significant (Zheng et al., 2011). To the best of the author's knowledge, this is the first study to report how physical activity, workers' age, and WBGT could be used to determine workers' physical workload without calculating their %HRR. With respect to $\geq 40\%$ HRR, the accuracy rate is approximately 89.2%, based on the estimation of the judgment model of the health risks of workers. Thus, in an environment where HR_{max} and $HR_{resting}$ cannot be measured, it was indicated that health risk could be determined by this study. The practical implication of this study is that instead of the heart rate reserve used in previous studies, this study proposed a tool for measuring the health risk of construction workers.

4.2 Future Prospects for Understanding Construction Workers and mHealth

It goes without saying that mHealth provides an ecosystem where people's health and medical services will be seamlessly linked through the use of mobile devices and wearables linked by communication technology; this will ensure that people's health and medical services data will be in the form of integrated, centrally managed health and medical information rather than discrete points. Among other things, the introduction of wireless technology has augmented the accessibility of medical activities for healthcare professionals, thereby improving health, controlling costs, and providing superior mobility for users (Farahani et al., 2018). Mobile medical technology and health monitoring represent a clear and prominent business opportunity for manufacturers and users to provide products and services to an increasingly dynamic and complex target market. In preventing health hazards to people, mHealth is not limited to medical professionals and patients but can also be developed for many other fields of work (Steinhubl et al., 2015).

The study contributes to the promotion of integrated management technology for the entire construction site using information and communication technology (ICT) tools. For many applications in the construction industry, the introduction of construction robots, cooperation between big data and artificial intelligence, machine to machine (M2M) communication, and the introduction of the IoT are expected to further advance the use of technology in this new ICT field. Building information modeling (BIM) and civil information modeling (CIM) plays a key role in connecting the production process of construction, where research, planning, design, construction, and maintenance are separated and are considered to contribute greatly to improving productivity (Shirowzhan et al., 2020). The biometric data of the workers acquired by the mobile devices will also enable the visualization of the health status and workload of the workers as a quantitative workforce as well as enable coordination among construction sites. Construction companies can use the measured data of on-site workers to simulate the construction process, predict its progress, and estimate the safety of workers. Once a safe workforce can be visualized, collaboration and visualization by construction companies will ease human resource management at construction sites, and the subsequent efficiency, reduced labor requirement, and improved construction quality will further contribute to improved safety. However, apart from utilizing mobile device technologies and investing in system construction, training human resources to utilize these technologies is also an important issue.

5 Limitations

There were only 12 workers from a Japanese company that served as our sample. Due to this limited number of participants, the dataset used the average values of physical activity and heart rate collected at 5-min intervals. However, previous studies have used data collected at approximately 30-min and 5-min intervals

for heart rate and physical activity, respectively, and the author recognizes that these were sufficient observation periods to analyze the workers (Borg, 1998; von Scheidt et al., 2019; Matsuura et al., 2019; Caballero et al., 2020; Nakanishi et al., 2018).

6 Conclusion

This study measured heart rate and physical activity, age, BMI, and WBGT of the work environment for construction workers in Japanese companies. Because these workers are highly mobile among companies, this study developed a new model to determine the health risk of workers instead of %HRR. Using the workers' physical activity, age, BMI, and WBGT of the work environment as independent variables, the workers' physical load without preparing HR_{max} and $HR_{resting}$ can be easily observed. The heart rate and physical activity of workers were measured using a smart device equipped with biometric and accelerometer sensors. Logistic regression analysis was used to analyze the risk to health due to the physical workload. The results showed that physical activity, age, and WBGT were important parameters for workload estimation.

This is the first study to report on the use of a mobile device to determine a worker's physical workload using physical activity, worker age, and WBGT without directly calculating %HRR. The results allow practical decisions to be made to estimate the workload risk of individual construction workers in real-time. This study demonstrates that quantitative workers can visualize the health and workload of construction workers. The theoretical and practical implications are that mHealth could very easily be proposed as a tool to measure worker health risks instead of %HRR, which has been used in previous studies. Hence, the quantified workforce could be linked and visualized across the construction company, which would lead to streamlined and safer workers.

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mHealth Beyond Healthcare-Fusion Approach Towards Better Wellness-

Shintaro Sengoku

ABSTRACT

This chapter extends the discussion beyond healthcare to the realm of wellness, highlighting the significance and benefits of mHealth as well as its challenges and prospects. A key issue discussed is the contribution of mHealth to social health. Given that humans are social animals, the scope of the concept of health is not limited to physical health. Especially in developed countries, where aging and loneliness are causes of concern, the ability of individuals to transcend geographical and physical constraints and connect with society through virtual communities is an effective solution, and digital technologies such as mHealth can be a precursor to this. First, the state of play of mHealth in the medical, healthcare, and wellness sectors was summarised, drawing on previous research and representative examples. Then in Sect. 2, the convergence between entertainment and wellness was focused on. Based on the case of Pokémon GO, which has undertaken gamification, I review and discuss in detail the impact of gamification and entertainment on health and wellness in a broader sense. Lastly, directions in which a variety of tools and content can be used to improve wellness were discussed in light of existing leading innovation theories.

1 The Use of mHealth in the Medical Healthcare Sector

1.1 mHealth for Disease Care

When looking at the medical use of mHealth by disease area, the cardiovascular (CV) and central nervous system (CNS) areas constitute the largest share

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(Onodera, Sengoku & Miyazaki, 2016). Naturally, there is a large body of literature on these areas. Additionally, product innovation in diagnostic applications and process innovation in drug development have been attempted (Sarwar, Vaduganathan, & Anker, 2018). However, there is an urgent need to develop systematic evidence-based guidelines and parameters for the effective utilisation of mHealth in cardiovascular clinical trials. The application of mHealth to mental illnesses is prominent in the CNS area. One study supports the use of common mHealth technologies for activity tracking in patients with serious mental illnesses, which may help in designing weight-loss interventions for this vulnerable patient population (Naslund et al., 2015).

Medical applications in the CV area can contribute not only to the prevention of diseases but also encourage physical activity (PA) and fitness. McConnell, Turakhia, and Harington (2018) argue that a primary application could be to show that mHealth provides sustained benefits with improved health outcomes. Alternatively, there exists a cautious view of these health-promoting effects: Kelli, Witbrodt, and Shah (2017) argue that although short-term behavioural changes have been observed with technologies such as Fitbit® (Fitbit, Inc., San Francisco, California, USA), it remains to be seen whether such technologies and interventions will lead to sustained behavioural change and reduced risk of myocardial infarction and death.

1.2 mHealth for Non-Medical Healthcare

The use of mHealth apps in non-medical healthcare is driven by increased PA, and according to a meta-analysis by Lee, Chavez, and Bian (2019), of the 19 PA outcomes assessed, subjective weekly PA (4 of 13) and objective daily moderate-to-vigorous PA (5 of 13) were reported most frequently. Additionally, five of the 13 studies with a control or comparison group found significant improvements in PA outcomes between the intervention and control or comparison groups. In a review on the effects on children, Tully, Burls, and Sorensen (2020) synthesised evidence on the treatment of overweight and obesity in children, mapped the breadth and nature of the literature in this area, and described the characteristics of the published studies.

A practical challenge in the healthcare domain is the ease of use of mobile health apps. As there is no institutional requirement for prescribing such apps, continuity of use depends mainly on the user's initiative. Improving usability is directly linked to solving this problem: (Jake-Schoffman, Silfee, & Waring, 2017) summarised methods for evaluating the content, usability, and effectiveness of commercially available health apps. Usability testing confirms whether an app can serve its intended purpose in the target population. Observational studies can examine the relationship between app use and clinical and behavioural outcomes. Finally, efficacy studies can use a variety of trial designs, including randomised trials, multi-stage optimisation trials, and N-of-1 trials, to determine whether a commercially available app has an impact on the intended outcomes.

Van Haasteren et al. (2019) focussed on five key themes that emerged from the focus group discussions: information content, organisational attributes, social impact, technology-related features, and user control factors. The mHealth app trustworthiness checklist was developed incorporating these five themes and subsequently modified following expert consultation. In addition to the trustworthiness theme, we identified characteristics that fall between trust and distrust (limited digital literacy and apathy), and 10 characteristics and behaviours that cause end-users to distrust mHealth apps.

Preferences for social features of mHealth vary and a one-size-fits-all approach may be difficult. A review by Tong and Laranjo (2018) shows that users' preferences for social features are mixed, with some feeling motivated by social support and competition, whereas others feeling anxious about comparison, indicating the insufficiency of a one-size-fits-all approach. In this respect, incorporating elements of gamification is a possible solution for the development of mHealth for health promotion (Lee, Lee, & Lee, 2017). Gamification can be effective in increasing the intention to use mHealth, especially in the healthy and younger age groups. These findings suggest that mHealth with a gamification component can encourage healthy (but inactive) individuals as well as unhealthy individuals to maintain their health status.

1.3 mHealth for Wellness

Amongst the first things that come to mind regarding the wellness field is the use of mHealth for diet and exercise; Fitbit is a prime example. Chung, Skinner, and Hasty (2017) developed an intervention approach: 'Tweeting to Health' using Fitbit, Twitter, and gamification to promote behavioural changes towards a healthy lifestyle in overweight/obese (OW) and healthy weight (HW) individuals.

Fitbit is expanding its range of applications, including sleep management. Guilodo, Lemey, and Simonnet (2020) argues that wearables allow acceptable, but unreliable, sleep monitoring. Wearable mHealth devices appear to be promising tools for ecological monitoring. As another example, pregnancy care is also considered a promising blue ocean zone, and Chan and Chen (2019) argue that social media and mHealth apps could be widely used to improve maternal well-being. Larger clinical trials focussing on multiple health outcomes are proposed for future research.

2 mHealth Beyond Medicine: Pokémon GO as a Case of Entertainment

2.1 Introduction

Pokémon GO is a location-based game application for smartphones developed by Niantic and Pokémon, Inc. Players can capture, raise, trade, and battle Pokémon

characters on the screen by moving around while using the GPS function of their smartphone. Basic play is free, but there are items to pay for. The game has been increasingly downloaded since its launch, with sales of \$950 million in 2016. Despite a decrease in sales in 2017, sales rose 35% year on year to \$795 million in 2018, accounting for \$2.2 billion in total.

The game's world is inhabited by strange creatures. In the Pokémon GO world, a man named Dr Willow collects and studies these creatures. One day, Dr Willow asks the player to help her with her research. The player begins a journey with the grand objective of catching as many unknown Pokémon as possible from around the world, registering them in the Pokémon Book, and sending them to Dr Willow. The player becomes a Pokémon Trainer, walking and exploring the real world to capture, train, battle, and trade Pokémon.

2.2 Key Characteristics

Although many people have started playing Pokémon GO, they constitute a relatively small proportion of the relevant populations; Pokémon GO may have activated those most in need of PA (Baranowski & Lyons, 2020). Diverse factors predict who would initiate the Pokémon GO play, but major determinants include anticipated fun, escapism, nostalgia, social ties, and the desire for PA. Environmental factors (e.g., unavailable GPS signals and trespassing laws) limit the Pokémon GO play. Multiple factors determine the duration of gameplay, but fun is a prominent determinant. The increase in PA because of Pokémon GO among youth and young adults appears to be small or undetected and of relatively short duration (<2 months). Among older adults, however, there was a modest increase in PA for up to seven months post-release. This intensity and duration of increased PA appears to be inadequate to stem the obesity epidemic but may have mental and social health benefits. Although many adverse outcomes of playing Pokémon GO have been reported, they appear to have a low incidence, which should primarily influence Pokémon GO players to exercise caution.

2.2.1 Increased Physical Activities

Marquet et al. (2017) extracted three interpretable factors from the clustering of motivations to start playing Pokémon GO: Pokémon and video game fans ($n = 26$, 55% of the sample), PA-seekers ($n = 8$, 17%), and curious and social ($n = 13$, 28%). The clusters differed significantly in terms of enjoyment of different aspects of the game, particularly battling, discovering new places, and meeting new people, as well as differences in agreement that playing improved mood and made them more social (Marquet et al., 2017). There were days when playing Pokémon GO was associated with a higher number of steps reported at the end of the day, especially among PA-seekers but also for Pokémon and video game fans (Marquet et al., 2017). Similar results were obtained in another study where playing Pokémon GO was associated with increased self-reported walking and decreased

sedentary behaviour. Such games hold promise as a technology to promote PA and discourage sedentary behaviour (Barkley, Lepp, & Glickman, 2017).

Althoff, White, and Horvitz (2016) found that Pokémon Go significantly increased PA over a period of 30 days, with particularly engaged users (i.e., those making multiple search queries for details about game usage) increasing their activity by 1,473 steps per day on average—a more than 25% increase compared to their prior activity level ($P < 0.001$). We estimate that in the short time span of the study, Pokémon Go has added 144 billion steps to the overall PA in the US. Furthermore, Pokémon Go has contributed to increased PA across sexes of all ages, weight status, and prior activity levels, showing its implications for public health. In particular, we find that Pokémon Go reaches low-activity populations, whereas all four leading mobile health apps studied in this work are largely drawn from an already highly active population (Althoff et al., 2016).

It has been suggested that once PA increases, it is sustained. One reason may be that playing games has become an established practice in other activities. Koh et al. (2017) demonstrated the utility of the theory of planned behaviour (TPB) in predicting a new behavioural domain—mobile use while walking. In summary, younger users who are habitual, impulsive, and less immersed are more likely to play a mobile game while walking. Another reason is the persistence of the acquired activity. Hino et al. (2019) confirmed a difference in step counts between players and non-players before and after the release of Pokémon GO. According to our analysis, step counts were higher until seven months after release. The player group maintained their step counts in winter, despite the decrease in step counts of non-players. In subgroup analyses, players were more likely to be men, aged < 55 years, workers, active, and subjectively in good health.

2.2.2 Enhanced Communication and Social Connectedness

Improving physical and social well-being is a value of gamification-based mHealth; Pokémon GO transcends traditional understandings of digital health and addresses users across generations (Militello, Hanna, & Nigg, 2018). Findings from this study highlight that over time, Pokémon GO fostered the social and physical well-being of children and families through a multifaceted approach. Arjoranta, Kari, and Salo (2020) identified eight types of behavioural changes and 13 game functions associated with these behavioural changes; these changes included: adding activities to life, reinforcing routines, exploring, increasing PA, strengthening social bonds, lowering social barriers, increasing positive emotional expressions, and self-therapy. Features of the game included reaching higher levels, catching new Pokémon, evolving new Pokémon, visiting PokéStops, exploring PokéStops, hatching eggs, fighting in gyms, fighting cooperatively, taking advantage of special events, finding specific Pokémon, finding Pokémon, using items, Pokémon themes, and the relationship between game locations and physical locations. All of these behavioural changes were associated with specific game features, with ‘game locations linked to physical locations’ and ‘catching new Pokémon’ being the most common. The results showed that the players surveyed changed their behaviour during or after playing Pokémon GO. The

respondents reported being more sociable, expressing more positive emotions, finding more meaning in their daily lives, and feeling more motivated to explore their surroundings.

The following research shows that gameplay can build social connections through real-world engagement. Vella et al. (2019) attempted to identify the social outcomes of gameplay and mechanisms facilitating social connections. To do so, they conducted a series of interviews ($N = 15$) and collected reports from online social fora about gameplay ($N = 880$). Thematic analysis showed that playing a Pokémon GO creates a sense of belonging linked to a sense of place, facilitates conversations with strangers, and strengthens social ties. This is because of the use of accessible technology that can be integrated into everyday life, a shared passion for the game, and a mechanism that invites players out of their homes. The 'shared passion' is linked to the nostalgia that many players feel for the game. This study showed that gameplay can build social connections through engagement with the real world.

2.2.3 Key Challenges and Perspectives

The first challenge is continuity. Attractive content, such as Pokémon GO, can motivate many users to download and start playing the game; however, many are light users and do not necessarily play continuously over time. Mobile apps that combine gameplay with PA can lead to a significant short-term increase in activity and, in contrast to many existing interventions and mobile health apps, have the potential to reach less active populations. Future research is needed to investigate the potential long-term effects of these applications (Althoff et al., 2016). Druce, Dixon, and McBeth (2019) argued that a fundamental challenge in app research is the rapid and seemingly ubiquitous phenomenon of substantial disengagement. For example, despite Pokémon GO being amongst the most successful smartphone games in recent years, it lost one-third of its daily active users (15 million) within a month of its launch. Research suggests that in almost all industries (e.g., media and entertainment, retail, lifestyle, business, etc.) approximately 71% of app users leave within 90 days (Druce et al. 2019). Playing Pokémon GO was associated with a statistically significant but clinically modest increase. The challenge for future PA interventions using Pokémon GO is to maintain active engagement after the initial novelty declines. Additional research with longer follow-up periods and experimental study designs is needed to assess the extent to which Pokémon GO and other augmented reality games can be used to promote sustained PA at the population level (Khamzina et al. 2020).

Another challenge is related to the environment. A safe environment in which games can be played is essential. In fact, in large cities such as Chicago, Detroit, and New York, areas with large African-American and Hispanic populations have been found to have significantly fewer PokéStops than areas with Caucasian and Asian populations (Brewer et al. 2020). Digital redlines (i.e., restricting certain communities from essential services based on race or ethnicity) were thought to be the cause; the developers of the Pokémon GO app referred to a map from one of their previous app releases, which was crowdsourced from mostly white males

residing in commercial areas. These uncovered structural and digital inequities show that technology can put certain groups at a disadvantage in the home court, although not intentionally.

Compliance with regulations and systems is essential for providing quality products and services. mHealth, as Terry (2015) argued, combines the decentralisation of healthcare with patient-centeredness. Mature mHealth applications and services can provide actionable information, coaching, or alerts at a fraction of the cost of traditional healthcare. Different categories of applications have different safety and privacy regulations. It is too early to tell whether these apps can overcome issues related to use cases, business models, and regulations. The need for sensible defaults and flexible privacy controls must be met to be able to choose different settings for different recipients and change sharing settings at any time (Prasad, 2012).

To address these issues, Lindqvist et al. (2018) identified the following three themes: (1) exciting and fun exploration; (2) dangers and disadvantages; and (3) cooperation trump competition. The first focusses on the current and future aspects of Pokémon GO that promote PA. The second focusses on undesirable aspects of playing the game. The third shows that cooperation and togetherness are highly valued by participants and that competition is fun but not important. Furthermore, they highlight the importance of the diversity of exciting elements (Rasche et al., 2017). A total of 81 current, 56 former, and 62 non-users of Pokémon GO were recruited. When asked about the amount of time they spent performing PA, active users shared that they were generally less physically active than former users and non-users. However, according to subjective ratings, active users were more motivated to be physically active because they played Pokémon GO. While the motivational aspect differed between active and ex-users, fan status was the same for both groups. Active users were more motivated by features directly related to Pokémon, such as catching all the Pokémon possible and reaching higher levels, whereas ex-users emphasised the importance of the general quality of the game, such as better augmented reality and more in-game challenges. They emphasised that the importance of personality did not influence whether they started playing Pokémon GO or whether they stopped playing the game.

3 Discussion and Future Outlook

Owing to the broad reach of mHealth and the resolution of technical challenges, it is now open to many firms and players, and the momentum for participation has never been greater. However, in reality, clinical development is limited to a few applications, such as medication guidance, and the devices used are often generic, with little participation from companies (Onodera & Sengoku, 2018). Why does such a gap exist between the ideal and the real? We would like to consider this point from the perspective of technology management in mHealth by drawing on some representative theories.

3.1 Innovation Process

Rogers (2003) classifies adopters in the diffusion process of new technologies and ideas into five categories: innovators, early adopters, early majority, late majority, and laggards. Moore (1999) argues that the so-called S-curve of technology, especially in the case of high-tech products that force users to change their behaviour, has a normal distribution, and the proportion of adopters is almost uniform (Fig. 1). Moore (1999) also describes a chasm in the so-called S-curve of technology, especially in the case of high-tech products that force changes in user behaviour, as a gap between individual categories, especially between early adopters and the early majority.

As mentioned, mHealth is currently in its infancy in the healthcare market. Following Rogers' analogy, the health management business using mobile phones and smartphone applications is considered to be in the early adopter stage. However, the adoption and diffusion of mHealth in the healthcare sector is rapidly increasing. According to one study, healthcare using mobile phones and smartphone apps accounted for about 7% of the total healthcare market in 2010, but in 2012, the proportion had increased to 19% (Fox & Duggan, 2013). It has also been observed that the rapid adoption of smartphones and wearable devices has led to an increase in healthcare-related IT products on a daily basis.

Gaming applications, represented with Pokémon GO as investigated in the previous section, have the potential to drive mHealth beyond the chasm. Various previous studies have shown that Pokémon GO contributes to improved PA and better mental health conditions, so it will probably be able to characterise and develop these features further for application in mHealth products as medical devices. At the same time, the gamification element that Pokémon GO mainly focuses on will contribute to attracting a much larger number of users, especially the early majority, in the context of entertainment than conventional mHealth products. In other words, it can be expected to exceed the chasm more easily

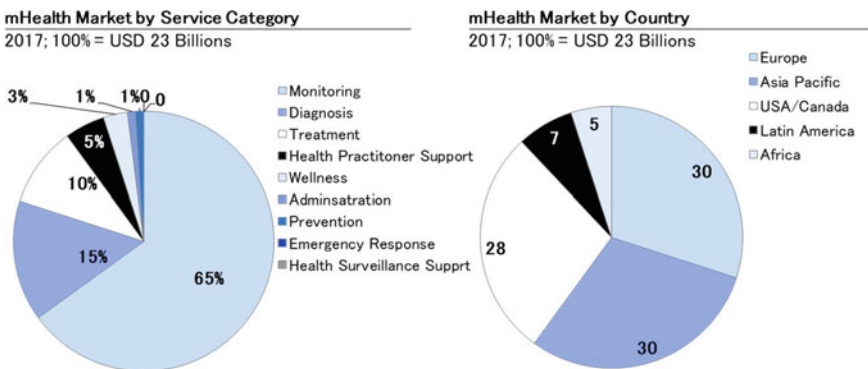


Fig. 1 mHealth market by service category (left) and country (right). *Source* Original data was derived from PricewaterhouseCoopers (2012)

than conventional mHealth products while achieving the specifications of mHealth. Moreover, the elevation of gaming apps to mHealth will be a strong deterrent to the critical challenge that even the wildly popular Pokémon GO failed to overcome: users' boredom and secession.

3.2 Modes of Innovation

Abernathy and Utterback (1978) classified innovation into product and process innovations and proposed a model based on the dynamic transition from the former to the latter (Fig. 2). Process innovation reduces product cost or improves quality and performance by improving the production process or technology of an existing product or creating a new process. Corresponding to this innovation is product innovation, which is based on the development of innovative new products. In the process of market acceptance of a product, the quantity demanded changes according to the introduction, growth, maturity, and decline phases (Rothwell, 1994).

In the case of conventional medical devices, product innovation includes catheters, portable blood testing machines that can perform various analyses with a single drop of blood, diagnostic equipment, and the development of surgical instruments that contribute to the early detection and treatment of diseases (Stafford & Garrett, 2011). Process innovation includes improvements in miniaturisation, weight reduction, non-invasiveness, and precision of instruments. Additionally, certain products with simpler functions and lower prices have been developed, mainly for emerging countries, and are being introduced in developed countries (Berumen, 2019). In other words, product innovation leads the way, whereas process innovation develops new therapeutic purposes and applications, and the two types of innovations are interlinked.

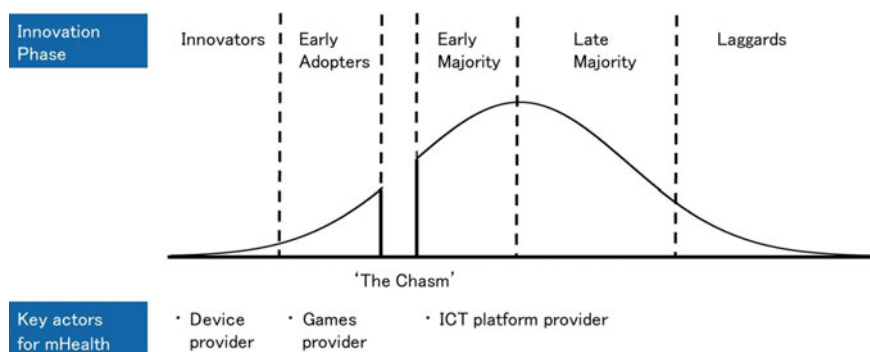


Fig. 2 Phases of innovation and chasm. *Source* Based on Moores's (1999). *Note* original diagram of the phases of innovation and the chasm, the author discussed the key actor in each phase. In order to go beyond the chasm, a games provider needs to lead the trend and scale up in collaboration with an ICT platformer

What, then, is the case with mHealth? One possibility is that mHealth itself could become a product innovation in the healthcare sector. For example, Otoharmonics developed the Levo System, an application for the treatment of tinnitus that received FDA 510(k) clearance in 2014. Doctors ‘prescribe’ the app to patients, which works by training the brain to ignore the sounds caused by tinnitus. Additionally, WellDoc developed BlueStar, a software application to guide treatment for type II diabetes, which was approved by the FDA, and established a system for doctors to prescribe and obtain insurance reimbursement. Interestingly, WellDoc considers BlueStar a mobile prescription therapy (MPT), suggesting its potential to go beyond supporting process innovation and become a type of product innovation, following pharmaceuticals, medical devices, cell therapy, and regenerative medicine.

Another possibility is the potential for mobile products/services other than mHealth to bring innovation to the healthcare sector, as described with Pokémon GO in Sect. 2. Although Pokémon GO has been (and still is) simply a game app and the originator was very particular about the ‘walking’ aspect of the game, i.e., it has not (and still is not) intended for healthcare and wellness applications. However, various post-release analyses and exploratory studies with Pokémon GO have shown that PA and other healthcare benefits, as well as wellness contributions such as social connectedness, can be achieved. By proactively transferring and applying best practices from other industries beyond the scope of mHealth, product innovation in mHealth will continue to accelerate.

3.3 Innovation Dynamics

Mowery and Rosenberg classified innovation patterns into technology push, which is based on improvements in technology performance, and demand pull, which is technological progress driven by specific market needs (Mowery & Rosenberg, 1979). Rothwell (1994) classified the mechanisms of driving innovation as linear models based on either technology push or demand pull as the first and second generations, coupling models between the two as the third generation, parallel models as the fourth generation, and network models with more complex relationships as the fifth-generation (Mowery & Rosenberg, 1979). Models of more complex relationships are classified as the fifth-generation (Rothwell, 1994).

Focussing on the technological aspects of mHealth, its recent growth is driven by advances in information and communication technologies. Starner, Mann, and Rhodes (1997) developed technologies using small, lightweight cameras and head-mounted displays (HMDs), which enabled the collection and storage of real-time data at low cost. Improved communication has enabled exchange of voluminous data, and developments in cloud services have facilitated quick and secure sharing of medical information. This suggests that technological push can be a driving force for innovation.

In contrast, the application of mHealth to cognitive behavioural therapy for mental illness presents a different picture. In this area, it is expected to be a tool

to promote collaboration between doctors, nurses, and patients as well as networking between patients and their families, thereby improving patient symptoms. However, despite the fact that many apps are available to treat and support the treatment of mental illness, there is lack of evidence regarding their effectiveness. This can be seen as innovation through demand pull.

4 Concluding Remarks

The mHealth and related industries have been growing steadily at the global level, with devices for monitoring and tracking applications triggering market expansion. However, at the current state of clinical trials, which are essential for medicines and medical devices, the applications and diseases covered by mHealth are still limited, the level of technology remains at the level of generic products and services, and companies are still at the stage of infancy. For the health of the industry and market growth, this condition needs to be improved immediately, and in addition to the development of elemental technologies, products, and services, the overall situation needs to be examined from the perspective of innovation theory. This study investigates the potential of mHealth in light of known innovation theories from the three perspectives of the innovation process, mode, and dynamics, and discusses the prospects for future innovation, illustrating the importance of development of advanced technologies and integration of different disciplines. Improving continuity in the use of products and services is a future challenge, and for this, voluntary motivation and medium- to long-term sustainability are vital. This will depend on the creation of sustainable ecosystems, active use by local authorities, and the use of social technologies to encourage consumers to change their behaviour. At the same time, companies need to reduce the digital divide and increase literacy in certain regions and among older people. From a wellness perspective, providing an affordable, good-quality, and pre-emptive approach could reduce the burden on the public and transform sick care to healthcare.

Acknowledgements The author thanks Prof Dr Tomoki Aoyama, Kyoto University, Dr Kota Kodama, Associate Professor of Ritsumeikan University, and an anonymous industry expert for their critical comments in writing the present chapter. Section 3 is based on the content of Onodera and Sengoku (2016) and has been reorganised to reflect new findings. I would like to express my gratitude again to all parties involved.

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Mobile Health for Preventive Healthcare

Tomoki Aoyama

ABSTRACT

An illness is caused by many factors, such as the environment, lifestyle, genetic disposition, and disease agents. Preventive healthcare aims to eliminate its causes before individuals realise that they have been affected or the disease has worsened. Education to obtain knowledge about the cause of the illness and a suitable lifestyle is the primary step in preventive healthcare, the second one being self-management for recognising the health status. Healthcare support provided by trained medical specialists is a robust way to maintain a suitable health status. Recent developments in communication tools have enabled mobile health to successfully develop consistency with classical preventive healthcare. There is accumulating evidence regarding it for hypertension and diabetes. The development of technologies and services for mobile health will be continued and that of new parameters to satisfy one's unmet needs are needed to expand the field of preventive healthcare.

1 Introduction

Understanding the principles of preventive healthcare is important when designing its mobile health (mHealth). Disease and disability are affected by many factors, such as the environment, lifestyle, genetic disposition, and disease agents. Preventive healthcare aims to eliminate the cause of the illness before individuals realise that they have been affected or the disease has worsened. Its strategy depends on the level of primary, secondary, and tertiary prevention levels. The primary preventive healthcare's objective is avoiding the occurrence of diseases

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Fig. 1 The intervention of preventive healthcare *Note* **a** Education and information about the disease and an appropriate lifestyle. **b** Self-management to determine health status. **c** Healthcare support by trained specialists promotes motivation and maintains health status

through lifestyle changes, eradicating disease agents, and increasing resistance towards them (Leavell & Clark, 1958; Patterson & Chambers, 1995). Secondary preventive healthcare purports to detect the existence of disease prior to its symptoms' appearance (Patterson & Chambers, 1995). It consists of 'early diagnosis' and 'prompt treatment' (Leavell & Clark, 1958). Furthermore, tertiary preventive healthcare attempts to reduce harmful symptoms, disability, being bedridden, or death, by suitable treatment and rehabilitation after the onset of an illness (Leavell & Clark, 1958; Patterson & Chambers, 1995). Additionally, primordial prevention is included as a separate category to forestall the source of the disease.

Interventions for preventive health are roughly classified into three elements: education, self-management, and healthcare support (Fig. 1). Education and information provided to enhance knowledge about the cause of an ailment and a suitable lifestyle are the first steps in preventive healthcare (Fig. 1a). Successful learning increases health literacy (Heine et al., 2021) and encourages health behaviour. The subsequent step involves the assessment of one's health status for self-management (Fig. 1b) that maximises productivity, improves performance, and helps in achieving professional goals efficiently. The development of a self-monitoring device that could be employed at home would certainly promote self-management. Healthcare support such as timely advice, consultations, and reminders by trained medical specialists boosts one's motivation to maintain one's health status (Fig. 1c). Formerly, it was conducted face-to-face in hospitals or communities. However, the recent development of communication tools has enabled its remote performance and that of informatics and data storage systems is modifying the way classical preventive healthcare is advancing mHealth.

2 Preventive Healthcare

When harmful factors are eliminated, 70% of the disease and the death of millions of people can be avoided (Fries et al., 1993). Preventive healthcare eludes not only illnesses, disabilities, and deaths but also reduces medical and care costs (Fries

Table 1 Levels of preventive healthcare

Levels	Definition	Example
Primordial	Primarily avoid the development of risk factors early in life	Inhibit the emergence and establishment of adverse environmental, economic, and conditions
Primary	Avert the occurrence of illnesses by eliminating disease agents or increasing resistance towards them	Heath promotion activities such as dietary control, daily exercises, and good sleep
Secondary	Detect an existing disease prior to the appearance its symptoms	Early diagnosis and prompt treatment. Screening of hypertension, diabetes mellitus, cancer, and locomotive syndrome
Tertiary	Reduce the harm of a symptomatic disease, disability, or death through treatment	Prevent pain and damage, and halt progression through rehabilitation, counselling, and systematic treatment

et al., 1993). Its classification is based on the prevention level (Leavell & Clark, 1958: Table 1).

As mentioned previously, primary healthcare aims to avoid the occurrence of illnesses through lifestyle counselling for eliminating disease agents and increasing disease resistance (Leavell & Clark, 1958, Patterson & Chambers, 1995, Table 1). Dietary counselling is a basic tool for it. By restricting the dietary content of cholesterol and fats, the risk of cardiovascular disease is reduced (Blum & Levy, 1987). Face-to-face individual or group counselling sessions are effective methods (Wadden et al., 2020). Furthermore, the promotion of adherence to lifestyle changes improves cardiovascular diseases (Palmer et al., 2021). Smoking cessation advice is useful in decreasing smoking-related illnesses, such as cardiovascular, respiratory, and malignant diseases (Patterson & Chambers, 1995). Regular aerobic exercise decreases all-cause mortality, increases bone mass and muscle strength, and maintains the cognitive function of the frail elderly (Patterson & Chambers, 1995). Sleep education has become increasingly important in generations (Meaklim et al., 2020). Insufficient sleep duration and extensive homework have been associated with reduced visual acuity among school students (Liu et al., 2021). A relationship between sleep duration and cardiometabolic risk factors has been reported in American and Jamaican adults (Rae et al., 2020). Moreover, sleep characteristics are correlated with cognitive decline in older people (Hu et al., 2021). A combination of exercise and sleep education is effective for healthy sleep. Additionally, community-based exercise has been reported to enhance sleep quality and lessen depressive symptoms and metabolic risks (Mendham et al., 2021).

While primary preventive healthcare addresses the root cause of the disease, secondary one purports to detect its existence before the symptoms' appearance (Patterson & Chambers, 1995). It comprises 'early diagnosis' and 'prompt treatment' (Leavell & Clark, 1958). Hypertension is a serious risk to the heart, brain, kidney, and other diseases. Currently, 1,130,000,000 people worldwide, mostly

those living in low- and middle-income countries, suffer from hypertension (World Health Organisation, 2021a). The epidemiologic countermove occurred from the beginning to the middle of the twentieth century; the mobility and mortality rates were reduced in high-income countries such as Europe (Erbel & Budoff, 2021) and North America (Marsh & Keyrouz, 2009). In Japan, annual healthcare check-ups, including blood pressure screening in accordance with the 'Industrial Safety and Health Law', have successfully contributed to the low incidence of coronary artery disease (Okamura et al., 2014). Nevertheless, an appropriate prevention approach is needed in Southeast Asian countries (Mohammed Nawi et al., 2021) and sub-Saharan Africa (Yuyun et al., 2020). A cost-benefit analysis is advantageous to alter the mindset of policymakers. The treatment for heart failure is expensive. Thus, early screening and education are valuable in reducing the cost of treatment and care (Kuklinski et al., 2021). Furthermore, cancer is a leading cause of death (Pan American Health Organization/World Health Organization, 2021b), eliminating harmful factors such as tobacco, excessive alcohol, and unhealthy diet, screening programs, and vaccination have been effective in reducing its certain types (World Health Organization, 2021b). The early examination was reported to decrease the mortality rate and the financial cost of colorectal (Hewitson et al., 2007) and breast cancers (Khan et al., 2021), respectively. In Japan, there is an ongoing unique secondary preventive approach. The average length of life in Japan has become the world's most long-lived country (Tsugane, 2020), and the need to elongate its healthy life span which means independence from long-term care. Falls and arthritic diseases are the fourth and fifth leading causes for the Japanese being bedridden (Ministry of Health, Labor and Welfare, 2021). To examine locomotive function, the 25-question Geriatric Locomotive Function Scale has been used, and a community-based approach is under development (Ide et al., 2021).

Tertiary prevention healthcare attempts to reduce harmful symptoms, disability, being bedridden, or death through suitable treatment and rehabilitation after a disease's onset (Leavell & Clark, 1958; Patterson & Chambers, 1995; Table 1). Compared to secondary prevention, its goal is to maximise the remaining capacities and functions (Leavell & Clark, 1958). Adherence to medication is critical in preventing the progression of cardiovascular diseases and type 2 diabetes (Khunti et al., 2017). Although many stakeholders, such as patients, families, healthcare providers, and social approaches, have been striving to improve adherence, the effect has been limited (Jaam et al., 2017). Supportive care in oncology is required to enhance the quality of life of patients and their families in advanced stages of cancer using physical, psychological, and social approaches (World Health Organization, 2020). Opioids are commonly used for pain control (Paice et al., 2016); however, given that they have certain adverse effects, such as nausea, vomiting, constipation, drowsiness, sleep diseases, cognitive dysfunction, myoclonus, pruritus, and dysuria, opioid control alone is insufficient (Mercadante, 2019). A multidisciplinary method between hospitals and communities is necessary for supportive care (Furman et al., 2018). Web- and mobile-based symptom management systems have efficiently decreased physical symptoms by facilitating the early sharing of information regarding them (Saeidzadeh et al., 2021).

3 Health Literacy

Information provision and education is the primary step in preventive health-care. Successful education increases health literacy and promotes health behaviour (Heine et al., 2021). The former is a new concept that describes a range of health training and communication activities (Nutbeam, 1998). Further, it is useful for assessing one's level of understanding and behaviour change when planning a health education strategy (Table 2).

The low level of health literacy includes having basic reading and writing skills (functional health literacy). The middle level has become additionally comprehensive and comprises having advanced abilities needed to apply new information to changing circumstances through social interaction (communicative health literacy). To analyse the information effectively and to use it to exert greater control over health circumstances (critical health literacy) is regarded as the high level of health literacy (Nutbeam, 1998).

The United States' population data on health literacy was evaluated using the 2003 National Assessment of Adult Literacy (Cutilli & Bennett, 2009). Half of its population was at an intermediate level, which includes the application of information presented in complex graphs, tables, and documents (Hersh et al., 2015). The 14-item Health Literacy Scale for Japanese adults reported that those who wanted to participate in medication-related decision-making had higher scores more frequently (Suka et al., 2013). High health literacy was associated with non-frailty among the Japanese elderly (Shirooka et al., 2017). A study investigating the relationship between health literacy, health knowledge, and adherence to treatment in patients with rheumatoid arthritis demonstrated that health literacy was associated with medication knowledge (Quinlan et al., 2013). Educational programs increased the health literacy scores (Nutbeam et al., 2018). Moreover, a multimedia intervention effectively improved short-term food label comprehension (Jay et al., 2009). If the goal is to promote mHealth, then eHealth literacy is also needed.

Table 2 Levels of health literacy

Level	Educational Goal	Benefit for an Individual	Benefit for the Community
Functional	Communication of information	Improved knowledge of risks and health services and compliance with prescribed actions	Increased participation in population health programs
Interactive	Development of personal skills	Enhanced capacity to act independently on personal knowledge; improved motivation and self-confidence	Improved capability to influence social norms and interact with social groups
Critical	Personal and community empowerment	Better individual resilience to social and economic adversities	Enhanced capacity to act on social and economic determinants of health

Source Extension of Nutbeam (2000)

Those participants who joined two weeks of learning websites to access reliable health information indicated increased knowledge, skills, and eHealth literacy (Xie, 2011). Although the role of eHealth literacy is not completely understood by people living with the human immunodeficiency virus, its importance has begun to be addressed (Han et al., 2018).

4 Self-Monitoring Device for Self-Management

Self-management maximises productivity, improves performance, and facilitates the efficient achievement of professional goals. Organisation, goal setting, time management, self-motivation, stress management, and accountability are examples of these skills (Indeed Editorial Team, 2020). In the field of healthcare, self-management is effective, especially for patients with chronic diseases (Holman & Lorig, 2004; Lorig et al., 2001).

The development of self-monitoring devices that can be employed in one's home promotes healthcare and health behaviour. In clinical settings, manual sphygmomanometers have been used to assess blood pressure. At the end of the twentieth century, they were replaced by automated blood pressure measurements (Myers, 2014); this development not only contributed to reducing the medical staff's work but also provided a new value to examining blood pressure. These measurements enabled the assessment of one's own blood pressure at home. Considering the 'white coat effect', nurse-measured blood pressures were lower as compared to those evaluated by doctors (Clark et al., 2014). Furthermore, home blood pressure was less than the clinic one, thus eliminating the white coat effect (Reims et al., 2001). In addition, blood pressure measurements at home enabled 24-h monitoring. Differences in the hypertension and related cardiovascular disease rates between the Western and Asian populations were found; specifically, high morning and nocturnal blood pressure readings were commonly reported in the latter (Sogunuru et al., 2019). As the Asian populations' age, white-coat hypertension gradually becomes a more serious issue; further, masked hypertension is prevalent in this population (Kario et al., 2020). Thus, these findings demonstrate that home blood pressure might be more resourceful for Asians. In combination with an education program, self-monitoring of blood pressure is associated with its net reduction (Glynn et al., 2010).

Overweightness and obesity are characterised by excessive fat accumulation that presents a risk of developing many lifestyle-related diseases. Previously, they were considered to be a problem only in high-income countries; however, presently, they are increasing in low- and middle-income countries, except the sub-Saharan Africa. Obesity is a major risk factor for hypertension, cardiovascular diseases, and diabetes; additionally, it is associated with musculoskeletal diseases and some cancers. Overweightness and obesity can be prevented by controlling the calories consumed and increasing physical activity (World Health Organization). Anthropometric measurements of the body height and weight are useful for assessing the nutritional status and the body composition (Bistrian et al., 1976). The body

mass index (BMI) is calculated by dividing the weight (in kilogrammes) with the square of the height (in meters). An individual with a BMI > 25 is considered to be overweight. The intervention for weight control consists of decreased calorie intake and increased expenditure. Self-monitoring of dietary consumption, physical activity, and weight are the three pillars of intervention against obesity. Paper diaries have been conventionally employed to record the nutritional intake and physical activity. Currently, many digital applications have replaced such recording systems. Self-monitoring of weight is a focus of the intervention, and its frequent practice is associated with a lower BMI and maintained weight (Burke et al., 2011). Recently, the home bathroom weighting scale was developed as a body composition analyser that enables the individual assessment of the fat, muscle, and bone compositions. Combined with suitable healthcare support, it is expected to be advantageous for weight control.

A pedometer can monitor physical activity and provide daily feedback on the steps taken by an individual. The first mechanical pedometer was envisioned by Leonardo da Vinci for military applications (da Vinci & McCurdy, 1938). The pedometer for healthcare use, called the Manpo-kei, is a 10,000 steps meter that was commercialised in Japan. It undoubtedly plays an important role in monitoring physical activity. Moreover, it has been employed by both, healthy populations and chronic disease patients for the purpose of primordial to tertiary prevention healthcare. It prevents falls and cognitive impairment in the elderly and decreases the risk and worsening of cardiovascular diseases and diabetes mellitus. In patients with musculoskeletal illnesses, continued physiological activity is needed to maintain locomotive function. Thus, a pedometer is an advantageous device for tracking daily activities and an easy tool for simple exercises.

5 Development of Communication Tools for Healthcare Support

Healthcare support such as advice, consultations, feedback, and reminders by trained specialists is a robust means for maintaining one's health status and increasing motivation. Recently, communication tools have been developing and changing its situation (Arigo et al., 2019). Formerly, healthcare support was conducted face-to-face in hospitals or communities. Telephones and telemonitors have enabled remote assessment and consultation. Using the latter, the patient's expression and pathological changes, such as dermatitis and keratitis, could be assessed and appropriate advice offered. In some countries, the use of insurance points for telephonic and telemonitoring consultation services is permitted. However, expensive devices and infrastructure are needed to access the latter. Therefore, telemonitoring services are limited in high-income countries. However, this situation has been changed by the development of smartphones that have many functions, including portable telephone, mail, network access, connection to social networking services, data storage, and ease of obtaining various applications. Moreover, considering these utilities, they are economically priced. Currently, they are widespread in

low- to high-income countries. Information about diseases and the recommended lifestyle can be easily accessed using smartphones. Combined with monitoring devices, such as automated blood pressure measures, self-monitored data can be accumulated and analysed by the applications. Additionally, this data can be easily shared with healthcare specialists for receiving suitable healthcare support. Chat services may reduce the costs of healthcare support. Further, social networking services provide a space for group cognitive behavioural therapy. Many services for mHealth have been developed based on the construction of communication tools, which is modifying classical preventive healthcare.

5.1 The Evidence of mHealth for Preventive Healthcare

5.1.1 Hypertension

The preventive healthcare for hypertension has been addressed, and many clinical trials have been performed. The Cochran hypertension group performed a review of 72 randomised controlled trials on interventions to improve the blood pressure control (Glynn et al., 2010). Self-monitoring demonstrated moderate reductions of -2.5 mmHg and -1.8 mm Hg in the systolic and diastolic blood pressures, respectively; however, the reduction effect of an antihypertensive drug therapy was -8.0 mmHg and -4.3 mmHg in the systolic and diastolic blood pressures, respectively. The results of education interventions were heterogeneous; moreover, nurse- or pharmacist-led care was a promising advancement. The Cochran hypertension group indicated that family practice and community-based clinics need to have an organised system for conducting regular follow-ups and reviews of hypertensive patients (Glynn et al., 2010).

Based on the classical preventive healthcare background, the development of mHealth for hypertension has been established. Educational information regarding a healthy lifestyle, self-monitoring of behaviour change, goal setting, reminder for medication adherence, prompts for behaviour change, feedback from personnel, social support, motivational encouragement, action plan, pharmacological support, stress management, and blood pressure monitoring were the contents of the application (Li et al., 2020). The applications of mHealth are classified in Table 3. Providing information about the disease promotes knowledge regarding it and a suitable lifestyle to prevent its onset and deterioration. The education aspect was included in all programs. Among these, self-management was reported as the most effective tool for mHealth. Self-monitoring of blood pressure (Table 3) strongly affected behavioural changes. Healthcare support was useful in maintaining motivation for continuous treatment and provide medication reminders to enhance medical adherence. Regarding monitoring the physical status, a suitable physical activity level was recommended and a regular lifestyle was provided (Table 3). A meta-analysis of mHealth intervention for hypertension demonstrated a significant effect of reducing -3.78 mmHg and -1.57 mmHg systolic and diastolic blood pressures, respectively (Li et al., 2020). In addition, there was a significant decrease in

Table 3 mHealth for hypertension

Purpose	Approach	Contents
Education	Providing information	Information on hypertension
		Information on lifestyle
Self-management	Self-monitoring	Blood pressure
		Physical activity
Healthcare support	Encouragement	Telemonitoring and supervision by care clinicians
	Action plan	Prescribe a weekly exercise and a diet plan
	Social support	Reminder of appointment
	Reminder	Medication adherence
		Behaviour change

the overall healthcare cost savings of over USD 20,000 between mHealth and classical preventive healthcare (Li et al., 2020). These results suggest that the former has been successfully utilised to treat hypertension.

5.2 Diabetes and Obesity

The contents of mHealth for diabetes and obesity had a lot in common with that for hypertension (Table 11.4). Education was the basis for mHealth. The measured blood glucose and the body weight data were accumulated and displayed. Physical activity was counted daily according to the number of steps. Based on the collected data, suitable text messages and reminders were sent by the healthcare providers to the patients (Table 4). The effect of mHealth intervention varied from low to high. The results of a meta-analysis indicated a reduction in hemoglobin A1c (HbA1c) from 0.25% to 0.48% (Wang et al., 2020). Furthermore, the body weight decreased from -1.04 kg to -2.35 kg. Behavioural changes, such as dietary intake, eating habits, and physical activity, were inconsistent. Patients with diabetes who received the text messaging intervention demonstrated moderately improved scores on the self-management capacity; however, they did not report enhanced knowledge of diabetes (Jongh et al., 2012). Although the impact of mHealth on the reduction of HbA1c and body weight was limited, that of tele-screening to prevent the increasing severity of diabetic retinopathy was cost-effective (Ullah et al. 2020). In addition to the short-term effects, the evaluation of the long-term ones is essential.

5.3 Rheumatic and Musculoskeletal Diseases

The mHealth's basic contents for rheumatic and musculoskeletal diseases were consistent with those for hypertension and diabetes mellitus (Najm et al., 2019; Table 5). A unique aspect was that patient-reported outcomes (PRO) were used as parameters to monitor the disease activity. PRO measures daily changes in one's

Table 4 mHealth for diabetes and obesity

Purpose	Approach	Contents
Education	Providing information	Information on diabetes and obesity
		Information on lifestyle
Self-management	Self-monitoring	Blood glucose
		Body weight
		Physical activity
Healthcare support	Advice and counselling	Text messages by healthcare providers
	Encouragement	Promoting motivation
	Health promotion	Increasing physical activity
	Social support	Communication
	Reminder, feedback, and alert	Treatment adherence
		Behaviour change

subjective assessment, such as pain, fatigue, sleep, mood, and overall well-being. Because the main symptoms of rheumatoid arthritis are polyarthritis, general fatigue, and morning stiffness, it is reasonable to employ it as a disease activity parameter. A patient diary that is employed to register the daily health status and physical activity was used to record the self-maintenance of joints and to maintain physical activity. The personal digital assist daily PRO began to replace the paper–pencil format (Heiberg et al., 2007). Fatigue, a major symptom of rheumatoid arthritis, was reduced by monitoring daily steps using a pedometer (Katz et al., 2018). However, the clinical effect of mHealth on disease activity itself was insufficient and quality assurance is desired (Najm et al., 2019). Currently, it is difficult to objectively demonstrate a patient’s subjective assessment. Thus, further development of the PRO is necessary.

6 Presenteeism as a Candidate of New Parameter for mHealth

Low back pain (LBP) occurs worldwide, interferes with the quality of life and work performance, and is the most common reason for medical consultations (Ehrlich, 2003). Acute LBP is widespread and usually self-limiting, lasting for less than three months regardless of treatment. However, chronic LBP is correlated with more complicated problems, such as psychological overlay, dissatisfaction with work, and boredom (Ehrlich, 2003). In addition to medical issues, LBP is attributed to the physiological and psychosocial effects of occupational stressors

Table 5 mHealth for rheumatic and musculoskeletal disease

Purpose	Approach	Contents
Education	Providing information	Information on rheumatoid arthritis
		Information on lifestyle
Self-management	Self-monitoring	Physical activity
	Patient reported outcome	Pain, fatigue, sleep, mood, and well-being
	Health data	Disease activity score, physical activity
Healthcare support	Reminder	Physical activity
		Medical adherence

(Punnett et al., 2005). As compared with managers and professionals, its relative risk was slightly higher (1.34) in clerical or sales workers, moderately higher (2.53) in operators and service workers, and the maximum (5.17) in farmers (Punnett et al., 2005). In addition to medical costs, chronic LBP also affects work productivity.

Presenteeism, defined as the situation in which people work while unwell and not functioning to their full capacity, has begun to be used as a parameter for work productivity instead of a sickness absence score (absenteeism; Vänni et al., 2018). When investigated in 1100 Japanese hospital working nurses, LBP's overall prevalence was 64.6%. The incidence of acute and chronic LBP was 47.5% and 17.1%, respectively. Presenteeism was associated with the latter, however, not with the former. It is useful for showing the influence of disease on work productivity. Chronic LBP was related to the subscales of presenteeism, such as time management, mental-interpersonal relationship, and output demands (Yokota et al., 2019).

Another major problem with LBP is that over 80% of it is non-specific, making its diagnosis using classic images and laboratory data challenging. The World Health Organisation recommends examining the disease history, physical examination, and pain on a visual analogue scale and using the LBP-related questionnaire for the diagnosis of non-specific LBP (Ehrlich, 2003). From a different perspective, it may be convenient to develop mHealth for non-specific LBP as an application. BackTech Inc. developed a smartphone application (Pocket Therapist®) that distinguishes it using a questionnaire and a decision tree analysis (Fig. 2; Odake et al., 2021).

According to the discrimination (Figs. 2 and 3a), the recommended exercise, cognitive-behavioural intervention, and workplace adjustment were provided (Fig. 3b). The trained physiotherapist sent a short message to promote motivation, feedback, and advice (Fig. 3c). Using this application, the LBP intensity and the risk of depression score were reduced. Owing to presenteeism, the monetary

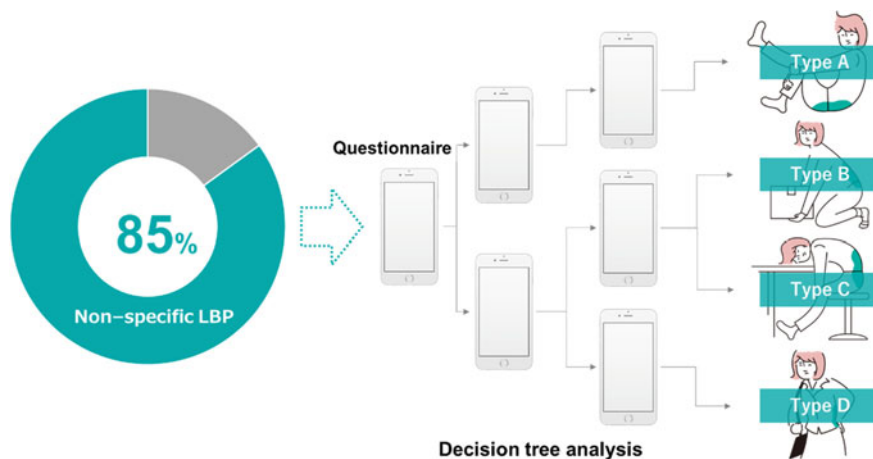


Fig. 2 The smartphone application, Pocket Therapist®, distinguishes the non-specific LBP using a questionnaire and a decision tree analysis

loss before the application use was USD 1,413.44 that reduced to USD 772.34 12 weeks after its utilisation (Odake et al., 2021). The company bears the expense of the worker's usage fee for the Pocket Therapist® to lessen the financial loss due to presenteeism, which may be a new parameter to promote preventive mHealth services.

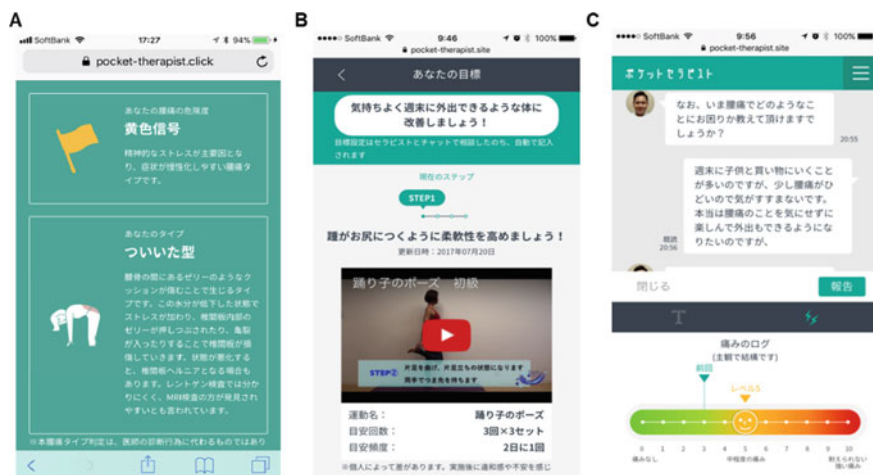


Fig. 3 The contents of Pocket Therapist®. *Note a* Type of LBP after discrimination. *b* Recommended exercise and cognitive behavioural intervention. *c* A trained physiotherapist sends a short message to promote motivation, feedback, and advice

7 Conclusion and Subsequent Steps

Although mHealth for preventive healthcare against hypertension and diabetes is useful, insufficient evidence was found for rheumatic and musculoskeletal diseases. Further research is needed to confirm the effectiveness of mHealth for preventive healthcare. Simultaneously, the development of a new technology that considers patients' unmet needs is important. Supportive care in oncology is defined as 'the prevention and management of the adverse effects of cancer and its treatment'. Its optimal provision using the PRO as a parameter has been attracting attention; it aims to enhance rehabilitation, secondary cancer prevention, survivorship, and end-of-life care (Aapro et al., 2020). Digital health solutions address many unmet needs, including increased communication between patients, providers, and their communities, educating patients and caregivers, integrating standard clinical assessments with the PRO measured during routine clinical practice, helping patients in monitoring their respective conditions, enhancing patient empowerment and self-management, and improving evidence from clinical trials on the basis of the PRO endpoints (Aapro et al., 2020).

The progress of communication tools and monitoring devices will continue; moreover, information processing technology will be further developed using artificial intelligence. As a practice, we attempted to develop a disease activity score prediction for rheumatoid arthritis based on the assessment of a smartphone application (Fig. 4). The disease activity score (DAS-28) was calculated by examining the number of tender and swollen joints evaluated by trained medical staff, the self-assessment of health using a visual analogue scale, and the C-reactive protein level, all of which were assessed in hospitals. Smartphones encompass many technologies. Surprisingly, the accuracy of the tri-axial accelerometer built on them was comparable to that in medical use (Nishiguchi et al., 2012). The gait pattern of rheumatoid arthritis was examined using this accelerometer (Yamada et al., 2012).

The gait parameters (Fig. 4a, b) were combined with the PRO that assessed tender joints (Fig. 4c) using a visual-analogue scale (Fig. 4d), and the actual DAS-28 score was predicted by the Spearman's correlation coefficient (Fig. 5a, b). The predictive and actual DAS-28 scores were well-correlated (Fig. 5c; Nishiguchi et al., 2014, 2015). The results of the feasibility study indicated new aspects of mHealth, and such challenges will be promoted.

In association with the development of mHealth technologies, many other services will be developed. The basic principle of preventive healthcare should be remembered; furthermore, ethical rules should be prepared simultaneously to promote mHealth for preventive healthcare.

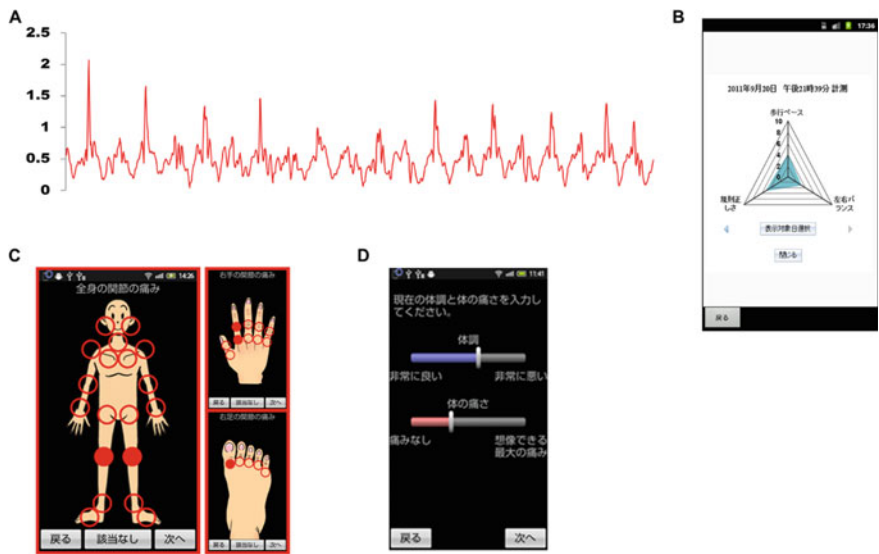


Fig. 4 Contents of the application for rheumatoid arthritis. *Note* **a** Gait pattern is assessed using a tri-axial accelerometer built on a smartphone. **b** Feedback data of the gait pattern. **c** Assessment of the number of tender and swollen joints evaluated by the patient. **d** The PRO, such as fatigue and pain, was assessed using a visual analogue scale

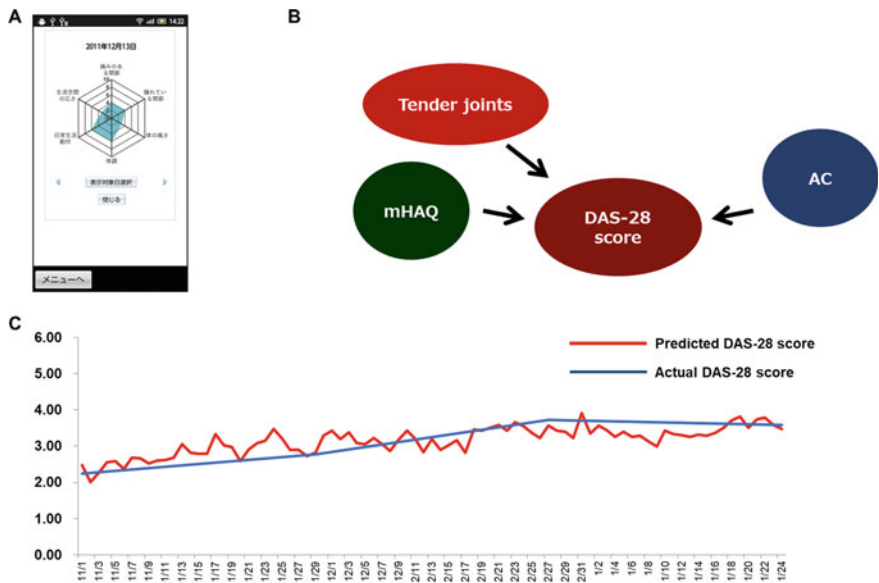


Fig. 5 Predictive disease score. *Note* **a** Feedback results for the self-assessment. **b** The actual DAS-28 score was predicted using informatics. **c** The predictive and actual DAS-28 scores

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Overall Summary

Shintaro Sengoku

ABSTRACT

In this chapter, we attempt to integrate the arguments developed in the other chapters, to confirm their significance as a general discussion of this book as a whole, and to extract the issues that need to be explored in depth in the future. It has been pointed out that the healthcare industry lags behind other sectors in terms of digital transformation (DX) (Kraus et al., *Journal of Business Research* 123:557–567, 2021). This is partly because of barriers to data use regulation, stemming from concerns about data security and operational issues, such as the complex processes requiring specific expertise to analyse personal health data. There are also underlying concerns among healthcare professionals regarding the reliability of data and a general distrust of technology. This chapter aims to explore ways of overcoming this situation so that DX can become a reality.

1 The Future of Digital Healthcare Systems

In this chapter, we attempt to integrate the arguments developed in the other chapters, to confirm their significance as a general discussion of this book as a whole, and to extract the issues that need to be explored in depth in the future. It has been pointed out that the healthcare industry lags behind other sectors in terms of digital transformation (DX) (Kraus et al., 2021). This is partly because of barriers to data use regulation, stemming from concerns about data security and operational issues, such as the complex processes requiring specific expertise to analyse personal health data. There are also underlying concerns among healthcare professionals regarding the reliability of data and a general distrust of technology. This

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chapter aims to explore ways of overcoming this situation so that DX can become a reality.

1.1 Medical Digital Data and Its Handling

As the average life expectancy increases and the number of people over 100 years of age is expected to grow, it necessitates the creation of a healthcare system that extends healthy life expectancy and enables people to enjoy life and play an active role in society. To achieve this, it is essential to shift from an approach that relies on the experience and knowledge of individuals to one that is based on big data, analysis, and evaluation. Thus, breaking down the barriers between health promotion, disease prevention, diagnosis, treatment, and care. Japan is the first country in the world to have a super-aged society, with 6.4 million people requiring support or care, estimated to be 9.3 million in 20 years. To promote these measures, it is necessary to open up and use healthcare, medical, and nursing care data as a basis for various fields and achieve cross-disciplinary innovation. These measures will improve the quality of medical and healthcare services and improve sustainability by optimising costs and benefits, and promoting industrial development, including the medical and healthcare industries.

The benefits of using digital medical data are manifold but can be summarised in the following areas. The first is to improve the safety and reliability of medical care by preventing human errors and medical mistakes through real-time and accurate communication and sharing of information between medical professionals. With regard to medicines, it is foreseen that the system will ensure error checking at the time of prescription orders, readability of order contents, and immediacy of changes. The second is the reduction of workload and improving efficiency. This is expected to lead to labour savings in the various operations of medical institutions, regional healthcare systems and efficiency improvements in business partnerships, and consequently, cost reductions. The third is the realisation of patient-centred medical services, involving the minimization of patient burden, duplication of tests through the coordination of information between medical institutions, and the improvement of the efficiency of medical practice through the disclosure of medical information. The fourth and final objective is to improve the quality of medical care, which will promote the use of the latest medical technology, improve patients' understanding of diseases, and realise personalised medicine. The application of 3D image processing technology to virtual reality surgery and ubiquitous medicine through the application of mobile and wireless communication technology are also promising new areas for development.

In general, this policy will lead to the creation of consumer-centric medical and healthcare information systems. In fact, in many countries, there is an accelerating trend to return personal data to individuals, which was previously monopolised by a few companies, such as those with mega digital platforms. A good example is the general data protection regulation (GDPR), which came into effect in the European Union in May 2018. The GDPR aims to give individuals back their

personal data collected by Google and other digital platforms originating in the United States. In the mainland China, the Cybersecurity Law, similar to the GDPR, came into effect in June 2017. The main difference between the Cybersecurity Law and the GDPR is that it ensures strict governmental control. There are severe penalties for breaches of security measures and information leaks, including fines and revocation of business licences.

The legal and institutional response to the openness of healthcare data is an essential issue in a democracy, and it is vital to building consensus at the societal level as early as possible. In Japan, personal information relating to medical and nursing care has been obtained and managed by medical institutions and providers, but to comply with the personal information protection law, it is necessary to confirm the usage of relevant information with the citizens, whether or not their data can be used or shared. This is a costly process, which has hindered the wider use of data. Anonymisation has been widely used as a solution to this problem, but it does not allow the results of data analysis to be fed back to the provider. This makes it impossible to achieve patient-centred healthcare and is also undesirable from a humanitarian perspective. Therefore, it is necessary to build a system that enables such data management while supporting independent decision-making, based on the premise that individual data subjects retain and manage their information and allow medical institutions and businesses to use it based on their own choices.

The solution to this problem is to clarify the background and context for the use of digital medical data, establish a perspective on what can be achieved by its use, and to sublimate this into a vision that can be shared widely with the public and citizens. In other words, it is necessary to share, analyse, and evaluate a wide range of information in the fields of medicine, nursing care, and health, including preventive health. It is also essential to design an information system with synergistic effects, which will be returned to the people through services that meet their diverse lifestyles and needs. Such an attempt is being promoted in Japan under the concept of a “comprehensive regional care system”, which aims to provide information and services efficiently and effectively through healthcare systems and next-generation information infrastructure.

In designing a comprehensive community care system, it is essential to respect national and local customs and cultures, to be sensitive to changes in social conditions, and to update houses, towns, local communities, and the surrounding environment to enrich the lives of citizens. At the same time, it is necessary to apply various cutting-edge technologies such as brain science and robotics. These efforts will pave the way for a sustainable society in which citizens can lead active lives according to their lifestyles while maintaining their dignity. The results will provide a solution to the national challenge of increasing healthy life expectancy, and will also be made available to other countries facing similar challenges, such as super-ageing, thus contributing to global sustainability.

2 Digital Innovation Platform for Mobile Health

This book aims to clarify the formation process of technology platforms in the interdisciplinary field of healthcare and information and communication technology (ICT) and promote innovations in this field. The role of ICT, such as big data analysis and machine learning, in the success of the healthcare industry will become significant in the future, and the formation and structure of technology platforms and will become key to innovation. The field of mobile health (mHealth), which is the subject of this book, is expected to see the convergence of wearable device, Internet of Things (IoT), artificial intelligence (AI) technologies, and the development of standardisation and platforms. This could lead to an entirely different ecosystem from conventional pharmaceuticals and medical devices. As a future prospect, based on the examples of mHealth products and services discussed in previous chapters, it is necessary to clarify the process of technology platform formation, based on the processes of (1) technology integration, (2) market and application integration, and (3) the cooperation and tension between relevant players and involved dynamic changes.

A stepwise model of ICT-induced technology-market convergence has been proposed. In the model, scientific knowledge induces technology convergence, followed by market/application convergence, and then industrial convergence (Hacklin et al., 2009). In the healthcare sector, this model has been applied in the case of functional foods (Curran & Leker, 2011), but, not in the healthcare system, where there is a complex relationship between legal regulations and institutional stakeholders, such as medical institutions and insurers. The foreseeable formation of technology platforms based on wearable devices, IoT, and AI technologies makes this area an ideal case study for discussing the future prospects of digital health ecosystems. The findings provided in this book will not only make an academic contribution but also serve as a cornerstone for the development of real-world technologies, products, and services and for the planning of technology platform strategies. Regional case studies from East Asia and Europe will also provide an intellectual basis for practice in countries with super-ageing societies.

In the following sections, we summarise and discuss the key issues for the transition of technology platforms into digital innovation platforms, based on each of the arguments in the book.

2.1 Optimising the Cost–benefit Balance in Regulatory Compliance

It has been suggested that the regulatory approval process ensures the quality of mHealth products and can accelerate digital innovation. The conventional wisdom is that regulatory compliance is costly, requires unique expertise and negotiation skills, and does not provide opportunities for all providers. Even if these requirements are met, prolonged marketing time and regulatory approval risks are inevitable challenges for all operators. On the other hand, regulatory compliance

confirms technical competitive advantages and quality control through a series of processes. When a product is approved, medical professionals achieve credibility and branding. This ensures a reliable operational process and drives new market entry. Support from national health insurance is a notable benefit, especially in countries that have universal health insurance, such as Japan. Taking all these factors into account, the benefits of regulatory compliance outweigh the costs and risks involved.

2.2 Innovation Path to Foster Innovative Technologies

As pointed out by Onodera and Sengoku (Onodera & Sengoku, 2018), the gap between ideals and reality in the technological aspects of mHealth is still significant. Industry expectations are that the current situation already has momentum for participation and high-end technology promises a wide range of usages. The end-users, businesses, and investors are eager to see innovative products and services. However, we still have limited industry-based trials, common needs, and conventional devices with legacy technology. The remedy for this challenge may be to improve the regulatory environment, as discussed in the previous section. A more proactive measure would be to carefully prepare market niches to foster innovative but budding technologies.

The most promising market niche in the development of pharmaceutical and medical products (PMPs), is mHealth-based patient monitoring, as discussed in chapter “[Mobile Health for Preventive Healthcare](#)”. This is because mHealth enables real-time, simple, and non-invasive collection of various vital data on the subject. The benefits of mHealth are manifold (Stafford & Garrett, 2021) as follows: it is easy to collect patients’ data in a non-invasive manner; detect patient safety issues earlier; identify early safety signals; evaluate the efficacy/safety of drugs; improve patient adherence and engagement; reduce the patient burden in the longer term; reduce site visits; enable remote participation; reduce the cost and time of recruiting subjects for clinical trials; contribute to studying investigational drugs; drive better and faster decisions in clinical trial management. Fortunately, the PMP providers are willing to collaborate across industry sectors and acquire ICT through mergers and acquisitions. In addition to contributing to the process innovation of existing PMPs, mHealth can pave the way for product innovation in its own right by refining its technology and improving the quality of its products and services in its ‘small market’. Such an innovation trajectory will be accepted as a straightforward and realistic path for mHealth providers.

Another important point is that the potential of the niche is not necessarily limited to the medical and healthcare domains. As discussed in detail in chapter “[mHealth Beyond Healthcare-Fusion Approach Towards Better Wellness](#)”, technological advances in implantable biosensors such as heart rate and skin temperature sensors enable efficient and predictive management by monitoring the health status and physical workload of workers using digital solutions common to mHealth. This approach is also relevant to the healthcare needs of

workers in labour-intensive environments in terms of quantifying their psychological and physical workload, improving their health, and preventing injury and illness. The gamification elements discussed in chapter “[Mobile Health for Preventive Healthcare](#)” provide a powerful motivation for consumers to embrace mHealth without resistance, leading to sustained behaviour change. The previously unthinkable paradigm shift toward health through gamification is already a reality. From BlueStar, a digital treatment app for type 2 diabetes, to treatments for central nervous system disorders such as epilepsy, mHealth will soon become a reality.

This diagram schematically illustrates the market penetration process of mHealth products based on the patient flow or the customer value chain (horizontal axis) and the product/service flow or the value delivery chain (vertical). The first path for mHealth products is to be used as adjunct/companion tools by existing PMP providers as the process innovation for their diagnostic or therapeutic products. In the second path, based on further technological developments in this niche market, some products may themselves be used as product innovation in preventive/diagnostic applications (2a) or post-therapeutic monitoring applications (2b), resulting in a matured market penetration.

2.3 Exclusive Reach to Specific Needs

In order to achieve breakthrough innovation through mHealth using pioneering technologies, specific needs need to be identified, and target markets must be carefully selected. According to Hwang and Christensen (2008), disease areas are organised along two axes: (1) motivation to comply with best-known therapies, and (2) the degree to which behaviour change is required. Using this matrix, potential target areas for mHealth are those where axis (1) is weak (i.e., consequences are deferred) and axis (2) is extensive. In this case, most of the target disorders are central nervous system disorders, such as schizophrenia, Alzheimer’s disease, obesity (psychogenic), bipolar disorder, and addiction. These results are consistent with those of the bibliometric keyword clustering analysis conducted in chapter “[Introduction of the Concept of AI in the Field of mHealth While Discovering the Trends in mHealth Research Field](#)” of this book. The common denominator of these disorders is low adherence levels and difficulties in disease management due to the lack of substantial measures to address this issue, which makes the future use of mHealth promising.

Abilify MyCite, an antipsychotic drug, is a good example of how this innovation path led to its launch. It is the world’s first combination therapy product developed as an integrated pharmaceutical and medical device and was approved by the US FDA in 2017 as a new value-added product. The combination of Otsuka pharmaceutical’s Abilify tablets with a tiny sensor developed by Proteus, a patch-type signal detector, and a dedicated app allows patients to monitor and record their medication use and share information with healthcare professionals and caregivers via mobile devices such as smartphones. In other words, medicines and mHealth

are complementary and synergistic and have overcome a development process that was originally difficult for mHealth.

In the context of health promotion and disease prevention, self-management using mHealth will continue to be a major trend, as discussed in chapter “[Mobile Health for Preventive Healthcare](#)”. In the case of athletes, mHealth enables them to maximise their productivity and performance and achieve their goals more efficiently. The organisation, goal setting, time management, self-motivation, stress management, and accountability are examples of such skills. Self-monitoring is particularly useful for patients with chronic diseases, and in combination with communication tools, remote assessment and consultation are now possible.

For mHealth to reach the right target areas, it needs to be flexible and adaptable based on the level of acceptance of novelty in the target area, existing diagnostic and therapeutic approaches, and the competitive environment. If the target area craves a new approach and no existing approach exists, then this is where the blue ocean strategy comes into play (Kim & Mauborgne, 2004). However, this is not always the case, and often the need for mHealth is ambiguous, and there are no existing approaches. In such cases, it is most effective to use the innovation path to foster new technologies, as described above. In the future, advances in communication tools and monitoring equipment, as well as information processing technology using artificial intelligence are expected.

2.4 Establishing Platform Leadership

A matured ICT provider in mHealth can be thought of as a platform that acts as a market intermediary or contributes to generating a platform ecosystem (Thomas et al., 2014). As reviewed in detail in chapter “[mHealth’s Potential for Measuring Work Attitudes in Psychological and Physical Factors](#)”, the market intermediary provides a two/multi-sided platform between two or more market participants. The platform ecosystem consists of a system or architecture that supports a collection of complementary assets. (HER)/patient health record, wearable devices, virtual reality (VR)/augmented reality (AR), artificial intelligence (AI)/machine learning (ML), telemedicine/health, etc., as reviewed in detail in chapter “[mHealth’s Potential for Measuring Work Attitudes in Psychological and Physical Factors](#)”. At present, there are few or no players who have reached this stage, let alone the market intermediary position, but we should anticipate the emergence of such players in the future and the entry of mega platformers into the healthcare industry.

In various consumer-facing industries such as social media, food delivery, and online search engines, platform competition is very likely to reflect winner takes all markets (Katz & Shapiro, 1994). Consumer-facing industries demonstrate market convergence due to platform envelopment (Eisenmann et al., 2011; Hermes et al., 2020). On the other hand, sensitive health data, complex clinical trials, control over core assets, and patent intensity might alter the common rules of platform competition which has usually been investigated in less regulated industries

(Cennamo & Santalo, 2019). Therefore, exploring how different industry structures shape platform competition seems fruitful especially as insights for platform regulation emerge.

3 Limitations and Future Perspectives

The limitations and prospects of the present works are as follows: First is the change in the concept of mHealth. The circulation of mobile devices in the 2010s, symbolised by smartphones, led to the emergence of the concept of mHealth as a way of using these devices for healthcare applications. However, in the 2020s, the concept of digital health, which integrates mobile devices with IoT and AI, is emerging as a replacement for mHealth. This book is framing mHealth as a conceptual stage, but we should be aware of the rapid technological progress and continue to expand and update the concept. Second are the regional characteristics of the innovation core. As seen in the introduction of chapter “[Introduction of the Concept of AI in the Field of mHealth While Discovering the Trends in mHealth Research Field](#)”, the core of mHealth research comprises a small number of regions in North America and the United Kingdom, but as described in chapter “[Mobile Health for Preventive Healthcare](#)”, product and service development spans other regions, including Europe, Asia, and Africa. The developmental histories of technologies, products, and services are different. We need to deepen our understanding of these regional developments, innovation modes, and dynamics. The third and greatest challenge is the COVID-19 pandemic, which has severely damaged human health and had a profound and irreversible impact on lifestyles, especially communication norms and habits. It also led to sporadic changes in how mHealth was adopted, and its significance and utility were recognised. The situation of mHealth or digital health in the post-COVID-19 pandemic era, which is still unpredictable at the time of writing, needs to be revisited.

In the future, mHealth and other information and communication technologies are expected to play two important and disruptive roles in driving changes in the proposed diffusion model of mHealth innovation (Fig. 1). Figure 3 in chapter “mHealth Beyond Healthcare-Fusion Approach Towards Better Wellness-” provides a diffusion model of mHealth innovation. One is the potential to improve operational efficiency by facilitating collaboration between healthcare providers and the digitisation of health and medical information. The other is the possibility of facilitating integration with other service areas, such as gamification, exercise, sports and travel. In this case, mHealth could be a driver for a shift in the healthcare industry from its classical linear and coupling models to networked business models.

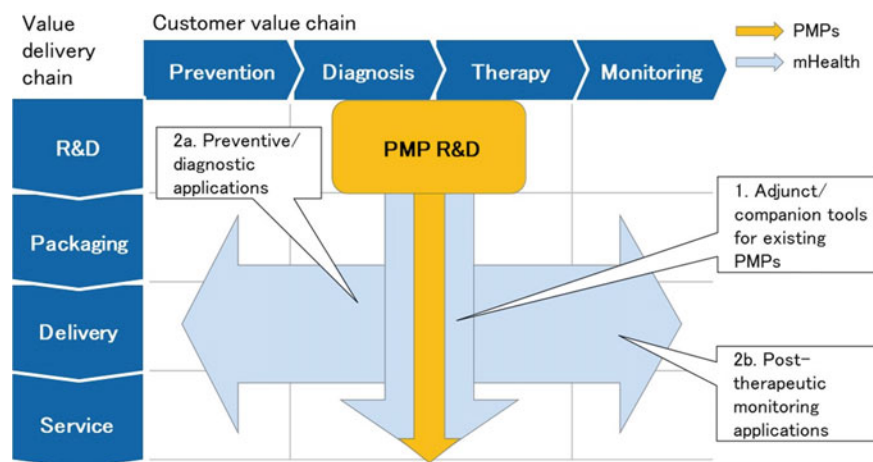


Fig. 1 A diffusion model of mHealth innovation

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