Data Collection Survey on the Digital Health for the Covid-19 Response (QCBS)

Final Report

February 2022

Japan International Cooperation Agency (JICA)

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QUNIE Corporation

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List of Abbreviation

4G		4th Generation Mobile Communication System
5G		5th Generation Mobile Communication System
ADB		Asian Development Bank
AI		Artificial Intelligence
AIDS		Acquired Immune Deficiency Syndrome
AMREF		African Medical and Research Foundation
ANAHP	Associação Nacional de Hospitais Privados	National Association of Private Hospitals
ANATEL	Agência Nacional de Telecomunicações	Telecommunications Authority
ANVISA		National Health Surveillance Agency
AR		Augmented Reality
ASEAN		Association of South East Asian Nations
AWS		Amazon Web Service
BAPPENAS	Badan Perencanaan Pembangunan Nasional	National Development Planning Agency
BoP		Bottom of the Pyramid
BOR		Bed Occupancy Rate
BPJS	Badan Penyelenggara Jaminan Sosial	Health Insurance Implementation Organization
BtoB		Business to Business
BtoC		Business to Consumer
CDS		Current Decision Support
CEH		City Eye Hospital
CFM	Conselho Federal de Medicina	Federal Medical Council
CFS		Certificate of Free Sale
CGTRH		Coast General Teaching and Referral Hospital
CGU	Controladoria-Geral da União	Federal Comptroller General
CNPJ	Cadastro Nacional da Pessoa Jurídica	National Register of Legal Entities
CoC		Certificate of Conformity
COFFITO		Federal Council of Physical Therapy and Occupational Therapy
COVAX		COVID-19 Vaccine Global Access
COVID-19		Coronavirus Disease 2019
Critt	Centro de Inovação e Transferência de	Innovation and Technology Transfer Center

	Tecnologia	
CVC		Corporate Venture Capital
DICOM		Digital Imaging and Communication in Medicine
DKI	Daerah Khusus Ibukota	Capital Territory
DRG		Diagnosis related group
DtoC		Doctor to Customer
DtoD		Doctor to Doctor
DtoP		Doctor to Patient
DX		Digital Transformation
EAP		East Asia & Pacific
e-CHIS		Electric Community Health Information System
EHR		Electronic Health Record
EoI		Expression of Interest
ESD28	Estratégia de Saúde Digital para o Brasil 2020-2028	Digital Health Strategy in Brazil
FDA		Food and Drug Administration
FHIR		Fast Healthcare Interoperability Resources
GDP		Gross Domestic Product
HCFMUSP	Hospital das Clínicas da Faculdade de Medicina da Universidade de São Paulo	Hospital of the University of Sao Paulo School of Medicine
HCUFPE	Hospital das Clínicas da Universidade Federal de Pernambuco	Pernambuco University Hospital
HIV		Human Immunodeficiency Virus
HKWCH		RSAB Harapan Kita Women and Children Hospital
HUJF	Hospital Unimed Juiz de Fora	Juiz de Fora Hospital
IADB		International Agency for the Prevention of Blindness
ICT		Information and Communication Technology
IEPS	Instituto de Estudos para Políticas de Saúde	Institute of Health Policy Research
IMF		International Monetary Fund
INA-CBG		Indonesian Case Mix-Based Groups
IoT		Internet of Things
IPTU	Imposto Predial e Territorial Urbano	Taxes on real estate and land in urban areas

ISSQN	Imposto sobre Serviços de Qualquer Natureza	Tax on services of any nature
IT		Information Technology
ITBI	Imposto sobre Transmissão de Bens Imóveis	Real estate transfer tax
JETRO		Japan External Trade Organization
JKN	Jaminan Kesehatan Nasional	National Health Insurance
JPEG		Joint Photographic Experts Group
KAPH		Kenya Association of Private Hospitals
KEBS		Kenya Bureau of Standards
KEMRI		Kenya Medical Research Institute
KEMSA		Kenya Medical Supplies Authority
KEPSA		Kenya Private Sector Alliance
KHSSP		Kenya Health Sector Strategic and Investment Plan
KPI		Key Performance Indicator
LAC		Latin America and the Caribbean
LAN		Local Area Network
LAR		Local Authorized Representative
LGPD	Lei Geral de Proteção de Dados	Personal Information Protection Law
LIS		Laboratory Information System
MICT	Ministry of Information, Communications and Technology	Ministry of Information and Communication Technology
MMR		Maternal Mortality Rate
MMSE		Mini Mental State Examination
MOH		Ministry of Health
MR.		Mixed Reality
NACOSTI		National Commission for Science, Technology and Innovation
NCDs		Non-Communicable Diseases
NGOs		Non-Governmental Organization
NHIF		National Hospital Insurance Fund
NMR		Neonatal Mortality Rate
ODA		Official Development Assistance
PACS		Picture Archiving and Communication System
PAM&A	Plano de Ação, Monitoramento e Avaliação	Supervision and evaluation plan for digital

		health activities
PCN		Primary Healthcare Network
PCR		Polymerase Chain Reaction
PDF		Portable Document Format
PERDAMI	Perhimpunan Dokter Spesialis Mata Indonesia atau	Indonesian Ophthalmologist Association
PERKANI		Indonesian Pediatric Cardiac Society
PERKONSIL	Peraturan Konsil Kedokteran Indonesia	Regulations of the Indonesian Medical Council
PHR	Personal Health Record	Personal Health Record
PMDA		Pharmaceuticals and Medical Devices Agency
PNG		Portable Network Graphics
PNIIS	Política Nacional de Informação e Informática em Saúde	National Policy on Medical Information and Information Science
PoC		Proof of Concept
PPB		Pharmacy and Poisons Board
PPE		Personal Protective Equipment
PVoC		Pre-Shipment Verification of Conformity
RADAR	Registro e Rastreamento da Atuacao Dos Intervenientes Aduaneiros	Registration and Tracking of the Actuation of Customs Agents
RIS		Radiology Information System
RNDS	Rede Nacional de Dados em Saúde	National Health Data Network
RU	Rancangan Undang-undang	Draft Law
SDGs		Sustainable Development Goals
SE	Surat Edaran	Circular Letter
SIK	Sistem Informasi Kesehatan	Health Information System
SIM		Subscriber Identity Module
SIP	Surat Izin Praktik	Medical Certificate
SJSN	Sistem Jaminan Sosial Nasional	National Health insurance System
SNI	Standar Nasional Indonesia	Indonesian National Standard
SNS		Social Networking Service
SSA		Sub-Saharan Africa
STR	Surat Tanda Registrasi	Registration certificate
SUS	Sistema Único de Saúde	Unified Health Care System
TKDN	Tingkat Komponen Dalam Negeri	Level of Domestic Parts

U5MR		Under-5 Mortality Rate
UFJF	Universidade Federal de Juiz de Fora	Federal University of Juiz de Fora
UFRJ	Universidade Federal do Rio de Janeiro	Federal University of Rio de Janeiro
UHC		Universal Health Coverage
UMC		Ushirika Medical Clinic
UNDP		United Nations Development Programme
USAID		United States Agency for International Development
USU	Rumah Sakit Universitas Sumatera Utara	North Sumatera University Hospital
VC		Venture Capital
VPN		Virtual Private Network
VR		Virtual Reality
WHO		World Health Organization
WIPO		World Intellectual Property Organization
WPP		World Population Prospects

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Exchange Rate

USD	United States Dollar	1USD = ¥115.2624
BRL	Brazilian Real	1BRL = ¥21.4793
KES	Kenyan Shiling	1KES = ¥1.01867
IDR	Indonesian rupiah	1IDR = ¥0.00802

Note: All rates are based on JICA's February 2022 rate.

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[Summary]

Summary of Final Report

I. Outline of the Survey

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１. Background of the Survey

There is an urgent need to address the worldwide spread of a new coronavirus infection (COVID-19) that occurred in 2020. In order to cope with the spread of COVID-19, countries are working on countermeasures such as lockdown and promotion of new lifestyles.

In many countries around the world, including Japan, information and communication technology (ICT) has been actively introduced to improve operational efficiency, reduce medical errors, and promote paperless medical practices. In Japan, the receipt computerization system and electronic medical records have been promoted ahead of the rest of the world. And not only the entire hospital system, but also department system such as PACS (Picture Archiving and Communication System), RIS (Radiology Information System), LIS (Laboratory Information System) and so forth have been introduced and improved the environment of the medical field. In addition, with the development of communication technology and networks, and the miniaturization and sophistication of terminals such as smartphones, large amounts of data can now be exchanged smoothly and easily accessed, which has led to the introduction of various forms of telemedicine. Also, the improved accuracy of sensing technologies such as face recognition using artificial intelligence (AI) has made it technically possible to monitor patients without contact. In addition, ICT is spreading not only in the medical field but also among health-conscious individuals, and many people are using smartphone applications for health management.

These digital healths are also effective in dealing with COVID-19, which is spread by droplet and contact infections, and the spread of COVID-19 has led to the rapid introduction of these ICTs in countries around the world, including developing countries, and the market scale is expanding. In each country, various ICTs are being developed to reduce the risk to healthcare workers and prevent the spread of infection, and accompanying deregulation is being promoted at a rapid pace. In Japan as well, telemedicine technologies such as online medical consultation and non-contact monitoring, contact tracing applications such as COCOA promoted by the Ministry of Health, Labor and Welfare, e-learning applications to promote behavioral change, and automatic operation robot technologies such as cleaning robots have been introduced to strengthen the healthcare delivery system for COVID- 19. The introduction of these technologies is expected to strengthen the medical provision system for COVID-19 and prevent the spread of infection.

Furthermore, these technologies are also valuable as an international contribution. If certain conditions, such as communication infrastructure, are in place, these technologies can be applied outside Japan, and it is expected that effective Japanese technologies will be shared as common COVID-19 countermeasures throughout the world.

JICA, the Cabinet Office, the Ministry of Economy, Trade and Industry, the Ministry of Health, Labor and Welfare, and other organizations in Japan have been conducting various surveys and demonstration projects to study the possibility of introducing and utilizing ICT in the field of health care in developing countries. In these projects, various approaches that have the potential to introduce and utilize ICT in developing countries are being studied based on the understanding of the environment surrounding ICT, such as the organization and analysis of local medical issues and demands, local policies, and the status of infrastructure development.

As of January 2022, JICA's Global Agenda 6: Health Care recognizes the importance of promoting the adoption of ICT-based digital health to solve the remaining challenges in health systems and achieve universal health coverage (UHC). Furthermore, it states that "from the perspective of overcoming the shortage of human resources and limited access to services in developing countries, the introduction of digital health from various aspects should be considered, a system should be established to apply appropriate technologies, and digital health technologies should be actively applied. The importance of introducing and using ICT in the healthcare sector is increasing.

On the other hand, there are various bottlenecks for ICT companies to enter the local market and continue or expand their business, and for JICA and the Japanese government to provide support to developing countries using digital health. The introduction and utilization of ICT generally requires not only simple introduction but also continuous technological improvement and software updates. In the case of developing countries, however, there are likely to be various challenges in terms of infrastructure environment, demand and market size, local government policies and strategies, and related laws and regulations.

Lack of infrastructure in developing countries may be an impediment to the expansion of the market and the business of private companies, as well as to the promotion of various types of support in the digital health field by governments and donors. The telecommunications infrastructure penetration rate and the ICT literacy of users, which are the conditions for the introduction of ICT, are not necessarily high, and the disparity between urban and rural areas tends to be significant. Due to the lack of easy access to infrastructure, although there are ICTs that can contribute to solving local medical issues, the number of users and the environment may be limited.

In terms of policies, laws and regulations, the environment is not always conducive to entry. In some cases, the priority is placed on various policies and strategies aimed at improving the quality of healthcare and the healthcare delivery system itself, as well as the development of related laws and regulations, and there are insufficient measures for the introduction of ICT in healthcare. In addition, many of the laws and regulations related to ICT for medical care are not yet in place, and foreign companies, especially those without local capital, need to be flexible in responding to local laws and regulations that change from time to time.

In planning measures for development cooperation using ICT in the field of health and medical care, it is necessary to examine the bottlenecks from the above perspectives as well as effective measures. The introduction and utilization of ICT are attracting attention for solving medical issues in developing countries. However, considering the environment surrounding ICT in developing countries, it is assumed that while there is potential demand for the introduction and utilization of ICT, the environment is not necessarily ready to capture such demand.

Up to now, JICA, the Cabinet Office, the Ministry of Economy and the Ministry of Health Labor and Welfare of Japan have been conducting various surveys and pilot projects to study the possibility of introducing and utilizing ICT in the field of healthcare in developing countries. In these projects, various possible approaches for ICT introduction and utilization in developing countries are being studied based on the understanding of the environment surrounding ICT, such as local medical issues, demand analysis, local policies, and infrastructure development status. In the "Basic Information Collection and Confirmation Study on the Formation of Technology Cooperation Facility and Ecosystem for Global Impact Investment" conducted by JICA's Economic Development Department, not only the local introduction of ICTs, but also the matching and pilot activities (Proof of Concept: PoC) of each technology in the target country by ICT companies (including Japanese, local, and third countries) are conducted. In addition, the role of JICA in the future formation of local ecosystems is being studied. While these projects share the common objective of examining support measures that contribute to solving medical issues in developing countries, and have similarities and affinities in terms of target areas and countries, they do not necessarily have cross-sectional coordination among them. It is expected to produce greater effects than implementing individual projects on its own, while making efficient and effective use of each.

２. Purpose of the Survey

Based on the above-mentioned background, this project aims to promote the digitalization of the health sector and the development of the digital health markets in developing countries, including the Republic of Indonesia, the Republic of Kenya, and the Federal

Republic of Brazil, in order to solve healthcare issues including COVID-19. The objective of this project is to examine specific support measures for the governments of Indonesia, Kenya and Brazil (Target countries), and for the private companies (Japanese, target country's and other third country's), involving collaboration and co-creation with various partners.

３． Method of the survey

In this project, in order to achieve the above-mentioned objectives, we will first grasp the overview of digital health in the world and Japan. Next, we will focus on Brazil, Kenya, and Indonesia, and investigate the situation and issues of healthcare in each country (from the perspective of the target countries), market trends and the environment for corporate activities (from the perspective of the companies), and the support of development donors to the target countries (from the perspective of JICA). To examine JICA's supporting measures in the field of digital health, hypotheses will be developed based on the above-mentioned perspectives of target countries, companies, and JICA, as well as desk research and analysis of digital health architecture in each country. These hypotheses will be developed through pilot activities (Proof of Concept : PoC) and interviews with stakeholders. In the finalization of the measures, specific supporting measures for the future by JICA will be developed and proposed based on the collation of hypotheses and results, issues and lessons learned from the PoC. With collaboration and co-creation with stakeholders in mind, we aim to develop specific JICA supporting measures that contribute to the sustainable and autonomous development of the digital health field by demonstrating added value to the target country government and private companies (including Japanese, target countries, and third countries).

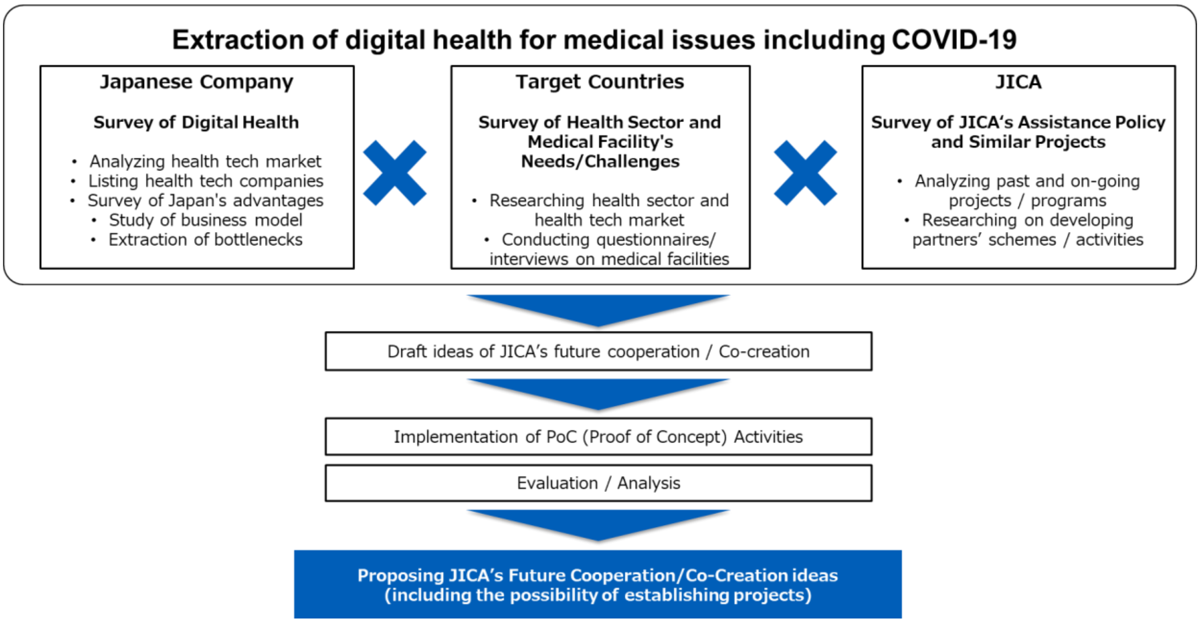

Figure I-1 Overall view of this project

Source: Compiled by survey team

４． Target of the Survey

The survey covers the entire world, of which the field survey and PoC are conducted in three countries: Brazil, Kenya, and Indonesia.

５． Schedule of the Survey

A large number of man-months are invested at the start of this work, and the project plan is top-heavy with information collection, analysis, and planning while dividing the work among the survey team members. In the 12-month research period of this project, it is required to conduct 3-month PoCs in each country after October 2021. Due to the limited time frame of the PoC, it will be conducted in parallel in 3 countries. In addition, the PoC will be conducted without delay while utilizing the resources of local subcontractors.

The overall schedule of this survey is shown in Figure I-2 Overall scheduleand the survey team members are listed in Table I-1 Members of the survey team.

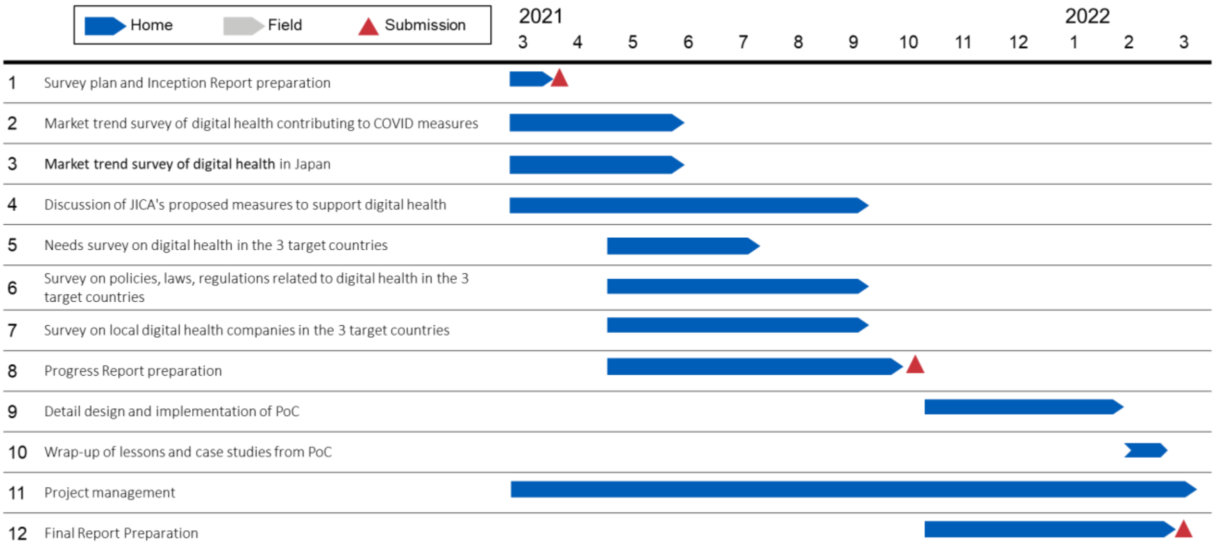

Figure I-2 Overall schedule

Source: Compiled by survey team

Table I-1 Members of the survey team

Name	Responsibilities	Company Name	Contact Address	
Dai Fujita	Healthcare	ITEC Ltd.	fujita-dai@itec-ltd.co.jp	∗
Juan Solis Gundin.	Digital health (1)	everis Brazil	juan.solisgundin@nttdata.com	
Tatsuya Matsuoka	Digital health (2)	ITEC Ltd.	matsuoka-tatsuya@itec-ltd.co.jp	
Kana Ohshima	Healthcare	Qunie Corporation	ohshimak@qunie.com	
Satoru Watanabe	Healthcare Policy	PSD Corporation	satoru.watanabe@psdjapan.com	

∗ : Project Leader

II. Market Trend of Technologies and Services Related to Digital Health

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１． Global Digital health Market and Impact of COVID-19

１－１． Recent Trends and Main Factors (Global)

The global digital health market[1] size is expected to reach USD 390.7 billion by 2024 (CAGR: 15.8%) from USD 187.6 billion in 2019. Accelerating government support for digital health, increasing accessibility of medical applications and services with the spread of smartphones, increasing use of big data in the medical field, high return on investment in digital health, and the need to control soaring healthcare costs are considered to be the major factors driving the digital health market. In terms of market size by region, North America is the largest market. North America is expected to be the largest market by region, while Asia Pacific is expected to grow at the highest CAGR.[2]

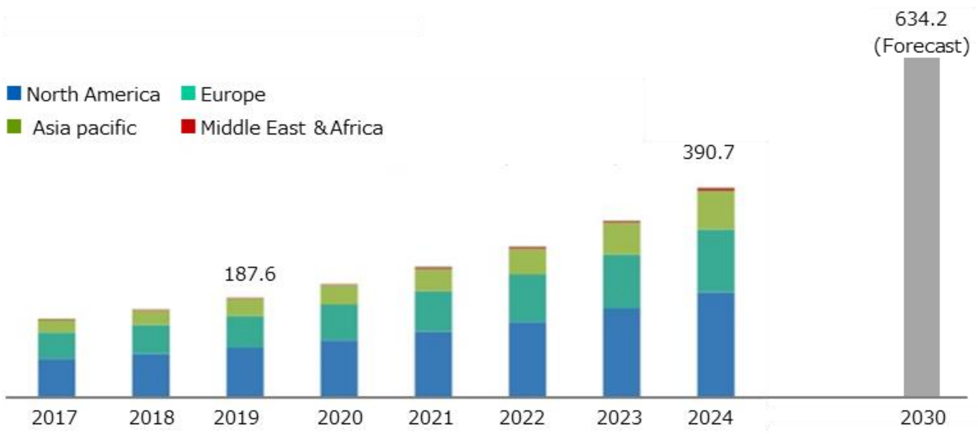

Figure II-1 Global digital health market size

Source: Based on research by MarketsandMarkets Research Private Ltd.[2]

Projected values for 2030 prepared by survey team

In addition to the widespread use of PCs and smartphones, various objects are now connected to the Internet, and the number of Internet of Things (IoT) devices is increasing every year. In the medical field, the number of IoT devices has increased 3.5 times between 2014 and 2021[3].

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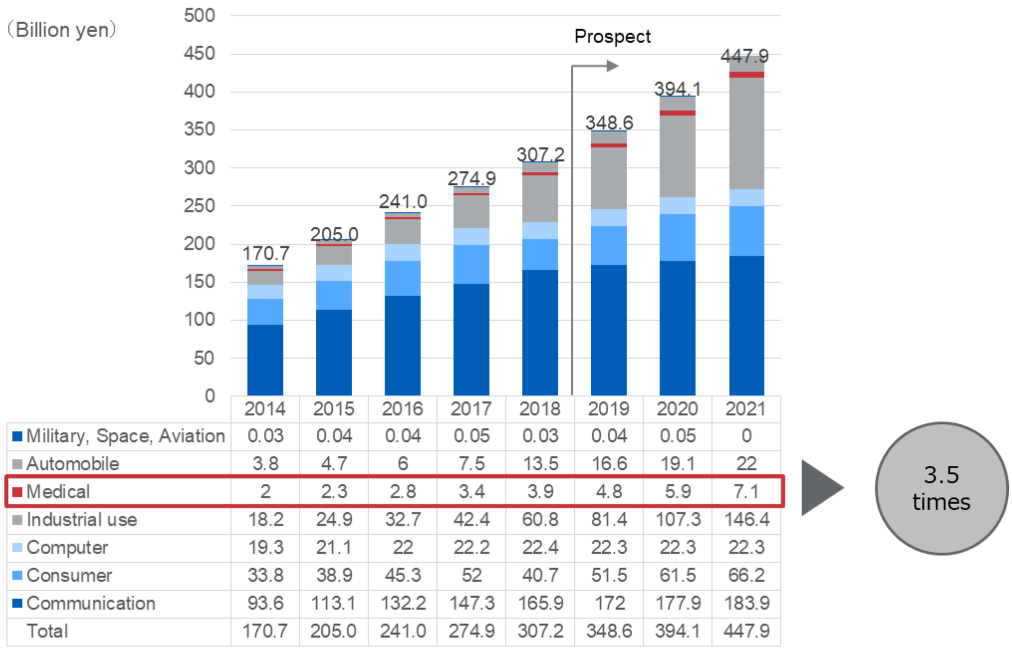
1 This refers to ICT products and services for healthcare providers and insurers, such as electronic medical records, various departmental systems, CRM, and mobile health applications. For more details, please refer to the "Products & Services" section of the following marketsandmarkets link.

2 https://www.marketsandmarkets.com/Market-Reports/healthcare-it-252.html

3 Ministry of Internal Affairs and Communications, 2039 Information and Communication White Paper



	2014	2015	2016	2017	2018	2019	2020	2021
Military, Space, Aviation	0.03	0.04	0.04	0.05	0.03	0.04	0.05	0
Automobile	3.8	4.7	6	7.5	13.5	16.6	19.1	22
Medical	2	2.3	2.8	3.4	3.9	4.8	5.9	7.1
Industrial use	18.2	24.9	32.7	42.4	60.8	81.4	107.3	146.4
Computer	19.3	21.1	22	22.2	22.4	22.3	22.3	22.3
Consumer	33.8	38.9	45.3	52	40.7	51.5	61.5	66.2
Communication	93.6	113.1	132.2	147.3	165.9	172	177.9	183.9
Total	170.7	205.0	241.0	274.9	307.2	348.6	394.1	447.9

Figure II-2 Trends and forecasts for the number of IoT devices worldwide

Source: Ministry of Internal Affairs and Communications, Information and Communication White Paper, 2019 [4]

With the spread of IoT devices, etc., it has become possible to collect information such as biometric data of individual patients in a minimally invasive and low-cost manner, without physical limitations as long as there is a communication environment. With the development of AI-based analysis technology, AI is now being used as the basis for many services in the medical field, such as drug discovery support and patient data analysis. Against the backdrop of such digitalization in the healthcare sector, tech giants such as Apple[5] have newly entered the market[6]. In particular, they are entering the diagnosis and treatment field by combining AI and other technologies developed by major tech companies with the demand in the healthcare sector. In addition, there is an increase in the number of healthcare-related products and services based on platforms formed by each company, and competition to form platforms is increasing in different areas and layers of the healthcare sector.

１－２． Impact of COVID-19 on Recent Trends (Global)

The demand for digital health is growing due to the match between the characteristics of digital health and the emerging demand for contactless technology in the context of the

[4] Ministry of Internal Affairs and Communications, Information and Communications White Paper, 2019, Section 2: ICT Trends Supporting the Digital Economy https://www.soumu.go.jp/johotsusintokei/whitepaper/ja/r01/pdf/n1200000.pdf
[5] Apple Inc., https://www.apple.com/jp/healthcare/
[6] JETRO, https://www.jetro.go.jp/biz/areareports/2019/7f61e78818a383cd.html

expansion of COVID-19.

（１） Accelerating DX in the healthcare sector

As a result of the increase in demand for non-contact and non-face-to-face medical services due to the spread of COVID-19 infection, and as a result of various measures and deregulation by governments to promote telemedicine from the perspective of preventing the spread of infection, the spread of telemedicine such as online medical treatment, which already existed, is accelerating[7]. In addition, to ensure social distance in medical facilities, technologies such as face recognition using cameras, robots that can be remotely operated or run autonomously with AI for transporting medicines, meals, etc., and remote monitoring of patients by doctors have been introduced[8].

（２） Accelerate Investment in the Health Care Sector

The amount of investment in the digital health field continues to increase every year. According to StartUp Health, investment in digital health[9] will reach US$21.6 billion in 2020 after the COVID-19 outbreak, up nearly 1.5 times from US$13.9 billion in 2019 and a record high for a single year. This is a record amount for a single year. The size of the investment market related to telemedicine will also increase from US$1.1 billion to US$3.1 billion in the year 2019-2020, nearly tripling[10].

[7] Changes in telepsychiatry regulations during the COVID-19 pandemic: 17 countries and regions' approaches to an evolving healthcare landscape,
https ://www.cambridge.org/core/journals/psychological-medicine/article/changes-in-telepsychiatry-regulations-during-the-covid19-pandemic-17-countries-and-regions-approaches-to-an-evolving-healthcare-landscape/3A5CC8F80DDD7B0105AEC70DC12BF7C2
[8] Ministry of Internal Affairs and Communications, 2020 White Paper on Information and Communications
[9] Size of VC, CVC, and PE investment funding for seed stage startups based on published data through December 31, 2020.
[10] StartUp Health, StartUp Health Insights, Year-end Report, 2020

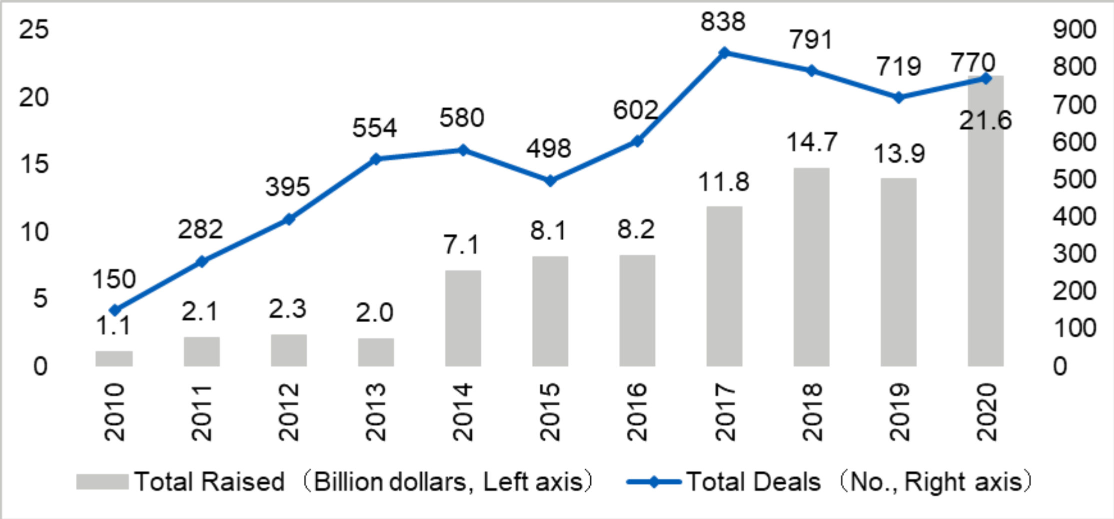


Figure II-3 Trends in investment in the digital health field (global, by year)

Source: StartUp Health, StartUp Health Insights, Year-end Report, 2020

（３） Increasing Demand for Infrastructure Development, including Legal and Regulatory Development and Data Collaboration

In response to the spread of COVID-19 infection, issues such as the implementation of various governmental policies and insufficient infrastructure for necessary information collection and coordination have become apparent[11]. With the global spread of digital health, the demand for the improvement of various laws and regulations, the implementation of government policies, and the improvement of communication infrastructure is expected to increase.

１－３． Future Prospects for the Digital Health Market (Global)

Based on the investment market trends, the following digital health areas are expected to grow in the future. In addition to AI and telemedicine, which have been the focus of attention for some time, the market specializing in mental illness and women is attracting attention, and progress in digitization in individual areas is expected. On the other hand, platform competition is also intensifying[12].

[11] Rock Health, https://rockhealth.com/reports/whats-ahead-for-digital-health-in-2021/
[12] CB Insights, State of Healthcare Q1'21 Report: Investment & Sector Trends to Watch, 2021
Rock Health, https://rockhealth.com/reports/whats-ahead-for-digital-health-in-2021/
Rock Health, https://rockhealth.com/reports/digital-healths-platform-wars-are-heating-up/
Startup Health, StartUp Health Insights, Year-end Report, 2020

（１） Platform

Companies from various industries are providing platforms in the healthcare sector, and competition is expected to increase in various fields and layers in the future. These include companies with supply chains such as convenience stores and pharmacies, as well as companies that provide digital platforms such as telemedicine and data management. In recent years, major tech companies such as Apple have also entered the market.

（２） AI

In the **first quarter of 2021, the scale of investment reached US$2.5 billion (the highest amount ever in the first quarter of 2021), and the number of deals is on the rise, with 111 deals, and the amount raised tends to be large.** As AI applications cover not only diagnostic imaging but also a wide range of fields such as drug discovery and applications, there is potential for further expansion in scale as technology develops and big data is accumulated.

（３） Remote Medicine

Although the spread of the vaccine may limit the impact of COVID-19 on the telemedicine market, the market scale will not return to the level before the pandemic of COVID-19, and demand is expected to continue over the medium to long term. In particular, there will continue to be demand for improved access to medical care in areas where there is a shortage of medical personnel and on islands.

（４） Women's Health

The market for a collection of medical applications and products that specialize in women's health promotion and management, healthcare delivery, etc. is likely to grow in the future. Ro, a company that provides telemedicine, online pharmacy services, and other services specific to women, has raised US$500 million in 2021, making this market likely to attract attention in the future.

（５） Medical device and Devices

New devices using advanced technologies are emerging, such as surgical navigation systems using augmented reality (AR), pain control technology using virtual reality (VR), and rehabilitation programs using mixed reality (MR). Other companies that develop and sell devices such as rehabilitation support and mobility support robots have also appeared in the early stage.

（６） Mental Health

The prevention of mental illness and digital medicine have been attracting attention in recent years, and one example is mental health support using avatars. The online psychological consultation system via avatars is said to have several advantages for users, such as reducing psychological hurdles by allowing consultation without showing oneself, allowing consultation from anywhere without worrying about the environment, and facilitating self-disclosure because the other party is an avatar[13]. The size of the investment market rose from about US$550 million to about US$850 million in one quarter from the fourth quarter of 2020 to the first quarter of 2021, an increase rate of about 1.5 times.

１－４． Future Challenges in the Digital Health Market (Global)

While market expansion and technological progress are expected, there are issues to be addressed in the development of human resources and systems on the user side, as well as in the development of social infrastructure for technology use. In addition, how to approach those who cannot use digital health may become a new issue in the future.

（１） ICT Literacy

With the diversification of digital health products, it is necessary for users to improve their skills in using digital health. This includes ICT literacy for mobile devices such as smartphones and wearable devices, which have spread rapidly in recent years, in addition to the conventional skills related to computers, mainly the Internet.

（２） Human Resources and Structure

It is necessary to secure human resources and establish a system to properly handle the relevant technologies and products in the organizations (hospitals, companies, organizations, etc.) that introduce digital health.

（３） Data Coordination

In addition to the information collected and stored at medical facilities, in recent years, individual users have been accumulating their own information via smartphones, wearable terminals, and other devices. In order to integrate, link, and utilize the various types of data stored individually in different locations, international standards for data linkage of electronic healthcare information such as FHIR (Fast Healthcare Interoperability Resources) have been introduced worldwide.

13 University of Tokyo press release, https://www.u-tokyo.ac.jp/focus/ja/press/z0110_00054.html

FFHIR is a new standard specification for medical information exchange developed by the HL7 Association in the U.S. It is attracting attention overseas as a highly mobile resource model, with features such as the ability to launch services in a short period of time and improved interoperability[14].

On the other hand, products that do not comply with standards are likely to be excluded from the collaboration platform. In addition, the competition to form platforms in the digital health field has accelerated in recent years, and the enclosure of users by each product and service may affect the realization of flexible and smooth data coordination in the future.

（４） Cybersecurity

As digital health becomes more widespread, the demand for security of the data being handled is expected to increase. In particular, cyber security will become an important issue for services via the Internet and the cloud.

（５） Speed of Implementation

In order to improve the ICT literacy of users, to secure the necessary budget, human resources, and systems in the facilities where digital health is introduced, and to clear the issues such as security assurance one by one, a mid- to long-term digital health introduction plan may be necessary. On the other hand, since the progress of digital health is constantly evolving, there is a risk that the digital health may have become obsolete by the time a decision is made to introduce and implement a certain digital health.

（６） New Divisions and Disparities

The spread of digital health is expected to contribute to a certain extent to those who have had difficulty in accessing healthcare, but it may also cause new fragmentation for those who do not have the necessary equipment and infrastructure. In its "Global strategy on digital health 2020-2025," the World Health Organization (WHO) states that the use of ICT in the medical field will benefit about one billion people. On the other hand, in the "Second round of the national pulse survey on continuity of essential health services during the COVID-19 pandemic," also conducted by WHO, it was found that the number of people affected by the COVID-19 pandemic was less than 10% of the 111 countries surveyed. On the other hand, in the "Second round of the national pulse survey on continuity of essential health services during the COVID-19 pandemic" conducted by WHO, about 68% of the 111 countries surveyed reported that "access to telemedicine by patients and health care workers is limited.

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[14] Ministry of Health, Labour and Welfare, Report of the Research Study on HL7FHIR, https://www.mhlw.go.jp/content/12600000/000708279.pdf

２． Japanese Digital Health Market and Impact of COVID-19

２－１． Recent Trends and Main Factors (Japan)

In Japan, there are growing expectations for the utilization of ICT in medicine as one of the solutions to various problems such as the increase in social security costs associated with the super-aging society, the shortage and uneven distribution of medical resources such as medical personnel, and the increasing burden in the medical field. Ministry of Internal Affairs and Communications (MIC) has been working on the establishment of the Electronic Health Record (EHR) infrastructure, the Personal Health Record (PHR) infrastructure, and the Medical Information and Communications Technology (MICS) infrastructure. In addition, we have developed an infrastructure that enables data sharing and linkage of data such as heart rate and other biometric data, maternal and child health handbook records, and medication records[15]. In addition, with the development and spread of AI and IoT technologies in recent years, Society 5.0 [16]proposed by the government aims to improve the efficiency of medical care and reduce medical costs through the analysis and utilization of big data using AI. In addition, the Health and Medical Care Strategy (March 2020), the Draft Growth Strategy Implementation Plan (July 2020), and other policies and policy proposals mention data sharing and utilization of health checkup information, utilization of IoT devices such as wearable terminals for health promotion, and expansion of online medical care.

Due to recent global technological development and domestic policy encouragement, various products and solutions have been developed and sold in the digital health field in Japan. Various devices, applications, and systems have been developed that have functions such as IoT terminals and wearable terminals that transfer measurement results from a measurement device to another devices or system, telemedicine (health consultation, health promotion, online medical interview and treatment, remote monitoring, etc.) for Doctor to Customer (DtoC) and Doctor to Patient (DtoP) (consultation and information sharing platform, remote image and pathological diagnosis, remote surgery, etc.), treatment support (digital medicine), e-learning (VR training, etc.), etc. Various devices, applications, and systems are being developed. In addition to these software, digital health is being used in a wide range of fields, including the development of hardware such as robots that patrol, guard, and clean the hospital premises.

[15] Ministry of Internal Affairs and Communications, https://www.soumu.go.jp/main_content/000518773.pdf
[16] Cabinet Office, https://www8.cao.go.jp/cstp/society5_0/

In Japan, too, the penetration rate of personal computers and smartphones is high, and the scale of the market for products and services using IoT technology is expanding[17], making the use of big data and AI technology a major trend, as it is worldwide. In particular, domestic companies are accelerating their R&D competition in the field of AI image diagnosis support. In addition, the use of AI in the fields of health promotion, medical questionnaires, and triage is beginning to spread.

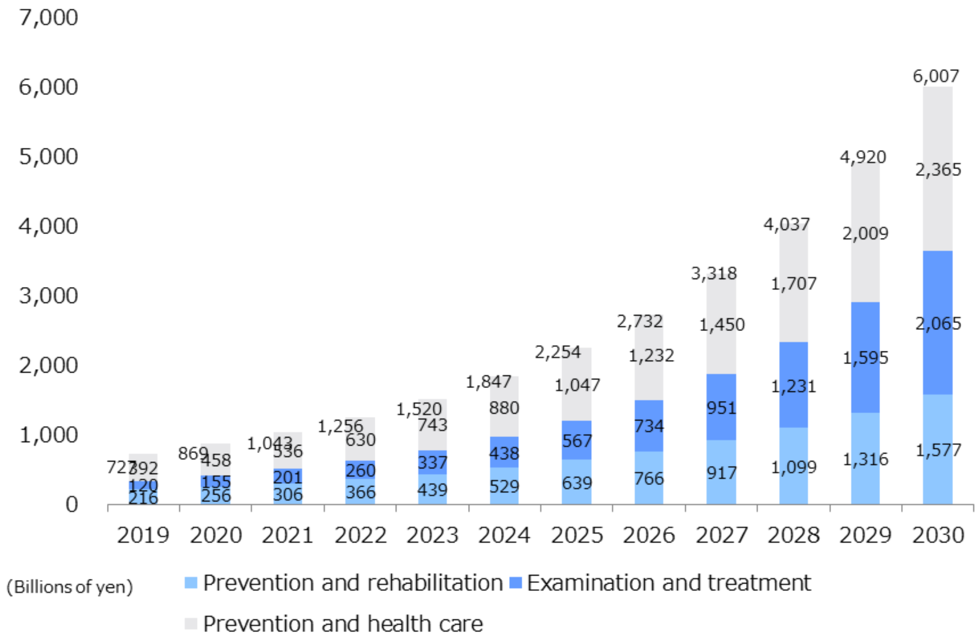


Figure II-4 Scale of the digital health market in Japan

Source: Nomura Research Institute, based on forecasts[18] to 2025 by IT Navigator 2020; forecasts to 2026-2030 (based on average annual growth rate) prepared by survey team

２－２． Impact of COVID-19 on Recent Trends (Japan)

As in the global market, the expansion of COVID-19 infection has led to increased demand for digital health in Japan. On the other hand, technical and institutional issues such as the lack of infrastructure for the use of digital health were highlighted.

（１） Accelerate DX in the Healthcare Sector

As with global trends, the spread of COVID-19 infection has created new demand for non-contact and unattended care. The introduction of online medical services, which already

[17] Nomura Research Institute, IT Navigator 2020 Edition

[18] From the IT Navigator 2020 edition, "the market will cover medical and healthcare solutions and services using equipment and ICT solutions. The market will not include the sales market for medical device such as CTs and MRIs, electronic medical records and other conventional ICT platforms for healthcare, or robots.

existed, has expanded due to temporary deregulation. In addition, automatic temperature monitoring devices using AI, automatic medical interviewing and sorting of COVID-19 patients using chatbot applications, non-contact patient monitoring terminals, and autonomous transport robots are newly attracting attention.

（２） Increasing Demand for Infrastructure Development, including Legal and Regulatory Development and Data Collaboration

With regard to the deregulation of online medical services in Japan, the government is currently studying the possibility of switching from a temporary measure to a permanent one[19]. In addition, demand for the construction of a data collaboration infrastructure is increasing as issues such as the delay in digitization and the increase in the workload in the medical field as a whole have been exposed, such as the use offaxes for reporting COVID-19 positive patients by medical facilities nationwide[20].

２－３． Health Tech Map (Japan)

The following map shows the technology types of major solutions in the Japanese digital health market, including solutions that have existed in the market for a long time and solutions that are attracting attention due to the spread of COVID-19 infection.

The horizontal axis shows the major flow from disease prevention to treatment and follow-up, and the vertical axis shows the main target users of each technology. In the area where the vertical axis and the horizontal axis intersect, the technology types of digital health solutions that are mainly used are mapped.

In order to understand the overview and trends of each technology category, the survey team randomly selected Japanese digital health companies and their solutions belonging to each technology category and interviewed them individually. In the process of categorization, a long list of about 250 digital health companies in Japan was created based on the desktop survey, and the solutions of each company were grouped by technology type. (For the use cases of each technology type based on the desktop survey and individual interviews, please refer to Appendix 4.)

[19] m3.com, https://www.m3.com/news/open/iryoishin/935391
[20] Information and Communication Technology Strategy Office, Cabinet Secretariat, Promotion of Digitalization, October 9, 2020

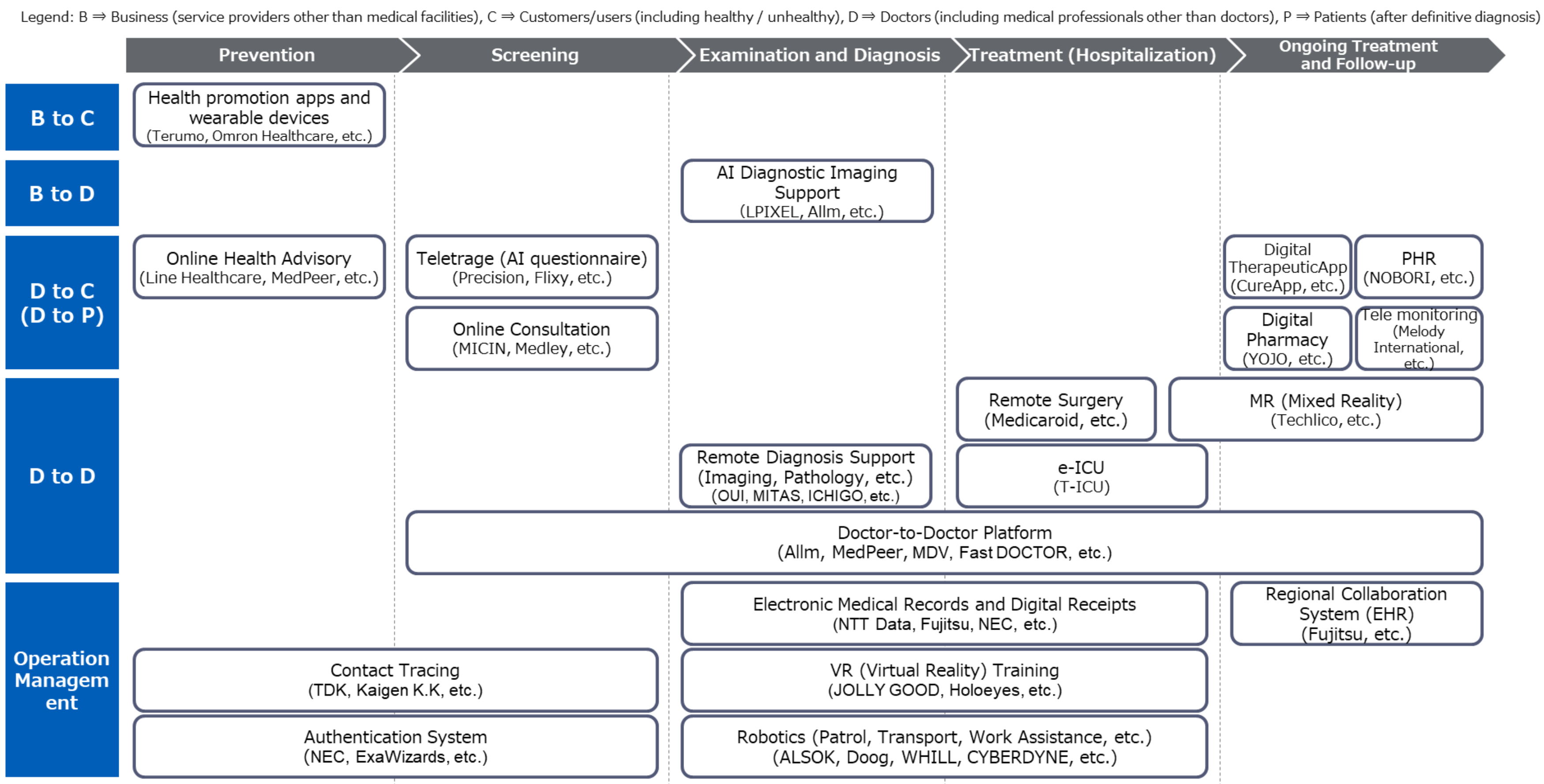


Figure II-5 Health Tech Map (Japan)

Source: Compiled by survey team

In Japan, there is a wide distribution of solutions used for DtoC, DtoP, DtoD, and operation management. In particular, for solutions that are used both inside and outside of medical facilities, such as DtoD and operation management, there are solutions that contribute to data management, collaboration, operational efficiency, and load reduction among different professions and facilities.

２－４． Future Prospects in the digital health market (Japan)

In response to the major demands (=medical issues) in Japan, the following digital health areas are expected to grow in the future[21].

（１） Automation and efficiency (AI, etc.)

Against the backdrop of regional disparities in medical services, shortages and uneven distribution of medical human resources, and issues such as the increasing workload of medical personnel, the following trends can be seen.

- Accelerated competition in the development of AI diagnostic imaging support and expansion of disease areas
- Automation of testing equipment, drug preparation equipment, etc.
- Reduction of workload for medical personnel through AI questionnaires, etc.
- Remote monitoring, automatic alerts, etc. to reduce staffing and workload

（２） Remote Medicine

In response to the uneven distribution of medical personnel to urban areas and depopulation of rural areas, and the increasing demand for non-contact and non-face-to-face services against the backdrop of COVID-19, the following trends can be seen in telemedicine services.

- Government study on making online medical treatment deregulation permanent
- Increased demand for online medical care based on complex information (quality assurance of medical care through the use of remotely accessible devices, etc.)
- Trend toward expansion of application areas to include telehealth medical consultation (prevention), treatment progress and disease management, various types of guidance, and treatment (rehabilitation, etc.)
- Increase in product development using VR and MR
- Development and launch of domestically produced surgical assist robots and expansion of insurance coverage.

[21] In: Hiroaki Kato (ed.), Digital Health Trends 2021: 100 Companies' Initiatives for the "Healthcare 4.0" Era (2021).

（３） Individualization

In addition to the recent rise in health consciousness, there is an increasing demand for post-treatment follow-up for the increasing number of lifestyle-related diseases, and there is a growing demand for individualized follow-up programs for users and individual patients using applications.

- With the advent of AI-based health promotion support applications and therapeutic applications (digital medicine), etc., it is possible to provide timely and appropriate follow-up and treatment according to the behavioral history, etc., of individual users. Promotion of behavioral change, continuation of treatment, and improvement of effectiveness of treatment by setting up treatment programs and giving advice based on the recorded information of each patient, etc.
- Target disease areas for therapeutic applications are expanding
- In Japan, therapeutic applications will be approved and covered by the Pharmaceutical Affairs Law for the first time in 2020 (in the U.S., Welldoc received approval for therapeutic applications in 2010).

（４） Data Collaboration and Utilization

With the increasing demand for telemedicine, the demand for information sharing and management among facilities and personnel is increasing. In addition, from the perspective of controlling the increasing social security costs, sharing and interoperability of personal patient information (medical information, prescription history, etc.) among facilities and personnel to avoid duplication of medical services provided to a single patient is expected to lead to the provision of efficient and effective medical services to patients and, consequently, to the control of social security costs. This is expected to lead to the provision of efficient and effective medical services to patients and, consequently, to the reduction of social security costs. Against this background, the following trends can be seen in terms of data coordination and utilization.

- With the spread of telemedicine, there will be an increase in demand for seamless transition and collaboration in treatment, guidance, prescription, and follow-up after consultation.
- With the rise in health consciousness and the spread of wearable devices, demand is increasing for the coordination and utilization of data managed by individuals and organizations, and for the optimization of medical costs through the efficient provision of medical care (prevention of duplication of care, etc.)
- With the rise in awareness of personal information, there is an increase in demand for the introduction of infrastructure and systems that allow patients to view and manage their personal information, such as medical information, which was originally stored at medical facilities. This will reignite demand for PHR and EHR.

２－５. Future Challenges in the Digital Health Market (Japan)

There are many areas where the system, infrastructure, and legal regulations for the development, dissemination, and utilization of digital health are not yet in place, and there are concerns that this will have no small impact on the growth of the digital health market in Japan.

（１） ICT literacy

Similar to the global trends described in "1-4. Future issues in the digital health market (global)," users need to acquire appropriate knowledge and skills as various digital health products appear in the future. It is necessary to consider the user interface and user experience to be intuitive and easy to use for users.

（２） Human Resources and Structure

While the development of digital health is accelerating, inadequate systems on the user side may become a barrier to the diffusion of digital health products and technologies in society as a whole. In Japan, most of the Information Technology (IT) engineers are employed by IT providers, and the IT personnel belonging to the user side (companies using services, medical facilities, etc.) account for less than 30% of the total[22]. Comparedto other countries such as the U.S. (65%) and the Federal Republic of Germany (61%)[23], the number of specialized human resources on the user side is currently low.

（３） Data Coordination

If common specifications and data linkage procedures are not in place among products and solutions, there are technical issues such as not necessarily smooth data linkage. In Japan, the specifications often differ from vendor to vendor, so the demand for data standardization from the user side is expected to increase in the future. In Japan, more than 200 EHR infrastructures such as regional medical cooperation networks[24] have already been introduced, but in many cases, information is only shared within a very limited network in the region. In many cases, however, the information sharing is limited to a very limited network in the region. In addition, there are many issues to be addressed, such as the fact that many EHR infrastructures were developed with the support of subsidies from the national and local governments, and may become difficult to operate when the subsidy period ends[25]. As there is a limit to the amount of money that can be spent by the participants in such a network, there are high

[22] Information Technology Promotion Agency, IT Human Resources White Paper 2019, May 10, 2019
[23] McKinsey & Company, The Nature of the Digital Revolution: A Message to Japan's Leaders, September 2020
[24] Ministry of Health, Labour and Welfare, https://www.mhlw.go.jp/content/10808000/000644575.pdf
[25] InterSystems Japan Corporation, Challenges in Medical Information Collaboration in Japan and InterSystems' Solutions

expectations for the development of a government-led information coordination infrastructure. However, as of February 2021, the penetration rate of online eligibility verification was less than 30% (less than half of the target).[26]

（４） Cybersecurity

As with global trends, the proliferation of digital health is expected to increase the demand for security of the data being handled.

（５） Speed of Implementation

As with the global trend, the introduction of digital health may require a mid- to long-term implementation plan, but even if digital health is introduced in accordance with the implementation plan, the rapidly advancing digital health may already be obsolete at the stage of introduction.

（６） Related laws and Regulations

The institutional barriers to the development and introduction of advanced technologies are higher than in other fields, such as the need for strict personal information protection and security management based on the revised Personal Information Protection Law and the Next Generation Medical Infrastructure Law, and the complicated procedures for filing and renewing pharmaceutical applications in the case of technologies for therapeutic purposes. In addition, there are cases where it is difficult to understand how to handle and operate existing systems for new technologies, which may result in delays in government decisions and R&D.

（７） Fundraising

It is pointed out that the supply of risk money to Japanese start-ups in the healthcare sector is insufficient[27]. In 2018, the amount of investment in digital health-related start-ups in the U.S. was about 100 times greater than in Japan, and the amount of investment in Europe and China was about 15 times greater than in Japan[28]. In 2018, the amount of investment in digital health-related startups in the U.S. was about 100 times greater than in Japan, and in Europe and China, the amount of investment was about 15 times greater than in Japan. In particular, R&D startups often require large-scale funding in their initial stages, so it is necessary to improve the

[26] Ministry of Health, Labour and Welfare, Status of Online Eligibility Verification and Other Systems, February 12, 2021
[27] Ministry of Economy, Trade and Industry, 1st New Business Creation WG Secretariat Presentation Material (Future Policy Direction), January 29, 2021
[28] Ministry of Economy, Trade and Industry, Interim Report of the Study Group on Promoting Private Sector Investment in the Utilization of Health and Medical Information (Healthcare IT Study Group), https://www.meti.go.jp/report/whitepaper/data/pdf/20180427001_02.pdf

funding and growth environment for these startups.

２－６． Challenges of Overseas Expansion by Japanese Digital Health Companies

According to the results of interviews with about 30 digital health companies, most of the companies recognize local laws and regulations, local ICT infrastructure, and business feasibility (difficulty of monetization in developing countries) as barriers to the overseas deployment of Japanese digital health, and are seeking support measures to overcome these barriers. In addition, the interviews were conducted with a number of companies. Among the digital health companies interviewed, this report focuses on the opinions of companies that have experience or interest in overseas development. In addition to Japanese digital health companies, the survey team also interviewed domestic consulting companies that support the overseas development of such companies and domestic venture capital (VC) that support start-up companies in the digital health field to extract issues from various perspectives.

（１） Laws and Regulations

In **Japan, even if a product or solution is not directly related to medical treatment to avoid violating medical laws, it is necessary to check whether the same content is covered by local medical laws and regulations.** Especially in the case of equipment products (especially medical devices), import/export regulations, local sales permits, and necessary procedures in Japan and other countries have a significant impact on the lead time of the introduction, so confirmation is necessary.

（２） Communication Infrastructure

In the case of products and solutions that require communication, it is necessary to confirm the existence and status of the local communication infrastructure (base stations, etc.). (One company that the survey team interviewed had installed a base station as part of a local government project, and introduced the product after the necessary infrastructure was in place.)

In some cases, it is very difficult to collect medical information from local medical facilities. In some countries, patient medical information is rarely digitized, so it may be difficult to implement applications and systems, or they may not be effective even if implemented.

（３） Local Partner

The presence or absence of a local company that can be a partner will greatly affect the subsequent business development. Access to local hospital locations and medical information is difficult for Japanese companies alone, and may require the intervention of local companies. In cases where the local regulatory ministries are vertically divided, it is difficult to determine which department to communicate with, which may result in a roundabout way of proceeding.

（４） Business Feasibility

Considering the local price level and other factors, there may not be much business potential. Monetization is particularly difficult for businesses targeting the BOP segment. Unless the product or solution is something that other companies cannot follow, even if you take the trouble to develop it locally, there is a possibility that it will be imitated and will not be viable as a business.

（５） Scalability

In terms of efficiency, it is important to introduce the system to multiple facilities. In addition, it is necessary to consider how to expand the project in Japan and overseas.

（６） Human Resource

While domestic startups (especially those in the early stages of growth, such as those near the Series A stage of the investment round, where the amount raised is in the millions to tens of millions of yen) are likely to be interested in overseas expansion, startups generally place the highest priority on domestic listings and focus on advancing the business plan agreed upon with investors. In general, however, startups are focused on domestic listings as their top priority, and are focused on advancing the business plan they have agreed upon with investors. Therefore, it is difficult for them to respond flexibly to expansion into countries and regions that are not in their plans. In particular, research and development start-ups are generally short on manpower, making it difficult to allocate more manpower. Even if a startup company sees the business potential in overseas expansion and prepares for future expansion, the hurdle of securing additional funding is high. If investors (domestic institutions, etc.) provide funds at such a stage, it may be easier for startups to move forward. Some investors cannot ignore the social impact perspective, which adds to the process of impact evaluation and makes it difficult to move flexibly. In addition, since social impact is a medium- to long-term perspective, it is a high hurdle for companies such as start-ups that want to recover their investment in the short to medium term.

（７） Maintenance

If you don't have your own factory in the local area or neighboring countries, the main way to sell and introduce your products is by exporting them, but it is not easy to provide maintenance services. However, it is not easy to provide maintenance services, and in some cases, if a product malfunctions, it may have to be purchased again.

III. Overview in Brazil

III. Overview in Brazil

A. Perspective of Target Country

A－１. General Information

（１） Economic Situation

The growth rate of Gross Domestic Product (GDP) in recent years has been low, and there are concerns about further negative growth due to COVID-19. In 2019, GDP will be US$1,839.758 billion, GDP growth rate will be 1.1%, and GDP per capita will be US$8,717.2. GDP growth rate has been declining since its peak in 2010. After peaking in 2010, the GDP growth rate has been on a downward trend, with both GDP growth rate and GDP falling sharply in 2015-2016 and remaining at low levels since then. There is a large gap between the rich and the poor, and according to Japan's Ministry of Foreign Affairs, the country has an extremely high crime rate. There are concerns that the spread of COVID-19 infection will have an impact on the widening the gap between the rich and the poor. According to the "World Economic Outlook[29]" released by the International Monetary Fund (IMF) in October 2020, the forecast for Brazil's real GDP growth rate in 2020 is -5.8%, the smallest among the major Latin American countries. Compared to the Republic of Peru (-13.9%), the Republic of Colombia (-8.2%), and the Republic of Chile (-6%), where a curfew was imposed, the extent of economic contraction is small.

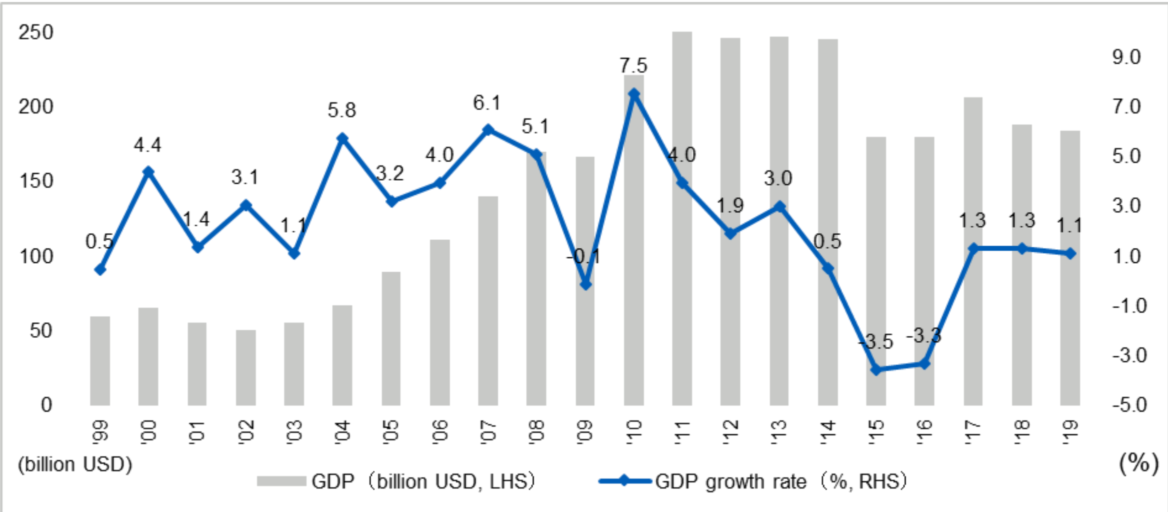


Figure III-1 GDP (US$) and GDP Growth Rate in Brazil

Source: Compiled by survey team based on World Bank, DataBank, and World Development Indicators

29 IMF, World Economic Outlook, October 2020, https://www.imf.org/ja/Publications/WEO/Issues/2020/09/30/world-economic-outlook-october-2020

（２） Population Movements

The population is growing steadily, but is experiencing a declining birthrate and aging trend.

In 2019, Brazil's total population was 211,049,000, with a population growth rate of 0.8%. The population is growing steadily, but the population pyramid shows a trend toward a relatively low birthrate and aging population, with a decrease in the number of young people over the past 20 years. In Rio de Janeiro, the number of deaths has exceeded the number of births for six consecutive months due to the spread of COVID-19 infection[30].

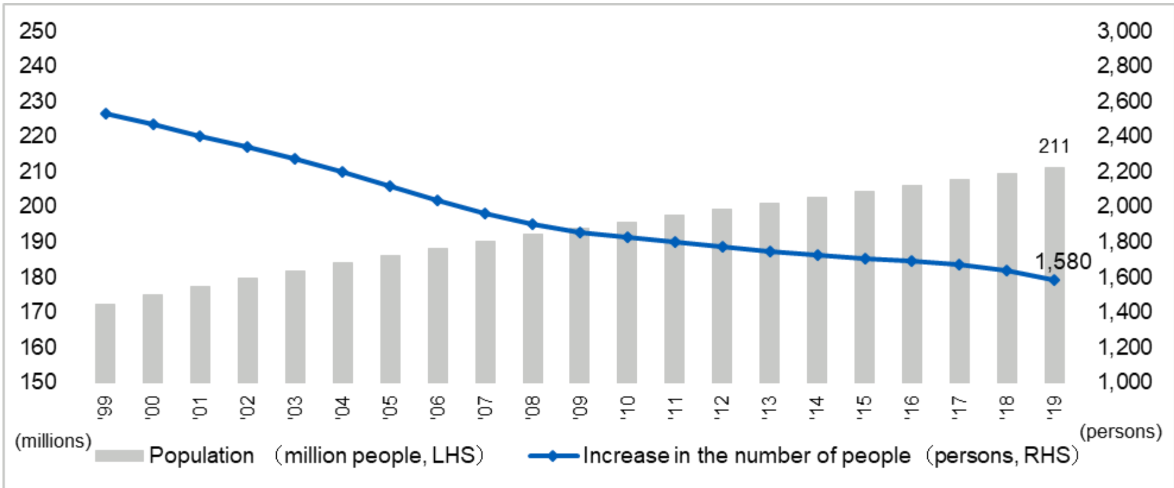


Figure III-2 Total population and population growth in Brazil

Source: Compiled by survey team based on World Bank, DataBank, and World Development Indicators

30 CNN, https://www.cnn.co.jp/world/35169329.html, (accessed Sep,6,2021)

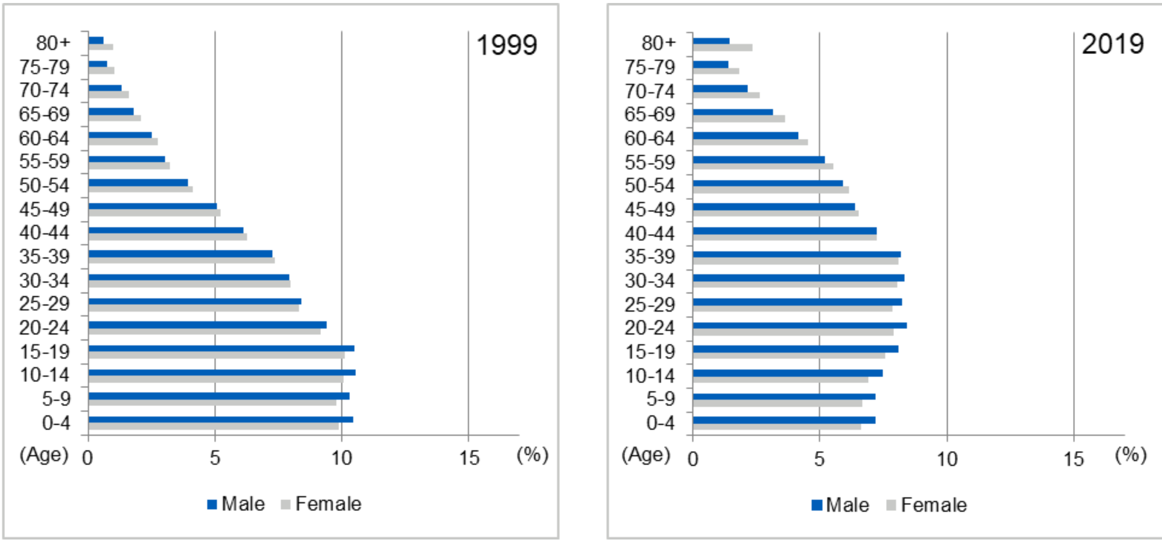


Figure III-3 Population pyramid in Brazil

Source: Compiled by survey team based on World Bank, DataBank, and World Development Indicators

A—２． COVID-19 Situation

The pandemic in Brazil was more severe than in the world as a whole. The mortality rate of patients is high due to the high obesity rate in the country. With the spread of the vaccine, the number of infections and deaths started to decrease, but as of February 2022, the number of infections has increased due to the mutant strain Omicron. As of February 16, 2022, the cumulative number of infected people is the highest in the world after the United States of America (USA), the Republic of India, and the United Kingdom. The World Obesity Federation (WOF) has published a study on the causal relationship between COVID-19 mortality and obesity rates[31]. According to the study, 17% of Brazilians are obese, and lack of exercise and weakened immunity may have an impact on COVID-19 mortality.

Currently, there is concern about the spread of the Omicron strain and an increase in cases of "flurona", a simultaneous infection with COVID-19 and influenza. In Brazil, as of February 16, 2022, a cumulative total of 27,538,503 cases of COVID-19 638,835 deaths, and average of 134,130 new infections paer day have been reported. The cumulative number of infections per million is 107,065, which ranks 75th out of 223 countries in the world, and is relatively high.[32].

[31] Nihon Keizai Shimbun, https://www.nikkei.com/article/DGXZQOGR04EII0U1A300C2000000/
[32] https://www.worldometers.info/coronavirus/#countries

Vaccination is lagging behind the original plan, but as of January 2022, approximately 78% of the population aged 18 years and older had received two doses of vaccine. The vaccination has been available in Brazil since January 17, 2021[33]. The government has already contracted with manufacturers for 370 million doses of vaccines, mainly from AstraZeneca, Pfizer, and Johnson & Johnson. In addition, the Butantan Institute of the State of Sao Paulo is developing a new vaccine that is 100% domestically produced, including the raw materials, and has announced plans to start vaccinating people in Brazil in the second half of 2021. The presidential administration, which promotes vaccines made in Europe and the United States of America, and the People's Republic of China, which insists on using vaccines made in Sao Paulo. On the other hand, the Brazilian government is promoting the use of the vaccine calendar to its citizens through an application called Conecte SUS Cidadão. Details are described later in "A-3. (1) COVID-19-related Policies.On August 27, 2021, the government of Sao Paulo promulgated Municipal Decree No. 60.488[34], which provides for the introduction of a vaccine passport system. The decree went into effect immediately, and from September 1, 2021, anyone attending a musical event, conference, sports game, or any other event where more than 500 people gather will be required to present a vaccine passport with proof of at least the first dose of vaccination[35].

As of February 16, 2022, 71% of the total population had completed two doses of vaccination, and more than 82% had completed at least one dose. Only about 26% have completed booster vaccinations[36].

[33] JETRO, https://www.jetro.go.jp/biznews/2021/03/358eeb07f43f7fc0.html
[34] City of Sao Paulo, http://legislacao.prefeitura.sp.gov.br/leis/decreto-60488-de-27-de-agosto-de-2021
[35] JETRO, https://medical.nikkeibp.co.jp/leaf/mem/pub/report/t344/202108/571336.html
[36] https://ourworldindata.org/covid-vaccinations?country=BRA

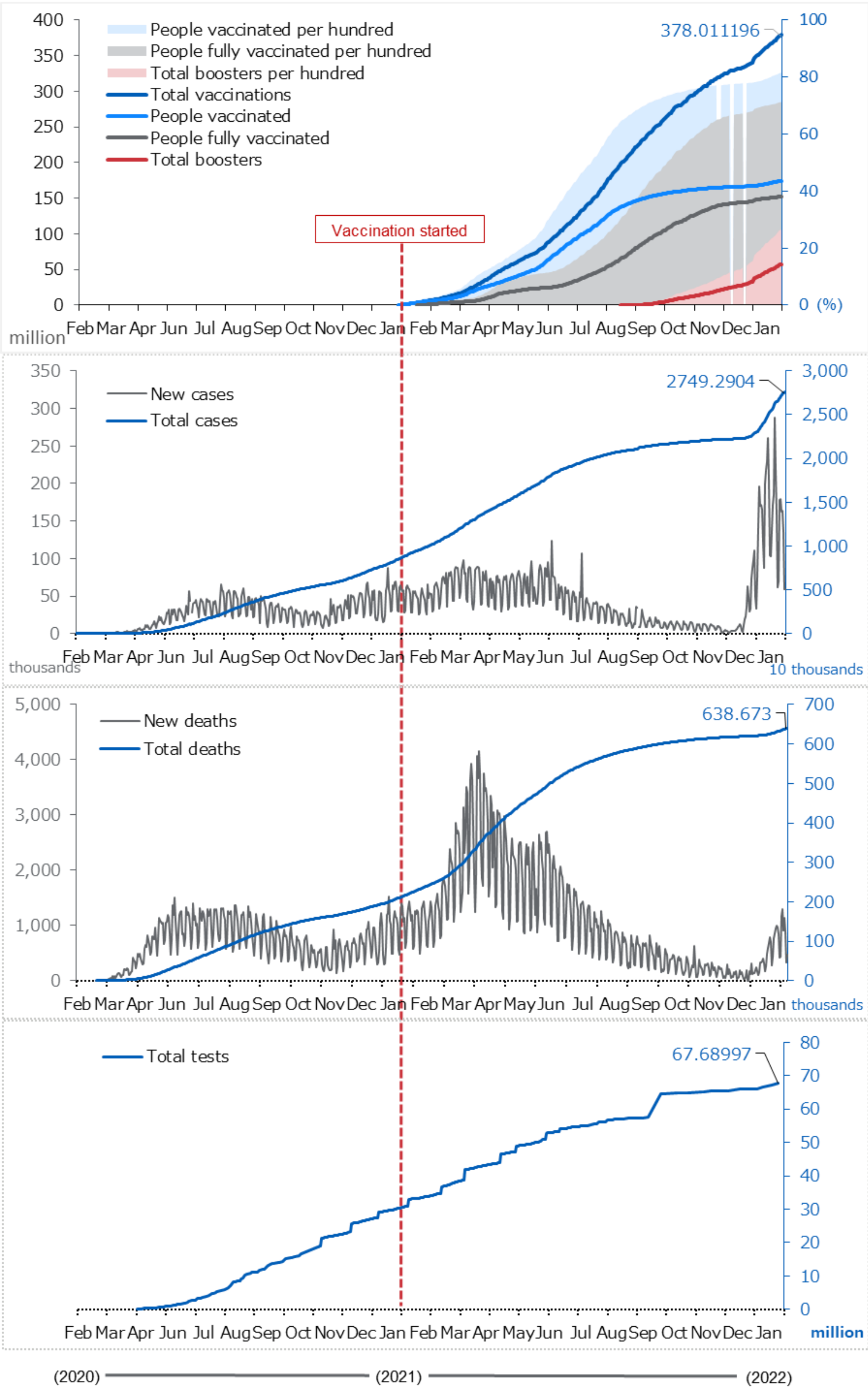


Figure III-4 COVID-19 infection and vaccination status in Brazil

Source: Compiled by survey team based on Our World in Data.

A－３．Health Care Policy, Digital Health-related Policy, COVID-19-related Policy

（１） Health Care Policy

The national unified health care system (Sistema Único de Saúde: SUS) has been established. The goal is to improve access to primary and specialized medical care based on the SUS. In addition, the system of tertiary medical information coordination based on SUS is being developed and its scope is being expanded.

The SUS is a national health insurance system established in 1988 by Article 198 of the Federal Constitution, and is financed by taxes. The SUS consists of three federations: the federal government (Ministry of Health), the provinces, and the local governments[37], each of which is jointly responsible for providing free medical services to all citizens at public medical facilities and private medical facilities under contract with the government[38]. The computer systems division of SUS, called DATASUS, has two servers in Rio de Janeiro and Brasilia, and is responsible for storing and managing medical information for all Brazilians.

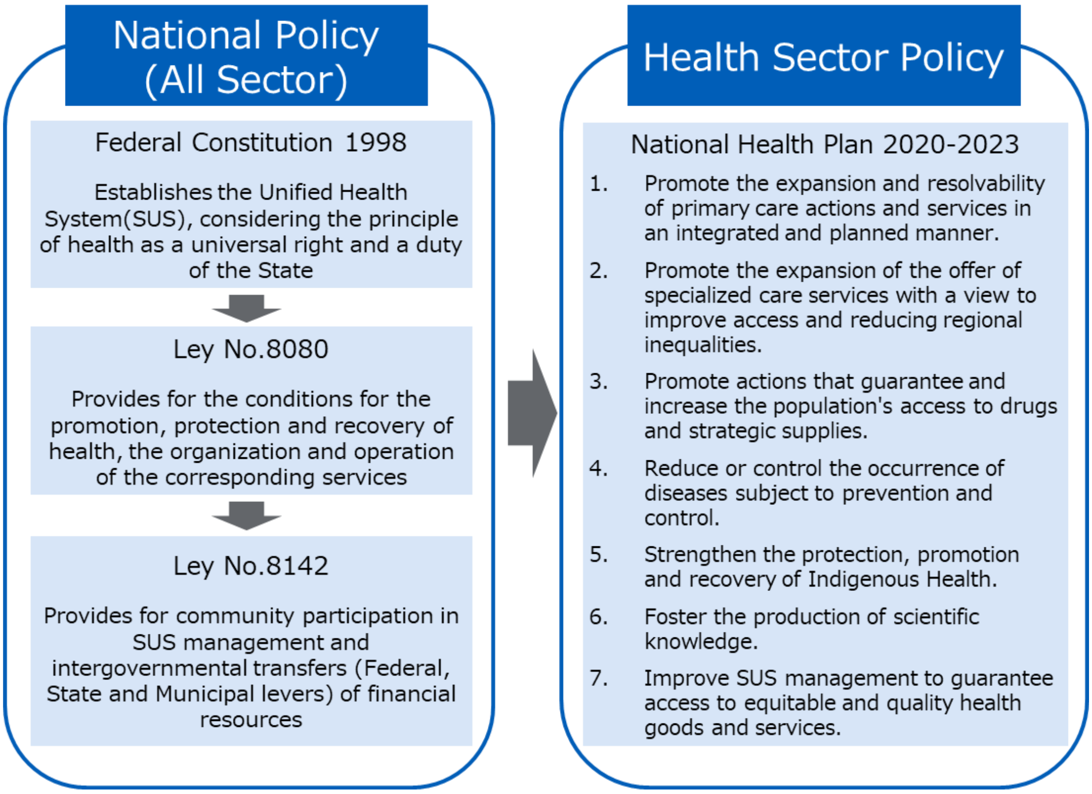


Figure III-5 Overview of Health Policies and Strategies in Brazil

Source: Compiled by survey team

37 Brazilian Ministry of Health, https://antigo.saude.gov.br/sistema-unico-de-saude

38 Ministry of Economy, Trade and Industry (METI), International Medical Development Country Report (Brazil), March 2021 Available at: https://www.meti.go.jp/policy/mono_info_service/healthcare/iryou/downloadfiles/pdf/countryreport_Brazil.pdf

１） National Health Plan (2020-2023)

It provides guidelines for planning, monitoring, and evaluating the policies and programs of the Ministry of Health, and establishes guidelines, priorities, goals, and indicators for the period 2020-2023 to guide federal actions in the coordination of the SUS. The main goals are as follows.

1. Promote expansion of primary health care services
2. Promote expansion of specialized medical services, improve access to healthcare, and reduce regional disparities
3. Promote timely access to medicines and materials with quality and safety
4. Promote development and public access to advanced medical technologies
5. Reduce and control the incidence of preventable diseases.
6. Strengthen health promotion, etc. of indigenous peoples
7. Improving SUS management (providing fair and quality medical products, improving access to services)

２） Other Major Themes

- Maternal and Child Health Network
  It aims to ensure an appropriate flow of family planning, birth and child care, postpartum, and early childhood care in order to provide quality care and address maternal and fetal mortality. The program is coordinated with federal and state government programs, among others.
- Emergency Medical Network
  The goal is to provide comprehensive and timely access to health care for patients who require urgent care.
- Medical network for patients with chronic diseases
  It consists of regional services for malignant neoplasms, obesity, diabetic medical support, etc.

（２） Digital health-related Policy

With the expansion of COVID-19 infection, the demand for data integration and interoperability is increasing, and the spread of digital health is expected to be further promoted.

１） National Policy on Medical Information and Informatics (Política Nacional de Informação e Informática em Saúde: PNIIS) (2015)

It targets public and private medical facilities and facilities related to the Ministry of Health in SUS, and aims to promote the use of information technology and interoperability.

２） e-Health Strategy (A Estratégia de Saúde Digital e a COVID-19) (Brazilian e-Health Strategy (created in 2017), revised in 2020)

The report describes 9 strategic action plans, including strengthening the governance of digital health strategy promotion, developing a legal framework for the strategy, and facilitating access to medical information by the public.

３） Supervisory Assessment Plan for Digital Health Activities (Plano de Ação, Monitoramento e Avaliação: PAM& A) (2019-2023) [39]

・ Connect SUS Program (Programa Conecte SUS) (2020)

It was enacted mainly against the backdrop of increased demand for data integration and interoperability due to the expansion of COVID-19 infection in Brazil. Within the framework of the SUS, it aims to promote the digitization of medical information and to establish and strengthen information coordination among different medical areas, including primary, and between public and private medical facilities. In addition, the Digital Health Education Program, which is part of the program, promotes the development of human resources for digital health, including a qualification system for medical professionals who use medical information.

・ National Health Data Network (Rede Nacional de Dados em Saúde: RNDS) (2020)

It is a nationwide medical information interoperability platform to realize Connect SUS. It is designed to receive, store, use, access, and analyze medical information from public and private medical facilities, and aims to connect all 27 states in Brazil with the platform by 2023[40].

４） Digital Health Strategy in Brazil (Estratégia de Saúde Digital para o Brasil 2020-2028: ESD28) (2020-2028) [41]

This is a continuation of the above PAM&A, which is mainly composed of the following three axes for digital health.

・ Strategic Vision

In particular, by strengthening, integrating, and expanding Connect SUS and RNDS, the strategy aims to connect all medical facilities to RNDS in all states and municipalities, and to expand the quantity and quality of medical services, including primary care.

・ Action Plan

It aims to establish a framework of relevant laws, regulations, governance, etc. that will enable collaboration among facilities. It also aims to identify ongoing domestic innovation initiatives,

[39] Brazilian Ministry of Health, https://www.gov.br/saude/pt-br/assuntos/saude-digital/a-estrategia-brasileira/PlanodeAoMonitoramentoeAvaliao.pdf
[40] Brazilian Ministry of Health, https://www.gov.br/saude/pt-br/assuntos/rnds
[41] Brazilian Ministry of Health, https://bvsms.saude.gov.br/bvs/publicacoes/estrategia_saude_digital_Brasil.pdf

identify international initiatives, and strengthen cooperation.

- Management and evaluation plan

It aims to develop a technical environment that promotes effective collaboration among facilities.

５） Digital Health-related Policies by Local Governments

In this project, the survey team researched the efforts of the local government to promote digital health and related fields, mainly in the cities where the medical facilities that responded the online questionnaire as described in A-7 and the local medical facilities that were the final candidates for PoC implementation belong. The following is a list of digital health-related policies and initiatives implemented by local governments.

(a) Initiatives in Juiz de Fora, Minas Gerais

In the city of Juiz de Fora, where Hospital Santa Casa de Juiz de Fora is located, there is an innovation and technology transfer center (Centro de Inovação e Transferência de Tecnologia: Critt), although it is not limited to digital health. The center was established in April 1995 and is a technology innovation center of the Federal University of Juiz de Fora (UFJF). The center manages UFJF's innovation policy and coordinates technology-based incubators, and introduces UFJF's projects to companies seeking advice on new product development and production process improvement in various fields. In addition to contributing to the economic development of the region, UFJF also contributes to social development, the spread of clean technology, and environmental protection and care for nature.

Currently, Critt is a partner in the following development and research organizations.

- National Science and Technology Development Council (CNPq)
- National Association for the Promotion of Innovative Enterprises (Anprotec)
- Financier of Studies and Projects (Finep)
- Minas Gerais State Research Support Foundation (Fapemig)
- National Institute of Industrial Property (INPI)
- Innovation Network of the State of Minas Gerais (RMI)
- Brazil SME Support Services (Sebrae/MG)

(b) Initiatives in Recife, Pernambuco

In the city of Recife, where the Hospital das Clínicas da Universidade Federal de Pernambuco (HCUFPE) is located, similarly to the city of Juiz de Fora, there is an initiative to promote the growth of the ICT sector in the region, although it is not limited to digital health. In order to promote the growth of the ICT sector in the region, the city of Recife, like the city of Juiz de Fora, offers tax incentives for the Imposto sobre Serviços de Qualquer

Natureza (ISSQN), a tax on services of any nature, as stipulated in Municipal Law n. 17244/2006. It provides tax incentives to companies that provide (i) IT and similar services, including educational services and certification of IT products, and (ii) services related to remote customer relationship functions through exchanges that handle large volumes of incoming or outgoing calls.

(c) Initiatives in Rio de Janeiro, State of Rio de Janeiro

In the city of Rio de Janeiro, where Complexo Hospitalar e da Saúde da Universidade Federal do Rio de Janeiro is located, the UFRJ Technological Park has been established. The park is an innovation environment within the Universidade Federal do Rio de Janeiro (UFRJ). Opened in 2003, the park houses research centers of major national and foreign companies, small and medium-sized start-ups, spaces for entrepreneurship development and integration, and UFRJ laboratories, etc. In this environment, companies can gain the infrastructure and expertise they need to overcome their business challenges. The center is not a facility limited to digital health, but a mechanism for co-creation in multiple fields is in place.

(d) Initiatives in São Bernardo do Campo, São Paulo

The city of São Bernardo do Campo has a law, Municipal Law Nº.6243 , of December 26, 2012, which provides for the establishment of a municipal program to encourage technological innovation. This law provides for the establishment of technology parks in the region and incentives for technological development.

(e) Initiatives in Campinas, São Paulo

In **the city of Campinas, where the Universidade Estadual de Campinas - Hospital de Clinicas is located, the Technology Parks of Campinas have been established.** The park is a project that promotes science, technology and innovation, providing opportunities for companies to commercialize their research and connecting the academic sector (universities and research centers) with the industrial sector (general companies). An environment conducive to the development of technology-based companies and the dissemination of science, technology, and innovation encourages synergies of experience among companies and increases their competitiveness.

(f) Initiatives in Atibaia, São Paulo

In the municipality of Atibaia, where Hospital Novo Atibaia SA is located, the Law on Complementary Municipalities of December 20, 2013（complementary municipal law Nº.678/13） established the Municipal System of Innovation and Tax Incentives, which aims to encourage scientific and technological research in productive environments,

develop and improve human resources, and encourage technology-based entrepreneurship. Under this system, the following local tax incentives are exempted for 10 years.

Taxes and fees imposed on real estate

- Real estate transfer tax (Imposto sobre Transmissão de Bens Imóveis, ITBI) imposed on the acquisition of real estate.
- Tax on urban real estate and land (Imposto Predial e Territorial Urbano: IPTU)
- Costs associated with project approval
- Inspection fees for issuing permits
- Permit issuance fee
- Taxes and fees imposed on activities
- Fees for issuing business licenses and location permits
- Inspection fees for issuing permits
- Advertising expenses
- Tax on all services (ISSQN)

（３） COVID-19-related Policy

In response to increasing demand for medical information coordination and interoperability throughout the country against the backdrop of the spread of COVID-19 infection, efforts are being made to promote the establishment and introduction of the Connect SUS program and RNDS. Applications are being used for information dissemination and vaccination promotion, and ICT is being used as a countermeasure against COVID-19.

１） Introduction of a Nationwide Medical Information Interoperability Platform (RNDS)

The Connect SUS program and the promotion of RNDS implementation in PAM&A 2019-2023 were partially changed from the original plan to meet the increased demand for information linkage in the context of the expansion of COVID-19 infection in the country. As of October 2020, approximately 3.7 million test results from 66 research institutes in Brazil have been integrated.

２） Introduction of the "Coronavirus SUS" Application (Aplicativo Coronavírus SUS)

As part of the aforementioned Connect SUS program, it provides information on COVID-19 countermeasures and prevention, as well as a function for self-checking of health status through a simple questionnaire. Since its release in February 2020, it has been downloaded more than 4 million times.

３） Introduction of "Connect SUS Citizen" Application (Conecte SUS Cidadão)

Through the app, users can access COVID-19 clinical test results and vaccine calendars from public and private institutions that have been integrated into the RNDS.

４） Emergency Aid

The government has started paying R$600 (≒US$110.9) per month in emergency assistance to informal workers, individual entrepreneurs, and others who will be severely affected by COVID-19, starting April 2020. The provisional measure (Provisional Measure Nº.1000/2020) extends the emergency assistance until the end of 2020. In addition, as a measure for SMEs, the FAT's Program for Employment and Income Generation (PROGER) has established R$5 billion (≒US$924,477,000) credit line to provide loans mainly to the tourism, export, and innovation sectors.

５） Restrictions on Economic Activity

Extensive social distance was secured early on by closing facilities, parks, theaters, cinemas, markets, and canceling events that attract large numbers of people.

The state of Sao Paulo has removed restrictions on the hours of operation of commercial facilities such as shopping malls, bars, and restaurants from August 17, 2021, as the figures related to infection are improving. The city of Sao Paulo has decided to require a vaccination certificate (at least one dose) to be presented at events with more than 500 people, such as live music events and soccer matches, starting September 1, 2021[42].

６） Deregulation of Pharmaceutical Imports

In order to expedite the registration of COVID-19 related products, the normal import permit process will be suspended, and a temporary permit process will be established for COVID-19 related products, with a special quota of up to six months for the import process. The definition of the targeted products are as follows;

- Products intended for surveillance, diagnosis, prevention or treatment to meet the health demands of COVID-19.
- Daily necessities that are difficult to obtain or are in short supply in the domestic market due to the spread of COVID-19

According to the National Health Surveillance Agency (ANVISA), the import process for all products related to the diagnosis of COVID-19 is prioritized, but the time required for the process depends on both the information provided by the companies and the number of orders received. If

[42] Jetro, Basic Information for Normalization of Business Activities, https://www.jetro.go.jp/ext_images/world/covid-19/cs_america/matome/br.pdf, September 7, 2021

the established criteria are met, the average time for evaluation is about one to two weeks, but the number of registered companies is large and that time is reported to be fluid.

７） Establishment of COVID-19 Ombudsman Channel

In March 2020, the Comptroller and Auditor General (Controladoria-Geral da União: CGU) opened a dedicated channel where citizens can send their opinions on the provision of services and actions of public authorities related to COVID-19. Examples of opinion reports include: shortages of hospital equipment and Personal Protective Equipment (PPE); lack of awareness of the need to protect the public; and failure to take precautions.

（４） Health and medical care budget situation

There has been no significant increase in the budget for health care over the past 10 years, and its share in the total budget has been decreasing year by year[43]. As described in A-4, while the demand for medical care is increasing, the budget for health care continues to be flat, which means that the budget is relatively underfunded and on a downward trend.

In addition, according to a survey by the Brazilian Institute for Health Policy Studies (Instituto de Estudos para Políticas de Saúde : IEPS) [44], the budget of the Ministry of Health in 2022 is R$147.4 billion (≒$26.5 billion), an increase of 1% compared to 2021. However, this budget includes about R$7.1 billion (≒$1.3 billion) for COVID-19 infectious disease control costs in 2022. Excluding this, the actual health budget for 2022 was confirmed to be about R$140 billion (≒$25.1 billion), which is much lower than the recent health budget, as shown in the figure below.

[43] https://www.jornaldocomercio.com/_conteudo/2017/05/geral/563055-orcamento-para-saude-no-brasil-fica-abaixo-da-media-mundial-revela-oms.html

[44] FARIA, M.; et al. A Proposta de Orc¸ amento para Saúde em 2022. IEPS, Instituto de Estudos para Políticas de Saúde. Nota Técnica n. 23. Link: https://ieps.org.br/wp-content/uploads/2021/11/IEPS_NT23.pdf

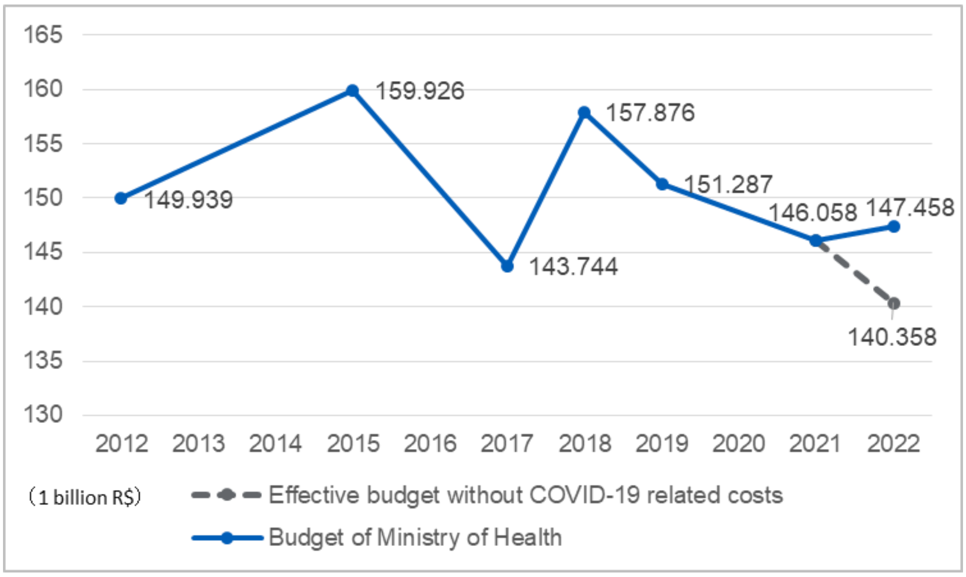


図 III-1 Change in the Budget of the Ministry of Health of Brazil

Source: Compiled by survey team based on survey of IEPS

Furthermore, the vaccine purchase budget may be inadequate if additional COVID-19 vaccinations are required. Although the budget for vaccine purchases reached R$6.9 billion in 2021, the budget for 2022 stands at R$3.9 billion.

The current situation shows that the public budget situation in the healthcare sector is very severe, and it is difficult to expand investment in the digital health sector in addition to the regular healthcare services and the urgent COVID-19 measures.

A－４. Health and Medical Care

（１） Basic Health Indicator

Life expectancy at birth is slightly higher than the average for Latin America and the Caribbean (LAC), excluding high-income countries, and continues to improve. The average life expectancy at birth in LAC is 75.6 years and the mortality rate is 6.3, and future projections by the United Nations indicate that life expectancy at birth in LAC and Brazil will continue to be the same until 2100. As life expectancy increases, the proportion of chronic diseases requiring relatively high level of medical services may increase, and the demand for higher quality medical services is expected to increase. In addition, since 1990, non-communicable diseases (NCDs) such as cardiovascular diseases, malignant neoplasms, and diabetes etc. have been accounting for an increasing percentage of deaths[45].

[45] Ministry of Economy, Trade and Industry, International Development of Medical Care Country Report (Brazil), March 2021: https://www.meti.go.jp/policy/mono_info_service/healthcare/iryou/downloadfiles/pdf/ countryreport_Brazil.pdf

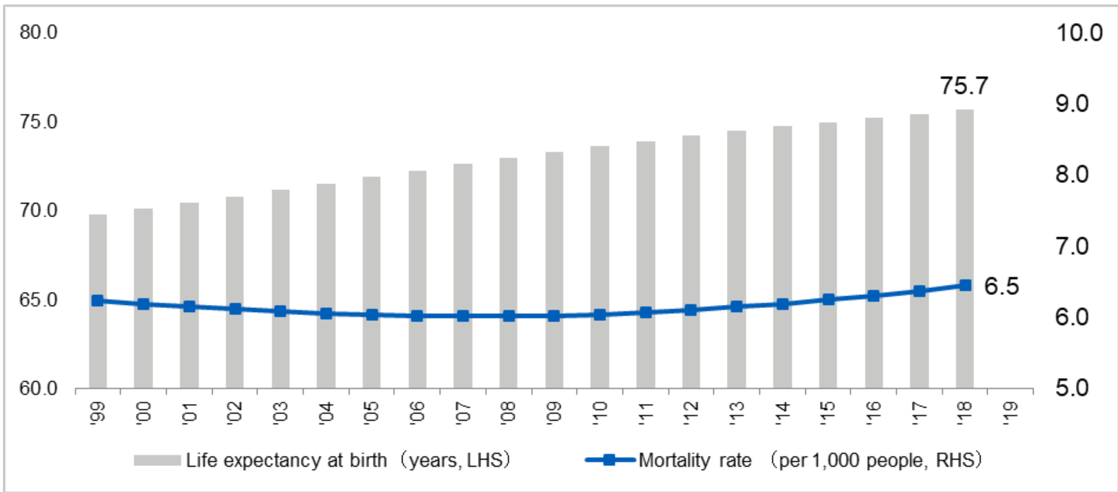


Figure III-6 Trends in life expectancy at birth and mortality rate in Brazil

Source: Compiled by survey team based on World Bank, DataBank, and World Development Indicators

（2） Maternal and Child Health-related Indicator

The Under-5 Mortality Rate (U5MR) in Brazil is 12.4, Neonatal Mortality Rate (NMR) is 7.9, and the Maternal Mortality Rate MMR) is 60, and those have been improving for about 20 years. But those are below the average values of each indicator in LAC (U5MR: 16.1, NMR: 8.9, MMR: 73) and the target values of the Sustainable Development Goals (SDGs) (U5MR: 25, NMR: 12, MMR: 70). This can be attributed to the nationwide implementation of health care programs since the 1980s, including improved sanitation, vaccination promotion, child health care, improved nutrition, and improved women's health. The rapid change in MMR since 2010 may have been triggered by the official adoption of the International Confederation of Midwives' Essential Competencies for Midwifery Practice by the Brazilian Association of Midwives and Nurses-midwives in 2007[46].

[46] BMC, Labor and birth care by nurse with midwifery skills in Brazil
https://reproductive-health-journal.biomedcentral.com/articles/10.1186/s12978-016-0236-7

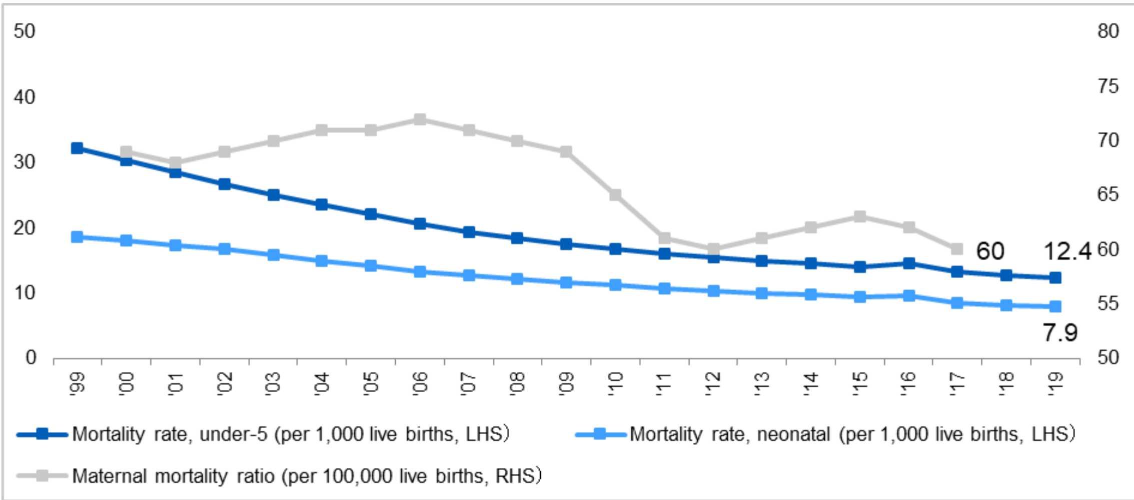


Figure III-7 Trends in U5MR, NMR, and MMR in Brazil

Source: Compiled by survey team based on World Bank, DataBank, and World Development Indicators

Both the number of births and the fertility rate are on a downward trend and remain low compared to the LAC average fertility rate of 16.3 in 2019. As mentioned, Brazil's population is continuously growing, but according to the World Population Prospects（WPP）, both the fertility rate and the number of births are expected to drop to around 80% between 2018 and 2035, which will lead to a rapid decline in birthrate and aging population.

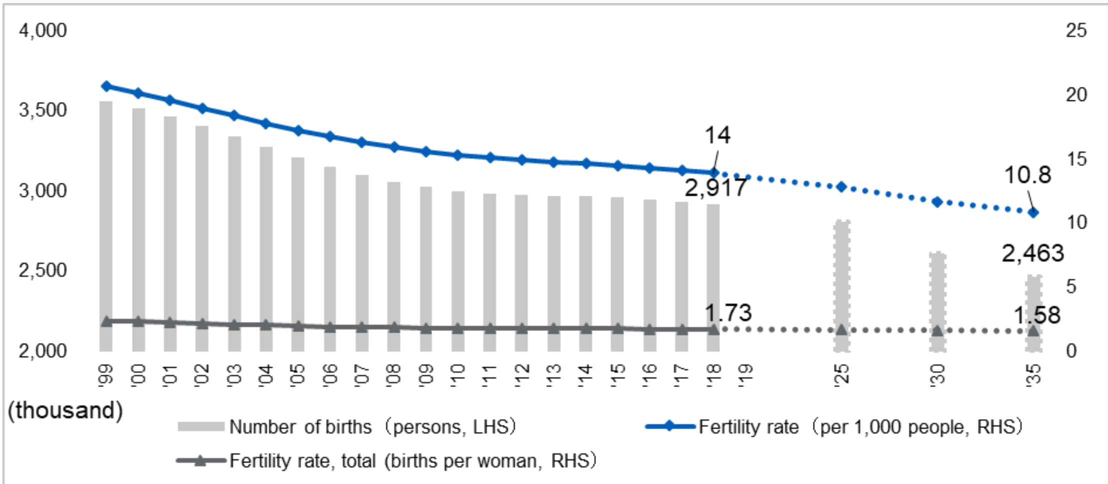


Figure III-8 Trends in number of births, fertility rate, and total fertility rate in Brazil

Source: Compiled by survey team based on World Bank, DataBank, World Development Indicators and United Nations, and World Population Prospects.

（３） Main Causes of Death

There has been no significant change in the disease structure over the past 20 years since 2000, with NCDs such as cardiovascular disease, respiratory disease, and diabetes topping the list. However, there is a concern that the spread of COVID-19 infection may lead to an increase in cardiac, neurological, and pulmonary complications and sequelae after infection, and COVID-19 may have an impact on overall morbidity and mortality in the future.

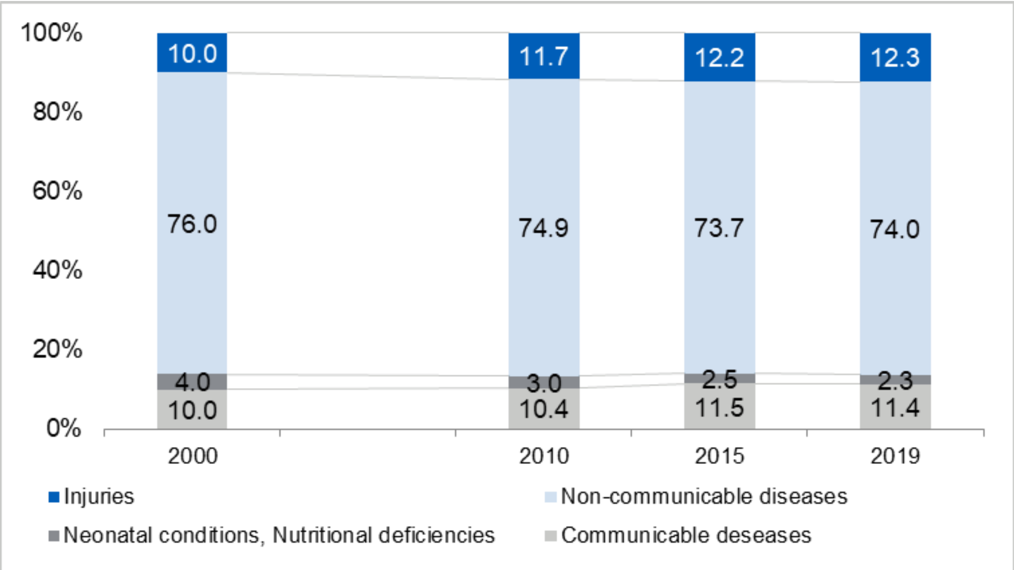


Figure III-9 Trends in major causes of death in Brazil

Source: Compiled by survey team based on World Bank, DataBank, and World Development Indicators

（４） Number of Hospital Bed

The number of hospital beds per 1,000 people in Brazil in 2017 was 2.1, slightly higher than the LAC average (1.9), and the trend over the past 20 years has been a gradual decrease. The number of medical facilities in Brazil has not changed significantly between 2013 and 2019, but the population is increasing, so the number of hospital beds per 1,000 people is probably decreasing[47]. In addition, as of March 2021, when the COVID-19 infection was spreading, the occupancy rate of hospital beds was more than 80% in most states, and in 15 state capitals including Sao Paulo, the ICU bed occupancy rate was more than 90%, suggesting that the pressure on hospital beds was serious. In light of this shortage of hospital beds, it is necessary to examine the nature of hospital beds for "after- COVID-19," including the possibility of home

[47] Ministry of Economy, Trade and Industry, International Healthcare Development Country Report (Brazil), March 2021: https://www.meti.go.jp/policy/mono_info_service/healthcare/iryou/downloadfiles/pdf/ countryreport_Brazil.pdf

treatment[48][49].

Figure III-10 Trends in number of hospital beds in Brazil

Source: Compiled by survey team based on World Bank, DataBank, and World Development Indicators

（５） Health Human Resource

Over the past 20 years, the number of doctors per 1,000 population has increased slightly while maintaining a certain level, and the number of nurses and midwives has increased significantly. The number of doctors per 1,000 people in Brazil is 2.2, which is close to 2.4 in Japan and 2.4 in the United States. The number of nurses and midwives per 1,000 population in LAC is 5.0, while the number of nurses and midwives in Brazil is 10.1, much higher than the average. In Brazil, legislation and other measures have been put in place since the 1990s to establish midwives as a newly qualified profession separate from nurses, and the establishment of the country's first professional midwifery course in 2005 is thought to have provided the impetus for the increase in the total number of nurses and midwives since 2007. In Brazil, the number of deaths of healthcare workers due to the spread of COVID-19 infection is the highest in the world[50], and it is expected that the number of doctors and nurses will need to be further increased in order to prepare for large-scale disasters such as infectious diseases.

48 BBC, https://www.bbc.com/japanese/57536531
49 BBC, https://www.bbc.com/japanese/56356530
50 The Nishinippon Shimbun, https://www.nishinippon.co.jp/item/o/612113/

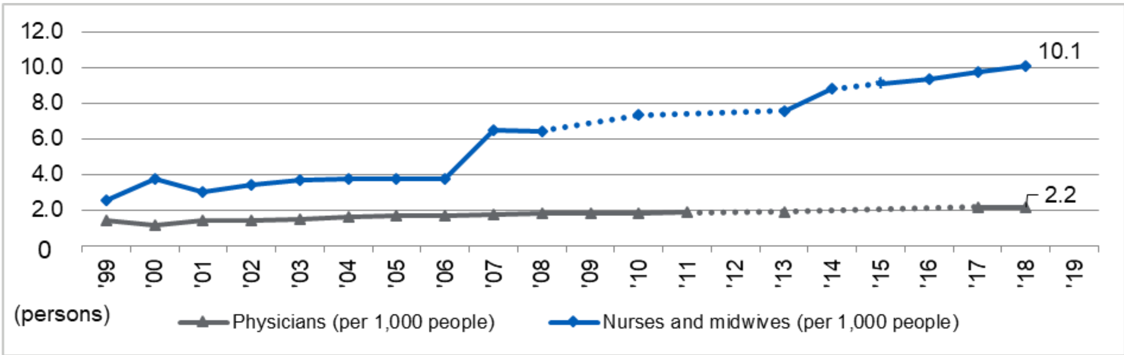


Figure III-11 Trends in number of doctors, nurses and midwives in Brazil

Source: Compiled by survey team based on World Bank, DataBank, and World Development Indicators

From the above, it can be said that the number of doctors in the country as a whole has reached a certain level, but there are issues with the uneven regional distribution of doctors. The following table shows the number of doctors in each region. The southeastern part of the country, where the major cities of Sao Paulo and Rio de Janeiro are located, accounts for 10.9% of the country's land area, but about half of the country's doctors are concentrated there. On the other hand, the Amazon River basin, where many indigenous peoples live, is located in the north of the country, and while it covers a vast area of 45.2% of the country's land area, the distribution of doctors is only 5%. The number of physicians per 1,000 people in the north is 1.2, which is less than half of the number of physicians per 1,000 people in the southeast, and the number of specialists per 1,000 people is only 0.6, which suggests that there are challenges in physical access to medical care.

Table III-1 Number of doctors by region in Brazil

Region	No. of doctors	Population distribution	% of total land mass	No. of doctors per 1,000 pop	No. of specialized doctors per 1,000 pop
North	21.727(5%)	9%	45,2%	1,2	0,6
Northeast	84.553(19%)	27%	18,2%	1,5	0,9
Southeast	234.938(52%)	42%	10,9%	2,6	1,7
South	75.358(17%)	14%	6,8%	2,5	1,4
Midwest	37.842(8%)	8%	18,9%	2,3	1,4
Total	**454.418**			**2,1**	**1,3**

Souce: Compiled by survey team based on CNES, 2021

A－５． Referral System

A referral network is formed in accordance with the unified healthcare system (SUS), which is a universal healthcare system. In principle, the primary medical facility is the first access point, and patients are referred to higher-order medical facilities depending on the nature of the disease.

Based on the SUS, it provides free medical services to the public, including primary to tertiary care and emergency services at public and some private medical facilities. People are referred to primary medical facilities as their first point of access, and then to higher-order medical facilities depending on their diseases, but the procedures are managed and referred by the management center. In addition, emergency, maternal and child care, chronic diseases, disabilities, and mental illnesses have their own additional care networks.

Table III-2 Outline of the referral system in Brazil

Type of medical facility	Outpatient clinic			Hospitals with inpatient functions	
	Primary	Secondary	Tertiary	Secondary	Tertiary
Public	64,213	40,725	2,803	3,983	753
Profit	35,771	118,008	5,470	3,246	1,049
Non-profit	2,863	6,497	1,106	1,874	648
TOTAL	145,222	240,844	9,641	9,103	2,450

Source: National Register of Health Establishments
(CNES, Cadastro Nacional de Estabelecimentos de Saúde).

In addition to the clinics and hospitals mentioned above, the system for providing primary health care consists of Community Health Agents (257,745 health care workers) and Family Health Teams (54,105 health care workers).

（１） Role of Primary Care Facility

Primary health care is mainly provided by the public sector under the SUS, which serves as the closest access point to health care for the local population. It is composed of Basic Health Unit (Unidade Básica de Saúde, UBS), Community Health Agent (Agente Comunitário de Saúde, ACS), Family Health Team (Equipe de Saúde da Família, ESF), and Health Support Center of the Family (Núcleo Ampliado de Saúde da Família (NASF). They provide services such as health promotion, disease prevention, diagnosis, treatment and rehabilitation in the community.

（２） Role of Secondary Care Facility

Not only public and private medical facilities that are part of the SUS network, but also private medical facilities that are not part of SUS are included in the referral system and provide medical services in a way that complements the SUS network. Secondary care facilities provide more advanced and specialized medical services than primary care facilities, dealing with acute and chronic diseases.

（３） Role of Tertiary Care Facility

Similar to secondary care facilities, public and private medical facilities provide complementary and advanced medical services through SUS and non-SUS networks. It provides more advanced and specialized medical services than primary and secondary medical facilities, especially for acute diseases.

A－６． Insurance System

（１） Overview of Public Health Insurance

Under the SUS, all residents of Brazil and all visitors, including foreign nationals[51], are eligible to receive comprehensive services, including delivery, free of charge at public medical facilities and private medical facilities under contract with the government. The program is funded by the federal and state governments.

[51] Secretaria de estado de Saúde, https://www.saude.mg.gov.br/sus

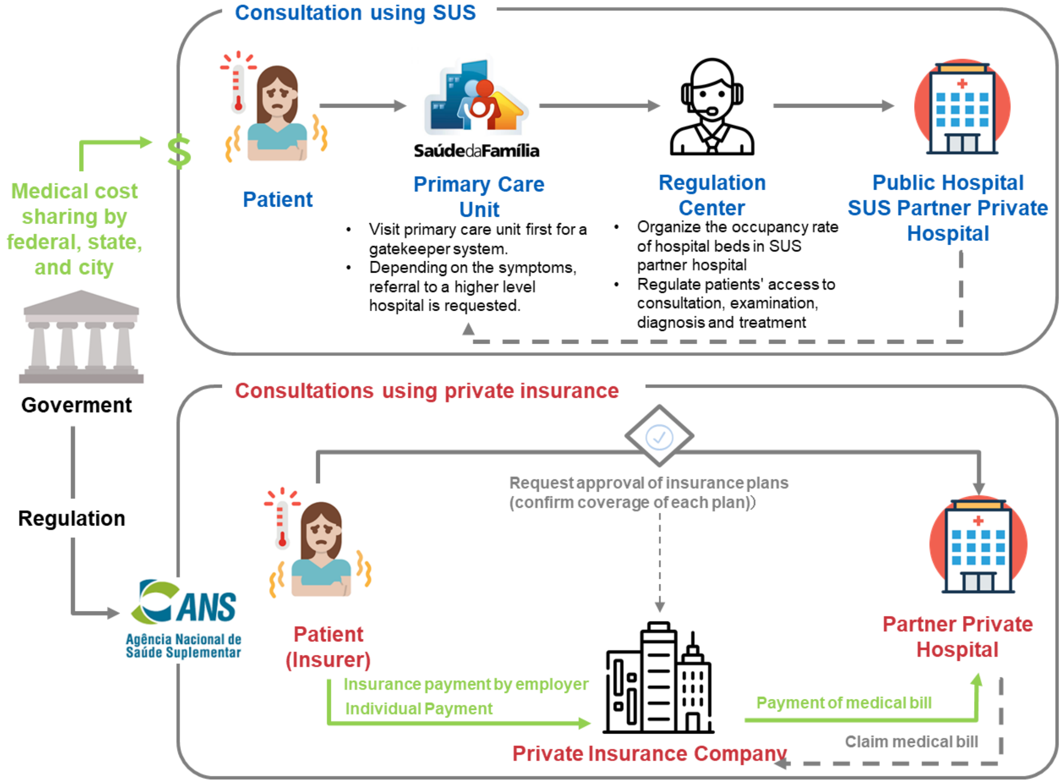


Figure III-12 Public and Private Insurance Systems in Brazil

Source：Compiled by survey team based on CONNAS[52][53][54]

While the SUS has greatly improved access to health care for the Brazilian people, and the benefits are significant, it has also been recognized that there are challenges in terms of funding, quality of services, and human resources. The SUS is financed by the federal government, provinces, and cities. The amount of benefits paid by the government to medical facilities is not uniform because each medical facility and local government negotiates with the Ministry of Health. The amount of benefits paid by the government is lower than the average amount of benefits paid by private insurance, and some medical facilities may incur losses by providing medical services to SUS patients[55].

[52] Brasil. Conselho Nacional de Secretários de Saúde. A Gestão do SUS / Conselho Nacional de Secretários de Saúde. – Brasília: CONASS, 2015. Link: A Gestão do SUS – CONASS
[53] Brasil. Conselho Nacional de Secretários de Saúde. A Atenção Primária e as Redes de Atenção à Saúde / Conselho Nacional de Secretários de Saúde. – Brasília: CONASS, 2015. Link: https://www.conass.org.br/biblioteca/a-atencao-primaria-e-as-redes-de-atencao-a-saude/
[54] Brasil. Conselho Nacional de Secretários de Saúde. Saúde Suplementar / Conselho Nacional de Secretários de Saúde. – Brasília: CONASS, 2015. Link: SAÚDE SUPLEMENTAR – CONASS
[55] International Medical Development Country Report Brazil, Ministry of Economy, Trade and Industry, 2021,

（２） Public Insurance Coverage of the Population

About 75% of the population uses SUS. On the other hand, about 25% of the population, who are considered to be the wealthy, are not satisfied with the public medical services, so they purchase private health insurance in addition to the SUS universal health insurance. According to a satisfaction survey of SUS users[56], patients complained of long waiting times for surgery (61%), long waiting times for diagnostic imaging (56%), long waiting times for appointments (55%), lack of access to specialists (52%), and difficulty in securing beds in intensive care units (52%).

（３） Compensation Coverage

All citizens can receive free of charge everything from preventive medicine to advanced medical services at public medical facilities or private medical facilities affiliated with the government.

According to Law No. 9,656/98, health insurance must provide minimum coverage for all diseases listed in the International Statistical Classification of Diseases and Related Health Problems of the WHO, with the exception of certain procedures such as the following;

- Experimental medical or surgical treatment
- Medical or surgical treatment for cosmetic purposes and orthotics and prosthetics for the same purpose
- Artificial insemination
- Rejuvenation or slimming treatment for cosmetic purpose
- Supply of imported drugs that have not been domestically produced, etc.

（４） Compensation Coverage for the Digital Health Sector

Against the backdrop of the increasing demand for non-contact technology due to the spread of COVID-19, the Federal Medical Council (Conselho Federal de Medicina: CFM) has authorized the government to consider medical services provided through telemedicine as covered by health insurance. The government considers medical services provided through telemedicine to be covered by health insurance. However, only a few medical facilities have been approved and are actually providing telemedicine. As a background, the new regulations on telemedicine stipulate that "services provided through telemedicine must be equipped with an appropriate technological infrastructure" and must comply with the institution's technical standards for storage, handling, data transmission, confidentiality, privacy, and professional secrecy guarantees. It also states that the institution must comply with technical standards for storage, handling, data transmission, confidentiality, privacy and professional

[56] Datafolha – Instituto de Pesquisas. Opinião dos brasileiros sobreo atendimento público na área da saúde. Conselho Federal de Medicina CFM, julho 2018. Link: https://portal.cfm.org.br/images/PDF/datafolha_sus_cfm2018.pdf (Accessed 10/02/2022)

secrecy[57]. Therefore, as of 2021, only a few years after the insurance coverage of telemedicine started, it is predicted that there are still not many medical facilities that meet these standards as a function of hospitals.

（５） Overview of Private Insurance

As of 2013, about 25% of the population, or 50.6 million people, were covered by private health insurance. The higher the insurance premium, the more medical facilities are available and the higher the level of care. Some companies require their employees to purchase private insurance as part of their corporate welfare program, and it is estimated that about 68% of those with private insurance are in corporate plans[58]. Competition among private insurance companies is fierce, and there are problems with insurance companies competing for member hospitals, causing the number of hospitals available to policyholders to change several times in a short period[59].

The rate of private insurance coverage varies greatly by region. In the state of Sao Paulo, about 42% of the population has some kind of private health insurance, while in the states of Roraima and Maranhão, the coverage rate is said to be less than 7%[60].

Private insurance is regulated by Law No. 9,656 of 1998 and overseen by the National Agency for Complementary Health Care (Agência Nacional de Saúde Suplementar: ANS).

A－７． Needs of Medical Facilities

In this survey, the online questionnaire was sent to seven medical facilities(Public:6, Private:1) in Brazil regarding the status of Covid-19 measures and operational issues of the hospitals. The summary of the results of the questionnaire to the medical facilities is as follows. The figures in the text indicate the percentage of medical facilities that selected the relevant items among the medical facilities that completed the questionnaire. However, there were some medical facilities that could not respond to the questionnaire in the first place because they were busy with COVID-19 measures, etc., and the level of medical facilities varied, so caution is needed in interpreting the analysis in this chapter as a general statement. For details of the questionnaire results, please refer to Appendix 6 and 7.

57 ANS (National Health Agency) Resolution 1643/02
58 ANS, Agência Nacional de Saúde Suplementa. Dados consolidados do setor 01/12/2021. Link: https://www.ans.gov.br/perfil-do-setor/dados-e-indicadores-do-setor
59 International Healthcare Country Report Brazil,Ministry of Economy, Trade and Industry,2021,https://www.meti.go.jp/policy/mono_info_service/healthcare/iryou/downloadfiles/pdf/countryreport_ Brazil.pdf
60 ANS, Agência Nacional de Saúde Suplementa. Dados consolidados do setor 01/12/2021. Link: https://www.ans.gov.br/perfil-do-setor/dados-e-indicadores-do-setor

（１） Online Survey Results

１） General Information

Respondents were from secondary to tertiary level medical facilities, and 0% of the medical facilities had no communication infrastructure at all. The stability of the connections varied, with stable connections (43%) and unstable or slow wifi connections (43%) being the most common.

２） Digital Health Status

The major issues for the introduction of ICT in the local medical facilities were the high cost of introduction (100%), the lack of IT personnel in the hospital to introduce and maintain the system (86%), and the lack of necessary equipment for digital devices and communication (86%). Online medical treatment (100%) and online health counseling (86%) were cited as the digital healths they would like to introduce in the future, and demand for remote and non-contact technologies is high. Next in line were doctor-to-doctor platforms (57%) and AI image diagnosis (57%), indicating high demand for data collaboration and improvement of doctors' diagnostic capabilities.

３） COVID-19 Support Status

In terms of Covid-19 measures, the shortage of human resources and operation (e.g., lack of thorough manuals) are recognized as more serious issues than hospital beds and medical device/materials. The shortage of doctors (71%) and nurses (71%) was the most serious issue, while the shortage of laboratory technicians and other staff (57%) was also an issue for more than half of the medical facilities.

All institutions provide inpatient care for moderately to severely ill patients, but more than half complained of inadequate ventilators (57%).

４） Operational Issues

In terms of disease prevention, the lack of educational guidance for local residents and patients (71%) and inadequate opportunities to consult a doctor before a serious illness develops (71%) were recognized as issues.

There was congestion in outpatient clinics (71%) and inpatient wards (71%), and while the number of staff was insufficient, the workload of individual staff was considered to be large (57%). In order to cope with the shortage of staff and the overload of work, it is inferred that there is a high demand for systems and structures that can efficiently carry out work.

Lack of collaboration with other departments in the hospital (71%) and lack of information collaboration with other hospitals (71%) were also recognized by many hospitals, suggesting that there is a high demand for communication tools that promote

collaboration among staff and platforms that promote collaboration among organizations.

In terms of the medical system, the lack of education and training for medical personnel including doctors, nurses and technicians (71%) was also recognized as an issue.

（２） Digital Health with the Potential to Help Solve Local Medical Issues

The following table summarizes the issues in the medical environment in the local target medical facilities obtained from the above online questionnaire and follow-up interviews, and describes the direction of the solutions to these issues using digital health. As in the health tech map, the issues in the medical environment are organized according to the main medical treatment processes, and the items for which more than 50% of the target medical facilities recognize some issues in each questionnaire item are extracted.

Among the medical treatment processes, more than 70% of the target medical facilities recognize that education and guidance to local residents are insufficient as issues related to prevention. Possible solutions include measures such as using digital health to encourage users (including health and unwellness) and patients to manage their behavior and change their behavior, and establishing contact with medical professionals at an early stage.

In addition, in the medical treatment process after screening, congestion in outpatient clinics and wards, shortage of medical personnel and other staff, and the resulting increase in the workload of medical personnel and staff have been recognized as issues. In response to these issues, the use of digital health is expected to contribute to the improvement of work efficiency and the reduction of workload by utilizing digitalization, AI, and robots in hospitals.

In addition, more than 70% of the target medical facilities recognize that collaboration among departments within the target medical facilities and information collaboration among facilities is an issue, and the introduction of digital health is expected to contribute to the realization of efficient and effective collaboration among related parties.

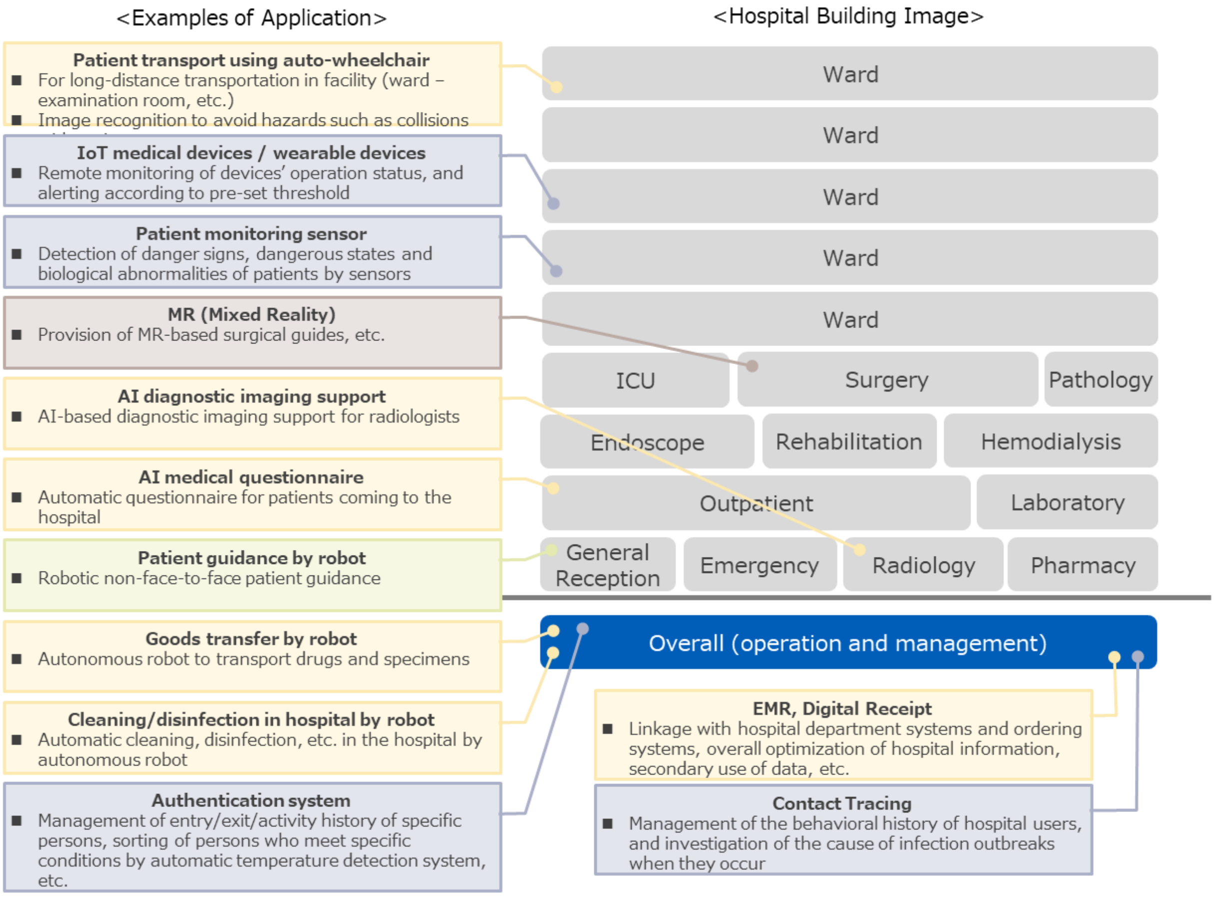
In addition, about 70% of the target medical facilities are concerned that their infection control systems, manuals, zoning, etc. are not in place and that their measures against infection risks are inadequate. Therefore, under appropriate zoning planning and management, contact tracing and access control using authentication systems may become technologies that contribute to solving these problems.

Procedure	Issues in the Medical Environment	Direction of Solution
Prevention	• Inadequate education and guidance for local residents • Few opportunities of pre-consultation for the local residents • Many patients visiting hospitals only after their disease symptoms become serious	■ **Promote users' own behavior management and behavior change** Behavioral change based on daily biometric data recording, AI analysis, etc. through health promotion apps ■ **Establish early contact with healthcare professionals** Advice and recommendation for medical consultation by medical professionals at the stage of pre-disease through online
Screening	• Congestion in outpatient consultation • Heavy workload for staff in reception and screening (e.g., handling medical interviews)	■ **Improve operational efficiency through the use of advanced technology** AI medical questionnaire, patient transport using automated wheelchair, etc.
Examination and Diagnosis	• Large number of inspections • Shortage or absence of specialists such as radiologists	■ **Collaborate with facilities and personnel outside the hospital** Tests at other facilities, sharing results, remote pathology/ radiology, etc. ■ **Improving operational efficiency through the use of advanced technology** AI image diagnostic support, etc.
Treatment (hospitalization)	• Congestion in the inpatient wards (insufficient beds in general wards, ICUs, etc.) • Clinical pathways have not been introduced and the application rate is low (lack of planned and homogeneous medical care) • Heavy workload for staff (biometric data measurement, etc.)	■ **Collaborate with facilities and personnel outside the hospital** Remote ICU, etc. ■ **Introduction of clinical pathways** Introduction of electronic medical records, systematic and homogeneous provision of medical care using clinical paths, etc.
Ongoing treatment and follow-up	• Insufficient guidance to patients on medication, lifestyle, etc. • Insufficient patient follow-up during and after treatment (regular consultations or check-ups, rehabilitation etc.)	■ **Promotes patients' own behavior management and behavior change** Management of patients' behavioral records through the use of therapeutic apps, automatic sending of guidance to encourage behavioral change, implementation of remote rehabilitation, etc.
Other (Operations Management)	• Insufficient coordination of work and information within the hospital (between professions and departments) • Insufficient coordination of operations and information outside the hospital (between other facilities)	■ **Promotes collaboration by introducing an information coordination framework** EHR, PHR, doctor-to-doctor platforms, etc.
	• Inadequate education and training of staff (doctors, nurses, technicians, etc.)	■ **Provide education and training opportunities using digital health** VR training, etc.
	• Inadequate infection control in the hospital (e.g. zoning of infection control areas)	■ **Zoning, non-face-to-face and non-contact to reduce opportunities for contact with infected patients** Zoning of infection control areas, even within existing facilities, with limited staffing Unmanned operations using automatic transfer robots, etc. ■ **Access control for specific persons by face recognition** Automatic face recognition system to control entry and exit of specific persons and trace their behavioral history, etc.

Figure III-13 Direction of solutions to medical issues in Brazil

Source: Compiled by survey team

As for the issues of the medical environment in the target medical facilities organized by the results of the questionnaire and follow-up interviews, there is a possibility of utilizing digital health in a wide range of fields both inside and outside the hospitals. Figure III-13 Direction of solutions to medical issues in Brazilshows the solutions that may contribute to solving the issues in and out of the target medical facilities based on the direction of solutions shown in Figure III-14 Solutions that may contribute to solving problems (in-hospital and out-of-hospital).



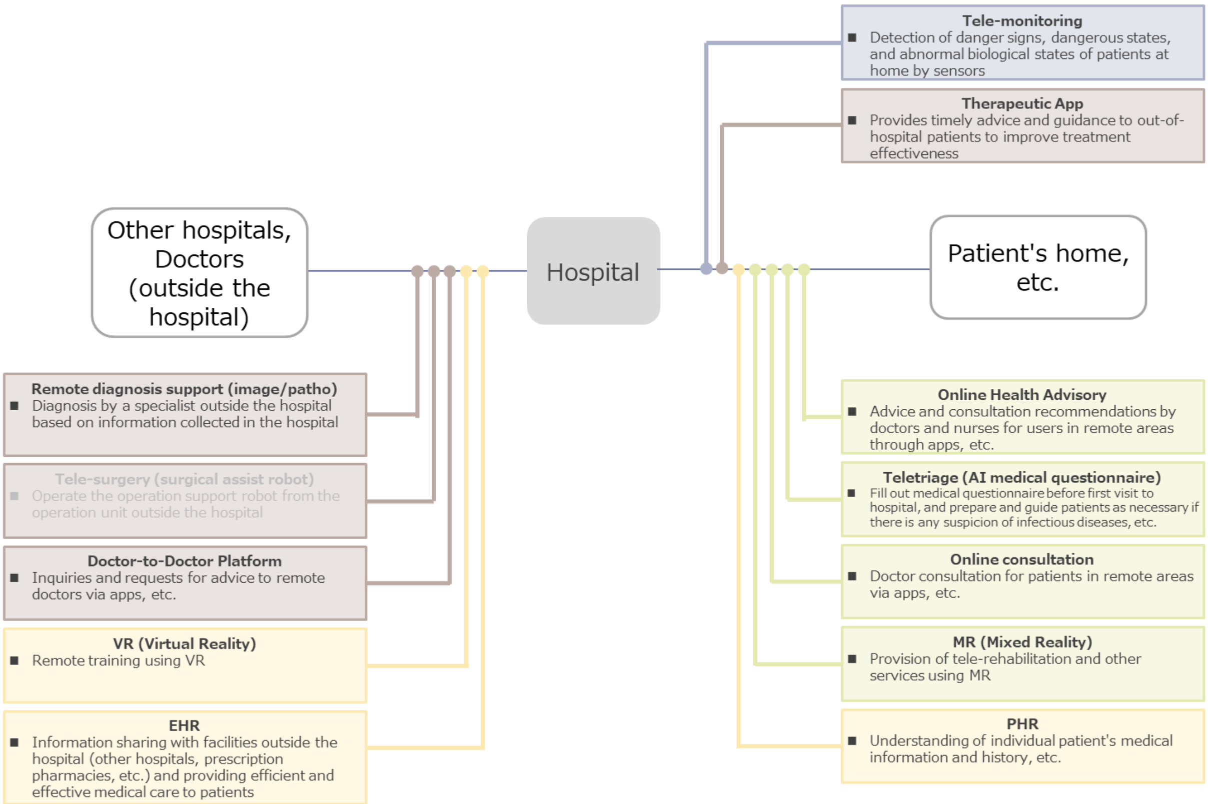


Figure III-14 Solutions that may contribute to solving problems (in-hospital and out-of-hospital)

Source: Compiled by survey team

B. Perspective of Company

B－１. Recent Trends and Main Factors

（１） Market Size and Estimates

The scale of investment in the digital health sector in Brazil is on the rise, and the scale of investment in 2021 is expected to increase significantly over the previous year.

According to IDC Brasil, the digital health market in Brazil is expected to grow by 7% by 2021, even under the COVID-19 infection expansion. Also, according to Inside Healthtech Report[61]Brazil has already invested more than US$90.1 million in digital health companies through February 2021, with 12 investment deals. In 2021, more than 50 investment deals worth more than US$200 million are expected to be made.

[61] DISTRITO, Inside Healtech Report, Abril, 2021.

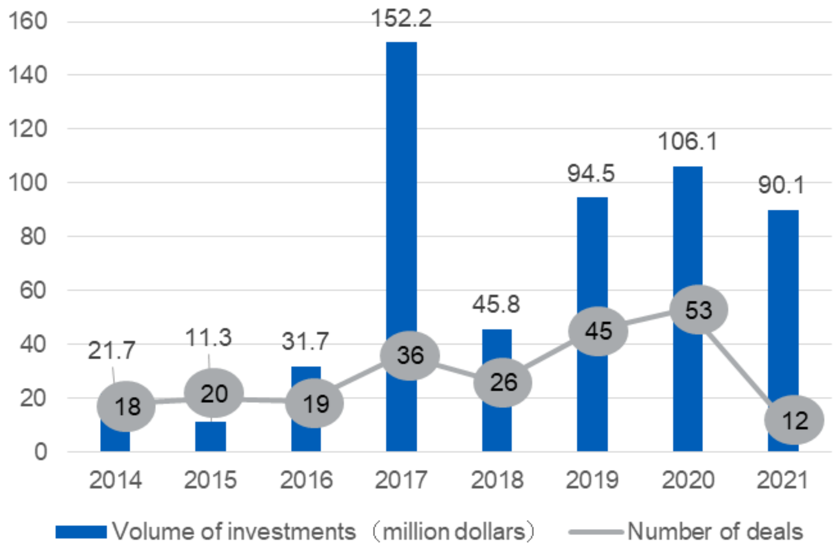


Figure III-15 Number of transactions and annual investment in Brazil's digital health market (million US$)

Source: Inside Healthtech Report, Jan 2021.

Although VC activity is increasing, the amount and number of transactions is still developing compared to the North American ecosystem. In Brazil, CVCs (Corporate Venture Capital) have been involved in 162 investments (212 including investments which do not disclose the investment amounts) with a total value of US$1.3 billion invested in this way over the past 20 years, mostly since 2013. About 70% of these investments are concentrated in the pre-seed and seed stages, indicating that CVCs in the country have been prioritizing investments in developing startups.

The majority of digital health companies are still in the early stages of development, with 50% of them having been in operation for less than five years. The most widespread business model for digital health is BtoB solutions, accounting for 48.3% of the total. This is followed by BtoC solutions at 31.25%[62].

Brazil will be ranked 62nd out of 129 countries in 2020 in the Global Innovation Index[63], a ranking of the innovation capacity of countries around the world published by the World Intellectual Property Organization (WIPO). Among the 18 economies in Latin America and the Caribbean, Brazil ranks a relatively high 4th, and is expected to grow further.

[62] DISTRITO. Distrito Healtech Report, Nov, 2020.
[63] Global Innovation Index is published by Cornell University, in association with INSEAD and the World Intellectual Property Organization (WIPO) - www.globalinnovationindex.org (accessed Sep. 06, 2021)

（２） Trends in the Development of Digital Health

According to a report[64] by Distrito, the digital health solutions being developed in Brazil include the following;

- Mental Health Support Platform
- Solutions to support the daily activities and safety of the elderly
- Solutions that enable access to and management of data on the transmission of infectious diseases
- Solutions for interviewing patients before their visit
- Solutions for patient triage
- Solutions for Telemedicine
- Solutions to improve hospital management, including management of bed occupancy, staff, and electronic medical records
- Solutions for managing drug and equipment inventory

B－２． Impact of COVID-19 on Recent Trends

In the last five years, innovation spaces in medical facilities and universities have been opened, incubation programs and investment funds have been established for the healthcare sector, and the development of the sector has been promoted. The COVID-19 outbreak and the demand for response measures are accelerating the development and digitization of the healthcare sector.

The spread of COVID-19 has underscored the importance of sharing medical information in a timely and accurate manner, and the need to utilize SUS for this purpose has increased dramatically[65].

RNDS and DATASUS served as a nationwide data repository for COVID-19, enabling the sharing of information pertaining to diseases, test results, and hospital bed occupancy rates by COVID-19. It also made it possible to provide online medical care, new applications for self-checking of users' health status, and information on the spread of infection for citizens and healthcare workers.

The introduction of a clinical information sharing model based on the FHIR format (HL7FHIR, 2019), with the aim of sharing COVID-19 test information among medical facilities, is an advance in interoperability in Brazil and contributes to the digital health strategy.

[64] DISTRITO. Distrito HealthTech Report, Nov, 2020.
[65] Brazil, Ministério da Saúde, A Estratégia de Saúde Digital e a COVID-19, https://www.gov.br/saude/pt-br/assuntos/saude-digital (accessed Sep. 06, 2021)

In addition, following the issuance of Ordinance GM/MS No. 1792[66] on July 21, 2020, the Ministry of Health made it mandatory for universities as well as public or private laboratories to submit data on COVID-19 test results to the Ministry of Health. This integration of data in public and private networks was a pioneering effort in the country. In July 2020, the number of laboratories on the RNDS network providing data on COVID-19 test results was 11, but it increased to 67 by the end of October 2020. In addition, the total number of COVID-19 test results submitted in the RNDS in July 2020 was very small, but reached 3,859,376 in October 2020, a number that has steadily increased in size over the months.

B－３．Health Tech Map

The main technology types of solutions in Brazil are mapped as follows, similar to the types in Japan. The main technology types that were confirmed to exist in the digital health market in Brazil through the desktop survey are mapped in white boxes. Among the technologies that are not widely used in the local market or whose existence was not confirmed, those that exist in the Japanese digital health market (technologies that could be introduced from Japan to the local market in the future) are mapped in blue boxes.

[66] Brazil, Portaria nº 1.792, de 17 de julho de 2020, Obrigatoriedade de notificação ao Ministério da Saúde de todos os resultados de teste diagnóstico SARS-Cov-2, https://www.in.gov.br/en/web/dou/-/portaria-n-1.792-de-17-de-julho-de-2020-267730859 (accessed Sep. 01, 2021)

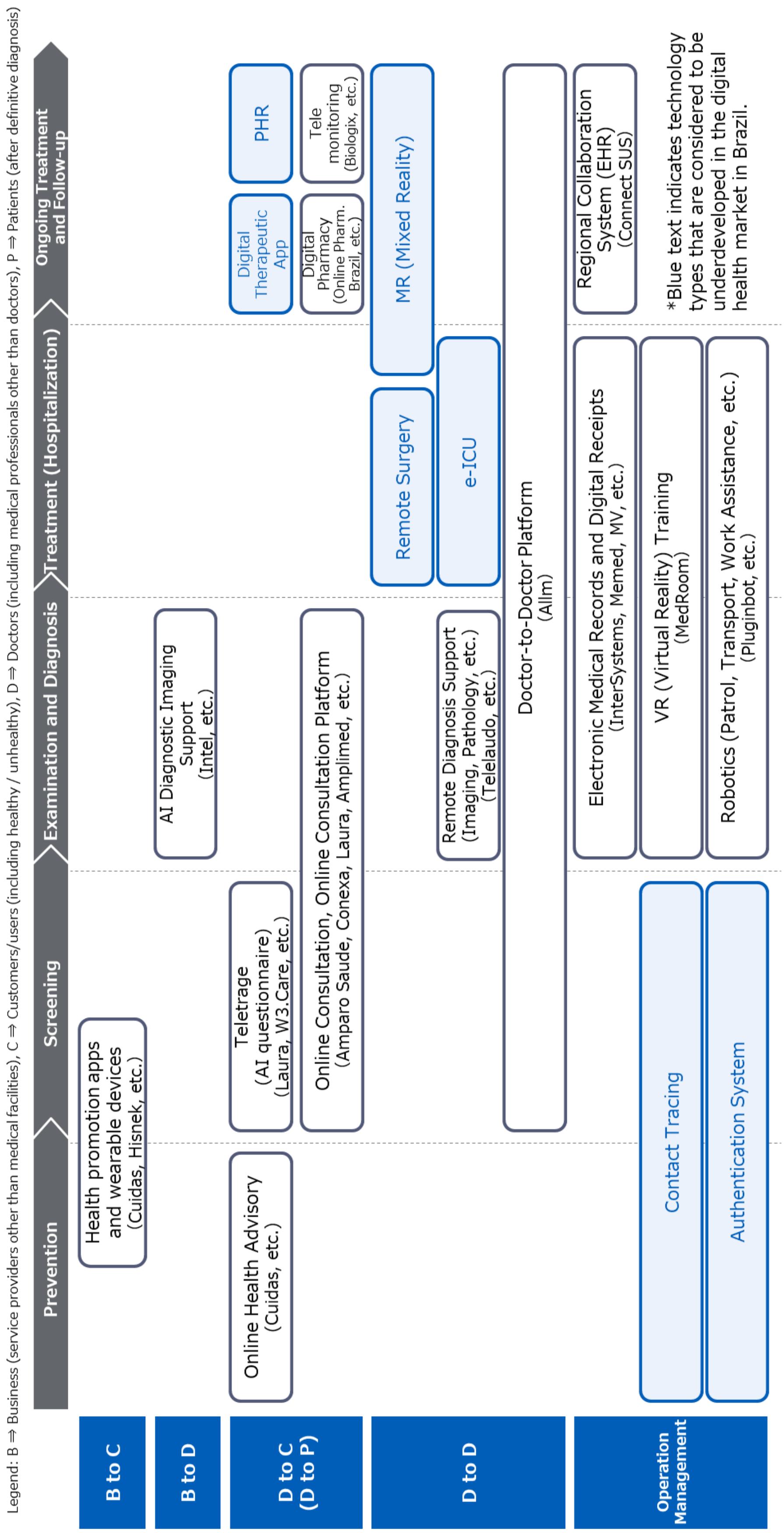


Figure III-16 Health Tech Map (Brazil)

Source: Compiled by survey team

As for the technology types of digital health in Brazil, relatively new technologies, such as therapeutic applications, may not have been widely adopted yet. In terms of DtoC technology types, in Brazilian digital health market, there was no evidence of widespread use of therapeutic applications, which have been attracting attention in recent years, or PHRs, which are attracting renewed attention in terms of patient data ownership and interoperability. In the field of DtoD, tele-surgery, which is being introduced on a trial basis in various countries with the introduction of 5G, and MR, which is expected to be used in the medical field in recent years, were also not widely adopted.

In addition, by comparing the above health tech map with the solutions for solving the issues shown in Figure III-14 Solutions that may contribute to solving problems (in-hospital and out-of-hospital) **in Chapter A-7, there is a possibility that Japan can introduce therapeutic applications, PHR, tele-surgery, e-ICU, MR, contact tracing, and authentication systems to the local market.** For these digital health there are few local companies that provide related products and services, and there is relatively little competition for Japanese companies to enter the local market.

B－４． Relevant Laws and Regulations Surrounding Digital Health

（１） General Laws and Regulations Related to Information and Communication

１） Telecommunications, Radio Waves, etc.

Table III-3 Laws and regulations related to telecommunications and radio waves in Brazil

Laws and regulations	Overview
General Telecommunications Law Lei Geral de Telecomunicações LGT, Law Nº.9472/97 (1997)	It systematically regulates telecommunications in the country, including the service delivery system and the establishment of the Agência Nacional de Telecomunicações (ANATEL), the regulatory body for telecommunications services. ANATEL is part of the federal executive branch, but is financially and administratively independent. ANATEL is the regulatory body for telecommunications services, which, among other things, regulates and monitors, grants concessions and permits, issues licenses, utilizes orbital and radio frequency resources, conducts inspections, and applies sanctions. It is an agency.
Cybersecurity regulations applicable to the telecommunications sector	It aims to promote cyber security in telecommunication networks. The regulation consists of (1) general provisions, (2) cybersecurity principles and guidelines, (3) cybersecurity within networks and

Laws and regulations	Overview
Regulamento de Segurança Cibernética Aplicada ao Setor de Telecomunicações, Resolution Nº.740 (2020)	services and risk mitigation for critical infrastructure, (4) performance of ANATEL and technical groups on cybersecurity, and (5) sanctions and final provisions. One of the main obligations placed on providers is to prepare, maintain, and implement a detailed cybersecurity policy, which includes references to national and international norms, standards, and good practices. The policy should also report procedures and controls for identifying vulnerabilities to the continuity of critical infrastructure and services presented in a hierarchical manner, as well as risk mapping and incident response plans. Other obligations include using products and equipment from suppliers that have adopted cybersecurity policies, conducting vulnerability assessment cycles, and reporting relevant incidents to Cisco.
A Framework for Citizenship on the Internet Marco Civil da Internet, Law Nº.12.965	It establishes principles, guarantees, rights and obligations regarding the use of the Internet in Brazil and provides guidelines for the performance of the federal, state, federal jurisdictions and municipalities in this matter. The regulation of Internet use in Brazil, in addition to respect for freedom of expression, is as follows; ・ Guarantees of freedom of expression, communication, and expression of ideas in accordance with the provisions of the Federal Constitution ・ Protecting privacy ・ Protection of personal information in accordance with the law ・ Maintenance and assurance of network neutrality ・ Maintain the stability, security and functionality of the network by encouraging technical measures and inputs from good practices that conform to international standards. ・ Accountability under the law ・ Maintain the participatory nature of the network ・ Freedom of business models promoted on the Internet, as long as they do not conflict with other principles set forth in this law. In interpreting this law, in addition to the aforementioned principles and others, the nature of the Internet, its special uses and customs, and its importance in promoting human, economic, social, and cultural development will be taken into account.

Source: Compiled by survey team

２） Personal Information Protection

Table III-4 Laws and regulations related to the protection of personal information in Brazil

Laws and regulations	Overview
General laws on the protection of personal information Lei Geral de Proteção de Dados Pessoais (LGPD), Law Nº 13.709 (2017)	It provides for the protection of the holder's freedom, privacy, security, express consent, and access to information; creates a series of new legal concepts (e.g., personal data, sensitive personal data); establishes the conditions under which personal data can be processed; defines the rights of data subjects; imposes specific obligations on data controllers; and It prescribes a set of procedures and rules for more careful handling and sharing of personal data with third parties. Similar to this law are the European Union's General Data Protection Regulation and the California Consumer Privacy Act in the United States. This law is based on the values of respect for privacy, informational self-determination, freedom of expression, information, communication and opinion, inviolability of intimacy, honor and image, economic and technological development and innovation, free enterprise, free competition and consumer protection, and the human right to freedom and dignity of people. Personal information protected by law is any data that can be used to identify an individual, including first name, last name, email, document and credit card numbers, banking data, medical information, geographic information, and IP addresses. It also includes racial or ethnic groups, religious beliefs, political opinions, membership in unions or organizations of a religious, philosophical, or political nature, health-related, sexual, genetic, or biomedical information that could be subject to discrimination if divulged (sensitive personal information).

Source: Compiled by survey team

３） Data Use

Table III-5 Laws and regulations related to data use in Brazil

Laws and regulations	Overview
Interoperability of medical information systems within SUS and medical information standards	It specifies and defines concepts that should form the basis of medical services for information coordination and interoperability. The main objectives of this regulation are as follows; ・ Promote the use of ontologies, terms, and conditions to describe

Laws and regulations	Overview
Ordinance Nº.2073, Padrões de interoperabilidade e informação em saúde para sistemas de informação em saúde no âmbito do Sistema Único de Saúde (2011)	concepts in the health care field ・ Achieve functional interoperability between information systems ・ Facilitating the identification of users in different information systems
Minimal medical data sets Conjunto Mínimo de Dados da Atenção à Saúde (CMD), CIT Resolution Nº.6 (2016)	It was established based on the CIT (Comissão iIntergestores Tripartite) resolution in light of the need to restructure the information model for medical data in Brazil. It is an official document that collects data from all medical facilities in the country and aims to reduce fragmentation in clinical and administrative data systems.

Source: Compiled by survey team

（２） Digital Health-related Laws and Regulations

１） Ethical Guidelines

Table III-6 Laws and regulations related to ethical guidelines in Brazil

Laws and regulations	Overview
anti-corruption law Lei anti-corrupção, Nº.12,846/2013 (2013)	It stipulates the objective liability in the civil and administrative fields of companies that have committed harmful acts against domestic and foreign governments. This law not only fulfills the international commitments Brazil has undertaken, but also fills a gap in Brazil's legal system by directly addressing the actions of corrupt individuals. In addition to strengthening investigations, the anti-corruption law provides for penalties such as administrative fines of up to 20 percent of a company's gross revenues and leniency agreements that can expedite compensation for damages. Within the scope of the federal executive branch, the Federal Audit Office (CGU) is responsible for most of the procedures, including the initiation and determination of administrative procedures for accountability and the conclusion of leniency agreements. In addition, companies must conduct their business activities in accordance with good market practices and comply with the LGPD.

Source: Compiled by survey team

２） Medical Device Registration

The handling of medical devices in Brazil is regulated by the ANVISA standard RDC nº 185/2001.As a registration requirement, the manufacturer must be based in Brazil or appoint a Brazilian Registration Holder (BRH) to complete the process.

The procedure for registration of medical devices is as follows.

1. Registration procedures with the Vigilância Sanitária (Sanitary Surveillance Agency)
   In order to register a medical device, the following documents must first be obtained and registered with the Health Surveillance Administration.
   - Corporate certification issued by ANVISA (Autorização de Funcionamento da Empresa)
   - Business license (Licença de Funcionamento) issued by the city or state sanitary inspectorate
   - Certificate of Good Manufacturing Practices (Certificado de Boas Práticas de Fabricação) issued by ANVISA

2. Determination of product classification
   Medical devices are classified into the following 4 categories based on their contact time with the patient, level of invasiveness, and the part of the body affected by the use of the product. Detailed classification criteria can be found in Annex II[67] of RDC Resolution nº 185/2001.
   - Class I (Low risk)
   - Class II (Moderate risk)
   - Class III (High risk)
   - Class IV (Maximum risk)

3. Submission of required documents to ANVISA[68]
   Based on the above classification, submit the prescribed documents to ANVISA respectively.
   - Class I and Class II: Notification procedure to ANVISA (Notificação)
     This procedure does not require a prior technical analysis by ANVISA to normalize the product, but requires the following documentation requirements to be met, as specified in RDC Resolution No. 40
     - Application form for notification of equipment or software

[67] https://bvsms.saude.gov.br/bvs/saudelegis/anvisa/2001/rdc0185_22_10_2001.pdf
[68] https://www.jetro.go.jp/ext_images/_Reports/01/47aef30b44ba7bcd/20200051.pdf

- Graphic images of each product, model, part, and accessory
- Brazilian System of Conformity Assessment (SBAC) Certificate of Conformity
- Product Family Registration Product Comparison Table
- Affidavit of the responsible manufacturer

Once an application is submitted, a series of document checks are conducted as an administrative review before a notification number is finally issued. Although there is no technical review, compliance with the conformity criteria is checked by ANVISA by selecting the target products from the notified product database at a reasonable frequency and conducting an audit at a later date. Therefore, notified titleholder companies are expected to keep the technical dossiers in their possession at all times so that they can be presented immediately upon request by health authorities. Note that there is no expiration date for Class I and Class II registrations.

- Class III and IV: Regular registration procedures (Registro)

In the case of regular registration, in addition to the above-mentioned notification procedures, documents such as technical reports including clinical trial data and copies of GMP certificates are required, and these documents must be submitted in paper form, which increases the burden of the procedures.

- Application form for registration by a manufacturer or importer of medical products
- Labeling model
- User's manual or manual
- Technical report
- Equipment model comparison chart
- Brazilian System of Conformity Assessment (SBAC) Certificate of Conformity
- Affidavit of the responsible manufacturer
- Registration document or free trade certificate of the country of origin
- GMP Certificate

Class III and IV registrations are valid for one 10 year. It is necessary to apply for reactivation 12 to 6 months prior to the expiration date, otherwise it will be treated as expired after the expiration date.

The cost of registration varies depending on the type of application (registration, notification, re-registration, amendment, etc.), product size, company size, etc[69]. The registration process takes

[69] https://bvsms.saude.gov.br/bvs/saudelegis/anvisa/2006/anexo/anexoI_res0222_28_12_2006.pdf

60~90 days.

３） Licenses for Import, Export, Distribution, and Sales

The body in charge of the regularization of health care products is ANVISA, which regulates, controls and inspects products and services. RDC (Resolução da Diretoria Colegiada), a resolution by the ANVISA Board members, clarifies regulations for maintaining the quality of products for health purposes and proper implementation of services[70].

Health care products are part of the related products defined in Law No. 5.991/19733 and comprise medical products consisting of equipment and materials used in medicine, as defined in RDC Nº.185/2001, and in vitro diagnostic products, as defined in RDC Nº.206/2006.

When importing products subject to normalization, the normalization number must always be indicated, regardless of the stage of the product. For the importation of products that are not considered health care products, it is necessary to file a petition for importation procedures according to the subject code related to the purpose of not being subject to sanitary inspection, in accordance with Chapter XXXVII of RDC Nº.81/2008.

Law No. 6.360/76 stipulates in its Article 2 that only companies regulated by ANVISA may import health products. 16/2014 and RDC Nº. 61/2004 are regulations on the granting of business licenses to companies intended to import these products.

Table III-7 Laws and regulations related to import, export, distribution, and sales in Brazil

Laws and regulations	Overview
Resolução da Diretoria Colagiada - RDC Nº 185 (2001)	It deals with registration, modification, re-evaluation and deregistration of medical products under ANVISA.
Resolução da Diretoria Colagiada - RDC Nº 81 (2006)	Provides for the technical regulation of goods and imports for the purpose of surveillance.
Resolução da Diretoria Colagiada - RDC Nº 40 (2015)	It establishes registration requirements for medical devices.
Resolução da Diretoria Colagiada - RDC Nº 40 (2004)	Prescribes rules for operating licenses for companies providing foreign trade services.

Source: Compiled by survey team

70 https://www.arghi.com.br/o-que-e-uma-rdc-e-o-que-significa

４） Intellectual Property

Table III-8 Laws and regulations related to intellectual property in Brazil

Laws and regulations	Overview
software law Lei do Software, Lei nº9609 (1998)	As a standard that summarizes the rights and obligations related to intellectual property rights, it defines all rights and obligations related to computer programs and who is responsible for their registration. Software registration is managed and implemented by a public organization called the National Institute of Intellectual Property (INPI). Software registration makes it possible to ・ Corporate Legal Security ・ Rights to computer programs shall be protected for a period of 50 years from January 1 of the year following their issue or, if not issued, January 1 of the year following their creation. ・ International Security (TRIPS) ・ Required for participation in government tenders ・ Rights can be transferred, guaranteeing the rights of contracting parties and third parties. ・ One of the criteria to be included in the BNDES MPME Inovadora (funding)

Source: Compiled by survey team

・ Regulations on software as a medical device (under public consultation)

On April 8, 2021, ANVISA's University Council launched a public consultation on a University Council resolution proposing the regulation of software as a medical device in the Brazilian market. The current Brazilian legislation does not include this item among the relevant equipment under the sanitary surveillance regime. In this regard, the aforementioned resolution takes steps to regulate healthcare software in the same process used for other products in this field, in order to promote quality and safety standards for healthcare software. This resolution determines the criteria and evidence that must be met for the normalization of software in the Brazilian market, including functional specifications, associated risks, interoperability specifications, safety and effectiveness, declaration of conformity according to international standards (software lifecycle processes, medical device which includes criteria such as the application of usability, the application of risk management to medical devices etc.).

５） Others

Table III-9 Other related laws and regulations in Brazil

Laws and regulations	Overview
Legal Framework for Startups Marco Legal das Startups, Lei Complementar nº 182/21 (2021)	According to the law, companies and cooperatives that are active in innovation as applied to products, services and business models, with total revenues of less than R$16 million (≒US$2,891,898) in the previous year and that have been registered in the National Corporate Registry (Cadastro Nacional da Pessoa Jurídica Companies with revenues of less than R$16 million (≒ US$2,891,898) and that have been registered with the National Corporate Registry (Cadastro Nacional da Pessoa Jurídica: CNPJ) for more than 10 years are classified as start-ups. Start-ups must declare in their articles of incorporation that they use an innovative model or fall under the special regime Inova Simples, as defined in the Microenterprise Charter. Inova Simples membership requires a gross income of less than R$4.8 million (≒US$867,538). Investors do not necessarily participate in the share capital of the startup company or the direction and decision-making power of the company. Investors can choose to purchase shares in the startup company in the future, redeem bonds issued by the beneficiary, and so on. Another way for startups to receive funds is through the seed capital category, equity funds (Law 13,800/19) or equity investment funds for startups, companies with economic production concentrated in research, development and innovation.

Source: Compiled by survey team

B－５． Future Prospects in the Digital health Market

Even before the spread of COVID-19, AI and blockchain in the healthcare sector were of growing interest as future digital health fields in Brazil, and since the spread of COVID-19, telemedicine, remote monitoring of patients, and interoperability of medical data have also attracted attention.

（１） Big data, AI, analytics

As more and more connectivity technologies are adopted, more and more data is being generated every year, and in the fields of big data, AI, and analytics, it is expected to be used in fields such as genomics, precision medicine, diagnostic imaging, and drug discovery, as well as to provide individualized treatments tailored to patients' lifestyles and medical data.

In recent years, healthcare providers have been digitizing their medical services to improve patient care, a trend that is further accelerated by the spread of COVID-19 infection. As a result of these trends, the digital infrastructure of healthcare and research institutions is expanding at an unprecedented rate. AI and analytics technologies are expected to be used for the secondary use as well as the storage of medical data for the benefit of patients, medical professionals, and medical facilities as a whole. AI and analytics technologies are attracting attention as technologies that can be used for the secondary use of such big data.

（２） Blockchain (Privacy and Data Security)

In the healthcare sector, blockchain, a powerful security technology, is expected to become a major safeguard against data breaches and contribute to information protection for patients and medical facilities in the future. The main objective of the Brazilian Personal Data Protection Law (LGPD) is to guarantee the privacy of people's personal data by establishing clear rules for the process of collecting, storing, and sharing it. The introduction of blockchain will make it easier to meet the information protection requirements of the LGPD.

Also, by 2020, about 60% of healthcare organizations will have this topic on their strategic agenda. The increased awareness of privacy and data security protection is expected to create a positive impact on the related markets by encouraging the implementation of necessary training for the concerned parties, updating and adaptation of applications, etc.

（３） Remote Medicine

Against the backdrop of the COVID-19 outbreak, regulations on telemedicine have been temporarily delegurated. By the ordinance No. 467[71] dated March 20, 2020, the telemedicine practice is allowed exceptionally and temporarily for the purpose of taking measures to cope with public health emergencies of international importance as stipulated in Article 3 of Law No. 13,9. The government had been reluctant to implement telemedicine, but after the outbreak of COVID-19, the government has temporarily deregulated telemedicine due to the need to combat COVID-19. Exceptional and temporary telemedicine practices are allowed for the purpose of taking measures to address public health emergencies of international importance.

As for future developments, the House of Representatives at the end of 2020 launched a parliamentary group to discuss the regulation of telemedicine, and CFM representatives indicated that the CFM was considering a resolution to regulate telemedicine, which will be presented after approval by the plenary session of the 28-member council. Although no official announcement has been made as of October 2021, the CFM says the resolution will set rules for both the Unified

[71] Brazil, Portaria Nº 467, de 20 de março de 2020, Regulamenta as Ações de Telemedicina https://www.in.gov.br/en/web/dou/-/portaria-n-467-de-20-de-marco-de-2020-249312996 (accessed, Sep. 01, 2021)

System of Health Care (SUS) and private medical facilities, which means that the introduction and deployment of telemedicine as a national health service is expected to continue.

In addition, the health insurance system also supports telemedicine. Many companies and medical facilities see telemedicine as a technology that can be deployed without large investments in software and hardware to provide medical care to their employees and patients**.** Telemedicine is becoming more and more popular as patients perceive it as a safe, comfortable and efficient option.

With the increase in the number of telemedicine users, the barriers associated with the technology have been removed, and this has been a driving factor for startups that provide solutions related to telemedicine. It is also possible that other solutions, such as electronic medical records, will be derived from this technology, and companies that provide such solutions will begin to offer services related to telemedicine to their customers.

（４） Remote Monitoring of Patients

According to a report[72] by the National Association of Private Hospitals (Associação Nacional de Hospitais Privados: ANAHP), in addition to telemedicine, remote patient monitoring efforts are also being intensified in response to the spread of COVID-19. To remotely monitor COVID-19 infected patients, applications, chatbots, and AI-related technologies are being developed and adopted.

The scale of services offering monitoring solutions is developing, both in smartwatches and in smartphone applications. According to the report, 90 percent of the doctors interviewed would continue to use telemedicine for routine care and follow-up, and 89 percent would use it for doctor-to-doctor interaction.

[72] ANAHP, Lições Da Pandemia: Perspectivas e Tendências (2021), https://conteudo.anahp.com.br/licoes-da-pandemia-perspectivas-e-tendencias-abril2021 (accessed Sep. 01, 2021)

（５） Digitalization and Interoperability of Healthcare Infrastructure

The government is investing in establishing RNDS to digitize the SUS. This will enable the efficient use of electronic medical records and other patient medical information.

Domestic interest in healthcare data interoperability is also on the rise. Zebra's "The Future of Healthcare," a survey based on data collected from interviews with industry technology leaders and executives, also cites interoperability as a key issue and trend for the next few years.

The main interoperability challenges in the Brazilian healthcare sector are technology, security and privacy, and cost, although the technical issues have already been partially solved by the adoption of the FHIR model as an international standard. On the other hand, there is still a lack of labor force and companies with the necessary technology to facilitate large-scale implementation.

B－６． Future Challenges in the Digital health Market

（１） Raising Funds for Development and Business Expansion

The financing of R&D and business development is a major challenge for digital health companies. As stated in the Global Innovation index report[73], the economic risks associated with innovation are higher in Brazil than in developed countries due to political, macroeconomic, and social uncertainties**.** Entrepreneurs in the innovation sector point out that banks are not interested in lending due to the lack of guarantees against risks.

Other challenges include strengthening measures to increase private sector investment in R&D and the rate of innovation in the economy. The link between investment in basic science and technological development needs to be further investigated and better understood[74].

（２） Disparities in Digitization

While the use of digital technology is increasing among the population due to the widespread use of cell phones and smartphones, there are differences in Internet penetration rates between urban (83%) and rural (70%) areas, as well as between high-income (92%) and low-income (67%) groups[75]. Many users have ICT literacy problems, and this is an obstacle to deeper use of services[76].

[73] Global Innovation Index 2020 https://www.wipo.int/edocs/pubdocs/en/wipo_pub_gii_2020.pdf (accessed Sep. 06, 2021)
[74] LEAL, C.I.S; FIGUEIREDO, P.N. Inovação tecnológica no Brasil: desafios e insumos para políticas públicas. Revista de Administração Pública. Rio de Janeiro, Brasil, 2021.
https://www.scielo.br/j/rap/a/th4kPMNYksKFkZDwSdWs7Zj/?format=pdf&lang=pt (accessed Sep. 06, 2021)
[75] https://cetic.br/media/analises/tic_domicilios_2020_coletiva_imprensa.pdf
[76] ABIMED, Os impactos da Transformação Digital na área da Saúde
https://www.abimed.org.br/files/Posicionamento/OS_IMPACTOS_DA_TRANSFORMACAO_DIGITAL_NA_AREA_DA_SAUDE.pdf

（３） Cybersecurity

Cybersecurity is an important topic as the LGPD mandates that hospitals develop a new model of data compliance for patient-health service relationships. A survey on TIC Health conducted by the Regional Center for the Development of the Information Society (cetic.br) reveals that less than 35% of providers have a formal information security policy as stipulated in the LGPD since 2014. Compliance with the LGPD is a major challenge for the industry and will require not only financial investment, but also technological efforts and changes in institutional culture and practices[77].

（４） Secure Engineers with the Necessary Qualifications and Skills.

According to Brasscom[78] (Brazilian Association of Information and Communication Technology Companies), there is a shortage of 120,000 positions in technical higher education in Brazil. This situation raises the concern that there is a shortage of qualified professionals to fill the positions currently available.

C. Perspective of JICA

C－１. Status of JICA Support

Brazil is in the process of graduating from Official Development Assistance (ODA) under World Bank standards, JICA has not provided any grant aid in the healthcare sector in the recent past.

The smart healthcare dissemination project, which was implemented through public-private partnerships, is expected to have relevance and potential for collaboration with this project.

The following is a list of JICA projects completed since 2015.

[77] ANS (Agência Nacional de Saúde Suplementar) NOTA TÉCNICA Nº 3/2019 http://cnsaude.org.br/wp-content/uploads/2020/10/Nota_Tecnica_LGPD_ANS_CNSAUDE.pdf (accessed Sep. 04, 2021)

[78] BRASSCOM, Relatório Setorial 2020, https://brasscom.org.br/relatorio-setorial-2020-macrossetor-de-tic/

Table III-10 JICA projects in the health care sector in Brazil

Technical cooperation	・ Project to strengthen research and reference cooperation between Brazil and Japan on the diagnosis of fungal infections, including drug resistance (August 2017 - August 2022)
Official Development Assistance Loans	—
Official Development Assistance Grants	—
Public-Private Partnerships	・ Case study on pressure ulcer (bedsore) prevention using high-function mattresses for medical and nursing care (C-Engage Corporation, October 2017-December 2018) ・ Basic Research on Improving the Medical Environment Using Mobile Medical Vehicles and Used Medical device (Nishimura Medical Instruments Co., Ltd., April 2018 - February 2019) ・ Smart Health Care Promotion Project in Curitiba City to Combat Lifestyle-related Diseases (Tanita Corporation and Tanita Health Link, Inc. joint venture, June 2014 - March 2015) ・ Project to promote the use of transradial artery catheterization for the treatment of ischemic heart disease (Terumo Corporation, April 2014 - March 2016) ・ Project to promote the spread of medical collaboration using PACS-based remote diagnostic imaging technology (FUJIFILM Corporation, March 2017 - March 2019) ・ Information collection and confirmation survey on the possibility of utilizing private sector technologies in developing countries under COVID-19 in the field of health and medical care (strengthening measures against infectious diseases and improving nutrition) (October 2020 - March 2021) ・ Information collection and confirmation survey on matching of demand from developing countries and private sector technologies related to global healthcare and welfare (aging and nursing care) (June 2021 - March 2022)

Source: Compiled by survey team

Table III-11 JICA projects related to ICT in Brazil

Technical Cooperation	・ ITS Master Plan Research Project (March 2012 - June 2013)
Official Development Assistance Loans	—
Official Development Assistance Grants	—
Public-Private Partnerships	・ Case Study on Landslide Early Warning System (2019)

Source: Compiled by survey team

Table III-12 JICA projects related to COVID-19 in Brazil

Technical Cooperation	・ Project on Strengthening Organizational Capacity against COVID-19 (R/D signed on September 21, 2021)
Official Development Assistance Loans	—
Official Development Assistance Grants	—
Public-Private Partnerships	・ Information collection and confirmation survey on the possibility of utilizing private sector technologies in developing countries in response to COVID-19 in the field of global health care (strengthening countermeasures against infectious diseases and improving nutrition) (October 2020 - March 2021) *Represented

Source: Compiled by survey team

C－２． Initiatives by international organizations and governments to promote digital health

In terms of investment in R&D related to digital health, the contribution of the private sector is still low in Brazil, and the state is taking the initiative.

. In the Ranking 100 Open Startups 2020, the number of open innovations between companies and startups more than tripled, from 8,050 in 2019 to 26,348 in 2021[79].

The main initiatives to promote digital health by international organizations and governments in Brazil include the following related organizations, acceleration programs, and innovation hubs.

（１） Initiatives of International Organizations

Table III-13 List of initiatives by international organizations

organization	Overview
Pan American Health Organization (PAHO) [80]	It is the regional office for the Americas of WHO, established in 1902, and is the specialized health agency for the Americas. It has a technical team that specializes in projects focused on innovation and strengthening of the health sector. It is engaged in the following activities; ・ Promote technological innovation and technology transfer in public and private research institutions responsible for pharmaceutical production and technology development ・ Strategic management of the health industrial economic complex

[79] Panorama da Open Innovation entre Corporações e Startups no Brasil | 2016-2021, https://www.openstartups.net/site/ranking/insights-2021.html (accessed Sep. 06, 2021)

[80] Organização Pan-Americana da Saúde. Portfólio de cooperação técnica OPAS/OMS. Representação no Brasil. 2ª Edição. Brasília, D.F.: OPAS; 2018 Available from: https://iris.paho.org/bitstream/handle/10665.2/34872/OPASBRA18007-por.pdf?sequence=5&isAllowed=y

organization	Overview
	・ Encouragement of technological development for SUS and support for its dissemination to the public ・ Support for R&D independent of overseas markets ・ Strengthen the country's capacity to regulate medical technology and implement cross-cutting activities to drive development and innovation of medicines and services ・ Promote dissemination of information on the health economic and industrial complex
Inter-American Development Bank (IDB)	It is working to promote trade and regional integration as well as socioeconomic development in Latin America and the Caribbean. The following projects related to digital health are being implemented. 【Open innovation in the health sector related to COVID-19】[81] In partnership with InovaHC and IPT, the project aims to support Ideia.Gov, the open innovation program of the state government of São Paulo, in identifying challenges, soliciting and selecting proposals, and financing and validating technology solutions to address healthcare needs in the COVID-19 disaster. 【Laura Digital Emergency Department (Laura Digital ED) with Artificial Intelligence (AI)】[82] To avoid congestion and unnecessary visits to the emergency room, support for screening and other hospital processes is being provided. 【Allm: Cross-border Telemedicine to Strengthen Responses to COVID-19 with an Existing Digital Health Solution for Stroke Care】[83] Based on an existing mobile application for stroke, it is developing a digital communication platform focused on addressing COVID-19 and other acute care patients in Brazil. It leverages Japan's knowledge and experience with COVID-19.

[81] Brazil, IDB Project Detail, Open Innovation for the Health Sector in the Fight Against COVID-19 https://www.iadb.org/pt/project/BR-T1457
[82] Brazil, IDB Project Detail, Laura Digital Emergency Department (Laura Digital ED) with Artificial Intelligence, https://www.iadb.org/pt/project/BR-T1459
[83] Brazil, IDB Project Detail, Allm:Cross-border Telemedicine to Strengthen Responses to COVID-19 with an Existing Digital Health Solution for Stroke Care https://www.iadb.org/pt/project/BR-T1453

organization	Overview
	【NeuralMed: Detection of Covid-19 Pulmonary Alterations on Chest X-rays using Artificial Intelligence】[84] AI is being used to analyze chest X-ray images to assist in making more accurate diagnoses for patients with suspected COVID-19.
World Bank [85]	Based on the Country Partnership Framework, World Bank is implementing initiatives focused on the following three pillars; ・ Improving financial sustainability and service delivery: financial support, including pensions and social protection schemes; improving efficiency of public services in education and health sectors ・ Increase productivity and private sector investment: reduce regulatory barriers and promote competition, invest in infrastructure ・ Inclusive and Sustainable Development: Promoting Global Partnerships, Supporting National Defined Contributions

Source: Compiled by survey team

（２） Efforts of Domestic Institutions

Domestic policies range from direct support for scientific research to tax incentives and subsidies for start-up companies. The main government institutions include public universities, technological research institutes, research and development institutions, and more recently, the Brazilian Company for Industrial Research and Innovation (Embrapii). In the innovation scenario, there are incubators, technology parks, private investors, companies, and systems such as the National Industrial Learning Service (Senai) and its Innovation Institute, and the Brazilian SME Support Service (Sebrae) [86]. In the health care industry, Brazil has developed an extensive system of public laboratories, including the Oswaldo Cruz Foundation (Fiocruz), the Adolfo Lutz Institute, and the Butantan Institute. These systems have made Brazil an important center for epidemiological research and have played an important role in addressing the COVID-19 crisis.

84 Brazil, IDB Project Detail, NeuralMed: Detection of Covid-19 Pulmonary Alterations on Chest X-rays using Artificial Intelligence, https://www.iadb.org/pt/project/BR-G1009
85 The World Bank, Brazil, https://www.worldbank.org/en/country/brazil/overview#2
86 LEAL, C.I.S; FIGUEIREDO, P.N. Inovação tecnológica no Brasil: desafios e insumos para políticas públicas. Revista de Administração Pública. Rio de Janeiro, Brasil, 2021. https://www.scielo.br/j/rap/a/th4kPMNYksKFkZDwSdWs7Zj/?format=pdf&lang=pt (accessed Sep. 06, 2021)

１） Government Initiatives

Table III-14 List of government initiatives

Institutions, programs, etc.	Overview
StartupsxCovid19	The Ministry of Economy has invited Brazilian startups to participate in the StartupsxCovid19 campaign launched by Comunidade Governança & Nova Economia (Gonew.co) with the support of the Brazilian Startups Association (Astartups). Brazilian startups with innovative solutions in the areas of infection prevention, treatment and technological solutions for remote work to combat the COVID-19 crisis have been invited to share their knowledge and projects.
UAITEC	Seeking solutions to analyze financial support. The Government of the State of Minas Gerais is attempting to obtain financial support by mapping innovative projects and ideas of companies and scientific, technological and innovation institutions located in Minas Gerais that promote solutions to fight the spread of COVID-19 and overcome the social and economic losses caused by it. The project is an attempt to obtain financial support.
IdeiaGov	Technological Challenges Against Covid-19 It aims to select innovative solutions to solve specific challenges faced by public health institutions in the fight against COVID-19. IdeiaGov's COVID-19 fight, promoted by the Ministry of Economic Development and Impact Hub, is being carried out in collaboration with various government agencies, including the São Paulo State Health Department, the Clinica Hospital of the University of São Paulo's School of Medicine, the Institute of Technology (IPT), and the São Paulo Data Processing Company (PRODESP).
InovaSUS [87]	It is an initiative of the Ministry of Health, coordinated by the Department of Health and Labour Management and Regulation (Degerts) of the Department of Labour Management and Health Education (SGTES), and aims to identify, recognize and evaluate innovative practices in health and labour management.

Source: Compiled by survey team

[87] saude.gov.br/component/tags/tag/inovasus.

２） Other Initiatives

Table III-15 List of other initiatives

Institutions, programs, etc.	Overview
Get off the paper [88]	With the support of the Startup Rio Program, the accelerator is launching a challenge, "Solutions to COVID-19," aimed at encouraging quick, viable and effective solutions to the problems caused by COVID-19.
Tecnopuc, PucRS-Ideia [89]	This program provides labs to support solutions on COVID-19.
Rio Startup RIO [90]	An acceleration program that provides mentoring to startups with solutions already under development for COVID-19 to help them improve and complete their projects.
COVID-19 Task Force - Brazil Lab [91]	The COVID-19 Task Force aims to accelerate digital technologies that support the challenges faced by governments in the areas of public sector digitization, education and productivity enhancement.
Inovativa Brasil [92]	In partnership with ABStartups, the program organizes weekly demo days aimed at introducing startup solutions to institutions such as the Ministry of Health, Ministry of Economy, MCTIC, BNDES, Embrapii, Finep, ABDI and Banco do Brasil.
GROW+ Aceleradora de Startups [93]	GROW+ An online hackathon conducted by Aceleradora de Startups, Grow+ is an online-only event that seeks structural ideas to mitigate the impact of COVID-19 on society.
Shell Iniciativa Jove [94]	An acceleration program for technology startups in the areas of energy, smart cities and the fight against COVID-19, launched by Shell Brazil.
Abimed. [95]	It works with public health agencies to promote the implementation of policies and regulations that allow the public to have quick access to new technologies and innovations in an ethical business environment.
Brazilian Association	It was founded in 2016 with the goal of empowering entrepreneurs to join

88 www.saidopapel.com.br/covid-19
89 pucrs.br/coronavirus/tecnopuc-available laboratories-to-support-demands-related-to-covid-19
90 startuprio.rj.gov.br
91 forcatarefacovid19.brazillab.org.br
92 inovativabrasil.com.br/coronavirus
93 growplus.com.br/hack-for-brazil-covid-19-online hackathon
94 www.iniciativajovem.org.br/site.
95 abimed.org.br/AboutUs

Institutions, programs, etc.	Overview
of Healthcare Startups [96]	forces to develop their vision of transforming healthcare through technology.
Medical Valley [97]	The organization, which originated in Germany and was brought to Rio Grande do Sul, aims to improve the healthcare sector by creating synergies among the players that make up the ecosystem.
Empreendeda Saúde Award [98]	Evaluate projects in terms of their potential to contribute to the improvement of practices, processes, technologies, and management methods in the healthcare sector, and promote solutions that impact the efficiency of healthcare networks, patients, and hospitals.
InovaHC District (São Paulo/SP) [99]	It functions as a hub for collaboration between academia and the private sector. As an innovation hub, it not only promotes joint development of AI with Siemens and other companies, but also serves as an incubation facility for start-up companies. It also provides advisory services to start-up companies, introduces them to medical facilitys, and provides support for technology diffusion and business expansion. It is collaborating with the World Bank, IDB, UNDP, etc.
Cubo Health (São Paulo/SP) [100]	Cubo is an acceleration facility under the umbrella of Itau, a major bank in Brazil. It is a cross-sectional collaboration between multiple domains such as healthcare, education, and fintech, and provides an environment to promote open innovation and mentorship for startups to raise funds. Most of the participating companies are from Brazil, but there are some from Latin American countries. There are no Japanese companies now, but they can participate.
Ebserh	It is one of the largest network of 40 public hospital in the country and is under the Ministry of Education. It has been working on DX since before COVID-19, and is also promoting research and development using medical big data accumulated in its hospitals to improve the efficiency of the medical treatment process, support decision-making by doctors, reduce the risk of medical errors, and promote preventive medicine.

96 abssaude.com.br
97 medical-valley-brazil.com/en/overview
98 premium.com.br.
99 content.district.me/district-inovahc.
100 https://cubo.network

Institutions, programs, etc.	Overview
Biominas (Belo Horizonte/MG) [101]	An innovation hub focused on projects and companies in biotechnology, healthcare, and information technology.
ICC BioLabs (Fortaleza/CE) [102]	An innovation hub that aims to educate and inspire entrepreneurs to develop advanced technologies and solutions for the health care sector, with a focus on improving the quality of human life.
Hub Mandic (Campinas/SP) [103]	An initiative of Faculdade São Leopoldo Mandic, an innovation hub that fosters and supports the connection between the fields of science, innovation and technology and the medical sector.
Open D'Or Hub (Rio de Janeiro/RJ) [104]	A platform to connect innovative startups with stakeholders from the ecosystem, corporations, investors, and the academic health sector.
BioTech Town (Minas Gerais)	It is a center dedicated to the development of companies, products and businesses in the field of biotechnology and life sciences.
FAPESP	It directs research initiatives to combat COVID-19 and provides funding to encourage small and medium-sized companies to develop projects that will bring about technological innovations to diagnose and treat patients.
Super challenge 100 Open Startups COVID-19	Emerging companies and the scientific community are now able to quickly and effectively confront the COVID-19 crisis and present and provide solutions to mitigate its impact as much as possible.
ENAP	Four challenges have been launched to confront COVID-19. With a total prize pool of R$400,000 (≒US$72,295), divided into two categories: individual and corporate, the Covid-19 Challenges were launched by BNDES, IDB, the Federal Audit Office, Flacso, and the United Nations Development Programme (UNDP). Covid-19 Challenges is a project of ENAP supported by BNDES, IDB, the Federal Audit Office, Flacso and the United Nations Development Programme (UNDP). Covid-19 Challenges is an outcome of ENAP supported by BNDES, IDB, Federal Audit Office, Flacso, and United Nations Development Programme (UNDP).
CAPES	This action will allocate R$200 million (≒ US$36,147,420) over the next four years for projects that directly or indirectly deal with work related to COVID-19 research. In addition to the amount envisaged in the scholarship

[101] biominas.org.br.
[102] icc.org.br/biolabs
[103] hubmandic.com.br
[104] rededorsaoluiz.com.br/instituto/idor/inovacao/open-dor

Institutions, programs, etc.	Overview
	concession model, 2,600 scholarships will be awarded, and up to R$345,000 (≒ US$62,351) of funding and capital will be provided per project for up to 30 studies.
MCTIC / CNPq / FNDCT / MS / SCTIE / Decit No.07/2020	Research to fight COVID-19, its consequences and other severe acute respiratory syndromes It will be launched in April 2021 and envisages selecting proposals in the following themes: treatment, vaccines, diagnosis, etiology and natural history, burden of disease, health care, prevention and control. 2,219 proposals were received by CNPq from all units of the Federation.
SaúdetechPR	An initiative of the Civic Institute's Office of Innovation Oversight and the Araucaria Foundation, it aims to promote COVID-19 diagnosis, prevention and containment projects developed jointly by the Senai Institute of Technology and Innovation in Paraná and companies and startups.
Vale + Einstein + Mater Dei	Vale, in collaboration with Albert Einstein Israelita Hospital and Mater Dei Health Network, is providing US$1 million to expand its solutions to combat COVID-19.
First National Digital Project Contest "Use of Technology in the Fight against COVID-19" Brazilian Society for Medical Informatics (SBIS)	Under the theme "Use of Technology in the Fight Against COVID-19", the first National Digital Project Contest was held. The purpose of the contest is to encourage high-quality innovation in digital projects in the spread of infection, stimulate the development of talent, and reward outstanding work in digital health, with a focus on the fight against COVID-19.
Taking care of those who care for us	The program is the result of a partnership between Johnson & Johnson Brazil, Moodar, Distrito, and Vitalk, whose mission is to provide psychological support to healthcare professionals who dedicate their lives to helping others. It offers tips and self-care exercises through online therapy consultations and unlimited text chats via Vitalk, a platform that uses AI to solve mental health problems.

Source: Compiled by survey team

IV. Overview in Kenya

IV. Overview in Kenya

A. Perspective of Target Country

A－１. General Information

（１） Economic Situation

Although the impact of COVID-19 has resulted in negative GDP growth in 2020, economic growth has been high and is expected to continue in 2021. The GDP for 2019 is US$95,503 million, with a GDP growth rate of 5.4% and GDP per capita of US$1,816.5. The Kenyan economy continues to grow steadily, mainly in the agricultural sector. It is home to the largest port in East Africa, Mombasa, and plays a central role in the regional economy as the gateway to East African countries. As a result of the spread of COVID-19, exports of services and agricultural products were affected, and the real GDP growth rate for 2020 was negative at -0.3%, the first time in 30 years since 1992 that it turned negative[105]. Looking at the growth of real GDP by industry, it is noteworthy that the hotel and restaurant industry experienced a significant decline of 47.7%. Tourism is Kenya's key industry for earning foreign currency, but due to the suspension of flights by major countries and travel restraint, the number of foreign tourists visiting the country decreased by 1.45 million to 580,000 compared to the previous year.

On the other hand, according to the IMF, Kenya (7.6%) has the highest projected economic growth rate for 2021 among the 45 sub-Saharan countries defined by the IMF[106].

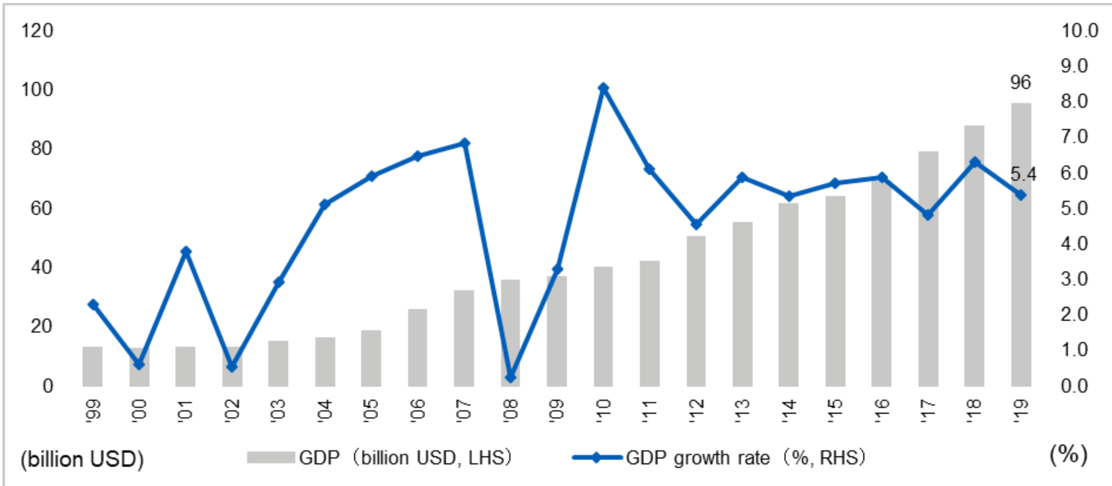


Figure IV-1 GDP (US$) and GDP growth rate in Kenya

Source: Compiled by survey team based on World Bank, DataBank, and World Development Indicators

105 Kenya National Bureau of Statistics, "Economic Survey 2021.
106 JETRO, https://www.jetro.go.jp/biznews/2021/04/d46932ee720e7c1f.html

Due to the prolonged COVID-19, the number of employed people has declined from 18,142,700 in 2019 to 17,405,200 in 2020. As for wages, the average annual income increased by 3% year-on-year to 801,708 Kenyan shillings (≒ US$7,245) against an inflation rate of 5.4% in 2020, effectively reducing disposable income. In 2022, a presidential election is scheduled to be held once every five years, and the pre-election campaign has already begun, so the economic situation may change[107].

（２） Population Movements

Although the population is growing steadily, the population pyramid shows a high fertilityand high mortality structure. The population in 2019 is 52,573,000 (male: 49.6%, female: 50.4%), with a population growth rate of 2.3%. The population growth rate has been high,, according to the WPP of the United Nations, the population is expected to continue to grow until around the year 2100.

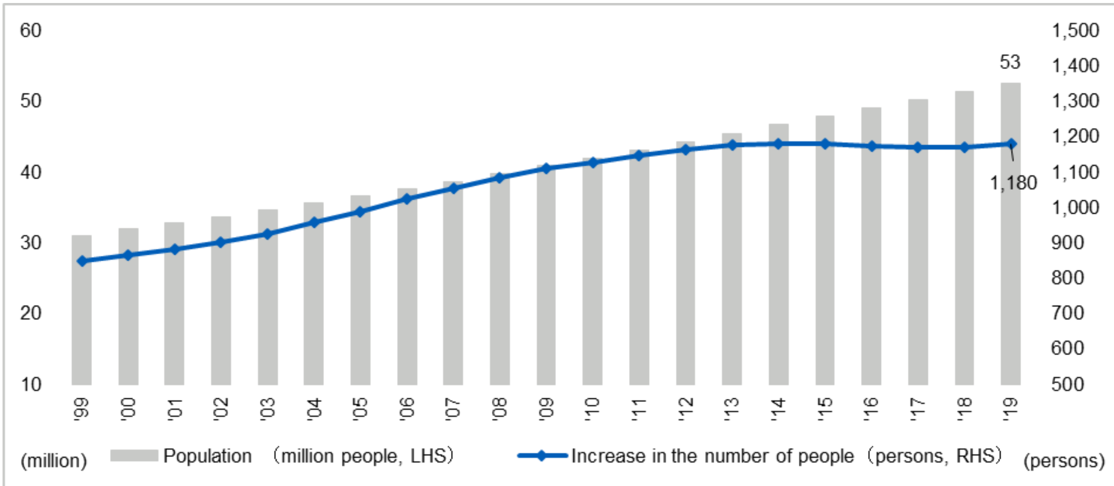


Figure IV-2 Total population and population growth in Kenya

Source: Compiled by survey team based on World Bank, DataBank, and World Development Indicators

[107] JETRO, https://www.jetro.go.jp/biznews/2021/09/4535013199875ef1.html

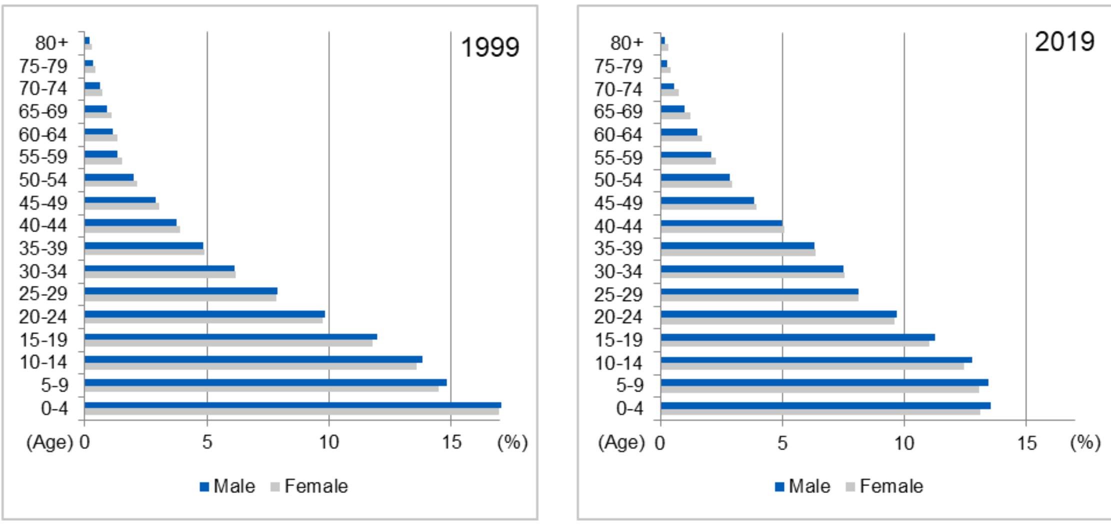


Figure IV-3 Population pyramid in Kenya

Source: Compiled by survey team based on World Bank, DataBank, and World Development Indicators

A－２． COVID-19 Situation

Although the fifth wave of the spread of COVID-19 infection came in December 2021, the number of infected people is currently on the decline. Vaccination is being promoted by the government, but supply to the public has been delayed due to delays in securing vaccine, negative opinions and misperceptions about vaccination by the public, etc[108]. As of February 16, 2022, the average number of new infections per day has decreased to 43, indicating that the fifth wave has come to end. The total number of infected people in Kenya is 322,517, and the number of deaths is 5,632[109]. The total number of infected people per million populations is 5,713, which ranks 169th out of 223 countries in the world[110]. Although there may be insufficient number of tests conducted, the infection situation according to statistics is relatively minor compared to the rest of the world.

[108] https://www.who.int/news-room/feature-stories/detail/kenya-increases-uptake-and-equity-for-covid-19-vaccinations

[109] REUTERS COVID-19 TRACKER, https://graphics.reuters.com/world-coronavirus-tracker-and-maps/ja/countries-and-territories/kenya/

[110] https://www.worldometers.info/coronavirus/#countries

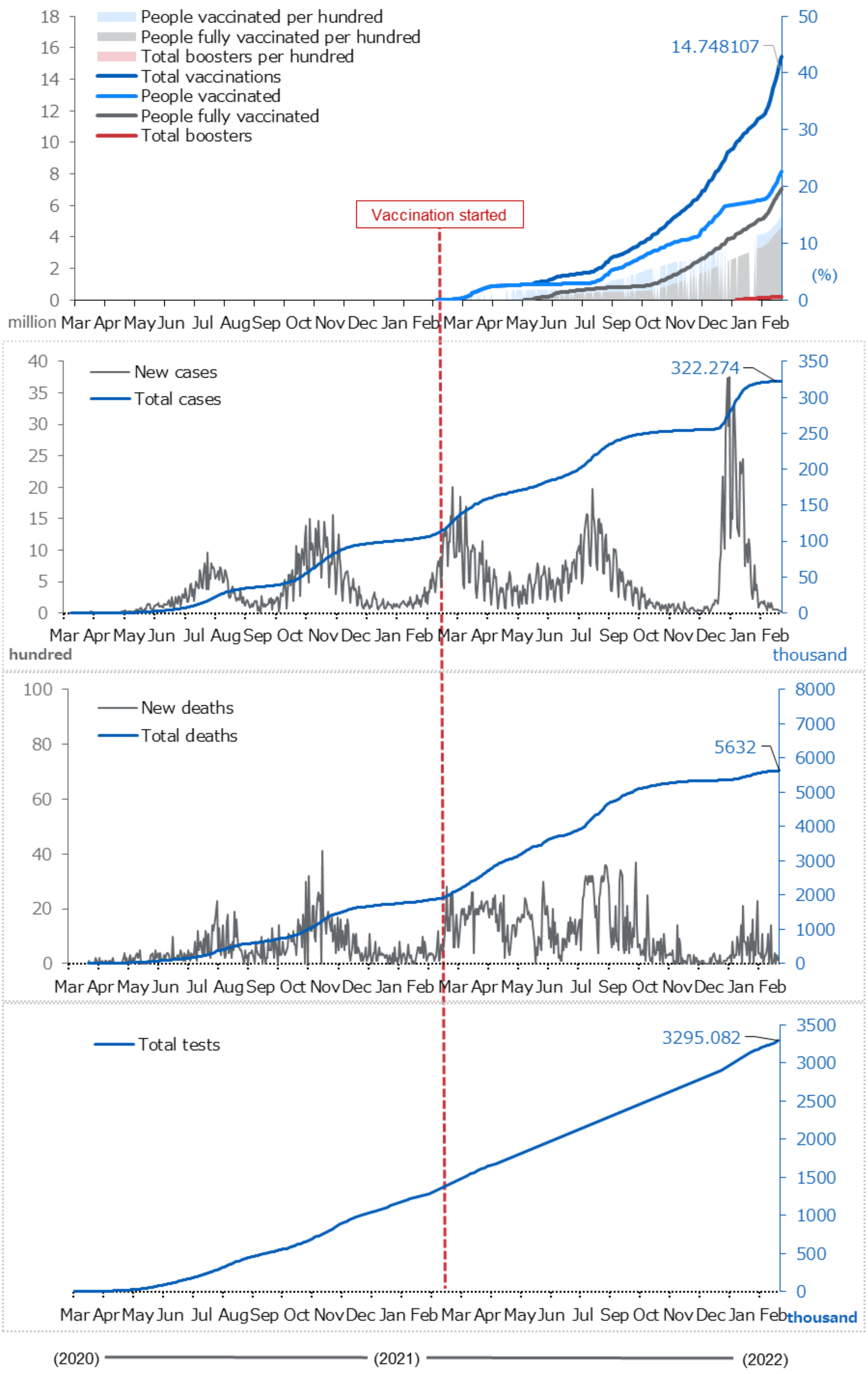


Figure IV-4 COVID-19 infection and vaccination status in Kenya

Source: Compiled by survey team based on Our World in Data.

COVID-19 test is done in designated health facilities, but many positive patients, mostly asymptomatic, are referred to home care services by the Ministry of Health. Not all health facilities provide COVID-19 services, and only high-level public facilities and large private hospitals, such as levels 4-6 (see A-5 referral system), provide COVID-19 services such as screening, PCR (Polymerase Chain Reaction) testing, and treatment. Tertiary hoapitals and Kenya Medical Research Institute (KEMRI) are responsible for the overall epidemiology of infectious diseases, including testing, monitoring and tracing of suspected cases, while primary care institutions such as level 2 and 3 and small private hospitals are required to conduct basic screening and refer suspected cases to higher level institutions for testing, inspection and treatment. Medical facilities should screen patients by checking for respiratory symptoms such as cough and dyspnea, fever above 38℃, travel history, and contact with positive individuals. If the test results are positive and there is a possibility of COVID-19 infection, the patient should be hospitalized and isolated for monitoring. After the symptoms have subsided, usually 10 to 14 days later, a second test is conducted to determine if the patient can continue to be hospitalized or if he or she can be discharged and monitored in home isolation until the results of the second test are negative.

The vaccine manufactured by AstraZeneca arrived at Kenya on March 2, 2021, under the framework of the COVAX (COVID-19 Vaccine Global Access)[111]. Vaccination began on March 5, 2021, with the aim of vaccinating 16 million people, or 30% of the population, in 18 months through a total of three phases. In the first phase, the target population for vaccination was supposed to be medical personnel, police personnel, education personnel, immigration personnel, etc. However, as of August, the population over 58 years old has been added. The vaccine currently being offered is manufactured by AstraZeneca and is available free of charge to those who qualify for the vaccination[112]. Globally, there are major challenges in the vaccine supply chain, and Kenya has been affected by these challenges. Of the 4.1 million doses planned at the start of the program, Kenya has received only 1.02 million doses, which is far behind the original plan.

In the second phase, approximately 9.7 million people aged 50 years and older and people aged 18 years and older with underlying diseases will be vaccinated. In the third phase, about 4.9 million people other than those mentioned above who wish to be vaccinated are scheduled to be vaccinated[113]. According to the Kenyan Ministry of Health, as of January 12, 2022, 15% of the population had received at least one dose of vaccine, 13% had completed two doses, and 0.42%

[111] https://www.gavi.org/covax-vaccine-roll-out/kenya
[112] Embassy of Japan in Kenya, Information on the current situation and countermeasures against the new coronavirus in Kenya, https://www.ke.emb-japan.go.jp/files/100222981.pdf
[113] JETRO, https://www.jetro.go.jp/biznews/2021/03/55e281bc2ab553b3.html

had completed a booster dose, causing delays in planning.[114]. According to WHO, 22 out of 42 sub-Saharan African countries, including Kenya, have a first dose vaccination rate of less than 20%[115].

A－３． Health Care Policy, Digital Health-related Policy, COVID-19-related Policy

（１） Health Care Policy

Barriers and regional disparities in access to quality healthcare continue to be recognized as a major problem. As part of the infrastructure development for the provision of healthcare services, the use of ICT in the healthcare sector has been positioned as one of the priority policies.

The long-term health policy is the Kenya Health Policy, the policy-based strategy is the Kenya Health Sector Strategic and Investment Plan, the president's priority measures during his term are the Big Four Agendas, and the law is the Health Act 2017.

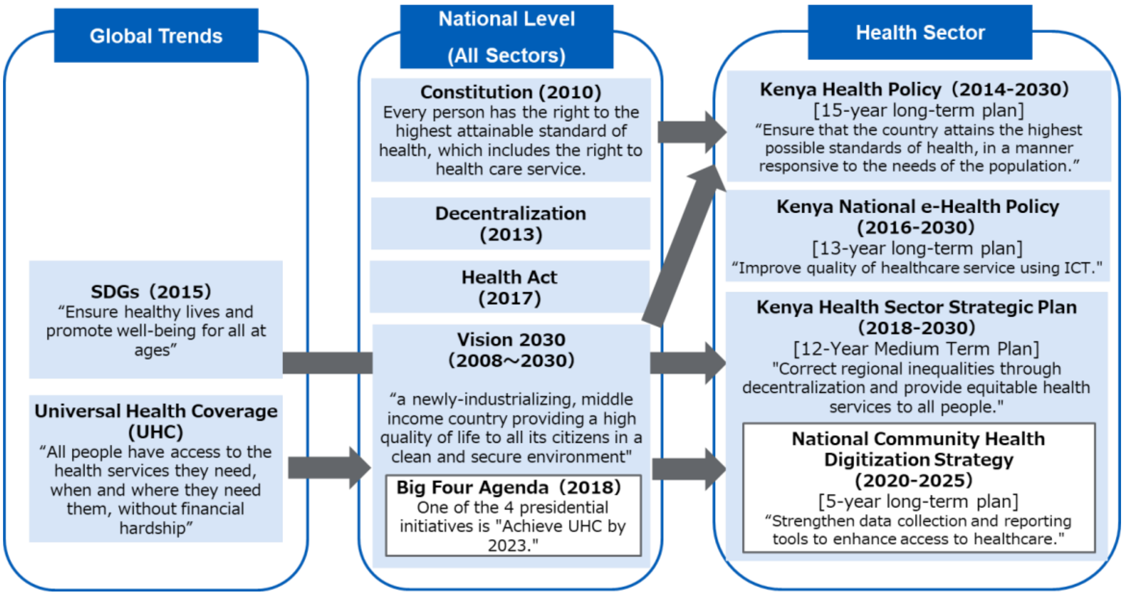


Figure IV-5 Overview of Kenya's health policies and strategies

Source: Compiled by survey team

１） Kenya Health Policy (2014-2030)

This is the Long Term Health Care Policy (15 year plan) for Kenya. It was prepared based on global commitments such as the Long Term Development Plan VISION 2030, the new Constitution (2010), decentralization and achievement of UHC which was implemented in

[114] Kenya Ministry of Health, https://www.health.go.ke/
[115] https://covid19.who.int/region/afro/country/ke

2013.

Although infectious diseases and maternal and child health indicators have improved in recent years mortality rates due to neonatal deaths, human immunodeficiency virus (HIV), and acquired immunodeficiency syndrome (AIDS) remain high. The policy also states that NCDs such as malignant neoplasms are on the rise, and therefore the main health policy objectives are maternal and child health, nutrition, control of infectious diseases, enhancement of measures against NCDs, provision of essential health services, and promotion of public-private partnership. The policy issues to be addressed to achieve these goals are health financing, governance (leadership), pharmaceuticals and technology, health information, human resources, service delivery systems, infrastructure development including the development of digital health, and the enhancement of research and studies. In addition, about 46% of the population is poor[116], and there is a shortage of medical facilities and human resources in poor areas, so improving access to health services is an issue.

２） Kenya Health Sector Strategic Plan (KHSSP) (2018-2023)

This is the second Kenya Five-Year Medium Term Health Care Strategy based on the Kenya Health Policy, which includes a strategy for implementing the Big Four Agenda, a presidential initiative aimed at achieving UHC.

The main objective is to provide equitable health services to all citizens by reducing regional disparities due to decentralization. Diseases of strategic importance include diarrhea, HIV/AIDS, malaria, tuberculosis, hypertension, and diabetes. Although maternal and child health indicators have improved compared to 2013, the rate of four antenatal check-ups is still low at 48.8% as of 2018, and further measures are needed. Furthermore, although the prevalence of diabetes mellitus, an NCD, is low at 2%, 41% of all patients are diagnosed and about 7% are treated, indicating the need for improved diagnosis.

It mentions that the quality of healthcare delivery is low and that human resources, drugs, operating rooms, supplies, and emergency systems do not meet basic standards, and indicates support for infrastructure development. In addition, the enhancement of ICT is one of the priority policies. Although progress has been made in the timely management of information for policy formulation, the development of online logistics for procurement, and the automation of laboratory equipment to reduce the workload, the situation of wide disparities among regions in the development of computers and other information and communication equipment and the Internet remains a barrier.

[116] Kenya Economic Survey 2013

３） Big Four Agenda (2017)

VISION 2030, the new Constitution of 2010, is a policy agenda formulated by President Uhuru Kenyatta that overlooks policies in various fields. The four areas of particular emphasis are industrial development, housing provision, UHC, and food security. In the health sector, in order to achieve UHC by 2022, the government has set the goals of free payment for essential medical services (Benefit Package) and a 54% reduction in the share of household medical expenses. To achieve this goal, the national budget allocation to the health sector will be increased from 7% in 2017 to 10% in 2022. The Government of Kenya will also reform the structure of the National Hospital Insurance Fund (NHIF), which is responsible for public insurance, expand public insurance coverage, improve public financial management, promote digitalization, and review health service packages. The Government of Kenya has launched a pilot project in four counties (Kisumu, Machakos, Nyeri, and Isiolo) that includes all of the above measures with the aim of ensuring that all residents have access to necessary health services. On October 31, 2020, the President announced the UHC scale-up, including coverage of 1 million poor households and NHIF reform.

４） Health Act 2017

The Act governs human health, animal health, water and environment, and food in Kenya. In particular, it aims to protect and promote the rights of children to basic nutrition and health care services. The Act permits the use of technology for health care delivery and provides for digital health service providers, health-related products, health tech, etc. It also regulates the collection, use and storage of data. It recognizes that Kenya's health care system includes both public and private health institutions at the national and county levels, and gives equal authority to both. 60The article talks about equal application of standards between public and private institutions, while the 86article talks about the intention to optimize the use of private health institutions to reduce the burden on the public sector.

（２） Digital Health-related Policy

With the establishment of the e-Health Unit within the Ministry of Health in 2020, the Kenyan government has begun to promote e-Health and telemedicine. While the implementation of digital health policy is a function of the MOH, its development and regulation is done by the Ministry of Information, Communications and Technology (MICT). The MOH has an ICT Department, which works with the MICT to establish regulations. While the MICT is responsible for regulations and licensing, the ICT Department of the Ministry of Health oversees the compliance of ICT companies with the set regulations. The e-Health Unit was established under the ICT Department and is tasked with the implementation and oversight of solutions including remote delivery of health services using ICT and mobile platforms. The e-Health Unit is also tasked with creating an enabling environment for the sustainable adoption, implementation and efficient use of e-Health products and services at all levels of health care delivery. The MICT and the MoH have jointly developed a Digital health Policy that governs the adoption and uptake of digital health. Digital health in Kenya is commonly referred to as e-Health.

１） Kenya National e-Health Policy (2016-2030) and e-Health Bill[117]

This policy document is based on an analysis of the e-Health situation in Kenya and aims to improve the quality of health services through the use of ICT. The policy recognizes challenges such as lack of collaboration between the MICTand the e-Health Unit of the MoH, high cost of development and implementation of e-Health systems and innovations, inadequate technical infrastructure, low ICT literacy, and low government involvement. To address these challenges, its vision is to create an enabling environment for the sustainable adoption, implementation, and efficient use of e-Health products and services at all levels of the health care sector. Initiatives such as tele-diagnosis and treatment, m-Health, and tele-healthcare education are being undertaken to reduce healthcare disparities among regions.

In line with this policy, the Ministry of Health has prepared the e-Health Bill which is expected to be approved by the Parliament in 2021. In addition to recognizing the need to share patient data among medical facilities and making provisions for sharing such data, the bill also focuses on issues such as data protection and use, which have hindered the adoption of digital health in the past.

２） Kenya Standards and Guideline for mHealth System (established in 2017, revised in 2020)

m-Health (Mobile Health) in Kenya is positioned as a part of e-Health. In this guideline, m-Health is defined as "interventions and programs designed to support the delivery of health care services through mobile technologies and devices" and guidelines for its implementation have been developed. The scope ranges from simple applications for transferring medical information to cell phones via short message services to remote diagnosis applications that require sophisticated systems.

３） National Community Health Digitization Strategy, 2020-2025[118]

It aims to strengthen access to health care in community health, increase productivity, reduce poverty, and address hunger and preventable diseases. The five priority areas are as follows:

1. Leadership and governance

[117] https://health.eac.int/file-download/download/public/86
[118] https://www.health.go.ke/wp-content/uploads/2021/03/eCHIS-Strategy-2020-2025.pdf

2. Service delivery
3. Technology
4. Capacity development
5. Quality control, monitoring and evaluation

With regard to 3. Technology in particular, it is mentioned that the weakness of data collection and reporting tools in the provision of community health is a hindrance to data utilization. The following strategies are summarized for the establishment of an electronic community health information system (e-CHIS).

- Support the development and implementation of an e-CHIS that supports service delivery at the community level and integrates with other systems in the health sector, according to current standards
- Support ICT infrastructure, including centralized servers and monitoring infrastructure.
- Support ICT equipment and facilitation for community health workers.
- Support information security implementation and compliance with data protection laws and guidelines
- Support integration of eCHIS data into existing Ministry of Health databases.
- Develop a didactic framework to standardize reporting documents on design, implementation, and maintenance aspects of the e-CHIS.
- Develop a data dictionary (back-end and background) for the e-CHIS.

４） National Broadband Strategy (NBS) (2018-2023)

The second phase of the National Broadband Strategy (NBS), based on the reflection that the first phase of the NBS, formulated in 2013, failed to achieve most of its goals, has the following strategies for the second phase;

- Improve access to optical communications, improve 3G and 4G connectivity and introduce 5G
- Promoting digitization in public hospitals, public schools, and government agencies
- Improve communication conditions in rural and depopulated areas, and introduce tax incentives and subsidies for broadband deployment.
- Review of frequency distribution and tariff system in line with current market conditions

５） Digital Health-related Policy by Local Governments

At present, there are no officially announced policies related to digital health by local governments. The survey team's interviews with the National Governors' Association confirmed that some local governments (about five counties) are moving to develop strategies for digital health, but no detailed information was available. The adoption and implementation of digital health is governed by 1) National e-Health Policy, ICT Policy and Data

Protection Act (2019) above. While the national government will oversee implementation, enforcement will take place at the county level. The approval process involves submitting a proposal to the respective county health department for review for compliance with relevant laws and regulations and interoperability within the existing health policy framework. In addition, approval from the Pharmacy and Poisons Board (PPB) is required, a process that takes about two or three months.

（３） COVID-19-related Policy

In accordance with Presidential Decree No. 2 of 2020, the government established the National Emergency Response Committee on COVID-19 in February 2020. This committee is tasked with announcing the infection situation, developing the capacity of health care workers and other professionals, strengthening surveillance at entry points, coordinating the preparation of national, provincial, and private isolation and treatment facilities, coordinating the supply of test kits and critical medicines, conducting economic impact assessments, developing mitigation strategies for the spread of the disease, and raising public awareness. It has been charged with the task of using Facebook for publicity, etc.

The Kenyan government is playing a role in educating the entire population about COVID-19 as part of a rapid response plan to control the spread of the disease. The Ministry of Health has been working with county governments, African Medical and Research Foundation (AMREF), World Bank, WHO, Kenya Private Sector Alliance (KEPSA), Kenya Medical Alliance, the United Nations, Kenya Red Cross and other stakeholders to support COVID-19 awareness raising activities among community health volunteers across the country.

１） Establishment of National Emergency Response Committee (NERC) on COVID-19

The committee, established by the government under Presidential Decree No. 2, is tasked with developing the capacity of health care workers and other professionals; strengthening surveillance at entry points; coordinating the preparedness of national, county, and private isolation and treatment facilities; coordinating the supply of test kits and critical medical supplies; conducting economic impact assessments; and developing mitigation strategy development.

２） Establishment of National COVID-19 Taskforce

The National COVID-19 Taskforce has formulated the Kenyan COVID-19 Contingency Plan, which serves as a risk assessment and response policy. From the early stage of infection confirmation, measures have been taken by issuing presidential decrees such as suspension of international flights, closure of schools, curfew, ban on travel between cities, and restrictions on attendance at weddings and funerals.

As of June 2021, schools have reopened, travel between cities is possible, and international flights are still operating except in countries where the outbreak has spread, such as India. As of July, the government (Ministry of Health) has instructed the following measures: no going out at night (10pm-4am), no meetings or gatherings, avoid crowded places, worship no more than one-third of the capacity in accordance with the rules of the religious committee, keep people at a distance, promote hand washing, regulate the business of restaurants, and ensure remote work.

３） Issue of Interim Guidelines on Management of COVID-19 in Kenya (April 2020)

It is a guideline issued to Kenyan health care providers in response to COVID-19, based on international standards including WHO. It specifies protocols for infection prevention and control, patient triage, emergency care, case management, and laboratory algorithms.

４） Establishment of the COVID-19 Fund

It was launched by the Kenyan government to collect donations to support the poorest and most vulnerable people in the country. In addition, the COVID-19 Foundation supplies PPE procured from domestic manufacturers to medical facilities in need.

５） Others

In addition to the above, 16 protocols and guidelines have been issued, including the following, which can be downloaded from the Kenya Ministry of Health website.

- Guidance for Hospital Discharge, Disposition, and Ending Isolation of COVID-19 Patients in the Context of Widespread Commnuity Transmission from the Department of Health County Government, August 2020)
- ADDENDUM - Covid-19 Antigen Rapid Diagnostic Testing Interim Guide -January 2021
- A Comprehensive Guide on Mental Health & Psychosocial Support during the Covid-19 Pandemic
- COVID Results submission guidelines, etc.

A－４． Health and Medical Care

（１） Basic Health Indicator

The basic health indicators are relatively improving in Sub-Saharan Africa (SSA), excluding high-income countries. The life expectancy at birth is 66.3 in Kenya compared to the SSA average of 61.6, and the mortality rate is 5.5 in Kenya compared to the SSA average of 8.4.

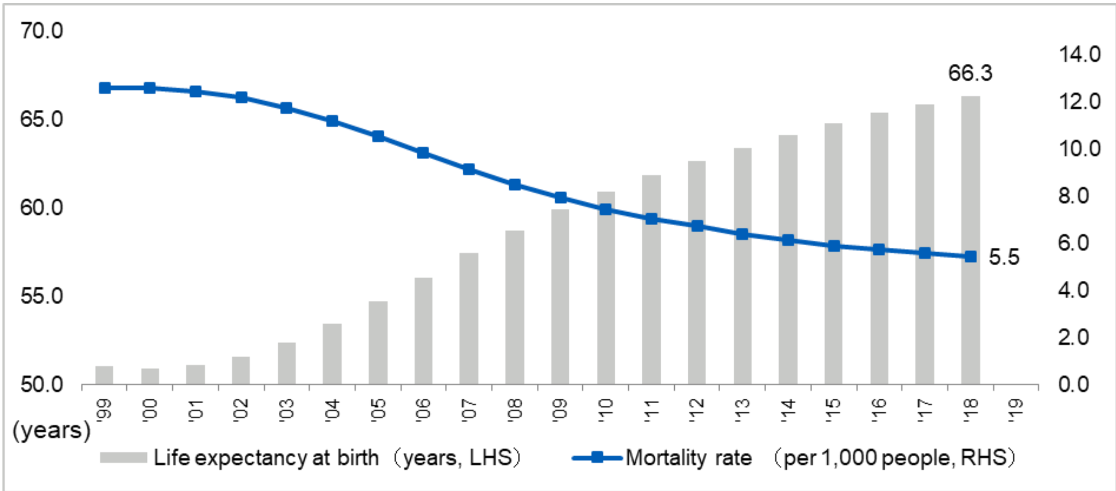


Figure IV-6 Trends in life expectancy at birth and mortality rate in Kenya

Source: Compiled by survey team based on World Bank, DataBank, and World Development Indicators

（２） Maternal and Child Health-related Indicator

The maternal and child related indices, U5MR, NMR, and MMR, have been improving year by year at levels below the SSA average (U5MR: 75.7, NMR: 27.5, MMR: 534), but are still well above the SDG targets (U5MR: 25, NMR: 12, MMR: 70). Improvement is still required. In particular, most of the cases of U5MR are caused by infectious diseases, which are considered to be caused by inadequate infrastructure including water and difficulty in accessing medical services. In adittion, the improvement in NMR and MMR has slowed compared to neighboring countries such as the Republic of Rwanda (NMR: 16, MMR: 248) and the Federal Republic of Tanzania (NMR: 20) in East Africa.

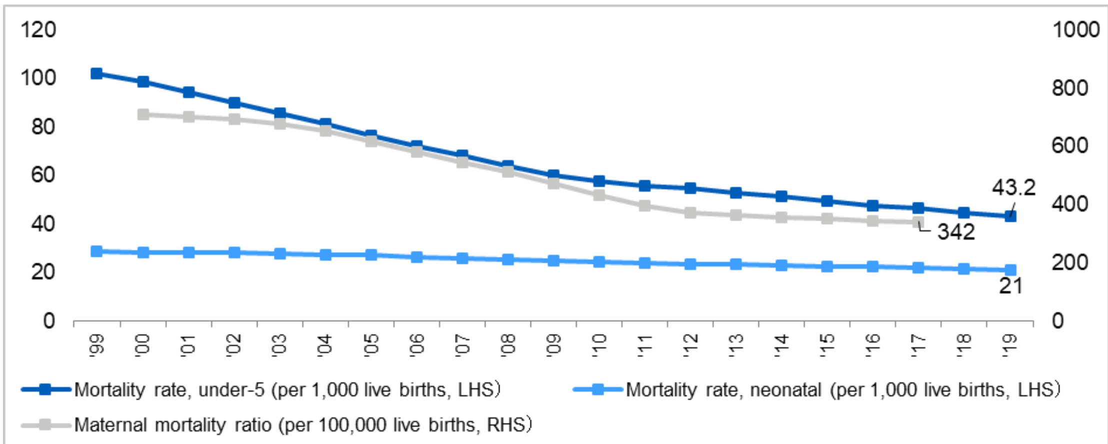


Figure IV-7 Trends in U5MR, NMR, and MMR in Kenya

Source: Compiled by survey team based on World Bank, DataBank, and World Development Indicators.

The fertility rate and total fertility rate have been on a gradual downward trend, remaining low compared to the SSA average fertility rate of 34.8 and the SSA average total fertility rate of 4.6.In addition, the number of births in Kenya in 2019 is 1.48 million (birth rate 24.4 per 1,000 population) compared to 870,000 (birth rate 7.0 per 1,000 population) in Japan, indicating a high demand for medical services in maternal and child health. . According to the WPP, the birth rate will continue to decrease after 2019, but it is expected to increase by a factor of 1.2 between 2018 and 2035, making improvement of U5MR, NMR, and MMR an important issue.

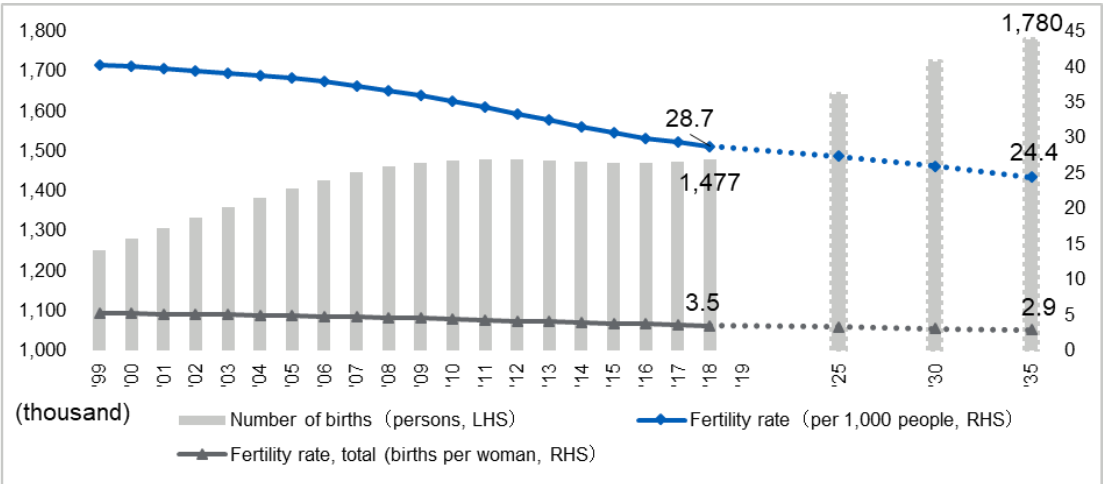


Figure IV-8 Trends in number of births, fertility rate, and total fertility rate in Kenya

Source: Compiled by survey team based on World Bank, DataBank, World Development Indicators and United Nations, and World Population Prospects.

（３） Main Causes of Death

In the 2000s, the proportion of deaths due to communicable diseases, mainly HIV/AIDS, was the highest, and the structure of the causes of death was typical for developing countries in terms of the high proportion of communicable diseases. However, in recent years, the proportion of deaths due to NCDs (cerebrovascular diseases, ischemic heart diseases, diabetes, malignant neoplasms, etc.) has been increasing. It **is** estimated that investment in facilities and equipment that can provide medical services for NCDs will be necessary in parallel with measures against infectious diseases, including those of children.

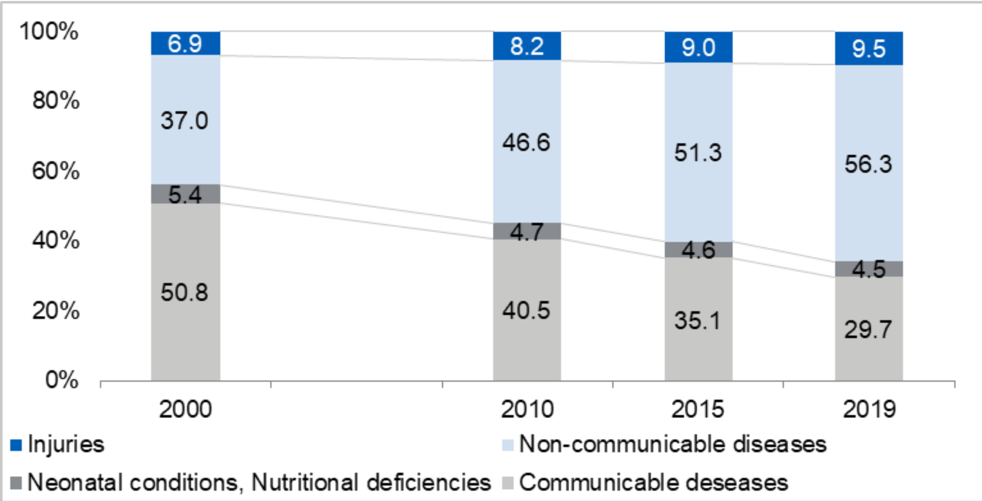


Figure IV-9 Trends in major causes of death in Kenya

Source: Compiled by survey team based on World Bank, DataBank, and World Development Indicators.

（4） Number of Hospital Bed

According to the Kenya Health Sector Strategic and Investment Plan, the number of beds per 1,000 people in SSA will increase to 1.8 beds per 1,000 people by 2023, which is similar to the average of 1.6 beds per 1,000 people in Rwanda (2007) and 1.4 beds per 1,000 people in Middle East & North Africa (2007). According to the Kenya Health Sector Strategic and Investment Plan, the goal is to increase the number of beds to 1.8 per 1,000 population by 2023, but progress is unclear. As of April 6, 2021, the number of ICU beds available for COVID-19 critically ill patients is limited to 38 in Nairobi and 32 outside Nairobi (514 ICU beds overall, 94% utilization), and a shortage of beds in medical facilities is expected to continue.

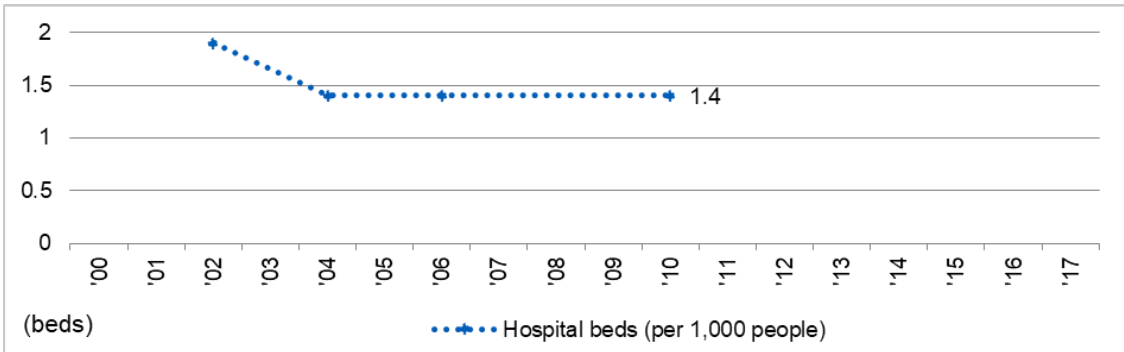


Figure IV-10 Trends in number of hospital beds in Kenya

Source: Compiled by survey team based on World Bank, DataBank, and World Development Indicators

（５） Health Human Resource

The number of doctors, nurses and midwives per 1,000 population in 2018 was 0.2 and 1.2, respectively, suggesting that the expansion of COVID-19 has made the shortage of healthcare professionals a serious challenge in the healthcare system. The 2006 World Health Report estimated the need for a minimum of 2.28 skilled health care workers per 1,000 population, but based on the tracking indicators of the SDGs, 4.45 health care workers per 1,000 population was set as the minimum SDG Index and the WHO standard.

The significant decrease in the number of nurses from 2012 to 2013 is presumably related to the implementation of decentralization. This may be due to the discrepancy between the number of registered nurses and the number of nurses actually working, caused by the compilation of information that had been managed by the national government at the county level, and turnover of nurses due to unpaid salaries, etc. However, no literature has been found that clearly shows the basis for this.

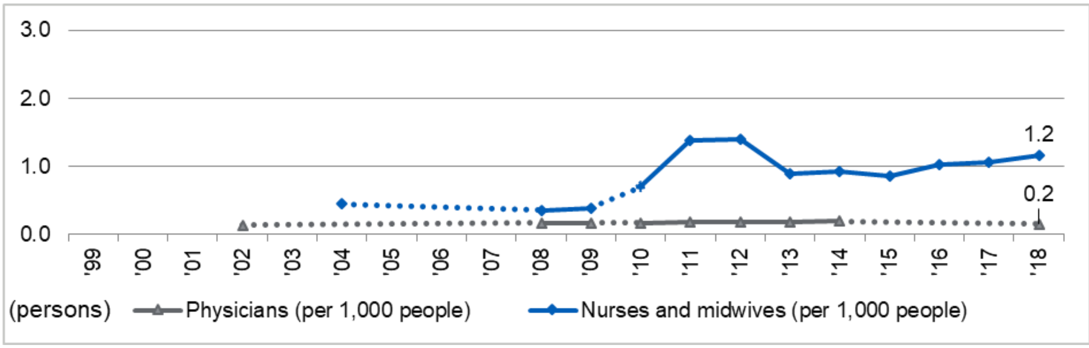


Figure IV-11 Trends in number of doctors, nurses and midwives in Kenya

Source: Compiled by survey team based on World Bank, DataBank, and World Development Indicators.

The uneven distribution of medical personnel is also considered a major issue. The following table shows the number of doctors by region in 2015. In the base data, the number of doctors is calculated for each of the 47 counties, but following the provincial demarcation used until 2013, the 47 counties are grouped into 8 regions as follows.

Of the 8 regions, 59.7% of the doctors are concentrated around the capital city, Nairobi. The population distribution is only 9.3%, and the number of doctors per 1,000 population is 0.677, which is outstanding compared to other regions. The northeast region has the lowest number of doctors, with 0.012 doctors per 1,000 people. The difference in the number of doctors between the depopulated areas and the metropolitan area is up to 56 times.

表 IV-1 Number of doctors by region in Indonesia

Region	No. of Doctors	Population Distribution	% of total land mass	No. of Doctors per 1,000 population
Nyanza	252(5.1%)	13.2%	2.2%	0.040
Eastern	198(4.0%)	12.8%	25.0%	0.033
Western	109(2.2%)	10.6%	1.3%	0.022
Rift Valley	733(14.7%)	26.8%	32.5%	0.058
Northeastern	39(0.8%)	6.8%	22.7%	0.012
Coast	407(8.2%)	9.1%	14.2%	0.094
Nairobi	2,979(59.7%)	9.3%	0.1%	0.677
Central	273(5.5%)	11.5%	2.0%	0.050
Total	4990			0.105

Source: Compiled by survey team based on Kenya Health Workforce Report 2015[119]

A－５． Referral System

In Kenya's public health service system, health activities in communities without facilities are classified as Level 1, and health facilities from clinic level to top referral are classified as Level 2-6. Private hospitals are classified as profit or non-profit. The size of each facility differs, but there is no clear division into levels as in the case of public hospitals.

Because of the free medical treatment system, there are no institutional referrals, but referrals are made from lower-ranking medical facilities to higher-ranking medical facilities according to the extent of the disease, regardless of whether they are public or private.

119 https://taskforce.org/wp-content/uploads/2019/09/KHWF_2017Report_Fullreport_042317-MR-comments.pdf

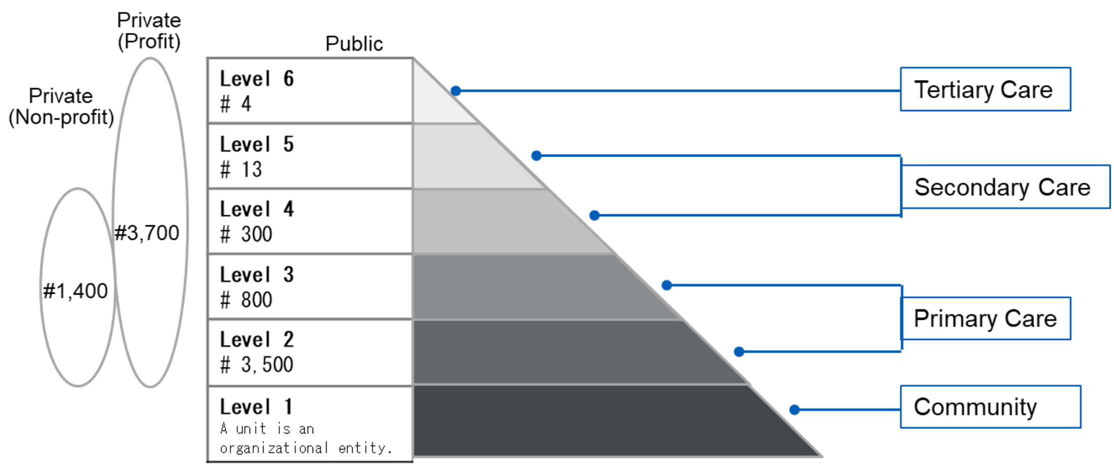


Figure IV-12 Overview of the referral system in Kenya

Source: Compiled by survey team

（１） Role of Primary Care Facility

Each medical area has its own level of medical facilities, and in sparsely populated areas such as arid lands, there are mobile medical units. In sparsely populated areas, such as arid lands, there are mobile medical units. They are responsible for treatment, prevention, delivery, health promotion activities, etc. Among the primary medical facilities, there is further functional differentiation as follows.

Level 1: Community-level, non-institutionalized community organization.
Provide health services through Community Units

Level 2: Providing medical care in areas close to the local population after the community level

Level 3: Handle 4 deliveries/day in addition to the usual treatment

（２） Role of Secondary Care Facility

It will provide more comprehensive medical services, as well as serve as an internship, research and training center for medical professionals and co-medical personnel.

Level 4: As a sub-county hospital, it complements the medical services provided at Levels 2~3 and provides more comprehensive medical services.

Level 5: As a county hospital, it functions as the core hospital for the region. However, 33 of the 47 county hospitals are classified as Level 4 due to the limited services they provide. As of February 2022, the following 14 public medical institutions are classified as Level 5 hospitals[120].

- Embu Level 5 Hospital
- Mama Lucy Kibaki Hospital (Nairobi)

[120] https://hosikenya.co.ke/list-of-level-5-hospitals-in-kenya-with-maternity-charges/

- Othaya Level 5 hospital
- Thika Level 5 Hospital
- Machakos Level 5 Hospital
- Meru Level 5 Hospital
- Garissa Level 5 Hospital
- Kakamega Level 5 Hospital
- Nakuru Level 5 Hospital
- Kisumu Level 5 Hospital
- Coast General Level 5 Hospital
- Nyeri Level 5 Hospital
- Kiambu Level 5 Hospital
- Murang'a Level 5 Hospital

（３） Role of Tertiary Care Facility

Level 6: As a top referral, it provides the most highly specialized medical services in Kenya. Their functions include training of medical specialists and biomedical research, and they also serve as internship and practice centers for medical specialists. As of February 2022, there are 7 public medical institutions classified as Level 6 as follows[121]

- Mathari Hospital
- Kenyatta National Hospital
- Kenyatta University Teaching, Referral & Research Hospital
- Moi Teaching and Referral Hospital
- National Spinal Injury Referral Hospital
- Kisii Teaching and Referral Hospital
- Nakuru Level 6 Hospital

（４） PCN: Primary Healthcare Network

In the PRIMARY HEALTH CARE NETWORK GUIDELINES released in 2021, the Ministry of Health aims to improve health services at the primary health care provider level through the establishment of a Primary Healthcare Network (PCN)[122]. The PCN is an effective implementation approach of the Kenya Primary Health Care Strategic Framework 2019 - 2024 that will create a network of primary care facility (clinics and health centers) and linkages to secondary care facility (level 4 hospitals). The PCN adopts a "hub and spoke model" where

[121] https://hosi.co.ke/explore/?sort=top-rated&category=national-referral-hospital
[122] P5 PRIMARY HEALTH CARE NETWORK GUIDELINES, Ministry of Health Kenya

hubs (level 4 facilities as defined by the Kenya Essential Package for Health (KEPH) criteria) support spokes (level 3, 2 and 1 facilities and community health units). In particular, the network encourages the use of digital health to improve access to a range of healthcare services, and the high importance of healthcare innovation to improve access to affordable, quality healthcare at the community and medical facility levels for the establishment and sustainability of PCNs. The importance of health care innovation to improve access to affordable and quality health care at the community and medical facility levels for the establishment and sustainability of PCNs is demonstrated. At the PCN launch on February 10, 2022, a key speaker pointed out the importance of digitizing information at the PCN level.

A－６． Insurance System

There is a public insurance system in place, but the participation rate is low and coverage is limited. Public insurance coverage for the digital health sector has not been confirmed at the time of the survey. The public insurance system has been introduced, but the coverage rate is limited to about 40%. At the time of the survey, there was no public insurance coverage for digital health sector. The National Hospital Insurance Fund (NHIF), which is a public insurance system, is introducing digital technology, and will soon introduce a flat-rate payment system by diagnosis-related group (DRG). The payment is to be made within the scope of medical treatment through digital health technology.

（１） Overview of Public Health Insurance

A public insurance scheme, the National Hospital Insurance Fund (NHIF), covers all civil servants and formal sector workers. In addition, public insurance is now being extended to the informal sector, primary health care is being subsidized, free medical checkups, treatment and delivery for pregnant women and newborns, and medical expenses for the poorest and disabled are being covered.

The NHIF, established in 1964, is the public insurance provider and determines the scope and maximum limits of health insurance coverage; it makes recommendations to the parliamentary health committees in the Senate and the House of Representatives, from which revised bills are drawn up, passed by parliament, and implemented. The law is periodically updated every five years.

Kenya's healthcare expenditure is financed by the private sector (42.4%), government (42.1%), and patient out-of-pocket (OOP) (23.6%)[123].

The NHIF Amendment Bill of 2021 aims to increase the financial strength of the NHIF and

123 “Current health expenditure (% of GDP) - Kenya | Data.” https://data.worldbank.org/indicator/SH.XPD.CHEX.GD.SS?locations=KE (accessed March 1, 2021).

strengthen its ability to pay medical facilities by making the following 3 changes[124]

- All citizens will be required to join the NHIF.
- Employers will be required to match the NHIF contributions of their employees.
- For those who have both NHIF and private insurance, medical facilities will be required to bill the private insurance company first.

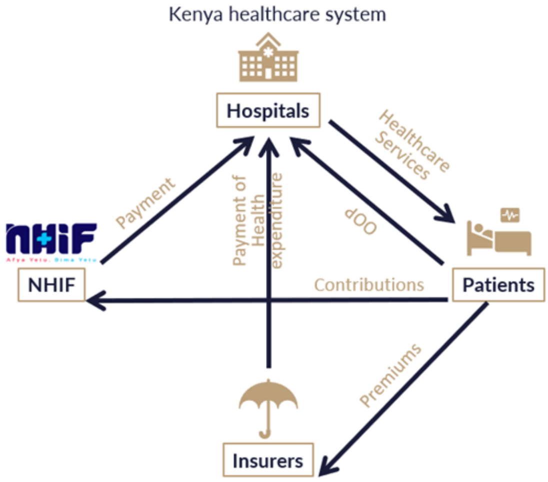


Figure IV-13 Public Health Insurance System in Kenya

Source: Compiled by survey team

（２） Public Insurance Coverage of the Population

According to the Economic Survey 2021 (Kenya Bureau of Statistics), in 2019/20, there will be 22 million NHIF subscribers (about 42% of the total population), although according to the NHIF, 49% of the population is covered. The exact number of enrollees is unknown due to shifts in the number of households and enrollees. Originally established to cover the medical expenses of civil servants and their families, the NHIF later became a legal cover for formal sector workers and their families. Informal sector workers and their families, who are said to account for about 80% of the workforce, are now voluntary rather than compulsory members. It is also said that the coverage rate is low due to lack of trust in the quality of medical services, especially among these informal sector workers[125].

124 https://thinkwell.global/kenya-health-insurance-bill-universal-health-coverage/
125 Draft, Kenya Health Financing Strategy, 2016.

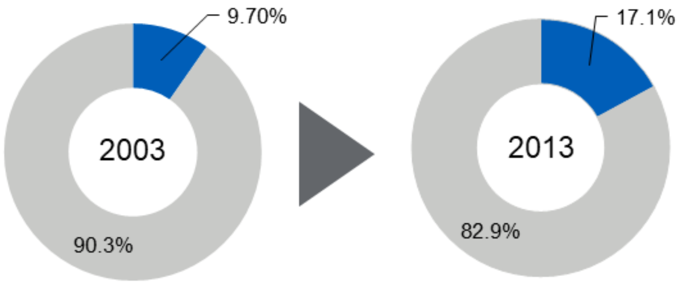


Figure IV-14 Public Insurance Coverage in Kenya

Source: Compiled by survey team based on Trends in Health Insurance Coverage in KHHEUS.

（３） Compensation Coverage

The NHIF has a separate Benefit Package that covers the services covered by its insurance, but it is capped. The cost of COVID-19 treatment is high, depends on the medical facility, and is not covered by NHIF or private insurance companies, or there is no package to cover it, so it is either supported by the donor or borne by the patient In the early days of the COVID-19 outbreak, the cost to be borne was high due to PPE shortage, but now the cost has come down as local PPE manufacturers have improved their production capacity to meet the demand.

（４） Compensation Coverage for the Digital Health Sector

The desktop survey did not find any coverage of the digital health sector by the NHIF. On the other hand, insurance coverage is reviewed biennially in a phased manner in line with the increase in medical costs, and it is likely that the changes and expansion of coverage will include the digital health sector.

（５） Overview of Private Insurance

Although the number of private insurance subscribers in Kenya reached 1.5 million in 2016, the coverage rate is about 3 percent, and the market is relatively small. Most of the subscribers are workers in the formal sector and the wealthy. Typical private insurance companies include Jubilee, AAR, UAP, Resolution, and APA[126].

A－７． Needs of Medical Facilities

In this survey, the online questionnaire was administered to 15 medical facilities (Public:7 Private:8) in Kenya regarding the status of Covid-19 measures and operational issues of the hospitals. The following is a summary of the results of the questionnaire to the medical facilities. The figures in the text indicate the percentage of medical facilities that

[126] https://www.icnet.co.jp/wp-content/uploads/2021/03/3_kenya_hlt.pdf

selected the relevant items among the medical facilities that completed the questionnaire. However, there were some medical facilities that could not respond to the questionnaire in the first place because they were busy with COVID-19 measures, etc., and the level of medical facilities varied, so caution is needed in interpreting the analysis in this chapter as a general statement. For details of the questionnaire results, please refer to Appendix 6 and 7.

（１） Online survey results

１） General Information

Of the medical facilities that were surveyed, 40% reported that they had no Internet connection. Most of the medical facilities that said they did not have Internet access were primary medical facilities in the Quelichó region, indicating a low penetration of telecommunications infrastructure in rural areas.

On the other hand, medical facilities located in large cities such as Nairobi and Mombasa have a certain degree of widespread communication infrastructure, although there are differences in communication speed and stability.

２） Digital health status

The major issues for the introduction of digital health are the cost of introduction (87%) and the lack of communication devices and facilities (73%). This was followed by the lack of external services and systems for implementation and maintenance (60%), lack of ICT literacy among staff (53%), and lack of IT personnel in the hospital to implement and maintain the system (53%).

Even for electronic medical records, which is the most common type of digital health, only 47% of the respondents have adopted it, indicating that the diffusion of ICT is still in its infancy. However, there is a high willingness to introduce ICT in the future, and the potential demand is considered to be high.

Demand is particularly high for teletriage using AI questionnaires (73%), remote and non-contact technologies such as online health consultation (60%), data collaboration such as doctor-to-doctor platforms (60%), and improved diagnostic quality through AI image diagnosis (60%). There is also high interest in disease prevention through health promotion applications (67%).

３） COVID-19 support status

Most of the medical facilities that responded to the survey were primary medical facilities, and outpatient consultations (93%) were the main way of dealing with COVID-19.

There is an overall shortage of human resources such as doctors (60%), nurses (53%), and laboratory technicians (53%), as well as supplies and medical device such as PPE (60%),

ventilators (53%), and medical oxygen (53%).

４） Operational issues

Lack of education and guidance for local residents (67%) was cited as an issue at primary and secondary local medical facilities. Furthermore, it can be inferred that one of the reasons for the high number of cases where patients are already severely ill when they come to the hospital (87%) is inadequate psychological access to medical care, where there are few opportunities to consult a doctor before the disease becomes severe (67%).

When it comes to diagnosis and treatment, 67% of all medical facilities complained of a shortage of medical specialists, mostly in rural primary medical facilities.

Sixty percent of medical facilities felt that it was inconvenient to link information with other hospitals, suggesting that there is a high demand for inter-facility information linkage of patient examination records and test images.

（２） Digital health with the potential to help solve local medical issues

Organize the issues of the medical environment in the local target medical facilities obtained from the above online questionnaires and follow-up interviews, and examine the direction of solutions to these issues using digital health. In organizing the issues in the medical environment, as in the health tech map, the issues are organized according to the main medical treatment process, and the items for which more than 50% of the target medical facilities recognize some issues in each questionnaire item are extracted.

Based on the results of the questionnaire and follow-up interviews, many of the target medical facilities recognized that there are challenges, especially in prevention, testing and diagnosis, ongoing treatment and follow-up, and operational management.

In the area of prevention, there is a lack of education and guidance on prevention and community, and inadequate access to healthcare, especially in primary and local secondary medical facilities. In order to address these issues, it is necessary to take measures such as behavior management and behavior change for users (including healthy and unwell) and patients using digital health, and to provide opportunities for early contact with healthcare professionals.

In addition, in the examination and diagnosis process, about 70% of the medical facilities surveyed reported that there is a shortage or absence of specialists such as image readers, and the shortage of specialists in individual medical facilities is a major issue. To address the issue of a shortage of medical specialists, it is expected that digital health technologies such as remote diagnosis support and AI image diagnosis support will be utilized to enable the establishment of a collaborative system with individual specialists outside of hospitals and higher-order medical facilities that have specialists. In addition, devices and applications that enable data measurement and transfer in remote areas may also contribute to solving problems, especially for medical facilities in rural areas where resources are scarce.

In the process of continuous treatment and follow-up, the most common issue recognized by the target medical facilities is the shortage of medicines. Although the supply of medicines is affected by local logistics and supply networks, ICT-based digital pharmacies have become an area of focus in Kenya in recent years, and several companies are already providing local services.

In terms of other operational management, 60% of the medical facilities surveyed felt that information linkage with outside hospitals was a problem. In relation to the shortage of medical specialists mentioned above, the introduction of a framework to promote information collaboration with individual specialists and other medical facilities will be essential to improve access to healthcare. In order to introduce a framework for information collaboration, there is room for the use of EHRs, PHRs, and doctor-to-doctor platforms that enable information collaboration and advice among doctors.

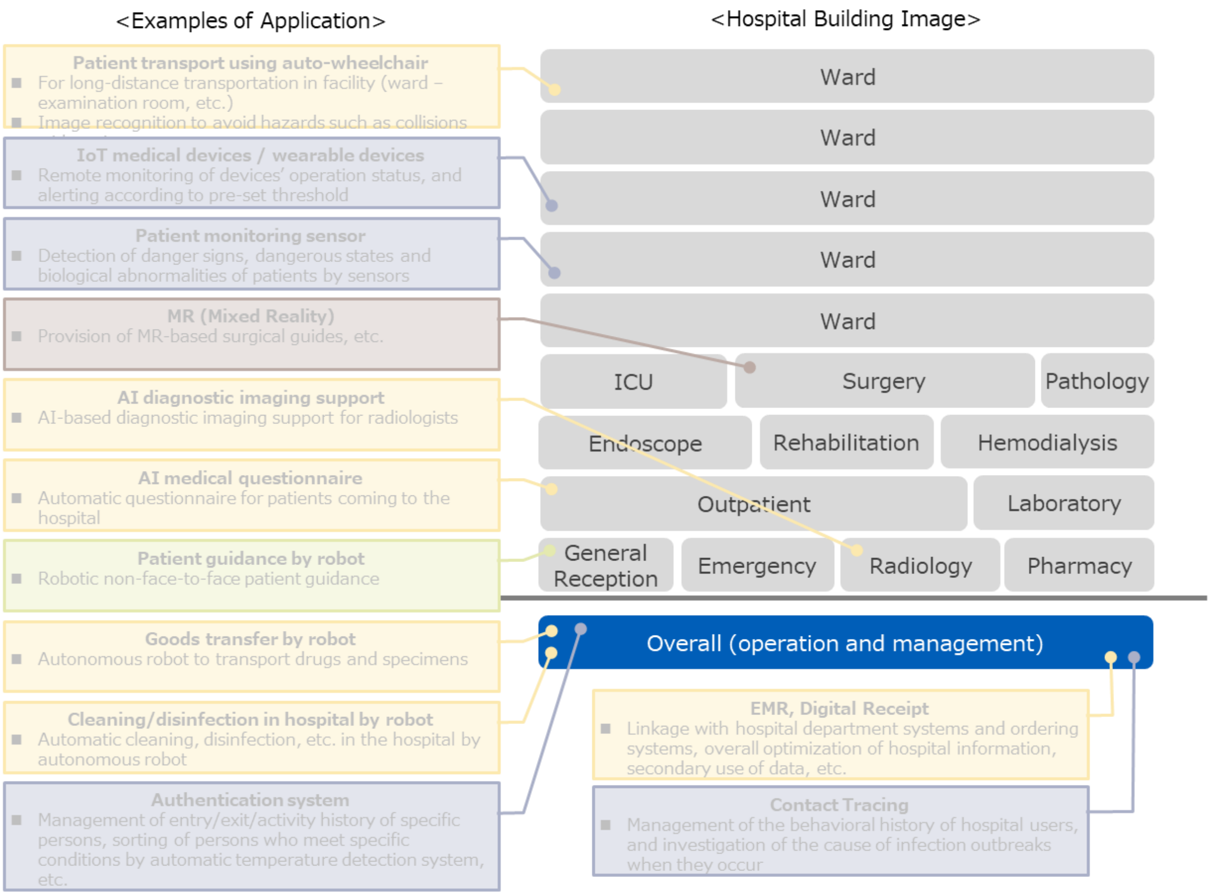
Of the medical facilities surveyed, about 50% responded that education and training for their staff, including doctors, nurses, and technicians, was inadequate. There are financial and physical barriers to participating in training from remote areas, and even in urban areas, there is a lack of time for staff to receive training, making it difficult to secure education and training opportunities for medical professionals to maintain and improve their skills. In response to these issues, the use of digital health technologies that can be used remotely, such as VR training, is expected to reduce the physical and time constraints of medical personnel participating in training and create training opportunities.

Procedure	Issues in the medical Environment	Direction of Solution
Prevention	• Inadequate education and guidance for local residents • Few opportunities of pre-consultation for the local residents • Many patients visiting hospitals only after their disease symptoms become serious	■ **Promote users' own behavior management and behavior change** Behavioral change based on daily biometric data recording, AI analysis, etc. through health promotion apps ■ **Establish early contact with healthcare professionals** Advice and recommendation for medical consultation by medical professionals at the stage of pre-disease through online
Screening	-	-
Examination and Diagnosis	• Shortage or absence of specialists such as radiologists	■ **Collaborate with facilities and personnel outside the hospital** Tests at other facilities, sharing results, remote pathology/ radiology, etc. ■ **Improving operational efficiency through the use of advanced technology** AI image diagnostic support, etc.
Treatment (hospitalization)	-	-
Ongoing treatment and follow-up	• Insufficient medicines for patients	■ **Pharmaceutical supply by ICT** Digital pharmacy, etc.
Other (Operations Management)	• Insufficient coordination of operations and information outside the hospital (between other facilities)	■ **Promotes collaboration by introducing an information coordination framework** EHR, PHR, doctor-to-doctor platforms, etc.
	• Inadequate education and training of staff (doctors, nurses, technicians, etc.)	■ **Provide education and training opportunities using digital health** VR training, etc.

Figure IV-15 Direction of solutions to medical issues in Kenya

Source: Compiled by survey team

Regarding the issues of the medical environment in the target medical facilities organized as a result of the questionnaire and follow-up interviews, most of the target medical facilities recognize that there are more issues in the medical environment outside the hospital than inside the hospital. As for the issues in the medical environment inside the hospital, the room for utilization of digital health is limited. On the other hand, more than a majority of the target medical facilities recognize that there are problems in inter-institutional and inter-professional cooperation for the medical environment issues outside the hospital, and there is room for the utilization of digital health for the purpose of information coordination. Based on the direction of solutions shown in Figure IV-15 Direction of solutions to medical issues in Kenya, Figure IV-16 Solutions that may contribute to solving problems (in-hospital and out-of-hospital) shows the solutions that may contribute to solving the problems in and outside the hospitals of the target medical facilities.



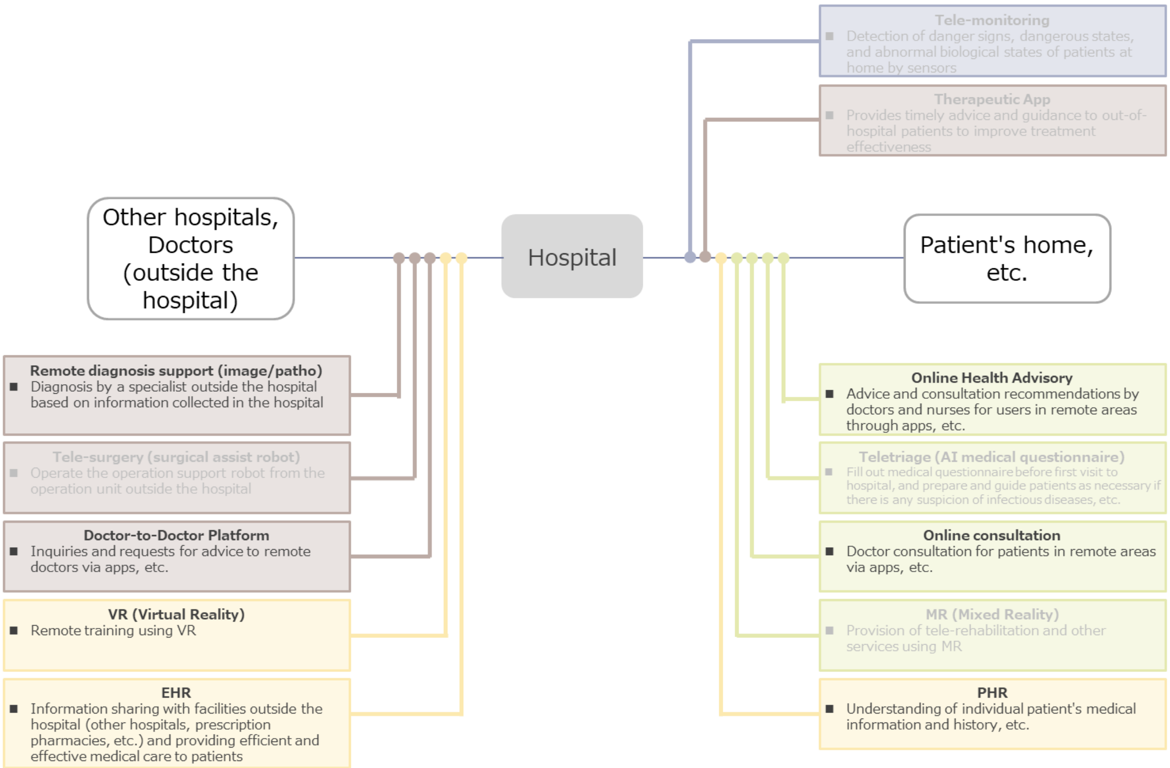


Figure IV-16 Solutions that may contribute to solving problems (in-hospital and out-of-hospital)

Source: Compiled by survey team

B. Perspective of Company

B－1． Recent Trends and Main Factors

In East Africa, Kenya tops the list for growth and demand in the digital sector, followed by Rwanda and Tanzania, according to the Digital Economy Report released by World Bank[127]. The technology sector in Kenya is one of the fastest growing business sectors. Internet access in Kenya (85%) is the highest in Sub-Saharan Africa[128], and the rise of 4G and 4G LTE services in 2020, government-approved universal 4G coverage, and increased smartphone usage (51%[129]) are likely behind the growth of the digital health market. Innovative e-money platforms such as M-PESA[130] are driving digitization in various sectors, including healthcare. In addition, Kenya's urban areas, especially Nairobi, with its highly educated and English-speaking

[127] SDM East Africa, World bank group, "A SINGLE DIGITAL MARKET FOR EAST AFRICA",2018, Available at: https://documents1.worldbank.org/curated/en/809911557382027900/pdf/A-Single-Digital-Market-for-East-Africa-Presenting-Vision-Strategic-Framework-Implementation-Roadmap-and-Impact-Assessment.pdf

[128] https://www.statista.com/statistics/1124283/internet-penetration-in-africa-by-country/

[129] Deloitte, 2019. Global Mobile Consumer Survey. Available at: https://www2.deloitte.com/content/dam/Deloitte/ke/Documents/technology-media-telecommunications/Deloitte_GMCS_Report_The_Kenyan_Cut_August_2019.pdf [Accessed 22 March 2021].

[130] Safaricom, https://www.safaricom.co.ke/personal/m-pesa/m-pesa-home

multi-lingual citizens, its strong entrepreneurial tradition, and its relatively ICT-literate young population with about 79% of the total population under the age of 35, may also be related to the growth of the ICT market.

（１） Market Size and Estimates

The Kenya digital health market (including mobile health, wearable devices, telemedicine, health information technology, and personalized medicine) is expected to grow at a CAGR of 6.0% in USD terms from 2019-2024, expanding from USD 150 million currently to USD 180 million by 2024, and is expected to grow at a high rate from 2024 The growth rate is expected to remain high after 2024. The growth of the digital health market is driven by the government's priority on e-Health and m-Health, as well as the country's demand to provide better quality healthcare services in underserved areas. In addition, the availability of international funding, increasing prevalence of chronic diseases, especially malignant neoplasms and cardiovascular diseases, and the prevalence of private healthcare delivery are also driving the growth of the digital health market. The following graph shows the growth forecast (2019-2024) of the digital health market.

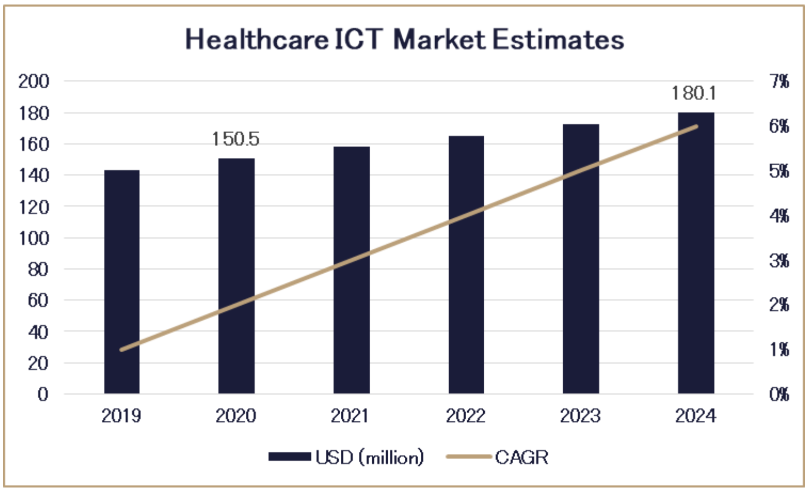


Figure IV-17 Digital health market scale forecast

Source: Fitch Solutions, Kenya Medical Devices Report, 2021

The **key stakeholders in the Kenyan digital health market are mainly the Ministry of Health, Ministry of Information and Communication Technology, development partners such as donors and international organizations, SMEs including foreign capital, and startups.** Development partners such as World Bank, African Development Bank, Tele-Health Society of Kenya, and Anadach Consulting Group are supporting the implementation of e-Health solutions for the delivery of healthcare services in different regions. Major donors, such as the

United States Agency for International Development ("USAID"), are supporting the implementation of e-Health solutions in various regions. And other major donors continue to fund companies with digital healths delivered through platforms available on mobile devices due to the high cell phone penetration in Kenya.

（２） Trends in the Development of Digital Health

Kenya's socio-economic development is heavily dependent on mobile communications. Kenya has a high penetration rate of mobile networks and cell phones, which has led to the growth of technologies such as telemedicine, tele-radiology, e-learning, digital pharmacy, and m-Health. The government continues to innovate mobile phone-based financing solutions in collaboration with institutions and companies such as Living Goods, Safaricom, CarePay, PharmAccess, and Huawei. Many other digital health solutions, such as m-Tiba, have been successfully piloted and are being expanded nationwide. m-Health unit has been set up at Kenyatta National Hospital to promote telemedicine and m-Health. In addition, several private hospitals, including Aga Khan University Hospital in Nairobi, are expanding their services to include telemedicine.

B－２． Impact of COVID-19 on Recent Trends

The expansion of COVID-19 infections has spurred innovation in the digital health sector, making this sector one of the biggest investment opportunities. Gaps in healthcare remain large, leaving opportunities for digital health startups to fill. The changing environment in healthcare has increased the need for partnerships that bring together the private sector, investors, governments, experts, and innovators. Stakeholders are urged to continue to work together to develop local capacity and infrastructure, and strengthen programs to influence digital health-related policies and frameworks. Ministry of health, donors, and others are eager to be a partner with digital health companies that offer sustainable solutions.

The spread of COVID-19 has increased the demand for non-face-to-face consultations, telemedicine, electronic transmission of test results, digital pharmacies, etc. The e-Health strategy has created new priority areas and targets for investment, including systems for transmission of test results, automated patient appointments, communication systems for health care providers, emergency alert response systems, and procurement systems for medical products. After the end of COVID-19, both national and county governments are expected to continue to prioritize the provision of home health care to patients with chronic diseases. The spread of COVID-19 has prompted health care providers to adopt telemedicine to examine patients and monitor the spread of COVID-19. Private facilities are investing in the digital health sector to expand their reach to patients in different locations. e-Health applications such as myDawa provide a platform for remote ordering of medicines without the need to visit a pharmacy. In the medium and long term, telemedicine is expected to become a key component of the healthcare system. In the medium to long term, growth will be driven by the increasing demand for chronic disease management through telemedicine and home care programs.

B－３． Health Tech Map

The main technology types of solutions in Kenya, as well as in Japan and other target countries, are mapped as follows. The main technology types that were confirmed to exist in the digital health market in Kenya through the desktop survey are mapped in white boxes. The technologies that are not widely used in the local market or whose existence was not confirmed, but exist in the Japanese digital health market (i.e., technologies that could be introduced from Japan to the local market in the future) are mapped in blue boxes.

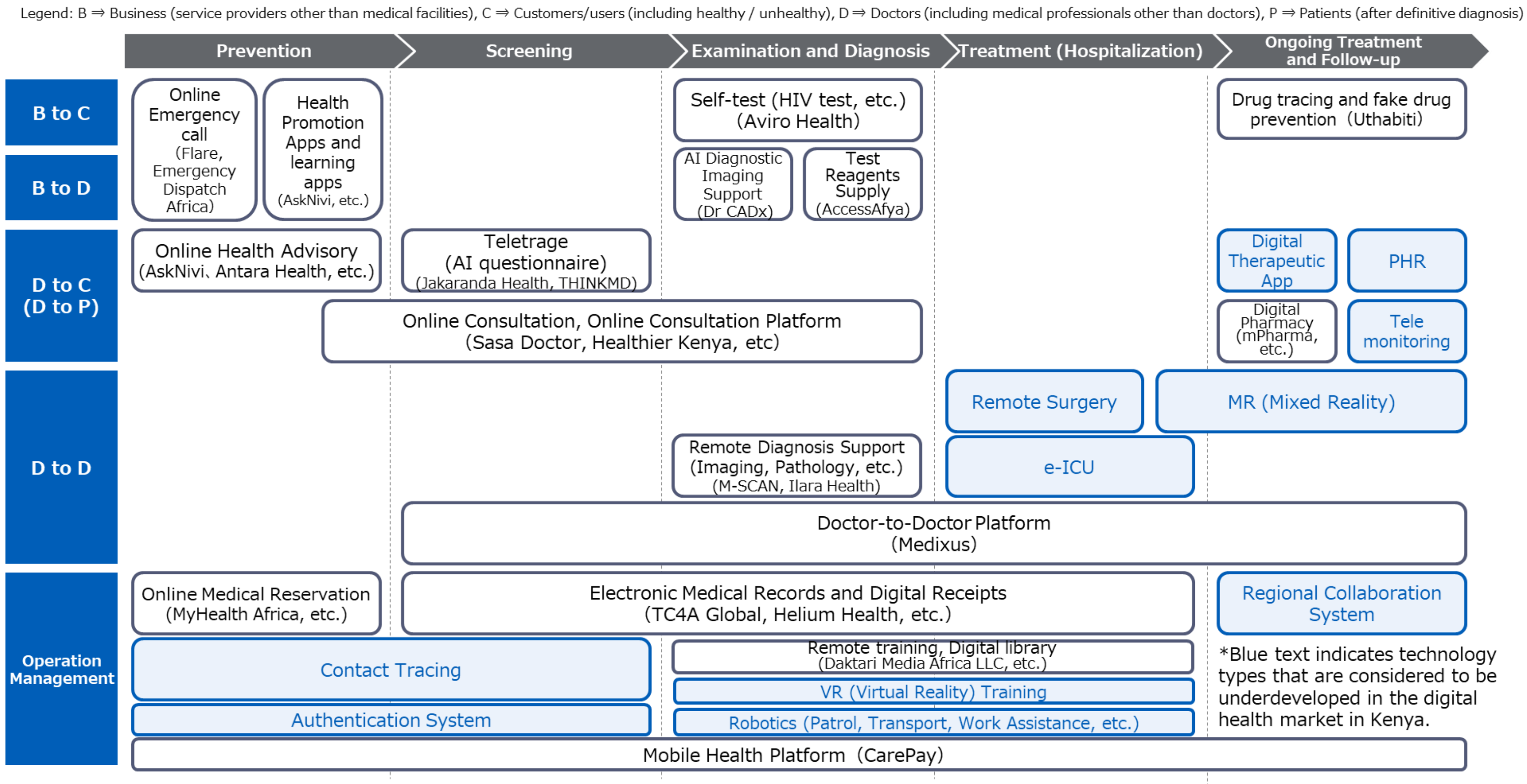


Figure IV-18 Health Tech Map (Kenya)

Source: Compiled by survey team

The technology types of digital health in Kenya tend to reflect local conditions, such as inadequate healthcare delivery systems and pharmaceutical supply chains. There are some types of technologies that are not found in the health tech maps of Japan and other target countries, such as online emergency calls and drug tracing to prevent fake drugs. In addition, compared to health tech maps in Japan and other target countries, there are more types for customers and patients, such as BtoC.

Relatively new technologies, such as therapeutic applications, MR, and VR, may not have been widely adopted yet. In addition, the widespread use of technologies that enable data linkage among patients, professions, and facilities, were not confirmed through the desktop survey. For technologies that require data linkage between various points, such as PHRs and regional collaboration systems, or large-capacity communication, such as remote surgery, unstable local communication infrastructure may be one of the barriers to their adoption.

In addition, by comparing the above health tech map with the solutions for solving the issues shown in Figure IV-16 Solutions that may contribute to solving problems (in-hospital and out-of-hospital)**of Chapter A-7, digital health that can be used for telemedicine, such as PHR, EHR (regional collaboration system), remote surgery, e-ICU, MR, VR, etc., robotics, contact tracing, and authentication systems that can be used for material transport, etc., there are few companies that provide related products and services in the local market, and therefore, Japanese companies have comparatively few competitors in the local digital health market.**

On the other hand, it should be noted that a market with little competition may be a relatively unattractive market for companies. Many of the medical facilities surveyed did not have an adequate communication infrastructure, and many of them said that they lacked human resources and funds to utilize digital health. If this situation reflects the general state of medical facilities in Kenya, it is possible that the lack of resources such as human resources and funds is a barrier to the introduction of digital health, leading to a situation where there is latent demand but not growth in the related market.

B－４． Relevant Laws and Regulations Surrounding Digital Health

In Kenya, existing regulations related to digital healths are not sufficiently disseminated and enforced. Existing ICT and digital health related laws and regulations are based on the Constitution and Acts of Parliament and are enforced by the relevant government agencies and ministries. In some related areas, such as copyright, the Constitution provides for such rights, but specific laws and regulations are not yet in place. There is a need to create a level playing field by strengthening competition among companies, enforcing anti-monopoly laws, and standardizing. The Ministry of Health has submitted e-Health bill to Parliament, and it is under consideration.

（１） General laws and regulations related to information and communication

１） Telecommunications, radio waves, etc.

Table IV-1 Laws and regulations related to telecommunications and radio waves in Kenya

Laws and regulations	Overview
Kenya Information ACT (2013)	It was enacted by The Communications Authority of Kenya, the regulator of the entire telecommunications sector in Kenya. The Authority is responsible for promoting the development of the information and communication sector, including data usage, broadcasting, cyber security, multimedia, telecommunications, e-commerce, and postal and courier services. The Authority licenses telecom operators and service providers and continuously monitors them to ensure that they are fulfilling their obligations as stipulated in the licenses.

Source: Compiled by survey team

２） Personal Information Protection

Table IV-2 Laws and regulations related to personal data protection in Kenya

Laws and regulations	Overview
Data Protection Act (2019)	Although the digital health sector was largely unregulated in Kenya, the Act has been enacted to protect the personal information of the subject. It stipulates standards for information collaboration, which is a component of the seamless and secure exchange of medical information for better health service delivery and outcomes. Digital health companies are required to guarantee the protection of the subject and the subject's personal information in relation to the conditions of use. In addition, the law encompasses regulations on information security, personal data protection, and data use.
Kenya National Cyber Security Strategy (2014).	It secures the nation's cyberspace by strengthening its cybersecurity posture in a way that promotes national growth, security and prosperity.
e-Health Standards and Guidelines	It is based on the e-Health Policy 2016-2030, the ICT Policy, and Article 31 of the Constitution of Kenya 2010, which guarantees the privacy of all citizens with respect to their personal information.

Source: Compiled by survey team

３） Data use

Table IV-3 Laws and regulations related to data use in Kenya

Laws and regulations	Overview
Kenya Information Act (2013)	The Kenya Information and Communications Act of 1998 was amended to include the principles of information and data collection.
Data Protection Act (2019)	It provides guidelines for regulating the processing of personal data. It also sets forth the rights of data subjects, the obligations of data controllers and processors, and the purposes involved. In addition, it prioritizes the complete privacy of the data subject and provides for the control of the use of the collected data.
Kenyan Archives Act (2019)	It provides guidelines for the management and preservation of public records, archives, and government publications. It prescribes mechanisms for the disposal of records and related purposes.

Source: Compiled by survey team

（２） Digital health-related laws and regulations

The digital health market lacks an organization with strong leadership to promote digital health, clear and binding standards and laws enforced by the same organization, and a clear roadmap for scaling up.

According to the report by the Ministry of Foreign Affairs of Kenya[131], digital healths must comply with ethical and legal requirements related to the following;

- Ownership of data and information
- Access and disclosure of patient data
- Use of patient data
- Storage of personal medical information and personally identifiable information
- Storage of medical information
- Maintain confidentiality in accordance with e-Health policy guidelines
- Non-infringement of intellectual property rights

The Ministry of Information and Communication Technology (ICT) and the Ministry of Health collaborate in the development of policies for digital health regulation. Under the Ministry of Health, the ICT Unit is responsible for the implementation of regulatory measures and licensing through various health councils such as the Kenya Medical Practitioners and Dentists Council. The e-Health Unit is also helping to create an enabling environment for the sustainable adoption and implementation of e-Health solutions. The e-Health Bill is currently being prepared by the

131 2021 Kenya Medical Devices eHealth, (https://www.rvo.nl/sites/default/files/2021/05/2021-Kenya-Medical-Devices-eHealth.pdf)

Ministry of Health to improve and strengthen regulations and policies related to e-Health business, so that Kenya can develop telemedicine, ensure the safety and security of patients, and attract quality investors from home and abroad.

１） Ethical Guidelines

The National Commission for Science, Technology and Innovation (NACOSTI) licenses all research and accredits Internal Ethical Review Boards (IRBs) in hospitals, research institutes and universities. There are 27 IRBs in Kenya that are accredited by NACOSTI[132]. Ethical guidelines in the field of health care have been established by each county government and tertiary care institutions. The KEMRI Institutional Review Board (IRB) is often consulted to identify and address ethical issues when conducting research studies in the field of health care by Japanese researchers and others.

Table IV-4 Ethical Guidelines in Kenya

Laws and regulations	Overview
KEMRI ethical guidelines (2020)	This guideline is applied at the national level. KEMRI reviews all research involving human subjects from an ethical perspective, including the protection of personal information.

Source: Compiled by survey team

２） Medical Device Registration

Medical devices are approved by the PPB, an independent agency under the jurisdiction of Ministry of Health. Medical devices are categorized into classes A through D according to risk, with A being the lowest risk and D being the highest. In Kenya, medical device registration covers not only hardware but also software. The application procedure based on the medical device registration guidelines is as follows

The procedure for application based on the Guidelines[133] for Registration of Medical Devices is as follows:

1. The registration requirement is that the company must have a manufacturing base in Kenya. It is recommended that foreign companies partner with a distributor in Kenya. In the case of foreign companies, a power of attorney will be required to show authority to handle all processes related to the application on their behalf. This must be notarized by a

132 https://research-portal.nacosti.go.ke/researcher/AccreditedInstitutions/View/T02.html

133 https://pharmacyboardkenya.org/files/?file=Final%20Guidelines%20for%20Medical%20Devices%20and%20IVDs.pdf

notary public in Kenya and submitted to PPB.

2. Obtain an application form from the PPB office or portal and submit it with the following required documents
   - Certificate of Free Sale (CFS)
   - Certificate of Quality System (for sterile products)
   - Declaration of Conformity
   - Description of medical use and device
   - Clinical and preclinical data, test reports, etc. supporting the safety and efficacy of the device

3. Submit a certificate of pre-market approval or medical device approval that corresponds to one of the following
   - South African Health Products Agency (SAHPRA), Australia, Brazil, Canada, Europe, Japan, USA
   - Free marketing certificate issued by the regulatory authority of the country of origin
   - ISO 13485:2016 certificate by the manufacturer in the country of origin

4. Pay the fee based on the medical device class.

Table IV-5 Cost of Kenya Medical Device Registration (US$)

Classification	Initial Registration Fee	Evaluation Fee	Renewal Fee	Change Notice Fee
Class A	25		20	10
Class B	150	200	100	20
Class C	200	250	150	50
Class D	250	350	200	70

Source: Compiled by survey team

If the application is approved after going through the above process, a medical device registration certificate will be issued. The application process usually takes about three months. The registration is valid for 5years (renewable)[134].

[134] https://www.jetro.go.jp/ext_images/_Reports/02/2021/9b33dc8a948ba799/202105.pdf

３） Licenses for import, export, distribution, and sales

Medical device certification procedures are required in Kenya for the import and export of medical devices. The Kenya Bureau of Standards (KEBS) and the PPB ensure that new imports comply with Kenyan quality standards and technical regulations, thereby contributing to importer compliance and improving the standards of the Kenyan medical device market. Imported products are required to have a Certificate of Conformity (CoC) at the time of customs clearance. Therefore, importers are required to obtain a CoC using the Kenya National Single Window Electronic (Kentrade) system before applying for an import license from PPB. In addition, a Pre-Shipment Verification of Conformity (PVoC) is required for imported goods. A Local Authorized Representative (LAR) must be approved in the exporting country to verify compliance with the PVoC and to register the product with PPB. The LAR must be approved by the exporting country. Imports are also required to obtain the Kenya Import Standardization Mark (ISM) to enable consumers to identify KEBS certified imports in the domestic market.

４） Intellectual Property

Table IV-6 Laws and regulations related to intellectual property in Kenya

Laws and regulations	Overview
Intellectual Property (IP) rights granted to developers by the Constitution of Kenya, 2010.	The Constitution secures legal rights to innovation and design for the exclusive use and control of intangible assets by intellectual property rights holders. Intellectual property rights motivate innovators to develop innovations and creative works that are beneficial to society without fear of misappropriation by third parties.

Source: Compiled by survey team

５） Procurement of medical devices.

The Kenya Medical Supplies Authority (KEMSA) controls and oversees the procurement of medical device, medicine and consumable in the public sector. All public medical facilities are required by law to purchase equipment, medicine and consumable through KEMSA, and can procure equipment from other private vendors only if the desired equipment is not available through KEMSA. KEMSA has a quality control mechanism within the agency and also works with quality certification agencies such as National Quality Control Laboratories and KEBS to ensure the quality of all medical supplies, including drugs and medical device.

In order to place a foreign company's medical device on the market, it is necessary to register with the regulatory authority PPB, designate a LAR, and submit a Letter of Authorization by the LAR.

６） Research Permission

The NACOSTI licenses research for all research, including digital health.

B－５． Future Prospects in the Digital Health Market

As described in "B-1 (2) Development Trends", digital health in Kenya has been greatly influenced by mobile networks. In addition, open-source and highly public civic technologies are also attracting attention.

（１） m-Health

Digital health in Kenya is widely used in the field of m-Health, which is provided through a platform based on mobile networks and mobile payment services. Some of the leading m-Health companies in Kenya are listed below.

1. m-Tiba [135]

It is electronic money that can be used on cell phones to save money and receive money transfers. It can also be used to pay fees, but only for medical bills. The system is directly linked to users, healthcare providers, and healthcare payers such as insurance companies and donors, making both treatment and payment fast, efficient, and transparent.

2. MyDawa [136]

It is an online digital pharmacy that provides access to thousands of original quality medicines, health care, wellness and personal care products.

3. Maisha Meds [137]

They provide digital tools that allow providers to manage sales and inventory, procure high-quality medications, and offer discounts and subsidies to help patient’s access high-impact healthcare products.

4. Ponea Health [138]

It provides a platform for booking and telemedicine, including back-end services and price discovery for doctors.

[135] https://mtiba.com/
[136] https://www.mydawa.com/
[137] https://maishameds.org
[138] https://poneahealth.com/

5. eChanjo [139]

A portal developed by the Ministry of Health in response to COVID-19 that aims to monitor the progress of COVID-19 vaccination. It records the dates when vaccinations were administered and issues certificates of vaccination.

（２） Civic Technology

Using civic technology and open data, they are building a digital democracy where citizens have timely and free access to practical information. Code for Kenya is the representative[140]. It also promotes active citizenship by facilitating access to information so that citizens can reach out to their leaders and hold their governments accountable.

B－６． Future Challenges in the Digital health Market

With the exception of a few solutions, most of the digital healths in Kenya are still in the pilot phase and have not yet been scaled up. The main reasons for this are financial constraints and technical issues surrounding interoperability and infrastructure requirements. The government does not have a central registry of all digital health projects being implemented in Kenya, which makes it difficult to monitor and coordinate progress in reaching national scale in various solutions. Many of the solutions that have been successfully scaled up have comprehensive and sustainable frameworks and are able to function on existing digital infrastructure. The majority of current digital health solutions are provided through m-Health due to the high geographic coverage of mobile networks. These solutions are mostly based on short message services due to infrastructure constraints. The following are some of the challenges encountered by digital health companies.

（１） Infrastructure and Ecosystem Gap

１） Lack of funds and liquidity

There is a lack of funding and liquidity for the costs that ordinary users pay for solutions, and in the case of utilities, for the piloting and large-scale implementation of solutions. Since users are often unable or unwilling to pay, and the market is price-sensitive, companies need to make the cost of their solutions affordable or design viable pricing and credit mechanisms. Also, the cost of mobile data and the willingness of users to pay for it should always be considered. The public sector needs to go beyond pilots and proofs of concept to finance large-scale adoption of the technology.

139 https://portal.health.go.ke/
140 https://codeforkenya.org/

２） Insufficient infrastructure

For the use of digital healths, there is a need to develop stable internet connections, infrastructure, etc. According to the 2018 Kenya Harmonized Medical facility Assessment for UHC (KHHFA), on average, 50% of health facilities have information and communication equipment (88% in Mombasa and 5% in Wajir), and internet at 31% on average (77% in Nairobi and 5% in West Pokot), infrastructure development is lagging, especially in rural and remote areas. In terms of emergency response, transportation infrastructure problems (roads and urban structures causing traffic congestion, insufficient number of ambulances, lack of equipment on board ambulances, etc.) cannot be solved by digital technology alone.

３） Lack of trust from end users

With on-demand digital information services and other digital health services targeted at consumers, it is often difficult to gain their trust in terms of the accuracy and usefulness of the information and the quality of the services provided.

４） Health Financing / Disparities in Health Insurance Coverage

Effective health care financing and expanded health insurance coverage are important to promote the adoption of digital health. The strategic use of service data and analysis of medical claims data should be used to provide health insurance to more people more efficiently.

（２） Gap between user's knowledge and technology

１） Gap between knowledge and awareness

Many digital health solutions are not well known among professionals and consumers. Training by experts, media, and word-of-mouth promotion can play an important role in raising awareness of technology solutions. There is a need for those in leadership positions to increase their understanding and competence in technology, including understanding of terminology. For automated analysis, there is a gap in knowledge and skills in terms of standard classifications such as the International Statistical Classification of Diseases and Related Health Problems, and clinical terminology in the medical field, and data analysis software tools that are available at little or no cost.

２） Gap between skills and abilities

In order to expand the use of digital health solutions, it is necessary to build a technical understanding and system from the users' and companies' side of the problems that the solutions are trying to solve. The following are some examples.

- Solutions that address health care quality issues and improve the reputation of health care organizations require an understanding of and support for the principles of quality assurance.

- Solutions to support classification of diseases and causes of death need to be fully staffed at the medical facility level with an understanding of key related concepts
- In order to utilize the solution for emergency response, medical facilities need to have enough qualified medical personnel to shorten the distance of transporting patients in critical conditions and to adequately staff the ambulances.
- For automated data analysis, it is possible that local companies will need to recruit talent to develop local solutions. Some of the best talent will move to international companies and organizations.

（３） Lack of capacity and funding for developers and vendors

１） Lack of management and marketing skills

According to experts in the field of innovation in Kenya, organizations seeking to introduce innovative products and services related to digital health need to strengthen their business models. This includes understanding the flow of funds and clarifying the business model, taking an entrepreneurial approach, and systematically and rigorously examining assumptions early on to understand the potential for market penetration. In addition to a stronger business plan, companies will need to have the following skills and knowledge;

- Attracting and retaining high quality employees
- Effective engagement with consumers and customers through multiple channels
- Market research
- Ongoing and appropriate collaboration with national and county government agencies to increase visibility and credibility

２） Lack of funding for product developers and vendors to improve their products and marketing

There is a lack of sufficient capital for organizations to succeed. Some companies are beyond the product idea stage but not yet mature enough to attract investors. In order to bridge the institutional gap between investment needs and actual investment acquisition, companies need to have the following understanding beforehand.

- Develop an understanding of what it takes (and how long it takes) to attract capital investment
- Institutional capacity to attract talent (e.g., highly qualified professionals in software development, medical informatics, business management, marketing, etc.)
- Understand project cycle logic and have the financial liquidity necessary to do so when seeking to raise grant funds from donors

（４） Gap between product features and demand

１） Solutions do not match the real-world healthcare ecosystem

While some issues related to infrastructure and ecosystems can be solved by the function of the technology itself, developers need to go beyond the narrow framework of the technology and fully understand the healthcare system and market environment in which the technology will operate. As an example, it is necessary to design the technology in accordance with the following environment.

- Working on low feature phones with less than 2,000KES
- Seamlessly connected and fully interoperable with technologies already in the market or likely to enter the market in the near future
- Adapting to a culture that is accustomed to paper-based records
- Can be operated without dependence on continuous use of the Internet

２） Solutions not intended for corporations or private companies

For a solution to be viable for private, for-profit healthcare providers, it must also meet those private demands. The solution must be flexible enough to accommodate different demands, and in some cases, it must be customizable. It needs to satisfy high-priority demands and convince management by demonstrating reliable results. It also needs to gain strong commitment at the facility and departmental levels to reduce the cost and effort required for change management. It is also important that effective technical training and end-user support is available locally.

３） Solution is not user-friendly

For existing solutions, the users need to adapt to the solution, rather than the solution side adapting to the existing knowledge, demands, and trends of the users. The interviews and literature indicate the following requirements for a user-friendly solution.

- Must be designed to minimize the need for training. Be easy to use and user-friendly.
- Developers and vendors should avoid overstating the capabilities of their solutions to account for human and technological limitations.
- It must be relevant and immediately useful to the people who use it on a daily basis, and it must meet their expectations. A user-centric approach in product design is needed to make the solution intuitive and workflow-friendly, with close involvement of relevant target users (clinicians, patients, consumers)
- Consider cultural attitudes (e.g., users prefer face-to-face interaction) when designing solutions.

（５） Governance and Policy

１） Lack of clear and binding standards and regulations

There are several policies and guidelines on e-Health and electronic health records, but they are mostly at a general level and are not binding like regulations or laws. By proper regulations and laws, it is expected to promote collaboration among ICT companies, donors, and non-governmental organizations (NGOs). The development of clear laws and regulations will also reduce uncertainty surrounding rules and responsibilities related to data privacy and data protection (the latter being partially applied by the Data Protection Act became effective on November 7, 2019).

In the absence of clear and enforceable regulations and widespread awareness of them, administrative barriers tend to increase at multiple levels. For example, the need to obtain permits from county governments to conduct certain activities related to digital healths has led to slow or insufficient adoption of the technology. In addition, due to the lack of international harmonization of regulations in the East African region, products targeting the East African market have to go through multiple rounds of registration/permissions, which is time-consuming and expensive.

２） Lack of decisiveness and competence in leadership and governance

In the planning and implementation of digital health policies and the introduction of digital health, it is necessary for the government to present clear policies and promote plans with strong leadership, but such leadership and governance are lacking on the government side.

The procurement of digital solutions in the public sector needs to be based on effective mechanisms that consistently pursue cost effectiveness and mitigate or eliminate potential conflicts of interest.

Finally, in order to have better control of development priorities in digital health, it is important that governments at the national and county levels make budgetary provision for promoting the adoption of digital health and do not divert the budget to other uses.

C. Perspective of JICA

C－１． Status of JICA Support

The Ministry of Foreign Affairs of Japan (MOFA) has designated health and medical care as a priority area in its policy on development cooperation by country, and among the three target countries, there is an abundance of projects in the field of health and medical care, mainly through technical cooperation, official development assistance loans and private sector collaboration. It is also expected that this project will collaborate with other projects in Africa, such as the "Information Collection and Confirmation Survey on Private Sector Utilization for Health Improvement in Six African Countries.

The following is a list of projects completed since 2015.

Table IV-7 JICA projects in the field of health care in Kenya

Technical Cooperation	・ Strengthening Accountability in County Health Services Management Project (January 2022 - February 2027) ・ Interdisciplinary research project for community-driven integrated strategies to sustain a malaria-free society (October 2020 - September 2025) ・ Tele-ICU support to Coast General Hospital, Mombasa District, within the African Health Systems Strengthening Partnership Project (Phase 2).November 2016 - September 2022) Strengthening County Health Systems Management under Decentralization Project (2014 (October - October 2019) ・ Development of a rapid diagnostic method for yellow fever and Rift Valley fever and its outbreak alert system (January 2012 - January 2017) ・ Community Health Strategy Enhancement Project (October 1, 2011 to September 30, 2014)
Official Development Assistance Loans	・ Health Sector Policy Loan for Achieving Universal Health Coverage(Phase 2) (August 2020)
Official Development Assistance Grants	・ Preparatory Survey for the Research Enhancement Plan of the Central Institute of Medical Research, Kenya (January 2022 to July 2022)
Public-Private Partnerships	・ Case study on a project to improve the sanitation environment in hospitals using electrolytic water generated by ceramic electrodes (G.E.S. Co., Ltd., June 2015 - May 2016) ・ Case study on the project to expand the number of health check-ups (Cancer Scan, Inc., December 2017-June 2019) ・ Preparatory survey for the project to improve access to medicines (promotion of BOP business collaboration) (Takeda Pharmaceutical Company Limited, March 2018 - May 2019) ・ Preparatory survey for a project to support the self-sustainability of local production and sales of low-cost preserved foods using sorghum (promotion of BOP business collaboration) (Joint venture between Nissin Food Holdings Co., Ltd. and Arata Sustainability Certification Organization, January 2014 - January 2015) ・ Preparatory Survey for Nutritional Food Business Using Traditional Japanese Fermentation Technology (Kikkoman Corporation, BOP Business Collaboration Promotion) ・ Project to Promote Catheters for Mitral Stenosis Patients (Toray Industries, Inc. and Toray Medical Inc. joint venture, December 2013 - November 2016) ・ Project for dissemination, demonstration, and commercialization of ultrasound diagnostic imaging systems through training of local supervising doctors in the perinatal field [Africa Problem Presentation Type] (FUJIFILM Corporation, February 2020 - January 2022) ・ Information collection and confirmation survey on the possibility of utilizing private sector technologies in developing countries under COVID-19 in the field of health and medical care (strengthening measures against infectious diseases and improving nutrition) (October 2020 - March 2021) ・ Report on a survey to collect and confirm information on the use of the private sector to improve health in six African countries (August 2019 - March 2020)

Source: Compiled by survey team

Table IV-8 JICA projects related to ICT in Kenya

Technical Cooperation	・ Development of a rapid diagnostic method for yellow fever and Rift Valley fever and its outbreak alert system (January 2012 - January 2017) Development of MSoS to improve the efficiency of infectious disease surveillance
Official Development Assistance Loans	・ Health Sector Policy Loan to Achieve Universal Health Coverage(Phase 2) (August 2020) The Ministry of Health is implementing health information integration using official development assistance loans
Official Development Assistance Grants	—
Public-Private Partnerships	・ Case study on the project to increase the number of people receiving health checkups (Cancer Scan, Inc., December 2017-June 2019) Trial introduction of a smartphone application to combat NCDs ・ Case study on the implementation of e-learning systems to improve the quality of education (May 2017 - June 2018) ・ Dissemination and demonstration project for the introduction of e-learning systems to improve the quality of education (March 2019 - June 2022)

Source: Compiled by survey team

Table IV-9 JICA projects related to COVID-19 in Kenya

Technical Cooperation	—
Official Development Assistance Loans	—
Official Development Assistance Grants	—
Public-Private Partnerships	・ Information collection and confirmation survey on the possibility of utilizing private sector technologies in developing countries under COVID-19 in the field of health and medical care (strengthening measures against infectious diseases and improving nutrition) (October 2020 - March 2021) *Represented

Source: Compiled by survey team

C－２． Efforts by international organizations and governments to promote digital health

The investment market for digital health in Kenya is still developing. The government continues to support the digital health investment market through policy recommendations for foreign investors and a harmonized regulatory environment. Through the Ministry of Information and Communication Technology, the government has formulated the Kenya National ICT Policy to increase the contribution of ICT to the digital and traditional economy to 10% of GDP by 2030. The policy lays out a plan to start a self-sustaining ecosystem that will produce world-class research, technology products and industry.

Foreign private companies and donors are developing their own digital health solutions and supporting local companies through pilot activities to promote the development and introduction of digital health in the country. With the spread of COVID-19, public and private hospitals are demanding solutions for logistics and transportation of critical drugs and tests, contact tracing applications, and patient monitoring. Foreign private companies are also working on developing their own digital health, while some domestic innovators are developing and implementing applications that enable health through mobile networks and payment systems. The IFC is also supporting local innovators in the pilot phase through targeted programs.

（１） Initiatives of International Organizations

Table IV-10 List of initiatives by international organizations

Institutions, programs, etc.	Overview
Tech Emerge (IFC, 2020)	It brings needed technologies to new markets to drive sustainable innovation. The program matches proven solutions from around the world with local partners in emerging markets, conducts pilot projects, and facilitates the development of business partnerships. In the East African market, more than 20 leading private healthcare organizations in Kenya, Uganda and Ethiopia have signed on to the program and are interested in working with digital health companies. Under the program, the shortlisted digital health companies will demonstrate their products at local medical facilities and discuss potential pilots, with the assistance of external technical advisors. The selected companies will receive funding and guidance from TechEmerge to pilot their solutions and pursue commercial deployment of the technology. The IFC will assist both innovators and healthcare organizations in the market entry and technology transfer process. In addition, IFC will mitigate the financial and operational risks associated with market entry for innovators and reduce implementation risks for local healthcare providers.

Source: Compiled by survey team

（２） Efforts of domestic institutions

１） Government Initiatives

Table IV-11 List of government initiatives

Institutions, programs, etc.	Overview
e-Health Standards and Guidelines	It is based on the e-Health Policy 2016-2030, the ICT Policy, and Article 31 of the Constitution of Kenya 2010, which guarantees the privacy of all citizens with respect to their personal information.

Source: Compiled by survey team

２） Other Initiatives

Table IV-12 List of other initiatives

Institutions, programs, etc.	Overview
Kenyatta University Teaching, Research and Referral Hospital (KUTRRH)	The Medical Innovation Accelerator Hub program provides programs for the development, adoption, and diffusion of high-value innovations in diagnostics, therapeutics, medical devices, and medical services.
AAIC and Rakuten Europe	AAIC and Rakuten Europe have launched the AAIC-Rakuten Africa Innovation Project to provide technical and managerial guidance to start-up companies across Africa in order to promote their business growth and create solutions to social issues across Africa. The project also targets medical facilities.

Source: Compiled by survey team

V. Overview in Indonesia

V. Overview in Indonesia

A. Perspective of Target Country

A－１. General Information

（１） Economic Situation

Indonesia's economic growth rate had been high, but COVID-19 restrictions on behavior affected the economy, resulting in negative growth in FY2020. 2019 GDP is expected to be US$1,119.191 billion, with a GDP growth rate of 5.0% and GDP per capita of US$4,135.6. In the aftermath of the Asian currency crisis in July 1997, the Indonesian government has undertaken structural economic reforms, particularly in the banking and corporate sectors, and economic growth since 2005 has been relatively high, in the upper 5% to 6% range, with the exception of 2009, which was affected by the global financial and economic crisis.

Due to the contraction of economic activity caused by the large-scale social restrictions implemented mainly in the capital region (Daerah Khusus Ibukota: DKI) of Jakarta, and the decline in tourism, the GDP growth rate for 2020 was -2.07%, the first negative growth in 22 years[141]. As of August 2020, the unemployment rate was 7.1%, up 1.8 percentage points from the same month last year, and the spread of COVID-19 is having a serious impact on employment[142].

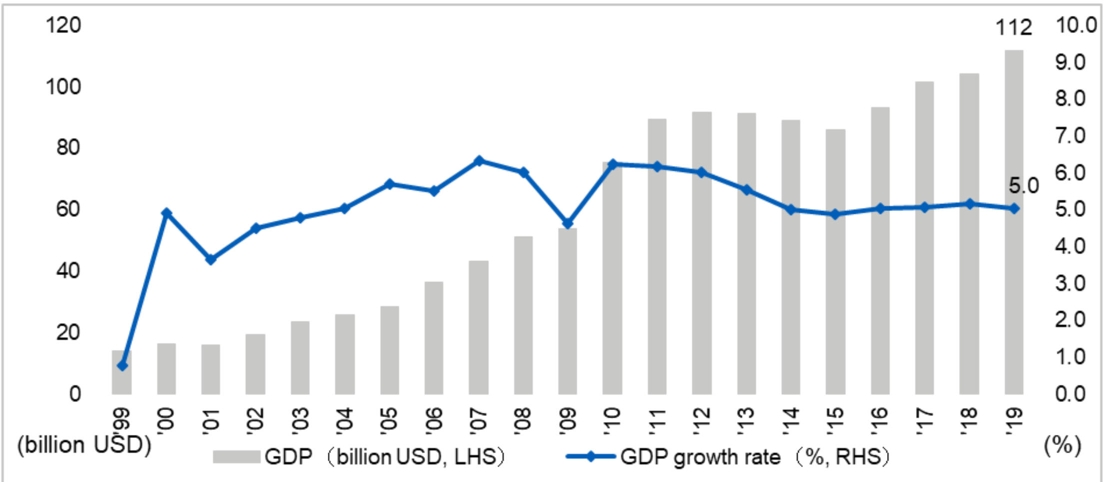


Figure V-1 GDP (US$) and GDP Growth Rate in Indonesia

Source: Compiled by survey team based on World Bank, DataBank, and World Development Indicators

141 Nihon Keizai Shimbun, https://www.nikkei.com/article/DGXZQOGM044J80U1A200C2000000/
142 IDE-JETRO, https://www.ide.go.jp/Japanese/IDEsquare/Eyes/2021/ISQ202120_007.html

（２）　Population movements

The world's **fourth-largest population is expected to continue to grow, but the rate of population growth is declining,** and **the population pyramid shows a declining birthrate and an aging** population**. The population of 2019 is expected to be 270.266 million. The** population is growing by 3 million every year, and according to the WPP, the population is expected to start declining around 2050 at the earliest. It has the second largest population after China, India, and the United States, and is expected to remain the world's fourth largest until 2030.

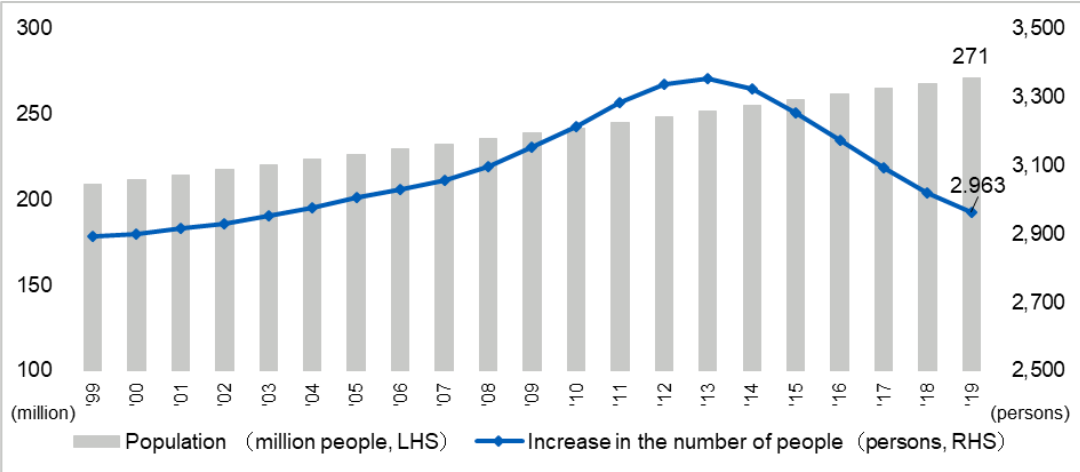


Figure V-2 Total population and population growth in Indonesia

Source: Compiled by survey team based on World Bank, DataBank, and World Development Indicators

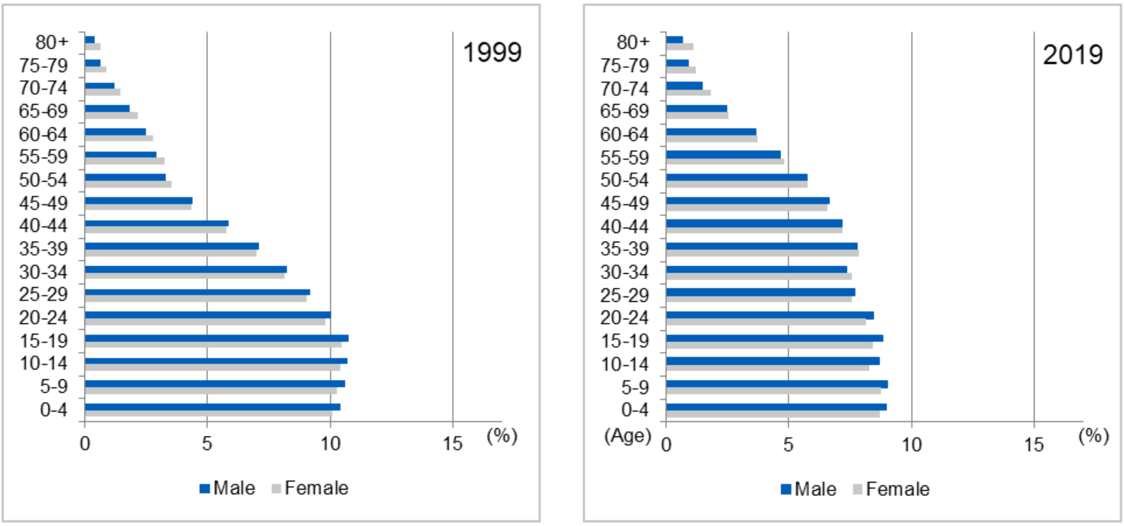


Figure V-3 Population pyramid in Indonesia

Source: Compiled by survey team based on World Bank, DataBank, and World Development Indicator

A－２． COVID-19 Situation

The number of infections and deaths has been on a downward trend since January 2021, when vaccination started, but in the second wave of infection spread in June 2021, the number of deaths per day at the peak exceeded 2,000, the highest in the world at that time. As of February 2022, the third wave is underway due to the influx of Omicron strains.

Although the first wave peaked in January 2021, the number of new infections and deaths began to decrease due to the long-term lockdown and the vaccination program started in January 2021. However, due to the influx of the highly infectious delta strain, the number of new infections and deaths increased explosively from June 2021 and entered the second wave. According to databoks.katadata[143], the Bed Occupancy Rate ("BOR") of hospitals responding to COVID-19 has been increasing since June 24, 2021. This figure exceeds the WHO's safety standard of 60%, with the six provinces of DKI Jakarta (90%), West Java (88%), Banten (87%), Central Java (85%), Yogyakarta (85%), and East Java (71%) showing very high figures. The government has stated that it will increase the number of hospital beds by 40% to overcome this situation. In addition, according to databoks.katadata[144], the number of deaths of health care workers due to COVID-19 in Indonesia as of June 24, 2021 is about 978, of which the number one is doctors (374), the second is nurses (311), and the third is midwives (155). As for dentists, 39 deaths have been confirmed. As a result, the shortage of medical personnel in many hospitals has worsened, and the Ministry of Health has requested additional medical personnel and volunteers. DKI Jakarta reported that an additional 2,156 medical personnel will be needed to respond to COVID-19[145].

On July 27, 2021, the number of deaths in one day exceeded 2,000, the highest number in the world[146]. However, strict restrictions were imposed in Java, where the capital Jakarta is located, and Bali, a tourist destination, and measures were taken in other areas according to the level of infection, and the number of new infections and deathsdeclined.

As of February 16, 2022, the number of new infections per day is 45,890, and the third wave of the pandemic due to Omicron strains is beginning. The total number of infected people in the country is 4,901,328, and the number of deaths is 145,455[147].

The cumulative number of infected people per million people is 15,367, which ranks 151st out of 223 countries in the world.

143 Pusparisa. databoks.katadata. 2021. Available at:
https://databoks.katadata.co.id/datapublish/2021/06/24/keterisian-tempat-tidur-rs-rujukan-covid-19-nasional-capai-69#
144 Bayu. databokskatadata. 2021. Available at:
https://databoks.katadata.co.id/datapublish/2021/06/24/hampir-seribu-tenaga-kesehatan-ri-meninggal-akibat-covid-19
145 Kompas. 2021. Available at:
https://megapolitan.kompas.com/read/2021/06/29/21360751/jakarta-kekurangan-2156-tenaga-kesehatan-untuk-tangani-covid-19
146 National Geographic Japan, https://news.yahoo.co.jp/articles/09d25d80dc61379c6b12266e371f44327e0753d6
147 https://graphics.reuters.com/world-coronavirus-tracker-and-maps/ja/countries-and-territories/indonesia/

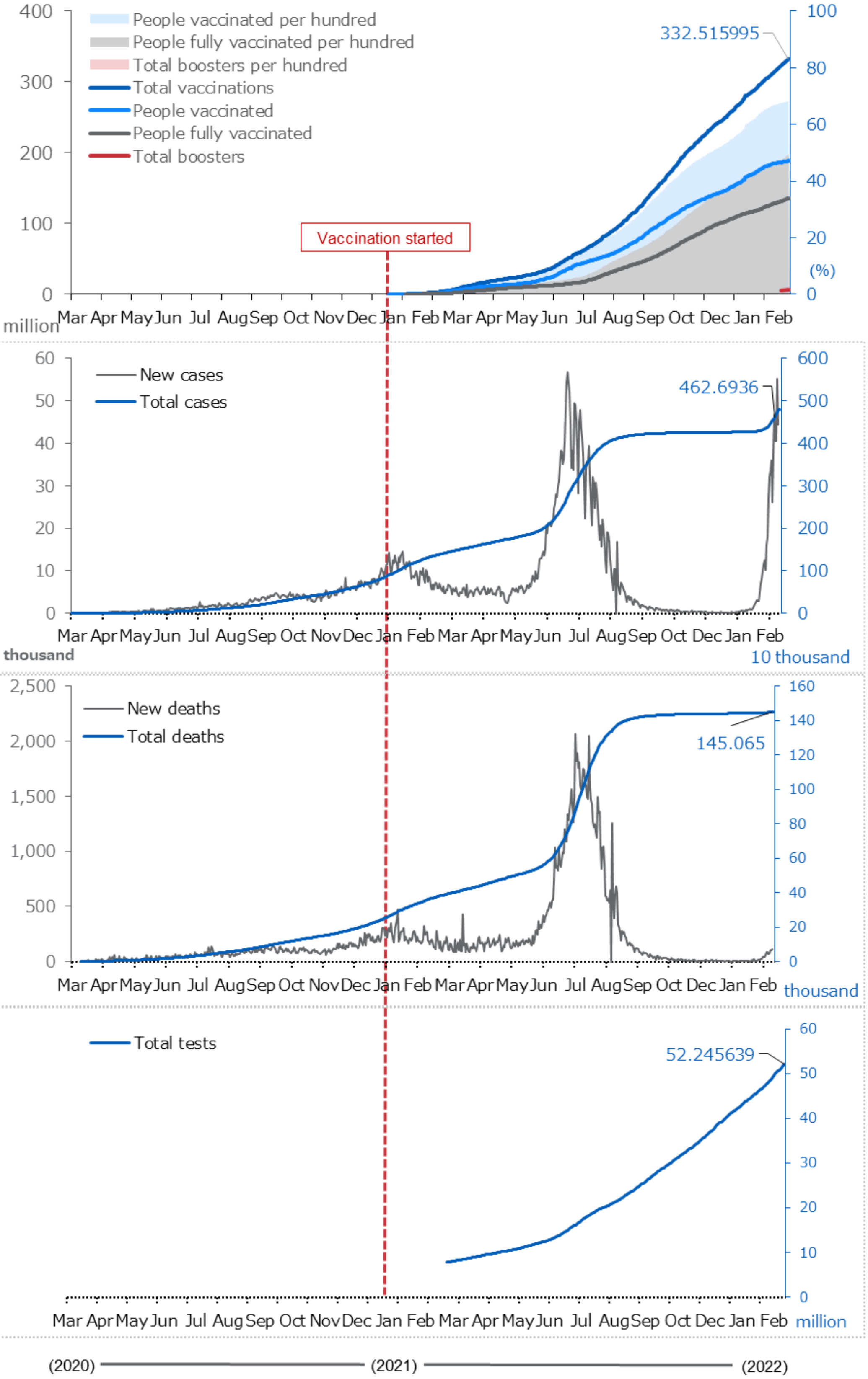


Figure V-4 infection and vaccination status in Indonesia

Source: Compiled by survey team based on Our World in Data.

Vaccination began on January 13, 2021, with vaccines manufactured by Sinovac and Sinopharm in China and AstraZeneca in the UK. As of February 16, 2022, approximately 68% of the total population had received at least the first dose, 19% had received the second dose, and only 2.6% had received a booster dose[148]..

The government has indicated its intention to implement a voluntary, private-sector-led COVID-19 vaccination program, the Mutual Aid Vaccination Program, to provide vaccination opportunities to private companies for a fee. In addition, the Indonesian government has announced a policy of prioritizing the vaccination of the working-age population between the ages of 18 and 59, due to the need to maintain employment for those who deal with an unspecified number of customers and to keep the economy running[149].

A－３． Health Care Policy, Digital Health-related Policy, COVID-19-related Policy

The policy goals for improving health care include improving access to health care facilities and developing and strengthening human resources such as medical personnel. Strengthening cooperation among various institutions and expanding joint development are also priority areas. In the field of digital health, telemedicine is being used more widely than before. The following figure shows the relationship between health care policies in Indonesia.

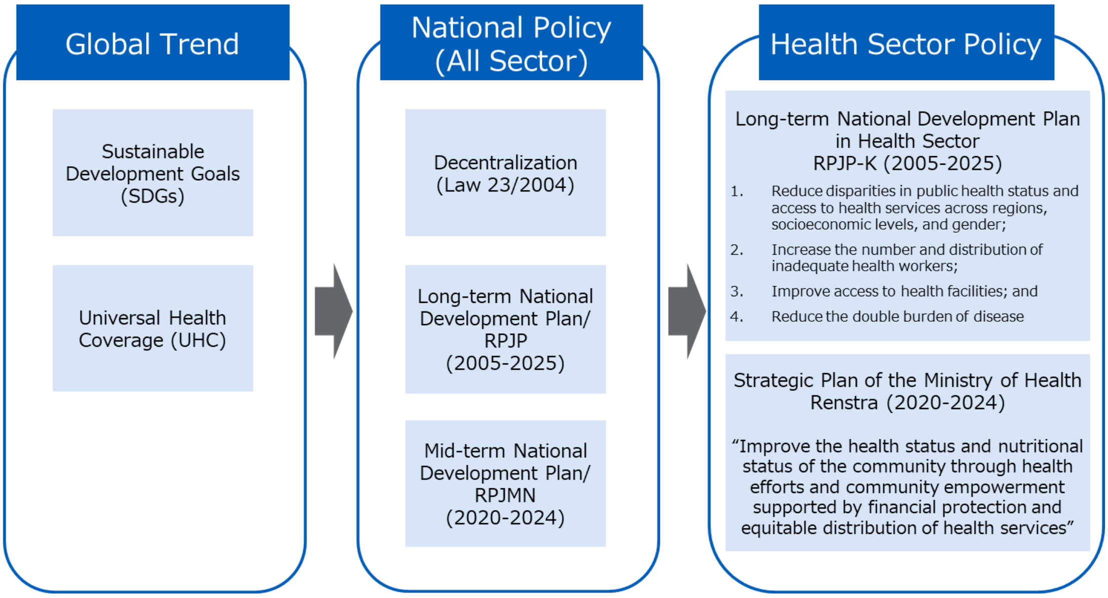


Figure V-5 Overview of Health Policy and Strategy in Indonesia

Source: Compiled by survey team

148 Our World in Data, https://ourworldindata.org/covid-vaccinations?country
149 NAA ASIA, https://www.nna.jp/news/show/2170603

The laws and regulations in the health sector, in order of increasing regulation, are as follows;

Table V-1 List of laws and regulations in Indonesia

1	Law	Undang-undang (UU)
2	Government Regulations	Peraturan Pemerintah (PP)
3	Presidential Regulations	Peraturan Presiden (Perpres)
4	Presidential Decree	Keputusan Presiden (Kepres)
5	Ministerial Regulations	Peraturan Menteri (Permen)
6	Minister's Decree	Keputusan Menteri (Kepmen)
7	Circular letter	Surat Edaran (SE)

Source: Compiled by survey team

Based on the Ministry of Health Regulation 21/2020 issued in August 2020, the four priority bills (Rancangan Undang-undang: RUU) to be completed are as follows;

- RUU on infectious diseases
- RUU on Medical Practice
- RUU on hospitals
- RUU on the revision of Universal Health Insurance Scheme (Sistem Jaminan Sosial Nasional: SJSN)

In addition to the above four RUUs, several other proposed government regulations, presidential regulations, and presidential decrees have been prepared to reduce maternal, infant, and neonatal mortality.

（１） Health Care Policy

１） National Long Term Health Development Plan (RPJP-K) (2005-2025)

The objective is for the government and the community, including the private sector, to realize the health and development goals in accordance with the vision and mission. The following priority areas have been identified: increasing the use of medical facilities, improving health insurance, properly allocating and improving the quality of medical personnel, providing medicines and medical device, strengthening the management of medical information, and reduction of maternal mortality rate through community development, etc[150]. The strategic objectives of this plan are as follows

- Reducing disparities in public health status and access to health services by region,

[150] RPJP-K 2005-2025. 2009. Available at: http://www.kmpk.ugm.ac.id/images/Semester_2/Blok%201%20-%20Sistem%20Kesehatan/Referensi%20Sesi_3_Blok_I_Rencana_RPJPK_2005-2025.pdf

socioeconomic level, and gender

- Increase the number of health care workers and appropriate distribution
- Improving access to health facilities
- Reducing the double burden of disease

２） Strategic Plan of the Ministry of Health 2020-2024 (stipulated in Regulation 21/2020 of the Ministry of Health)

It is positioned as part of the long-term plan described in 1) above. In this plan, Indonesia's national health vision is to "improve the health and nutritional status of communities through health activities and community empowerment, supported by economic protection and equitable distribution of health services," and the Ministry of Health has set the following goals and objectives.

Table V-2 Goals and Objectives in the Strategic Plan of the MOH, Indonesia

	Strategic Goals	Strategic Objectives
1	Improving community health through a circular approach	Improving maternal and child health and nutritional status in the community
2	Enhancing referral medical services	Improve the availability and quality of basic health service facilities and referral facilities
3	Disease prevention and control, and improved management in public health emergencies	Strengthen disease prevention and control, and management of public health emergencies
4	Improve medical resources	Improving access, independence and quality of medicines and medical devices Increase the percentage of medical personnel and competency fulfillment in line with the standards medical expenses subsidy system
5	Improving clean and innovative governance	Improved synergy between central and local governments, clean governance Establishing a medical information system to improve the effectiveness of research and development

Source: Compiled by survey team

As Key Performance Indicators (KPIs), the government has set specific numerical targets by 2025 for extending life expectancy, reducing maternal mortality, reducing infant mortality, and reducing the prevalence of undernutrition in children under five years of age.

３） Easing of Restrictions on Foreign Currency Investment in the Medical Sector

Presidential Decree No. 10 of 2021, Decree No. 5 of 2021, Decree No. 47 of 2021 and Regulation No. 14 of 2021 of the Minister of Health have eased foreign currency investment restrictions on hospital and clinic business in Indonesia. For private hospitals and major clinics (klinik utama), the Omnibus Law has removed restrictions on foreign investment. While foreign investors were previously limited to a maximum of 67% investment, or 70% in the case of corporations established in the Association of Southeast Asian Nations (ASEAN), they are now allowed to own shares in all private hospitals and major clinics. Hospitals financed by foreign capital were required to have at least 200 beds in both general and specialized hospitals, but in Decree No. 47 and Regulation No. 14, the minimum number of beds for general hospitals remained the same, but the minimum number of beds for specialized hospitals was reduced to 100.

（２） Digital Health-related Policy

１） Ministry of Health Regulation No. 46 (2017)

The regulation launched the development of the Indonesian National e-Health Strategy.

The seven key strategies for the development of Indonesia's National e-Health Strategy are as follows;

- Organizing and strengthening national e-Health governance and leadership
- Expand investment and develop strategies to accelerate implementation of e-Health
- Expansion and improvement of ICT to improve the quality of operation processes of medical services
- Standardization of medical information and enhancement of system interoperability to cope with the complexity of healthcare systems
- Expanding and strengthening the information infrastructure for widespread adoption of e-Health
- Strengthening the implementation of e-Health policies and regulations, ensuring the integrity of the health care system
- Improve and strengthen human resources for the use, development, and implementation of ICT in the healthcare sector

２） Presidential Regulation 39 on One Data (2019)

It was enacted for the purpose of centrally collecting, managing, and utilizing data that is distributed and managed among ministries and organizations, including the Ministry of Health. The data to be used must be accurate, up-to-date, integrated, and accountable; comply with data standards, metadata, and data interoperability; and be easily accessible and shareable between central and regional agencies through the use of reference codes and master data. This regulation will be promoted by the National Development Planning Agency (Badan Perencanaan Pembangunan Nasional: BAPPENAS), which will collect and coordinate data among ministries and agencies to eliminate differences. This regulation is described in detail in 5-5 (1) 3) Data Use.

３） Ministry of Health Regulation 21/2020 "Strategic Plan of the Ministry of Health 2020-2024"

According to the same regulation, health information system (Sistem Informasi Kesehatan: SIK) is one of the challenges and also one of the possibilities in the health sector.

Currently, SIK is very diverse, including an integrated tuberculosis information system, an HIV/AIDS information system, data communications, a family approach to health Indonesia program, and a malaria surveillance information system. There is a need for integration of data systems in order to produce valid and reliable data. The integration of data from the National Health Insurance (JKN) into the SIK, and the utilization of health service data from the health insurance implementing agency (Badan Penyelenggara Jaminan Sosial: BPJS) is also an issue.

This fragmentation of the SIK is the rationale for the development of the One Data initiative. This initiative is critical to improving the integration, interoperability, and use of government data. The use of government data is not limited to internal interagency use, but is a form of obligation to meet the public data demands of the community. The One Data Policy is to be implemented strategically through the development of one standard data, one standard metadata, and one portal.

By 2024, SIK will integrate its systems to become a medical information service that shares resources more quickly and effectively, and will enhance its application to medical facilities.

４） Ministry of Health Regulation 20/2019 on the implementation of telemedicine services between medical facilities

It is the only regulation currently issued for the implementation of telemedicine between medical facilities.

According to the regulation, the central and local governments may budget for telemedicine from other sources not bound by the provisions of the law. However, there are no further provisions on how to raise funds. Apart from funding and budgeting issues, the regulation also discusses the obligations and rights between medical facilities (medical facilities requesting telemedicine and medical facilities providing telemedicine) and the cost and payment mechanism. Article 15 of the regulation states that the cost of telemedicine services will be billed to "the medical facility requesting the telemedicine. The amount of the cost of telemedicine services for the health insurance program is to be determined by the Minister of Health.

On July 5, 2021, the government announced that it would partner with private telemedicine applications to provide free telemedicine services to COVID-19 patients to help them recover at home. 11 applications, Alodokter, GetWell, GoodDoctor, Halodoc, KlikDokter Alodokter, GetWell, GoodDoctor, Halodoc, KlikDokter, KlinikGo, LinkSehat, MilvikDokter, ProSehat, SehatQ, and YesDok, are currently available only in the DKI Jakarta region[151]. Most of these telemedicine services are a combination of remote consultation services and delivery of medicines using mobile applications. They provide online medical services through video calls, voice calls, and chats between doctors and patients, and can order tests for home use and order and deliver medicines from pharmacies that support the application.

５） Circular Letter No. HK.02.01/MENKES/303/2020 of the MOH on the Implementation of Information and Communication Technology Health Services to Prevent the Spread of COVID-19 and Regulation No. 74/2020 of the Indonesian Medical Council on Telemedicine Clinical Practice and Authority (Peraturan Konsil Kedokteran Indonesia: PERKONSIL) during the COVID-19 Pandemic in Indonesia.

Although telemedicine between medical facilities is stipulated in 3) above, there was no provision for telemedicine between doctors and patients. In response to the spread of COVID-19, the Ministry of Health and the Indonesian Medical Council have expanded the scope of telemedicine to include doctor-patient tele-consultation, remote-treatment, and e-prescription with the following restrictions;

- The patient needs emergency response.
- Patient consent must be obtained.
- The patient's medical records are recorded and stored in written or electronic form.

The Indonesian Medical Council was established in 2004 based on the Medical Care Bill, and has the authority to handle lawsuits from patients, formulate ethical education standards for medical personnel, and issue and revoke registration certificates. The council is composed of 25 members: 15 doctors, 4 officials from the Ministry of Health, 4 officials from the Ministry of

[151] Antara News. 2021.
https://www.antaranews.com/berita/2248786/pemerintah-sediakan-11-jasa-telemedicine-gratis-bagi-pasien-isoman

Education, and 2 citizens[152].

Doctors are required to have a certificate of registration in order to conduct telemedicine. Details are described in section 5-5 (2) (1) Ethical Guidelines.

６） Digital Health-related Policy by Local Governments

No specific independent efforts have been made at the local government level to deregulate digital healths; in the case of the spread of COVID-19, efforts have been made to comply with the guidelines of the central government, including the Ministry of Health. The central government supports the local governments through institutional support, supervision, and funding of general health service activities. However, most of the funding from the central government to local governments is allocated to offline activities rather than subsidizing and promoting digital health development.

（３） COVID-19 related Policy

The Government of Indonesia has formulated the National Response and Mitigation Plan for COVID-19 through the COVID-19 Response Acceleration Task Force. It has also strengthened investment in the health sector by building and upgrading hospitals and easing restrictions on foreign currency investment in hospitals.

The COVID-19 Acceleration Task Force was established on March 13, 2020, but was later dissolved by Presidential Decree No. 82/2020, and[153] its mandate was transferred to the COVID-19 Preparedness and National Economic Recovery Commission (KPC-PEN) on July 20, 2020, in accordance with the same Presidential Decree[154]. The KPC-PEN is more focused on economic recovery than the previous priority of accelerating the response to COVID-19.

１） Ministry of Health Circular on the Implementation of Health Services through Information and Communication Technology to Prevent the Spread of COVID-19, PERKONSIL No. 74/2020 on Clinical Authority and Medical Practice through Telemedicine during the COVID-19 Pandemic in Indonesia (*Reprinted)

The Ministry of Health and the Indonesian Medical Council issued the document, stipulating the implementation of patient-doctor telemedicine in the COVID-19 disaster

152 WHO, https://www.who.int/workforcealliance/members_partners/member_list/imcji/en/

153 https://www.cnnindonesia.com/nasional/20200720212317-20-526884/jokowi-bubarkan-gugus-tugas-percepatan-penanganan-covid-19

154 https://setkab.go.id/presiden-tanda-tangani-perpres-penanganan-covid-19-dan-pemulihan-ekonomi-nasional/

and temporarily waiving the rules on telemedicine. Until now, telemedicine has mainly been practiced in the realm of medical facilities, but direct doctor-patient interaction is now allowed, subject to some guidelines and restrictions.

PERKONSIL mainly regulates medical practices between doctors and patients, not between medical facilities and patients, which are subject to regulation. The relationship between medical facilities and patients is generally described in Law No. 44/2009 on Hospitals and regulated in Regulation No. 4/2018 of the Ministry of Health on the obligations of hospitals and patients.

Details are described in B-4 (2) ,1) Ethical Guidelines.

２） Communication and Information Ordinance 253/2020 on the amendment of Communication and Information Ordinance 171/2020 on the determination of PeduliLindungi application for the implementation of monitoring in the management of COVID-19

Under the said ministry, the Ministry of Communications and Information has released a mobile application called PeduliLindungi in response to COVID-19. This application regularly identifies the location of the user and can be used to track the infection status and zoning of COVID-19. As of August 30, 2021, PeduliLindungi has been used by 32.8 million users, which is relatively low considering that Indonesia will have 196.7 million Internet users in 2020[155]. However, downloads are increasing in urban areas such as Jakarta, as the government requires citizens to use PeduliLindungi to enter public facilities such as shopping malls and offices. On average, the number of users is increasing by 500,000 per day, and most of them are from urban areas such as Jakarta where the spread of COVID-19 was severe.

３） Government Regulation No. 43/2020 on Response to the Spread of COVID-19 and Threats to the Economy and National Financial System and Implementation of the National Economic Recovery Program, as amended by No. 23/2020

In response to the negative growth of the domestic economy due to COVID-19, an economic recovery program has been launched. The program focuses on three main areas: increasing domestic consumption, boosting business activity, and maintaining economic stability and monetary easing. These policies are being implemented simultaneously through the synergy of fiscal policy makers, monetary policy makers, and related agencies. The government has budgeted 172.1 trillion rupiah (≒ US$12,175.23 million) to increase the consumption and purchasing power of the people, with funds allocated for basic food aid, direct cash aid, employee salary subsidies, small business assistance, electricity subsidies, and promotion of consumption of domestic products. These domestic consumption efforts are expected to be a driving force for the

[155] Kabar24.2021.
https://kabar24.bisnis.com/read/20210202/15/1351163/aplikasi-pedulilindungi-sepi-pengunduh-ini-deretan-manfaatnya

national economy.

A－４． Health and Medical Care

The number of hospital beds per population and the number of medical personnel (especially doctors) have remained low, and it is presumed that there are issues in the development of medical facilities and the securing of healthcare personnel. As a result, people's access to healthcare is partially limited, especially in the area of maternal and child health.

In Indonesia, outside of Java and Sumatra, there is a lack of physical medical infrastructure and a 15-year difference in life expectancy between urban and rural areas due to geographical disparities in medical services[156]. In addition, investment in disease treatment is high and investment in preventive measures is low, which is thought to have led to the increase in medical expenditures[157].

（１） Basic Health Indicator

In 2019, Indonesia's mortality rate is 6.5 and life expectancy at birth is 71.5 years. Compared to the East Asia and Pacific (EAP) average (mortality rate: 7.0, life expectancy at birth: 75.4 years), which excludes high-income countries and includes Indonesia, the life expectancy at birth is slightly lower, but the life expectancy at birth is gradually increasing. As described in "A-1. General Overview," population growth is expected to continue. In Indonesia, the demand for high-quality medical services is expected to increase in line with the increase in life expectancy, the epidemiological shift described below, and rapid economic development. In particular, many wealthy patients are already traveling to the Republic of Singapore, Malaysia, and other countries for medical purposes, and the enhancement of domestic medical services is one of the priority issues[158].

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156 Oliver Wyman. 2018. Available at: https://www.oliverwyman.com/content/dam/oliver-wyman/v2/publications/2018/october/the-future-of-the-indonesian-healthcare-ecosystem.pdf

157 Jakarta Post. 2018. Available at: https://www.thejakartapost.com/academia/2018/12/27/jkn-should-shift-focus-from-curative-to-preventive-programs.html

158 Ministry of Economy, Trade and Industry (METI) Report on Research Project on Overseas Development of Japanese Medical Devices and Services
https://www.meti.go.jp/policy/mono_info_service/healthcare/iryou/downloadfiles/pdf/24fy_nexus.pdf

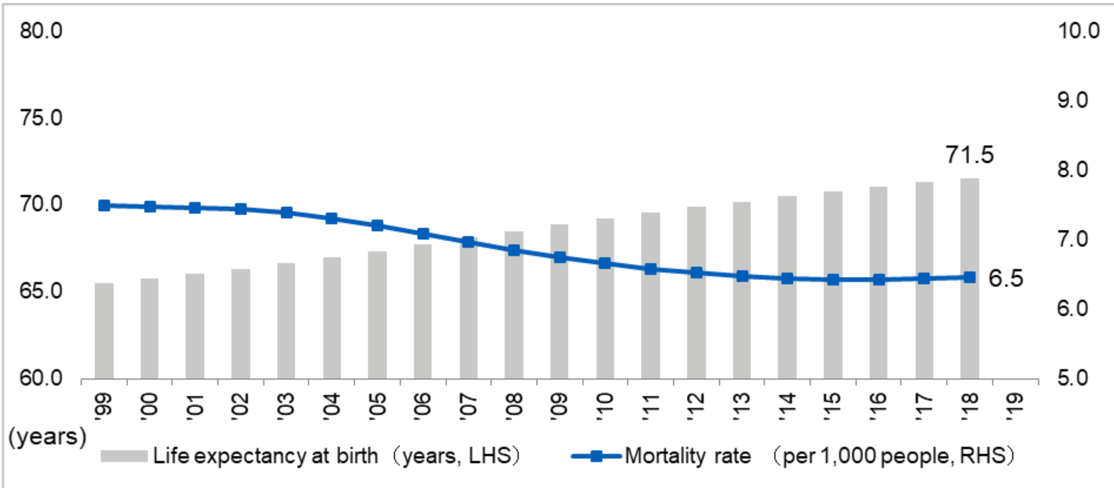


Figure V-6 Trends in life expectancy at birth and mortality rate in Indonesia

Source: Compiled by survey team based on World Bank, DataBank, and World Development Indicators

（２） Maternal and Child Health-related Indicator

In Indonesia, the level of maternal and child health care has been improved by reducing U5MR, NMR, and MMR to about 50% in about 20 years. The Indonesian Ministry of Health has set the improvement of MMR and NMR as the first target of its strategic planfor 2015-2019[159], and the government has achieved each target (MMR: 306, NMR: 24) by increasing medical human resources, early prevention of communicable diseases, and improving access to medical facilities. However, each indicator is high compared to the EAP average (U5MR: 15.0, NMR: 7.6, MMR: 73), and the NMR and MMR have not been achieved compared to the SDG target values (U5MR: 25, NMR: 12, MMR: 70).

[159]Ministry of Economy, Trade and Industry (METI), International Medical Development Country Report (Indonesia), March 2021 Available at:
https://www.meti.go.jp/policy/mono_info_service/healthcare/iryou/downloadfiles/pdf/countryreport_Indonesia.pdf

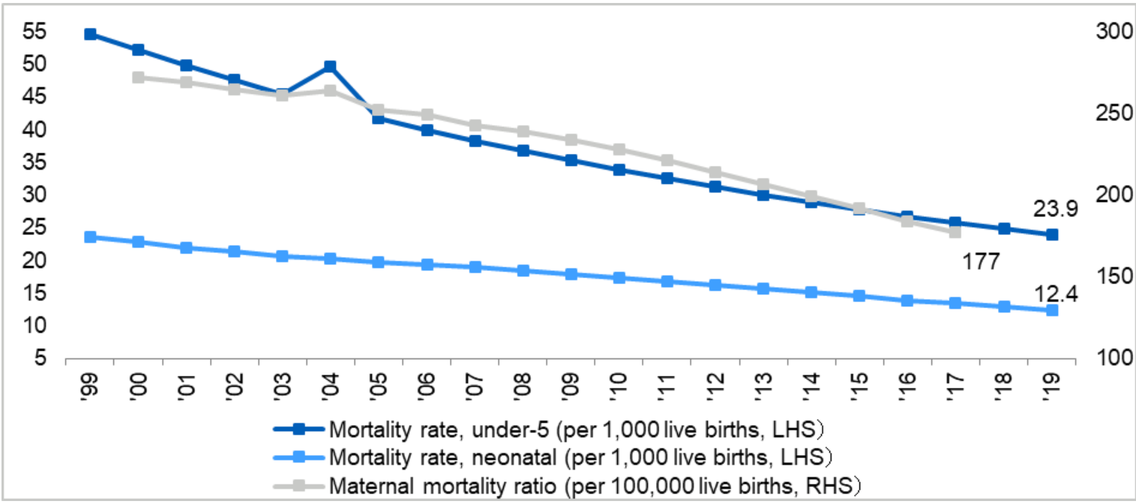


Figure V-7 Trends in U5MR, NMR, and MMR in Indonesia

Source: Compiled by survey team based on World Bank, DataBank, and World Development Indicators

In 2018, Indonesia's fertility rate and total fertility rate were 18.1 and 2.3, respectively, which are declining but still above the EAP average (fertility rate: 12.8 and total fertility rate: 1.9). According to the WPP, each indicator is expected to decline toward 2035, but is still high, and the aging of the population is expected to progress, taking into account changes in the disease structure.

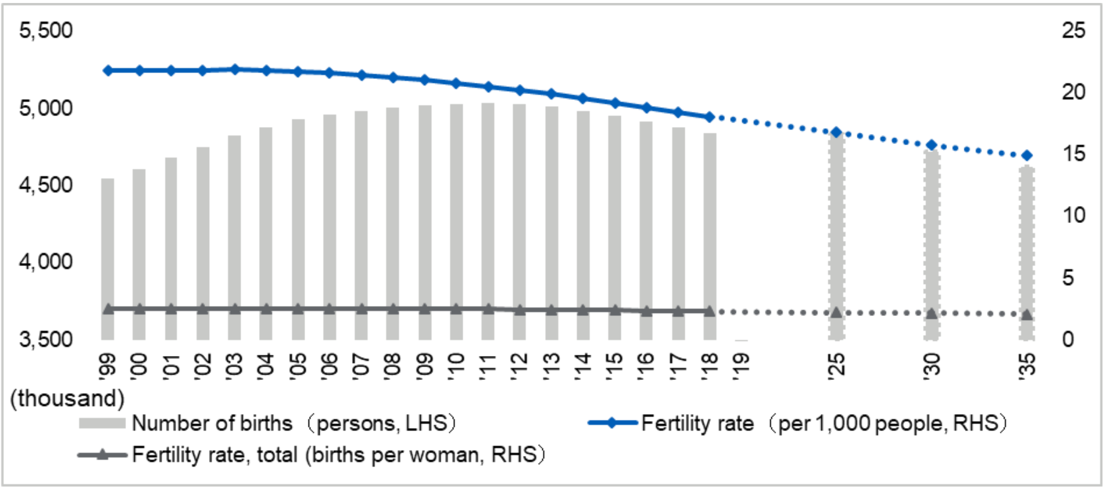


Figure V-8 Trends in number of births, fertility rate, and total fertility rate in Indonesia

Source: Compiled by survey team based on World Bank, DataBank, World Development Indicators and United Nations, and World Population Prospects.

（３） Main Causes of Death

In the 20 years since 2000, the proportion of NCDs has been increasing as the proportion of communicable diseases has been decreasing, and the proportion of NCDs is expected to increase further with economic development and improvement in the level of medical care in Indonesia. Regarding the development of medical facilities, it is estimated that not only the expansion of basic medical care but also investment in facilities and equipment that can provide advanced medical services for NCDs will be necessary. The burden of preventable diseases on the Indonesian healthcare system is estimated to be about US$5.8 billion in 2020[160].

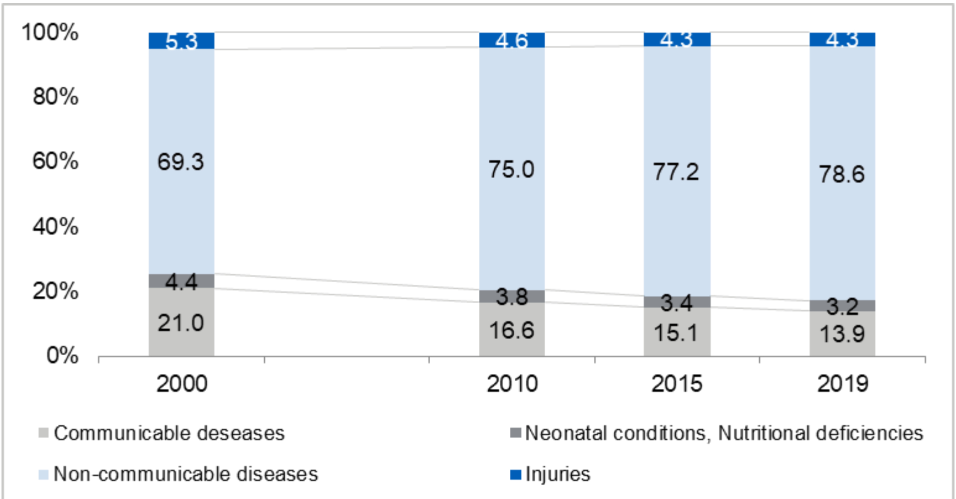


Figure V-9 Trends in major causes of death in Indonesia

Source: Compiled by survey team based on World Bank, DataBank, and World Development Indicators

（４） Number of Hospital Bed

The number of hospital beds per 1,000 people in Indonesia in 2017 was 1.0, well below the EAP average (3.7). However, according to the Strategic Planning Ministry of Health 2015-2019, the occupancy rate of hospital beds is only 65%, and the number of hospital beds in the country seems to be enough based on the occupancy rate[161]. However, it is necessary to take into account the possibility that the occupancy rate may be calculated low because early discharge from hospital before the completion of necessary medical services is sometimes a condition.

160 Jakarta Post. 2018. Available at: https://www.thejakartapost.com/academia/2018/12/27/jkn-should-shift-focus-from-curative-to-preventive-programs.html

161 STRATEGIC PLANNING MINISTRY OF HEALTH 2015-2019https://extranet.who.int/countryplanningcycles/sites/default/files/planning_cycle_repository/indonesia/restra_2015_translated_1.pdf

In addition, in January 2021, the government notified hospitals nationwide to allocate 30-40% of all hospital beds to COVID-19 patients[162]. In June 2021, when the second wave of infection peaked, the occupancy rate of hospital beds at DKI Jakarta was 93%, and the national average was 72%[163].

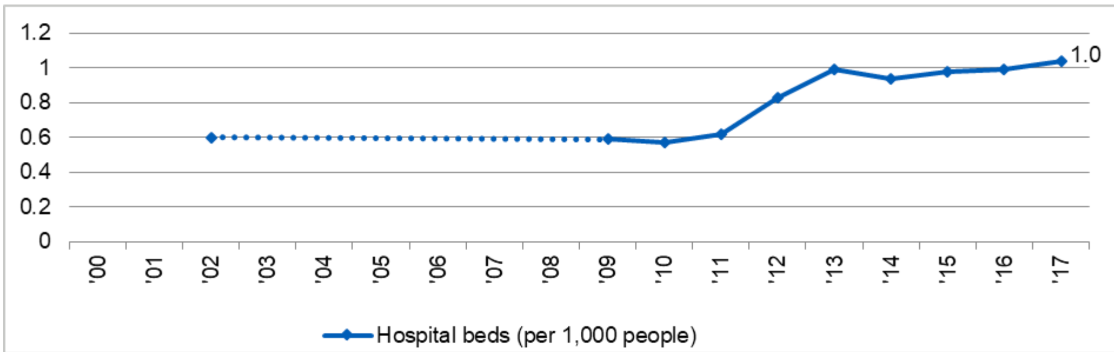


Figure V-10 Trends in the number of hospital beds in Indonesia

Source: Compiled by survey team based on World Bank, DataBank, and World Development Indicators

（５） Health Human Resource

In 2018, the number of doctors and nurses/midwives per 1,000 population was 0.4 and 2.4, respectively, which is not as high as the EAP average (1.6 doctors and 2.7 nurses/midwives), but is slowly improving. In ASEAN, Indonesia was one of the countries with the lowest number of health care workers until around 2010[164], but as a result of the government's policies to increase the number of health care workers, such as reviewing the education program for nurses[165], the number of health care workers cleared the standard of 2.5 per 1,000 population in 2018, which is the number of health care workers required to provide adequate primary care as specified by WHO. However, the SDG Index (4.45 health care workers per 1,000 population) has not been reached, and continuous improvement will be required in the future.

162 NNA ASIA, https://www.nna.jp/news/show/2139701
163 NNN ASIA https://www.nna.jp/news/show/2205852
164 JETRO, https://www.jetro.go.jp/ext_images/_Reports/02/2018/e999e1cbfd5a7b1f/report.pdf
165 Stratsea 2021, https://stratsea.com/the-surplus-shortage-paradox-of-nurses-in-indonesia/

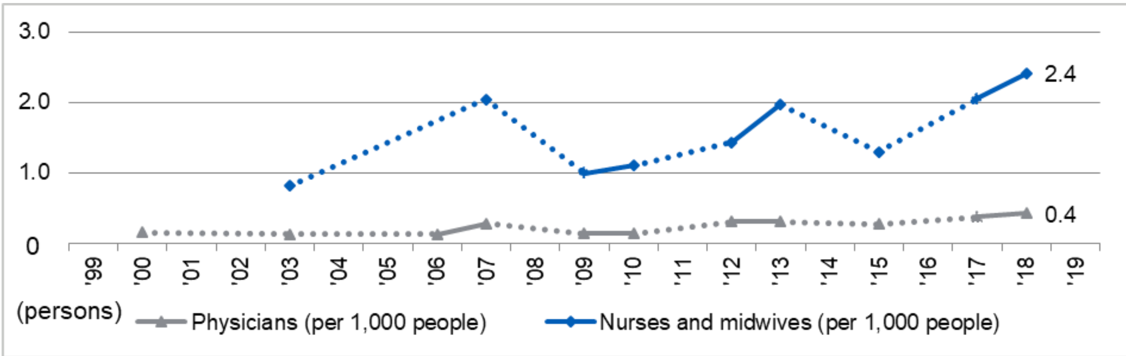


Figure V-11 Trends in number of doctors, nurses and midwives in Indonesia

Source: Compiled by survey team based on World Bank, DataBank, and World Development Indicators

In addition, medical professionals such as doctors, nurses, and midwives are generally concentrated in urban areas, so medical services vary by region[166].

[166] Hermawan, Asep (Ministry of Health). 2019. 2019. Health Workforce Distribution (Physicians, Nurses Midwives) Analysis in Indonesia 2013 by Gini Index.

Table V-3 Number of doctors by region in Indonesia shows the number of doctors in each region. The Maluku-NTT-Papua region, where many islands are scattered, has the lowest number of doctors per 1,000 people (0.03), but the population distribution in this region is 41.5%, which is the highest among all five regions. In the Kalimantan region, the number of doctors per 1,000 people is 0.37, but the area is vast (27.9% of the country), and it can be inferred that access to medical care is not easy. On the other hand, in DKI Jakarta, the number of doctors per 1,000 people is 1.7[167], and it can be said that the uneven distribution of doctors in the region is a major issue due to the concentration of medical and educational institutions in urban areas and the disparity in medical infrastructure between regions.

[167] The Conversation. 2019. Available at: https://theconversation.com/dokter-menumpuk-di-jawa-dan-kota-akar-masalahnya-pada-sistem-rekrutmen-dan-pendidikan-kedokteran-122391

Table V-3 Number of doctors by region in Indonesia

Region	No. of Doctors	Population Distribution	% of total land mass	No. of Doctors per 1,000 population
Sumatra	24,595 (24.2%)	13.6%	24.6%	0.44
Java-Bali	58,283 (57.4%)	36.7%	6.9%	0.39
Kalimantan	5,726 (5.6%)	3.8%	27.9%	0.37
Sulawesi	8,302 (8.2%)	4.6%	11.8%	0.44
Maluku-NTT-Papua	4,709 (4.6%)	41.6%	29.8%	0.03
Total	101,615			0.25

Source: Asia Pacific Observatory on Health Systems and Policies, The Republic of Indonesia Health System Review, 2017.

A－５． Referral System

Hospitals in Indonesia are classified into classes A to D and other primary medical facilities such as health centers. As a general rule, medical facilities that provide primary medical care (D class hospitals and health centers (puskesmas)) generally refer patients to medical facilities that provide inpatient and specialized care (A class, B class hospitals, etc.).

According to the Ministry of Health Regulation 3/2020 on Hospital Classification and Licensing, in general, there are two types of hospitals in Indonesia: general hospitals and specialized hospitals. General hospitals provide medical services for all areas of diseases, while specialized hospitals provide services based on the type and location of the disease, the age group of the patient, and other specialties.

If the private hospital cooperates with BPJS, the referral system in the private hospital is no different from the referral system in the public hospital. For patients with JKN to receive insurance treatment at a secondary or higher level medical facility, they must visit a primary medical facility and be referred. However, some private hospitals do not cooperate with BPJS Kesehatan and do not accept JKN patients. General patients who wish to see a doctor at their own expense can go directly to the private hospital of their choice. Only in case of emergency, patients can go directly to all hospitals, including those that do not cooperate with BPJS Kesehatan.

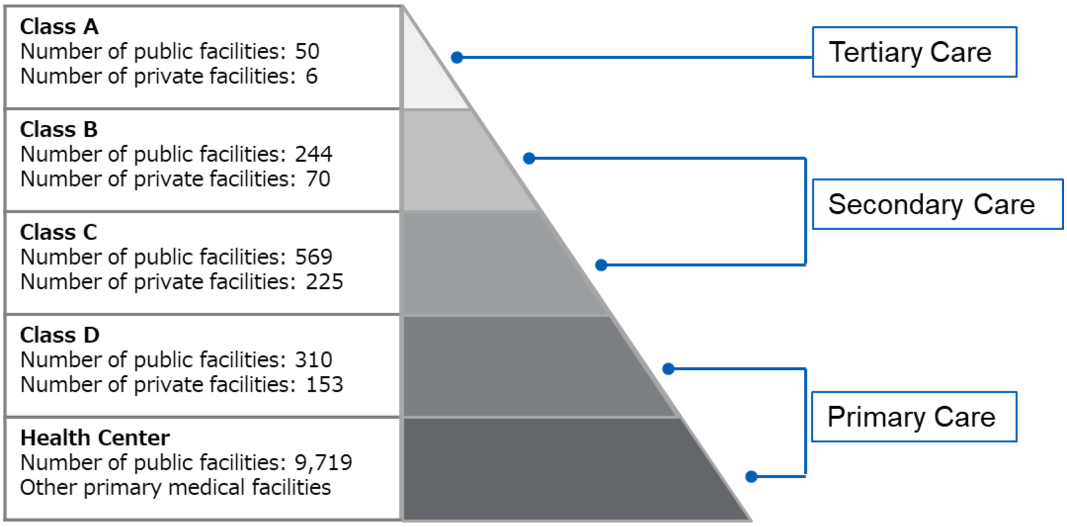


Figure V-12 Outline of referral system in Indonesia

Source: Compiled by survey team based on JETRO's "Overview of the Medical Device Market in Indonesia[168]".

（１） Role of Primary Care Facility

Health centers (puskesmas) play a central role in primary health care, providing promotion and prevention activities, health care education, testing, and treatment for the population. Some puskesmas with inpatient facilities also conduct deliveries.

Class D hospitals are hospitals in transition to Class C. The minimum number of beds stipulated is 50. Class D hospitals are usually located in remote areas of Indonesia where puskesmas is not available.

（２） Role of Secondary Care Facility

State and county level hospitals. Provincial and district level hospitals, which provide more advanced medical services to patients who need treatment that cannot be provided by primary medical facilities. It has a 24-hour emergency unit.

Class B hospitals, which fall under the category of secondary medical facilities, are located in all state capitals and receive referrals from city and district level hospitals. The minimum number of beds stipulated for Class B hospitals is 200.

Class C hospitals provide at least medical, surgical, pediatric, and obstetric services and receive referrals from Puskesmas, although the range of specialized medical services provided is limited compared to Class B hospitals. The minimum number of beds for Class C hospitals is 100.

[168] JETRO, https://www.jetro.go.jp/ext_images/_Reports/02/2017/86e615e453ca3d86/rpidn-medi201703.pdf

（３） Role of Tertiary Care Facility

Provide a wide range of specialized medical services and cross-departmental services. Provide more advanced medical services to patients who need treatments that cannot be provided by secondary care facilities. A well-developed team of specialists to provide more advanced medical technology.

The minimum number of beds stipulated for Class A hospitals, which fall under the category of tertiary care hospitals, is 250.

A－６． Insurance System

In Indonesia, a universal health insurance system has been introduced. The private sector is also strengthening its cooperation with the universal health insurance system, but the system needs to be strengthened continuously, including the reimbursement system for telemedicine.

（１） Overview of Public HealthHealth insurance

Under the universal health care system (SJSN), which was introduced in January 2014 based on Law 40/2014 on the National Social Security System, medical services are provided through public medical facilities and private hospitals that are affiliated with the health insurance implementing agency (BPJS). As of the end of December 2013, there are 533 public and 919 private hospitals that have signed the agreement. All Indonesian residents, including foreigners who have lived in Indonesia for more than six months, are required to have public insurance.

It is also noted in A-3 that the RUU on the SJSN amendment is listed as a priority under the MOH Reg. 21/2020, which focuses on the distinction of benefits between civil servants and private workers.

By showing their JKN card, patients enrolled in JKN can receive medical services free of charge, provided that the services are covered by JKN and the medical facilities are linked to BPJS. Unlike private insurance, with JKN, patients do not need to file claims themselves, but each medical facility will file a claim with the BPJS and receive payment based on the stipulated rate.

JKN subscribers are required to pay health insurance premiums to BPJS. The premiums vary depending on the class of inpatient room, and government subsidies are provided for the poor and low-income people.

The BPJS is responsible for managing insurance members, collecting premiums, and managing contracts with medical facilities. The BPJS also has the authority to make payments to medical facilities based on the rates set by the government and to initiate and terminate contracts with medical facilities.

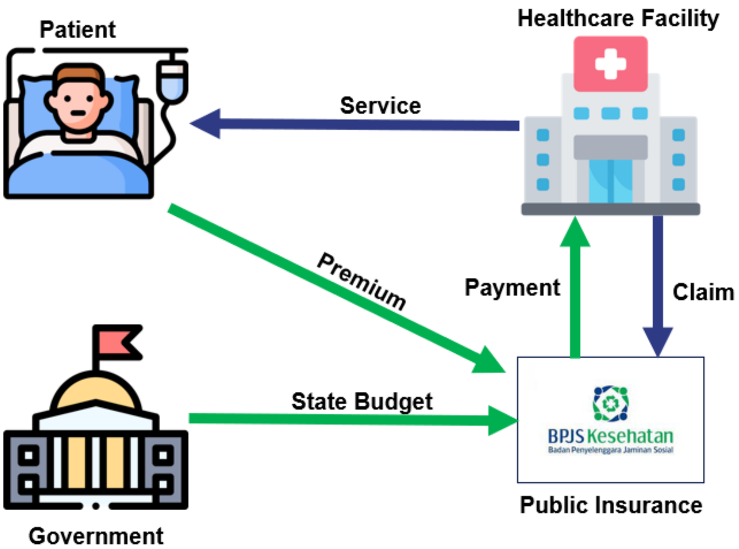


Figure V-13 Public Health Insurance System in Indonesia

Source: Compiled by survey team

In accordance with Presidential Decree No. 82/2018, public medical facilities are obliged by the government to become partners of the BPJS. On the other hand, private medical facilities may voluntarily apply to partner with the BPJS to increase their patient base. For the purpose of partnership, private medical facilities are required to be accredited by the Commission on Accreditation of Hospitals (Komite Akreditasi Rumah Sakit: KARS) in terms of competence of medical personnel, facilities, and quality of medical services.

The JKN contribution is paid by the central government through the Ministry of Health to the BPJS from the state budget funded by the Ministry of Finance. In terms of reimbursement mechanisms, JKN has two main reimbursement models, one for primary medical facilities and the other for secondary and tertiary medical facilities. The two main reimbursement models are called the "head-to-head method" and the "Indonesia Case Base Group (INA-CBG) method" respectively[169].

[169] JETRO, https://www.jetro.go.jp/ext_images/_Reports/02/2017/86e615e453ca3d86/rpidn-medi201703.pdf

The capitation method is a reimbursement mechanism for primary health care providers where the capitation rate per patient is multiplied by the number of members enrolled in the respective facility. Payments are made monthly in advance based on the number of enrolled members, without regard to the type or volume of health services provided. The challenge for the gatekeeper, Puskesmas, is to efficiently manage the available funds for health promotion and disease prevention, rather than for treatment and rehabilitation.

The INA-CBG method, on the other hand, targets secondary and tertiary care hospitals and is a reimbursement method based on case groups of patients classified by disease type and treatment type. In this system, hospitals are reimbursed based on the patient's disease type and treatment. Under the INA-CBG, payment rates are the same for both public and private hospitals. Since the reimbursement rate under the INA-CBG is relatively lower than the reimbursement rate in general hospitals The INA-CBG reimbursement rate is relatively lower than the general hospital reimbursement rate, so hospitals will need to adjust their expenses to limit financial losses when serving JKN patients.

The INA-CBG rate is determined by a unit cost calculation by the Ministry of Health's fee schedule team. The INA-CBG rate is the average cost required for a specific group of diagnoses, categorized by region, hospital class, and hospital ownership (public or private). Its calculation is based on costing data obtained from a sample of 137 public and private hospitals and 6 million case data.

Presidential Decree 111/2013 on health insurance mandates that tariffs be reviewed at least every two years. The initiative to review tariffs is aimed at encouraging tariffs to reflect more of the actual cost of services provided by hospitals.

The BPJS mandates that payment to health care providers for services rendered be made within 15 days of receipt of complete billing documents.

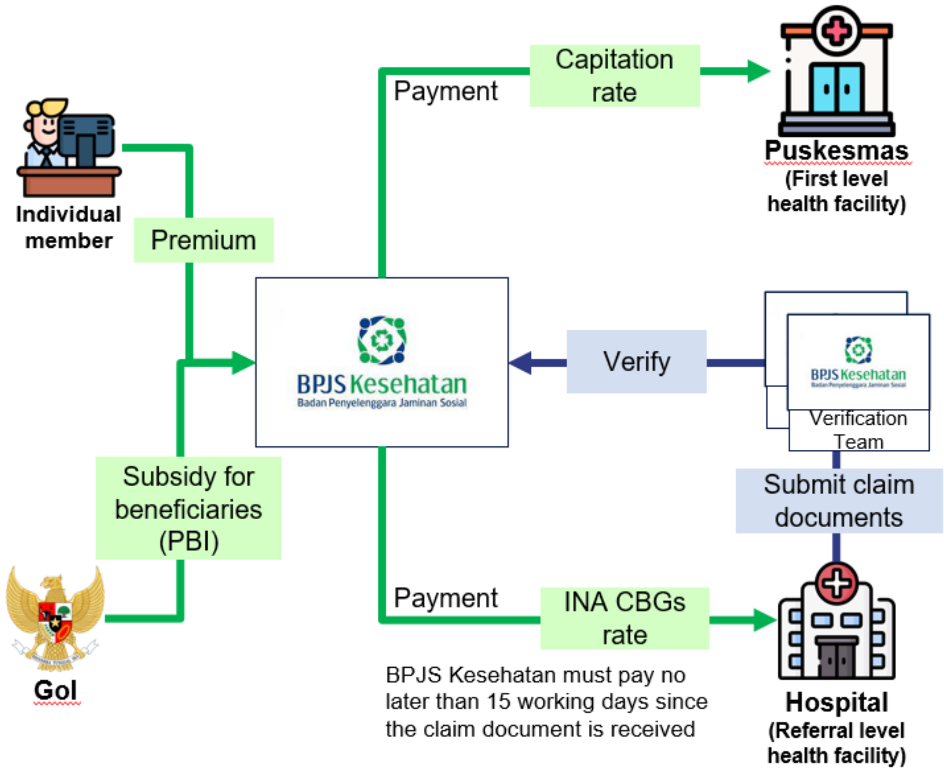


Figure V-14 Public Health Insurance System in Indonesia

Source: Compiled by survey team

Although the BPJS is increasingly addressing the issue of universal coverage as a goal, much of the cost of health care is still paid out-of-pocket. Even for BPJS-subsidized subscribers, out-of-pocket costs are relatively high[170]. On the other hand, from the perspective of health care providers and medicines, current pricing is inadequate to maintain the quality and access level of health care.

（２） Public Insurance Coverage of the Population

A universal health insurance system has been introduced, and about 90% of the population is covered by it.

（３） Compensation Coverage

JKN offers a comprehensive basic benefits package that covers primary to tertiary care, preventive care, inpatient care, emergency care, pharmaceuticals, rehabilitation, palliative care, mental health, dental care, and alternative medicine. Eyeglasses, hearing aids,

[170] Jakarta Post. 2017. Available at: https://nasional.kompas.com/read/2017/05/23/17413621/pengeluaran.masyarakat.untuk.kesehatan.masih.tinggi.meski.ada.bpjs?page=all

wheelchairs, canes, etc. are also covered with a set maximum amount. On the other hand, services such as cosmetics, general checkups, prosthetic dentistry, alternative therapies such as acupuncture and moxibustion, in vitro fertilization, and fertility treatments are not covered.

There is no difference in medical services, including medicines, due to the difference in insurance premiums, but there is a difference in the room class during hospitalization. JKN patients can only be admitted to wards I, II, or III, depending on the premium. Patients who wish to enter the VIP class or a class higher than Class I can either increase their eligibility or upgrade their accommodation, facilities, and other non-medical services by increasing their premiums.

（４） Compensation Coverage for the Digital Health Sector

Now, telemedicine services are not covered by public insurance. The Ministry of Health is piloting BPJS Kesehatan's telemedicine applications, Mobile JKN and Mobile JKN Faskes, in the 5cities of Medan, Serang, Jakarta, Yogyakarta, and Gorontalo in order to bring telemedicine services under BPJS reimbursement nationwide. Details of Mobile JKN and Mobile JKN Faskes are as follows**.**

V-1 Details of BPJS Telemedicine Application

App	User	Function
Mobile JKN	Patient	Bed availability, service registration, insurance premiums, consultation by doctor, surgical schedules, medical examinations, list of covered drugs, payment records, participant registration, payments, service history, information and complaints, JKN information, location, COVID-19 self-assessment, etc.[171]
Mobile JKN Faskes	Medical Facility, Doctor	The main functions of Mobile JKN Faskes are patient list, contact rate, chat room, and schedule[172]. The advantages of Mobile JKN Faskes for doctors are that they can easily contact individual patients and educate them about their health through the consultation and chat menus, and they can obtain information on patients' evaluation of the online contact services (chats) they provide.

Source: Compiled by survey team

171 BPJS Kesehatan. 2022. https://bpjs-kesehatan.go.id/bpjs/post/read/2022/2170/Fitur-Mobile-JKN-Terbukti-Permudah-Urusan-Peserta-JKN-KIS

172 BPJS Kesehatan. 2020. Available at: https://www.bpjs-kesehatan.go.id/bpjs/post/read/2020/1521/Mobile-JKN-Faskes-Mudahkan-Komunikasi-Antara-Dokter-Dengan-Pasien-JKN-KIS

The pilot aims to determine payment mechanisms for telemedicine services and to evaluate their effectiveness and efficiency. In 2021, approximately 9.3 million teleconsultation services were used between doctors and patients through BPJS Kesehatan's telemedicine platform[173]. The telemedicine services provided by BPJS Kesehatan through Mobile JKN and Mobile JKN Faskes are separate from the Ministry of Health's telemedicine platform, TEMENIN. The pilot period was 2019~2020 years, but BPJS Kesehatan is considering to continue the pilot further by expanding the project's coverage area. The details of the target areas have not been disclosed. As the pilot is still ongoing, it has not yet been institutionalized in official document.

（５） Private Insurance

Private insurance is supervised by the Ministry of Finance, but payment mechanisms are regulated by contracts with health care providers. the BPJS works with several private insurance companies to provide optional services for middle- and high-income national health insurance subscribers[174]. New developments include the development of unique insurance products by telemedicine application developers such as Alodokter, and the development of unique telemedicine applications by insurance companies such as AXA and Allianz.

A－７． Needs of Medical Facilities

In this survey, the online questionnaire was sent to 14 medical facilities (Public:10, Private:4) in Indonesia regarding the status of Covid-19 measures and operational issues of the hospitals. The summary of the results of the questionnaire to the medical facilities is as follows. The figures in the text indicate the percentage of medical facilities that selected the relevant items among the medical facilities that completed the questionnaire. However, there were some medical facilities that could not respond to the questionnaire in the first place because they were busy with COVID-19 measures, etc., and the level of medical facilities varied, so caution is needed in interpreting the analysis in this chapter as a general statement. For details of the questionnaire results, please refer to Appendix 6 and 7.

（１） Online survey results

１） General Information

Eighty-six percent of the medical facilities that responded to the questionnaire had a stable wired Internet connection, and 0% of the medical facilities responded that they had no connection. It can be inferred that the barriers to the introduction of ICT in terms of

173 Berita Satu. 2021. https://www.beritasatu.com/ekonomi/846541/pemanfaatan-telekonsultasi-bpjs-kesehatan-capai-93-juta-layanan
174 Asia Pacific Observatory on Health Systems and Policies. The Republic of Indonesia Health System Review. 2017. https://apps.who.int/iris/handle/10665/254716

communication infrastructure are not very high, as the communication environment is relatively good.

２） Digital health status

The top issues in the introduction of digital health are the lack of human resources in the hospital who can implement and maintain the system (86%) and the low ICT literacy of the staff (71%).

Electronic medical records (93%), online medical care (71%), and EHR (71%) have already been introduced to a high percentage of medical facilities. As for digital health that they would like to introduce in the future, there is a high level of interest in information collaboration, such as doctor-to-doctor platforms (64%) and remote diagnostic imaging (57%).

３） COVID-19 support status

In response to COVID-19, there was a shortage of human resources and equipment, including nurses (64%), ventilators (64%), and ECMO (57%).

As for the challenges in infection control, inadequate implementation of standard precautions by staff (64%) was recognized as a major issue. In addition, patients leaving the hospital without permission (36%) and payment problems (36%) were also recognized as issues. Since there is a high demand for face recognition and automatic temperature detection systems, it can be inferred that there is demand for tracing patients under treatment and access control (authentication, etc.).

４） Operational issues

As issues related to prevention, the lack of education and guidance to local residents (57%) was cited, and the issue of many patients coming to the hospital after they have become seriously ill (93%) was recognized. In addition, there are issues such as the heavy workload of staff in outpatient operations (71%), the time required for medical interviews (57%), and crowded outpatient clinics (50%), and there seems to be a high demand for the use of digital health to improve operational efficiency.

In addition, a high percentage of respondents were aware of issues related to information coordination, with some saying that it was inconvenient to share information with other hospitals (50%) and that coordination with other departments in the hospital was insufficient (43%).

As for the medical care system, the shortage of nurses (64%) is the main issue, followed by inadequate education of medical personnel (57%), which is recognized as a high demand for distance training.

（２） Digital health with the potential to help solve local medical issues

The following table summarizes the issues in the medical environment in the local target medical facilities obtained from the above online questionnaire and follow-up interviews, and describes the direction of solutions to these issues using digital health. As in the health tech map, the issues in the medical environment are organized according to the main medical treatment processes, and the items for which more than 50% of the target medical facilities recognize some issues in each questionnaire item are extracted.

In Indonesia, a high percentage (more than 90%) of the target medical facilities recognize that many patients come to the hospital after they have become seriously ill, and this situation presents a challenge in terms of prevention in the medical treatment process. As a direction for solution, measures such as promoting behavior management and behavior change of users (including health and unwellness) and patients using digital health, and establishing contact with medical professionals at an early stage can be considered.

In the screening, 50% of the target medical facilities recognized congestion in outpatient clinics as an issue, and more than 70% of the target medical facilities identified the high workload of staff as an issue. In response to these issues, it is expected that digital health will be utilized in the direction of reducing the workload of staff and improving work efficiency by utilizing advanced technologies such as AI, various systems and robotics, such as AI medical interview.

In terms of inpatient treatment, 50% of the target medical facilities cited ward congestion due to a shortage of hospital beds as an issue. With regard to the shortage of ICU beds in particular, the use of digital health, such as in-hospital and out-of-hospital expansion of beds and remote ICUs that contribute to the expansion of monitoring facilities, may contribute to solving the problem of the medical environment.

As for issues related to continuous treatment and follow-up, more than 50% of the target medical facilities recognize that guidance and follow-up to patients are insufficient. Since the effect of follow-up is limited to periodic medical examinations and checkups by medical personnel, the direction of the solution is to encourage patients to manage their own behavior and change their behavior by using digital health such as applications.

In terms of operation and management, it is recognized that 50% of the target medical facilities have problems in information linkage with outside hospitals. Indonesia is an island country, and information linkage through online medical services and remote image diagnosis is considered necessary to improve access to medical care in islands and rural areas. In the direction of solving the problems of the medical environment, it is necessary to develop a framework for information coordination that will serve as the basis for the utilization of digital health on the premise of such cooperation among facilities.

In addition, more than 50% of the target medical facilities responded that education and training for doctors and other staff is inadequate, suggesting that there is relatively high demand for effective provision of education and training; VR training, for example, is a possible direction for solving this issue using digital health.

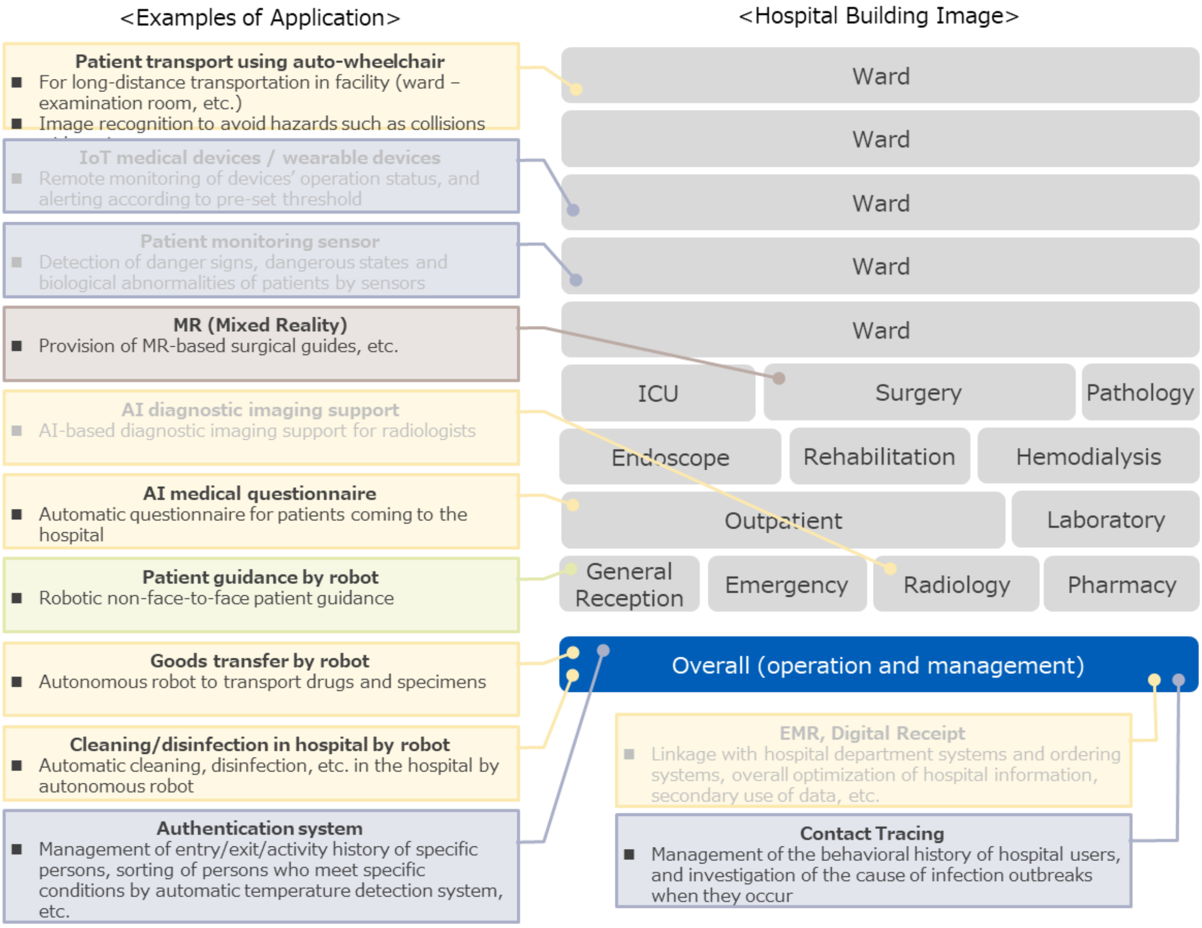
In terms of other operational management, 50% of the target medical facilities responded that they had nosocomial infection control issues because they could not identify the cause of an outbreak of infection in the hospital. As a direction for solving these medical issues, the introduction of digital health, such as access control and contact tracing, with appropriate zoning and management, will help to quickly identify the cause of an infection outbreak, and to consider and implement timely and appropriate countermeasures.

Procedure	Issues in the Medical Environment	Direction of Solution
Prevention	• Inadequate education and guidance for local residents • Many patients visiting hospitals only after their disease symptoms become serious	■ **Promote users' own behavior management and behavior change** Behavioral change based on daily biometric data recording, AI analysis, etc. through health promotion apps ■ **Establish early contact with healthcare professionals** Advice and recommendation for medical consultation by medical professionals at the stage of pre-disease through online
Screening	• Congestion in outpatient consultation • Heavy workload for staff in reception and screening (e.g., handling medical interviews)	■ **Improve operational efficiency through the use of advanced technology** AI medical questionnaire, patient transport using automated wheelchair, etc.
Examination and Diagnosis	-	-
Treatment (hospitalization)	• Congestion in the inpatient wards (insufficient beds in general wards, ICUs, etc.) • Unable to operate in their own hospital, patients travel to a distant medical facility	■ **Collaborate with facilities and personnel outside the hospital** Remote ICU, etc.
Ongoing treatment and follow-up	• Insufficient guidance to patients on medication, lifestyle, etc. • Insufficient patient follow-up during and after treatment (regular consultations or check-ups, rehabilitation etc.)	■ **Promotes patients' own behavior management and behavior change** Management of patients' behavioral records, etc. through the use of therapeutic apps, automatic sending of guidance to encourage behavioral change, implementation of remote rehabilitation, etc.
Other (Operations Management)	• Insufficient coordination of operations and information outside the hospital (between other facilities)	■ **Promotes collaboration by introducing an information coordination framework** EHR, PHR, doctor-to-doctor platforms, etc.
	• Inadequate education and training of staff (doctors, nurses, technicians, etc.)	■ **Provide education and training opportunities using digital health** VR training, etc.
	• Inadequate infection control in the hospital (e.g. zoning of infection control areas)	■ **Zoning, non-face-to-face and non-contact to reduce opportunities for contact with infected patients** Zoning of infection control areas, even within existing facilities, with limited staffing Unmanned operations using automatic transfer robots, etc. ■ **Access control for specific persons by face recognition** Automatic face recognition system to control entry and exit of specific persons and trace their behavioral history, etc.

Figure V-15 Direction of solutions for medical issues in Indonesia

Source: Compiled by survey team

As for the issues of the medical environment in the target medical facilities organized as a result of the questionnaire and follow-up interviews, there is a possibility of utilizing digital health in a wide range of fields both inside and outside the hospitals. Figure V-15 Direction of solutions for medical issues in Indonesia shows the solutions that may contribute to solving the issues in and out of the target medical facilities, based on the direction of solutions shown inFigure V-16 Solutions that may contribute to solving problems (in-hospital and out-of-hospital).



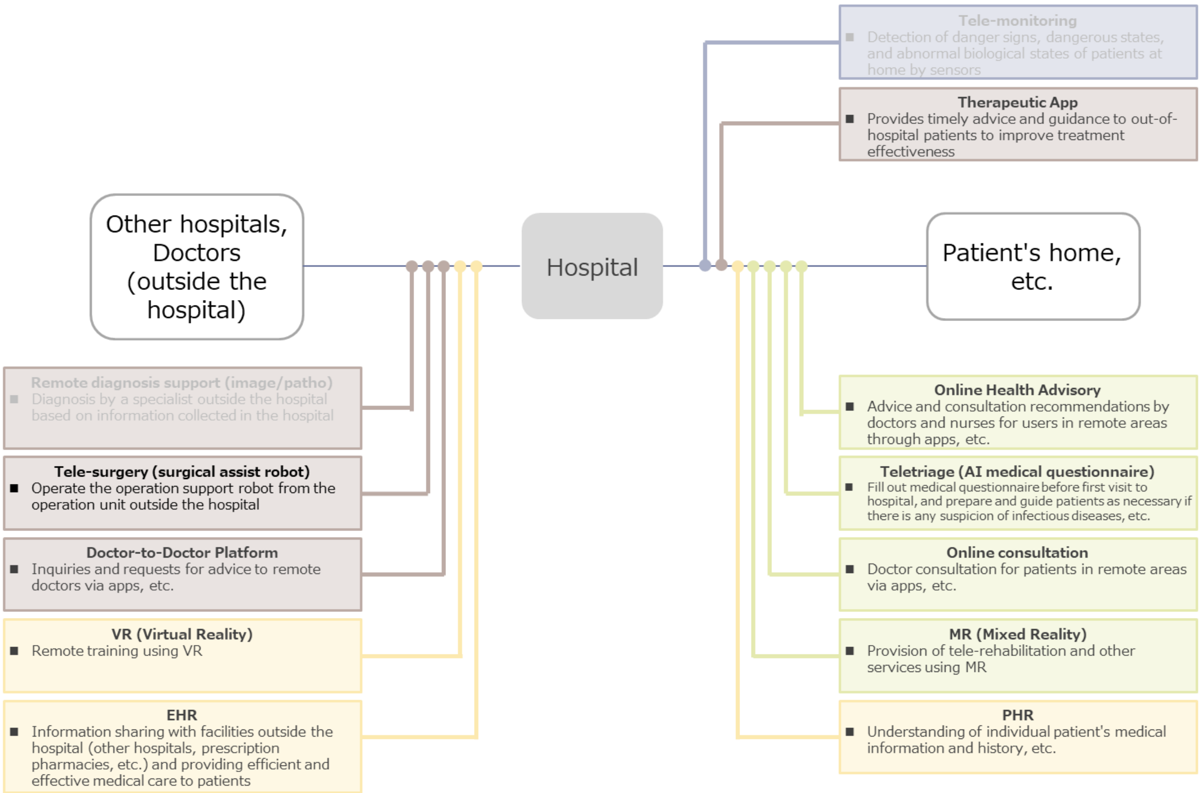


Figure V-16 Solutions that may contribute to solving problems (in-hospital and out-of-hospital)

Source: Compiled by survey team

B. Perspective of Company

B－１. Recent trends and their main factors

（１） Market size and estimates

The number of Internet users in Indonesia is 197 million, but is growing by about 5% annually and is estimated to reach 250 million by 2025[175]. Indonesia's overall digital investment is on the rise and is expected to more than double by 2020[176].

175 Badan Koordinasi Penanaman Modal. Statistik Indonesia. 2020.
176 Alpha JWC Ventures. Unlocking the Next Wave of digital Growth. 2021. Available at: https://www.alphajwc.com/wp-content/uploads/2021/03/Alpha-JWC-Ventures-Kearney-Study-Unlocking-the-next-wave-of-digital-growth.pdf

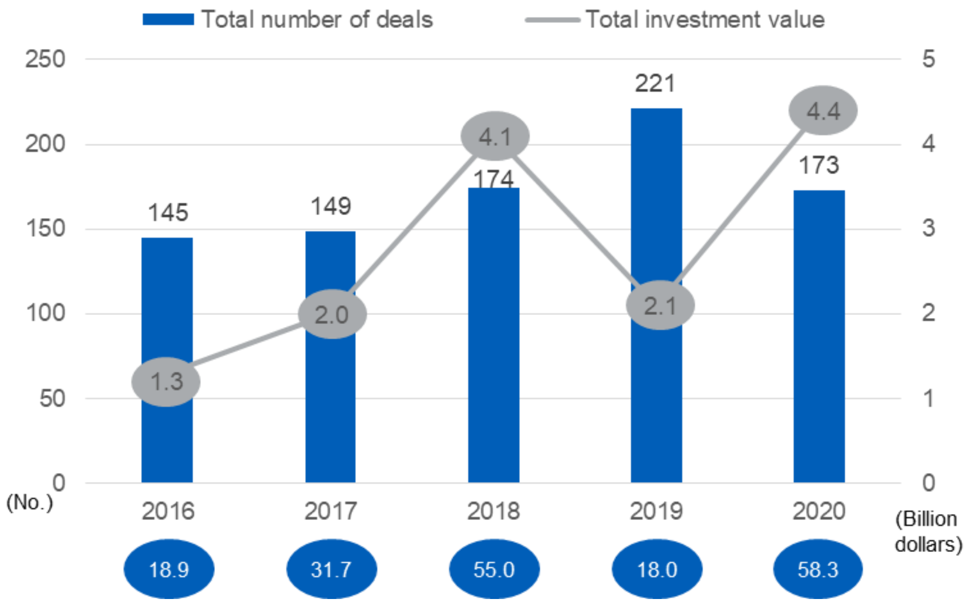


Figure V-17 Trends in Digital Investment in Indonesia (2016-2020)

Source: Alpha JWC Ventures (2021)

In **Indonesia, the digital health sector has been growing rapidly over the past five years. Revenue in the digital health sector is estimated to increase at a compound annual growth rate (CAGR) of more than 60%, from USD 85 million in 2017 to USD 973 million by 2022[177].** This trend is being influenced by multiple factors, including changes in consumer behavior, expansion of hospital services, and government digitization initiatives. In particular, the impact of the rapid development of new services and consumer usage, triggered by the spread of COVID-19, has been significant. This trend has been driven by increasing customer interest and usage of digital health platforms, increasing health awareness among the younger generation, development of new digital services by start-ups and healthcare organizations, emergence of associations, forums, and events dedicated to medical technology, government initiatives to digitize healthcare systems etc. are contributing significantly to the growth of the digital health market.

Online medical practice accounts for the largest share of the digital health market in Indonesia, followed by digital pharmacies. The largest revenue sources are patients who use online medical services, the general public who order non-prescription based medicines from digital pharmacies, hospitals that provide IT solutions, and clinics that use appointment systems[178].

[177] Frost and Sullivan. Digital Market Overview: Indonesia.
[178] Ken Research. Indonesia Health Tech Market Outlook 2025. 2020

More than 2 million people are already using telemedicine and the number is expected to increase by 67% year on year by 2020[179]. Alodokter, a provider of telemedicine applications, leads the market with 33 million active users, 61 million visits and 5.5 million mobile application downloads. Halodoc, the second largest provider of temedicine applications, has 12 million users and allows users to make appointments for rapid testing and PCR testing at hospitals in case of infection spread[180]. Good Doctor, on the other hand, has recorded an eight-fold increase in user traffic since the early days of the outbreak[181].

The digital health market is expected to grow rapidly, but is still in its early stages of growth by 2025[182]. By 2025, digital health penetration is expected to increase from about 3% to 16% of the population[183].

The Southeast Asian region has also seen a steady increase in digital health investments, with investments increasing at a CAGR of 63% in 2019[184]. Singapore and Indonesia continue to be the main targets for funding in the region, with two of the five largest digital health deals in Southeast Asia in 2019 based in Indonesia (Halodoc and Alodokter), raising a total of US$133 million[185].

179 Jakarta Post. 2020. https://www.thejakartapost.com/academia/2020/08/28/digitizing-health-care-is-the-new-normal.html.
180 Jakarta Post. 2020. Available at: https://www.thejakartapost.com/news/2020/04/21/the-time-is-right-covid-19-gives-more-room-for-telemedicine-to-grow-in-indonesia.html
181 Ciptadana. Market Outlook 2021: Healthcare Sector. https://www.ciptadana.com/news/1103
182 Alpha JWC Ventures. 2021.
183 Alpha JWC Ventures. 2021.
184 INSEAD, Southeast Asia VC HealthTech landscape, 2020, https://www.insead.edu/sites/default/files/assets/dept/centres/gpei/docs/sea-vc-healthtech-landscape.pdf
185 The Business Times, 2019. https://www.businesstimes.com.sg/garage/healthcare-firm-halodoc-raises-about-us100m-in-series-b-b-rounds and AsiaTechDaily. 2019. https://www.asiatechdaily.com/indonesia-alodokter-series-c/

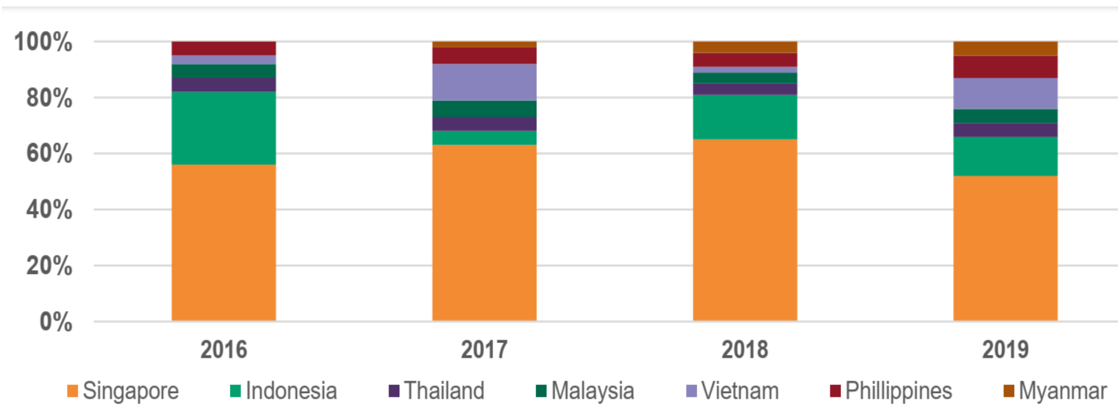


Figure V-18 Percentage of funds related to digital health in the Southeast Asia region by country

Source: INSEAD, 2020.

（２） Trends in the development of digital health

According to the Asia Pacific survey[186], consumers expect to use digital health services in the future, and are interested in telemedicine, self-checkup applications, and chronic disease management. In addition, consumers are increasingly interested in staying healthy and researching their own symptoms and treatments online.

In Indonesia, many private digital health companies are providing intervention services to customers/patients and healthcare providers by combining functions such as online medical care and delivery of medicines through mobile health applications. HaloDoc (US$145 million) and Alodokter (US$45.1 million) are two of the largest digital health companies. In addition to the above online medical applications, digital pharmacy services (e.g., Goapotik, Farmaku), health promotion applications (e.g., Pasienia), and digital clinic models that provide home services (e.g., KlinikPintar IDI) are also on the rise. In terms of interventions in data services, several EMRs have been identified as being offered in the market. On the other hand, technologies such as wearable devices, robotics, and AI are still in the minority.

The trend in development is toward small and non-invasive medical devices that consumers can easily operate at home, and that are increasingly used in conjunction with smart phones. Solutions that record information and act as reminders or alerts to the patients' doctors are also emerging.

186 Bain & Company. Asia-Pacific Front Line of Healthcare Report. 2020

B－２． The impact of COVID-19 on recent trends

Despite the negative impact of COVID-19 on many sectors, the ICT sector is growing strongly in general, growing 11% year over year in 2020, while other sectors such as mining, manufacturing, construction, trade, and transportation are growing negatively. Since the spread of COVID-19, there has been a growing trend to go online, and new digital habits are likely to continue after the infection ends[187].

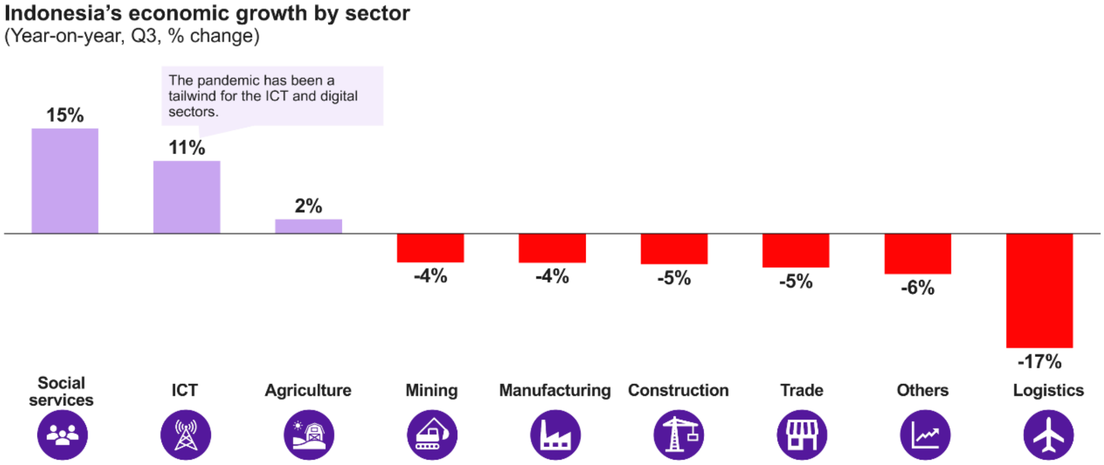


Figure V-19 Indonesia's Economic Growth Rate by Sector (2020)

Source: Alpha JWC Ventures (2021)

The long-term development of the ICT sector, including the digital economy, in Indonesia is considered promising. According to the Oxford Business Group, between 2015 and 2019, Indonesia's digital economy is quadrupling at an average annual growth rate of 49%, with an estimated market size of US$40 billion. Meanwhile, the digital economy is expected to grow to US$130 billion by 2025, driven by the proliferation of online payments, improved infrastructure, and the rise of domestic tech companies[188].

While the COVID-19 disaster has forced both consumers and businesses to stay home, and sectors such as tourism and airlines have been hit hard, the healthcare, sanitation, and e-commerce sectors have seen a market boom. The healthcare sector is experiencing a surge in demand, and consumers tend to prefer products and services through digital platforms. In the current outbreak, about 70% of consumers have tried at least one new digital service, with telemedicine applications topping the list at 38%, higher than online education (34%) and digital

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[187] Alpha JWC Ventures. 2021.
[188] Oxford Business Group. 2020. Available at: https://oxfordbusinessgroup.com/overview/bright-future-digital-economy-shows-potential-growth-service-providers-respond-rapidly-increasing

entertainment (25%), when looking at ICT as a whole, not just healthcare[189].

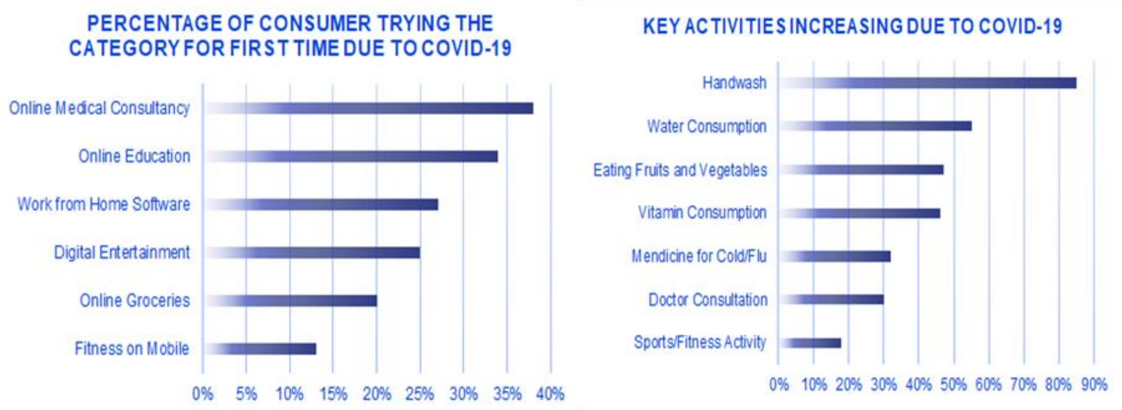


Figure V-20 Impact of COVID-19 on consumer behavior in Indonesia (2020) N=500

Source: Mobile Marketing Association. Impact of COVID-19 on Consumer Behavior in Indonesia.

In the wake of the pandemic of COVID-19, the government has temporarily waived the rules on telemedicine. In the past, telemedicine was mainly the domain of medical facilities, however, in accordance with "Circular Letter No. HK.02.01/MENKES/303/2020 of the MOH on the Implementation of Information and Communication Technology Health Services to Prevent the Spread of COVID-19 and Regulation No. 74/2020 of the Indonesian Medical Council on Telemedicine Clinical Practice and Authority" as described in III-3-3, direct doctor-patient interaction for consultation and prescription is allowed during the spread of the infection with some guidance and restrictions.

B－３. Health Tech Map

The main technology types of solutions in Indonesia are mapped as follows, similar to the types in Japan. The main technology types that were confirmed to exist in the Indonesian digital health market through the desktop survey are mapped in white boxes. The technology types that are not widely used in the local market or whose existence was not confirmed, but exist in the Japanese digital health market (technology types that could be introduced from Japan to the local market in the future) are mapped in blue boxes.

[189] Mobile Marketing Association. Impact of COVID-19 on Consumer Behavior in Indonesia. 2020

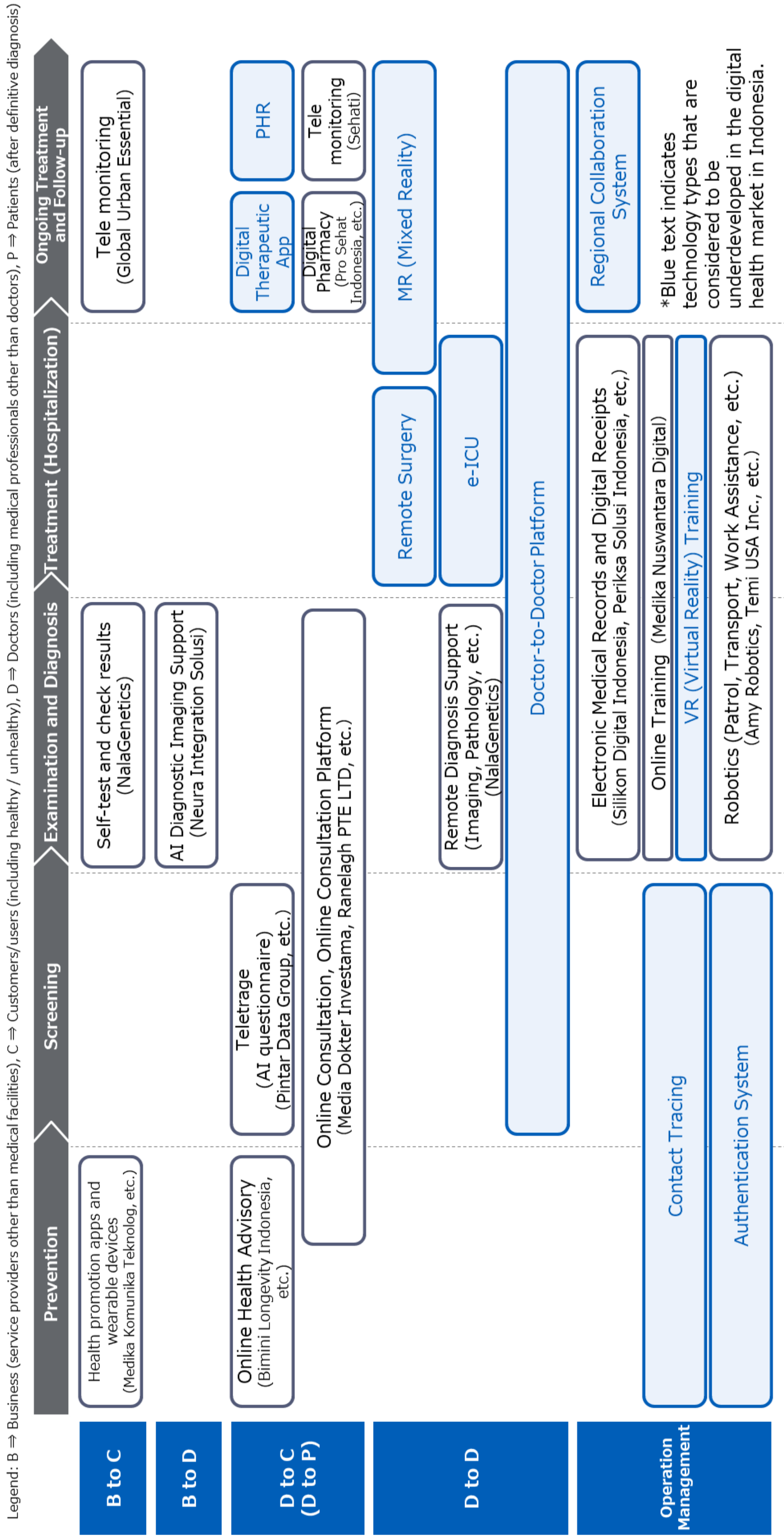


Figure V-21 Health Tech Map (Indonesia)

Source: Compiled by survey team

As for the technology types of digital health in Indonesia, the widespread use of the relatively emerging types were not confirmed, specifically, treatment applications, MR, VR, and e-ICU. Similarly, the widespread use of technologies that connect various points such as between professions and facilities to enable data linkage were also not confirmed. Since Indonesia is an island nation, it is expected that there is a certain demand for data linkage connecting different points. However, regarding solutions such as PHRs, which allow medical facilities and patients to share and refer to each other's data, EHRs, which allow medical facilities to connect and share patients' medical data, and doctor-to-doctor platforms, which allow doctors to communicate and collaborate with each other, there is still room for the spread of these solutions.

Now, let's compare the above health tech map with the solution to the problem shown in Figure V-16 Solutions that may contribute to solving problems (in-hospital and out-of-hospital) in Chapter A-7. There are few companies in Indonesia that provide related products and services for contact tracing and authentication systems, in addition to digital health that can be used for telemedicine, such as treatment applications, PHR, EHR, remote surgery, e-ICU, MR, and VR. In addition, the market is different from other target countries. As a different trend from other target countries, the desktop survey also showed that there are few local companies that provide related products and services for doctor-to-doctor platforms. In Indonesia, which is an island nation, there is a high potential demand for information collaboration and communication between facilities and professions, so the market for communication tools among healthcare professionals, such as doctor-to-doctor platforms, may grow in the future.

B－４．Relevant Laws and Regulations Surrounding Digital Health

（１） General laws and regulations related to information and communication

１） Telecommunications, radio waves, etc.

Regulations on telecommunications and radio waves describe the implementation of telecommunications services in general, and typical laws and regulations are as follows;

Table V-4 Laws and regulations related to telecommunications and radio waves in Indonesia

Laws and regulations	Overview
Law 36/1999 on Telecommunications (amended by Law 11/2020 on Job Creation)	This law governs the development and implementation of telecommunications. It aims to centralize the implementation of telecommunications, including applying for permits, setting tariffs, and providing government support to telecom operators to provide telecommunications infrastructure in a transparent, accountable, and efficient manner. In the operation of telecommunications, the central and local governments can provide shared facilities for passive telecommunications infrastructure to be used jointly by telecom operators at an affordable cost.
Government regulation 46/2021 on Post, Telecommunication, and Broadcasting	Government Regulation No. 52/2000 on telecommunications services is amended by this Regulation. It provides detailed regulations on the operation of telecommunication networks and services, operation of special telecommunication, and licensing.
Minister of Communication and Information (MCI) Reg. 13/2019 on Telecommunications Service Implementation	It defines the types of telecommunications services.
MCI Reg. 5/2013 on Group of Telecommunication Tools and Devices	All telecommunications equipment manufactured, assembled, traded, or used in Indonesia shall meet the technical requirements for telecommunications equipment.
MCI Reg. 7/2015 on the Operation of Telecommunications Network	It stipulates the procedures for the operation of telecommunications networks by telecommunications carriers.

Source: Compiled by survey team

２） Personal Information Protection

In Indonesia, there are still no regulations on personal information protection specific to the digital health sector, and those that are currently being applied are only general in nature. The regulations on personal data protection emphasize the need for consent and stipulate that any information must be used with the consent of the person concerned. In addition to consent, the processing of personal information must meet the following requisites;

- Fulfillment of contractual obligations where the owner of personal information is a party, or fulfillment of requirements of the owner of personal information at the time the contract is concluded.

- Fulfillment of the legal obligations of the personal data controller in accordance with the provisions of the law
- Implementation of the protection of the legal interests of the owners of personal data
- Fulfillment of the authority to manage personal data in accordance with the provisions of laws and regulations
- Fulfillment of obligations to manage personal data in public services in the public interest
- Fulfillment of other legitimate interests of the controller and/or owner of the personal data

The main provisions regarding the protection of personal information are as follows;

Table V-5 Laws and regulations related to the protection of personal information in Indonesia

Laws and regulations	Overview
Law 11/2008 on Electronic Information and Transaction (amended by Law 19/2016)	Any use of personal information through media or electronic systems must be done with the consent of the relevant parties involved. Therefore, it is necessary to guarantee the fulfillment of personal protection by requiring each electronic system operator to delete irrelevant electronic information and/or electronic documents under its control upon the request of the concerned party based on a court order.
Government Regulation 71/2019 on Implementation of Electronic System and Transactions	The processing of personal data must be in accordance with the provisions of a valid consent from the owner of the personal data for the specific purpose presented to him/her.
MCI Reg. 20/2016 on Protection of Personal Data in Electronic Systems	It is stipulated that the protection of personal information in electronic systems includes protection against the acquisition, collection, processing, analysis, storage, display, presentation, transmission, dissemination, and destruction of personal information. Its implementation must be based on the principles of personal information protection. If there are any deficiencies in the protection of personal information, the system operator must notify the owner of the personal information in writing.

Source: Compiled by survey team

３） Data use

Data use requirements for the management, processing, and storage of electronic data depend on the type of electronic system operator, which can be categorized into public and private operators. Private operators are regulated and supervised by the relevant ministries. Private operators can manage electronic data outside of Indonesia, but must provide access to the electronic data to ministries and agencies for supervision and law enforcement purposes. Public operators can manage, process, and store electronic systems and data in Indonesia. Implementation outside Indonesia is allowed only if the preservation technology is not available domestically.

The regulations on data use currently in effect are as follows;

Table V-6 Laws and regulations related to data use in Indonesia

Laws and regulations	Overview
GR 71/2019 on Implementation of Electronic System and Transaction	It covers provisions for data use and defines public and private electronic system operators. Electronic information is prepared, collected, processed, analyzed, stored, displayed, presented, transmitted, and distributed through a series of electronic devices and procedures called electronic systems. Private electronic system operators can manage, process, and store electronic systems and electronic data within and outside Indonesia. Private electronic system operators are required to provide access to electronic systems and data for supervision and law enforcement purposes. The system operator shall have the following obligations in the implementation of the electronic system; ・ Electronic information and/or electronic documents are displayed according to the retention period specified by law. ・ Protect the availability, integrity, authenticity, confidentiality, and accessibility of electronic information in the operation of electronic systems. ・ Follow procedures and instructions in the operation of the electronic system.
Presidential Regulation 39/2019	・ One Data Indonesia is the government's data governance policy and consists of planning, collection, checking and dissemination of data. This regulation states that state agencies and public corporations, including BPJS, may participate in the operation of One Data Indonesia.

Laws and regulations	Overview
	・ Parties must comply with data standards, metadata, and data interoperability, and must use reference codes and master data as specified in the regulations and their implementation guidelines.

Source: Compiled by survey team

（２） Laws and regulations related to digital health

１） Ethical Guidelines

Telemedicine is defined as "the provision of medical services by health care professionals from remote locations using information and communication technology, including the exchange of information on diagnosis, treatment, prevention of disease and injury, research and evaluation, and advanced education of health care professionals for the purpose of improving the health of individuals and communities. It stipulates that both the provider and the requesting party of telemedicine are required to have licensed medical practitioners conducting the practice, and that they must meet the requirements for other people's resources, facilities, infrastructure, equipment, and applications.

Telemedicine applications must be registered with the Ministry of Health through the Directorate General of Health Services and must use a data security system provided by the Ministry of Health in accordance with the law. Digital platforms that connect doctors and patients for online consultation must also be registered as electronic system operators with the Ministry of Communications. It should be noted that the regulations on digital health under the Ministry of Health Regulation No. 46/2017 on the National e-Health Strategy do not provide details on the reliability of the business model, service standards, workflow, patient safety, data protection, quality assurance, guidance and supervision of healthcare applications.

In addition, according to the Indonesian Medical Council Regulation on Telemedicine Authority and Medical Practice during the Spread of COVID-19 Infection in Indonesia, doctors and dentists who practice telemedicine must obtain a registration certificate (Surat Tanda Registrasi: STR) and a medical license (Surat Izin Praktik: SIP) in accordance with the provisions of the law. The general requirements and procedures for obtaining STR are described in PERKONSIL No. 6/2011 on Registration of Doctors and Dentists.

- All doctors and dentists practicing medicine in Indonesia are required to obtain a certificate of registration.
- Indonesian citizens who have graduated from an international medical or dental institution and wish to practice medicine in Indonesia must apply to the Indonesian Medical Council (Konsil Kedokteran Indonesia: KKI) for evaluation and submit a copy of their diploma and

academic records for evaluation. The evaluation process includes management evaluation and competency evaluation.

- STRs are valid for a period of five years nationwide and must be re-registered every five years, meeting the necessary requirements as stipulated by the law.
- The requirements for obtaining an STR are as follows;
  (a) A doctor/dentist who is an Indonesian citizen must have graduated from a domestic medical/dental educational institution that applies competency-based curriculum, and must apply to KKI under the conditions stated in this regulation.
  (b) Indonesian citizen doctors/dentists who have graduated from a foreign medical/dental educational institution must submit an application to KKI with a certificate of completion of the adaptation program and other required documents listed in this regulation.

The requirements and procedures for obtaining a medical license for doctors and dentists are described in the Ministry of Health Regulation No. 2052/2011 on Medical License and Practice of Medicine, which are as follows;

- In order for doctors and dentists to obtain a SIP, they must apply to the head of the public health center of the prefecture or city where the medical treatment is being performed, with the necessary documents attached.
- Doctors and dentists who meet the requirements will be given a SIP for one clinic.
- Doctors and dentists who already have STRs in local government medical facilities based on the relevant application form and meet the criteria for obtaining SIPs will automatically be given SIPs by the Director of Health. The referred SIP will be counted as one clinic.

SIPs for doctors and dentists are valid for five years.

Table V-7 Laws and regulations related to ethical guidelines in Indonesia

Laws and regulations	Overview
Ministry of Health Regulation No. 20/2019 on The Implementation of Telemedicine Services between Health Service Facilities	Telemedicine services refer to tele-radiology, tele-electrocardiography, tele-ultrasound, clinical tele-consultation, and other telemedicine services that have been developed with the development of science and technology. Clinical teleconsultation as described in these regulations refers to remote clinical consultation services that provide diagnosis and health care advice through written, audio, and visual means. The implementation of tele-consultation must be registered

Laws and regulations	Overview
	and recorded in the medical record in accordance with the provisions of the law. Telemedicine services must be performed by health care professionals licensed to practice in the health care facility where they are performed, and must meet requirements for human resources, facilities, infrastructure, equipment, and applications. The medical facilities referred to in this regulation include the medical facilities that provide consultations and the medical facilities that receive consultations. A medical facility that receives consultations is a medical facility that provides telemedicine services upon request, and it can be a hospital owned by the central government, local government, or a private company, as long as it meets the requirements.
Law No. 29/2004 concerning Medical Practice.	When doctors and dentists perform medical procedures, they must comply with the code of ethics established by their professional organizations, in addition to the provisions of the law.
Indonesian Doctors Council Regulation (PERKONSIL) No. 74/2020 concerning Clinical and Medical Practice through Telemedicine Authority and Medical Practice during the COVID 19	Medical treatment by telemedicine using applications and electronic systems can be performed by applying the principle of patient confidentiality. Telemedicine takes the form of written, audio, and live video online to obtain the information needed to establish a diagnosis and to manage and treat the patient, in accordance with the provisions of the law. Patients who wish to be treated by telemedicine need to give informed consent in accordance with the provisions of the law.
Letter of the Ministry of Health HK.02.01/MENKES/303/2020 on the Implementation of Health Services through the Utilization of Information and Communication Technology	In order to prevent the spread of COVID-19, doctors, dentists, specialist dentists, and paraprofessionals can provide ICT-based telemedicine services. Telemedicine service refers to a medical service in which a doctor uses ICT to diagnose, treat, prevent, and evaluate a patient's health condition based on competence and

Laws and regulations	Overview
	authority as evidenced by a certificate of registration (STR), while taking into account the quality of service and patient safety. Telemedicine can be provided by a doctor to a patient or by a doctor to another doctor. Doctors who provide telemedicine are accountable for the medical services they provide, including patient data security. The provision of telemedicine services between a doctor and another doctor will be carried out in accordance with legal provisions.

Source: Compiled by survey team

２） Medical Device Registration

According to the Ministry of Health Regulation 1189/Menkes/Per/VIII/2010 on the manufacture of medical devices, only companies that have obtained manufacturing certification are allowed to manufacture medical devices. The medical devices manufactured must comply with ISO 13485 "International Standard for Quality Management Systems Specific to the Medical Device Industry". Medical devices are classified into the following 4 classes based on the risks they pose during use.

V-2 Classifications of medical devices

Class	Risk Level	Example
A	Low	Surgical instruments, surgical gloves, oxygen masks, etc.
B	Middle Low	Sphygmomanometer, steam sterilizer, etc.
C	Middle High	Biometric monitor, X-ray equipment, etc.
D	High	Endovascular stents, pacemakers, etc.

Source: Prepared by the survey team based on ISO13485

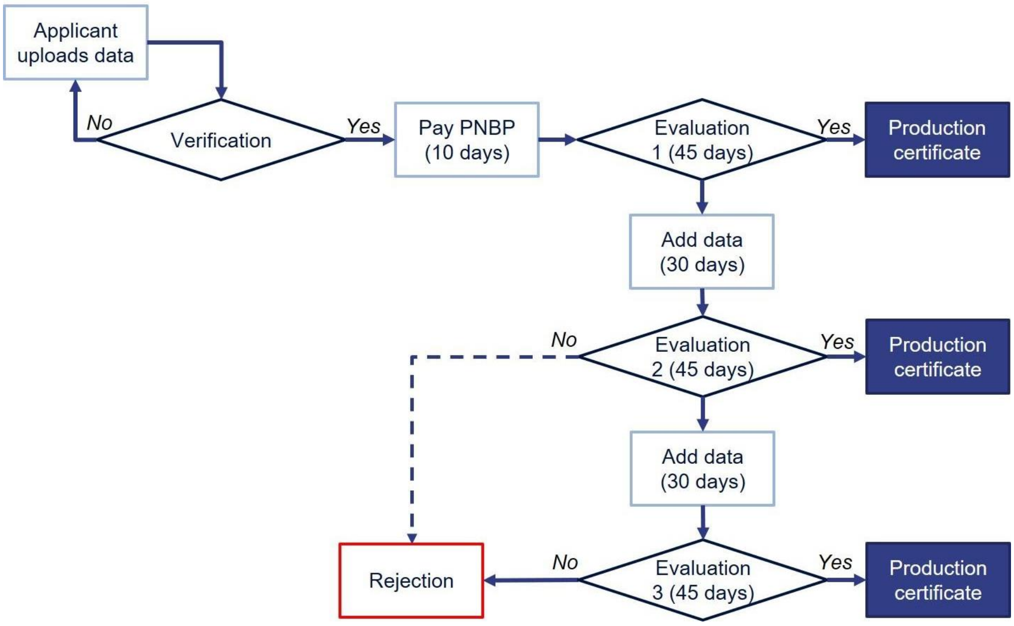
Medical device manufacturing permits are classified into the following 3 classes based on the risk of the medical device being handled.

V-3 Classifications of manufacturing permits

Class	Definition.
A	Permission to manufacture Class A, B, C and D medical devices for ISO 13485-compliant manufacturing plants
B	Permission to manufacture Class A, B and C medical devices for ISO 13485-compliant manufacturing plants
C	Authorization of ISO 13485-compliant manufacturing plants to manufacture Class A and B medical devices

Source: Prepared by the survey team based on ISO13485

The process of medical device registration is divided into the following 3 stages (1) facility inspection by the local health department, (2) verification to determine the category of medical device manufacturing, and (3) feasibility evaluation and verification of good production methods. In addition, the registration process requires 27 documents of recommendation from the local health department, proof of company registration, organizational structure, and other forms.[190]



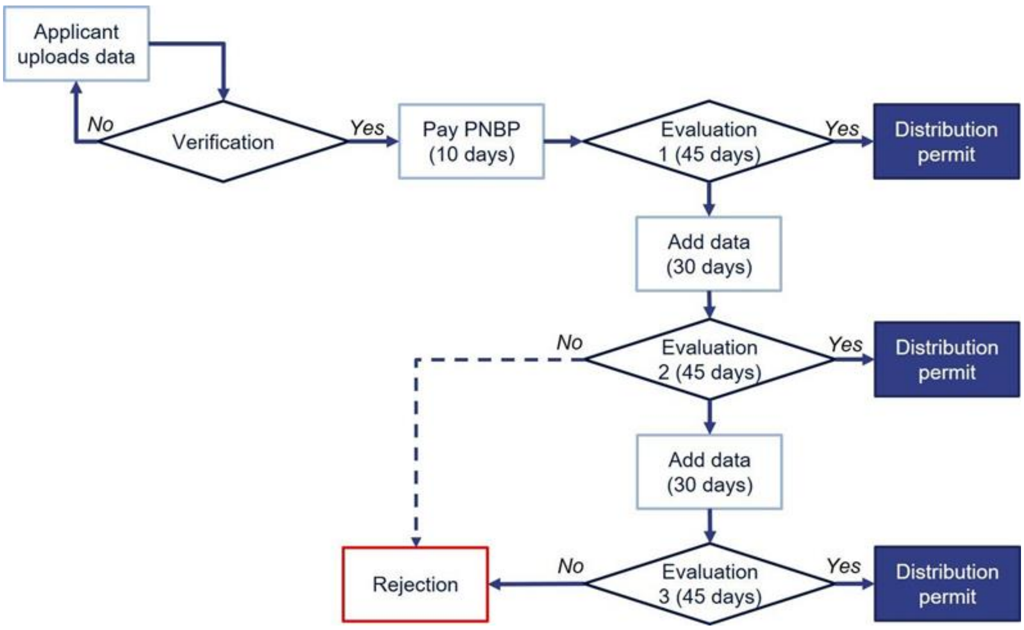
V-1 Flowchart of medical device registration

Source: Prepared by the survey based on Ministry of Health Regulation 1190/Menkes/Per/VIII/2010

190 http://regalkes.kemkes.go.id/informasi_alkes/Regulasi%20Lisensi%20Produk.pdf

３） Licenses for import, export, distribution, and sales

Permission to sell medical devices, whether domestically produced or imported, is granted by the Minister of Health (Director General of the Pharmaceuticals and Medical Devices Agency) after reviewing that the product meets the requirements for safety, quality, and efficacy. In order to sell medical devices in Indonesia, it is necessary to obtain a distribution permit and the medical device certification described in 2) above. Under urgent circumstances such as the COVID-19 disaster, import permit is not required to import medical devices to comply with COVID-19. The application process for a sales permit can be done online and is similar to the registration process for medical device manufacturers. The requirements for a medical device marketing license consist of administrative and technical requirements, and require the submission of Form A (operational management), Form B (product information), Form C (product specifications and warranty information), Form D (product usage), and Form E (post-sale surveillance).



V-2 Flowchart of Sales Permit Registration

Source: Prepared by the survey team based on Ministry of Health Regulation 1190/Menkes/Per/VIII/2010

The fact that many regulations and documents have been established regarding the distribution of medical devices in Indonesia shows the importance the Indonesian government attaches to the safety of citizens. At the same time, the government is taking flexible measures, such as relaxing the licenses required for the importation of medical devices that are needed in emergency situations. The regulations currently in effect for import, export, distribution, and sales are as follows.

Table V-8 Laws and regulations related to import, export, distribution, and sales in Indonesia

Laws and regulations	Overview
Law No. 36/2006 on Health	Access to medicines and distribution of medical device is only possible with a distribution permit from the Ministry of Health.
Minister of Health Regulation No. 62/2017 on Distribution Permits of Medical device, In vitro Diagnostic Medical device, and Household Health Supplies (PKRT)	The distribution license under this regulation permits medical devices manufactured by manufacturers and imported by medical device distributors and importers to be distributed within Indonesia based on an evaluation of safety, quality, and benefits. In addition to the distribution license, medical devices to be imported and exported require a certificate for medical devices, in vitro diagnostic medical devices, and household health products.
Decree of the Minister of Health No. HK.01.07/MENKES/218/2020 on Medical device, In vitro Diagnostic Medical device and Household Health Supplies Supplies (PKRT) Excluded from Import Trading Administration Licensing in the Context of Handling Corona Virus Disease 2019 (Covid19).	Under emergency conditions, such as the spread of COVID-19, import trade control permits for COVID-19-compatible medical devices are not required. In the event of an emergency situation, such as the spread of COVID-19, a COVID-19 import trade control permit is not required. An example of an exempted medical device is diagnostic testing equipment needed to test for the COVID-19 virus. Access to medicines and distribution of medical devices will only be allowed after obtaining a distribution permit from the Ministry of Health.
Presidential Decree No. 9/2020 on the Task Force for the Acceleration of Handling COVID19.	For the trading system for importing equipment, it is sufficient to use the exemption recommendations of the National Disaster Management Agency (Badan Nasional Penanggulangan Bencana: BNPB).
Ministry of Industry Regulation No.16/2020 on Provisions and Procedures for Calculating the Value of The Domestic Component (Local Content) Level of Pharmaceutical Products.	In terms of encouraging the domestic industry in medical devices, the Ministry of Industry supports the manufacture of domestic components by evaluating domestic components in various fields. For example, in terms of pharmaceuticals, the ministry evaluates products that use the process-based method rather than the cost-based method.

Laws and regulations	Overview
	It also regulates the level of domestic components of medical devices (Tingkat Komponen Dalam Negeri:TKDN) and the development of raw materials for medical devices. The government also regulates the development of raw materials for medical devices. Currently, the target index of TKDN for medical devices is 40%. In the same regulation, the TKDN of medical devices has been improved by 15% due to the change in the calculation method. This method is expected to promote the development of raw materials for the pharmaceutical industry, strengthen research and development of new drugs, and improve national independence in the health sector.

Source: Compiled by survey team

４） Intellectual Property

In Indonesia, intellectual property rights can be divided into two categories; copyrights and industrial property rights.

Regulations on intellectual property rights, such as patents, generally protect the intellectual property rights of foreign digital health companies in Indonesia. However, Government Regulation No. 82/2012 implies that foreign digital health companies wishing to import, sell, distribute, or use software in Indonesia must provide the source code of the software to the Indonesian government.

(a) Copyright

Table V-9 Laws and regulations related to copyright in Indonesia

<table>
<tr><th>Laws and regulations</th><th>Overview</th></tr>
<tr><td>Law No. 28/2014 on Copyright</td><td rowspan="3">Copyright has the broadest scope of protection among intellectual property rights, and protected creations include books, computer programs, lectures, songs, art, photographs, etc.
The term of copyright protection for computer programs is 50 years from the date of publication.</td></tr>
<tr><td>GR No. 36/2018 on the Recording of Intellectual Property License Agreements</td></tr>
<tr><td>GR No. 16/2020 on the Registration of Works and Related Rights Products.</td></tr>
</table>

Source: Compiled by survey team

(b) (1) Industrial property rights

(i) Patent

Table V-10 Laws and regulations related to patents in Indonesia

Laws and regulations	Overview
Law No. 13/2016 on Patent (amended by Law No. 11/2020)	A patent is an exclusive right granted to an individual or group of individuals for their inventions in a technical field. Inventions covered by a patent are those that are novel, progressive, and inventive from the existing technology, and can be applied to industry. The importation or licensing of a patented product or a product manufactured by that method is considered "working of the patent."
GR No. 36/2018 on the Recording of Intellectual Property License Agreements	
GR No. 9/2020 on the Organizational Structure, Duties, and Functions of the Patent Appeal Commission	
GR No. 18/2020 on the Form and Content of the Patent Letter;	
GR No. 34/2020 on Procedures for the Implementation of Patents by the Government;	
GR No. 46/2020 on the Terms and Procedures for Recording the Transfer of Patents;	
Presidential Regulation No. 77/2020 on Procedures for the Implementation of Patents by the Government.	

Source: Compiled by survey team

(ii) Trademark

Table V-11 Laws and regulations related to trademarks in Indonesia

Laws and regulations	Overview
Law No. 20/2016 on Trademarks and Geographical Indications	A trademark is a sign that distinguishes a product or service and can take the form of letters, logos, sounds, 3D, holograms, etc. Trademarks registered with the Directorate General of Intellectual Property (DGIP) are protected for 10 years from the date of receipt of the application for trademark registration, with the possibility of extension. It is not necessary to wait for the registration of an authorized trademark in order to apply to the Ministry of Health for permission to distribute medical device products. A trademark pending registration may be used in an
Law No. 7/1994 on Ratification of Agreement Establishing the World Trade Organization;	
GR No. 22/2018 on the International Registration of Trademarks Under the Protocol relating to the Madrid Agreement on the International Registration of The following table shows the current status of the Madrid Agreement;	
GR No. 36/2018 on the Recording of Intellectual Property License Agreements;	

Laws and regulations	Overview
GR No. 90/2019 on Procedures for Application, Examination, and Settlement of Appeals at the Trademark Appeal Commission	application for a distribution license for medical devices.

Source: Compiled by survey team

(iii) Industrial Design

Table V-12 Laws and regulations related to industrial design in Indonesia

Laws and regulations	Overview
Law No. 31/2000 on Industrial Design	Industry design is the creation of a shape, configuration, or combination of lines and colors that gives an aesthetic impression to a product, industrial product, or craft, and may take a two-dimensional or three-dimensional form. A design registered with the Directorate General of Intellectual Property is protected for ten years from the date of receipt of the application for registration and cannot be extended.
GR No. 1/2005 on Implementation of Law No. 31/2000 concerning Industrial Design;	
GR No. 2/2005 on Consultation on Intellectual Property Rights;	
GR No. 36/2018 on the Recording of Intellectual Property License Agreements.	

Source: Compiled by survey team

(iv) Trade secret

Table V-13 Laws and regulations related to trade secrets in Indonesia

Laws and regulations	Overview
Law No. 30/2000 on Trade Secrets	A trade secret is a right to information related to a technology or business that has economic value but does not need to be known to the public. The definition, application, and protection of trade secrets are specified.
GR No. 2/2005 on Consultation on Intellectual Property Rights;	
GR No. 36/2018 on the Recording of Intellectual Property License Agreements	

Source: Compiled by survey team

(v) Circuit Layout

Table V-14 Laws and regulations related to circuit layout in Indonesia

Laws and regulations	Overview
Law No. 32/2000 concerning Circuit Layout	A circuit layout refers to a finished or semi-finished product in which a number of formation elements are integrated to realize electronic functions.
GR No. 2/2005 on Consultation on Intellectual Property Rights;	
No.9/2006 concerning Procedures for Application for Registration of Integrated Circuit Layout Designs	
GR No. 36/2018 on the Recording of Intellectual Property License Agreements	

Source: Compiled by survey team

５） Information Security

Information managers shall maintain, store, and provide regular backups of medical information, and shall establish systems to prevent the failure of medical information. In accordance with PP 46/2014 on medical information systems, security of medical information should be implemented to ensure that the information remains available and uncorrupted, and confidentiality should be maintained for closed medical information.

However, detailed provisions on information security have not been identified. In addition, in accordance with the Ministry of Health regulations on the National e-Health Strategy, the results of the 2013 e-Health assessment made no reference to national e-Health standards, which still need a lot of strengthening. Standards can be viewed from different perspectives, such as functional standards for electronic information systems, data standards, medical terminology standards, security and privacy standards, and even electronic data communication standards (data exchange protocols). e-Health standardization efforts have been conducted in several approaches. For example, standards and terminology for medical data. For example, the use of medical data standards and terminology is included in the National Health Data Dictionary, launched through the Ministry of Health in 2013. Electronic data exchange standards have been done by adopting already existing international standards within the framework of the Indonesian National Standards (Standar Nasional Indonesia (SNI)) led by the Ministry of Communications and Information.

In the various types of e-Health applications that already exist, there is a need for national e-Health standards management as well as related to data standards and medical terminology. There is a need to develop standards for privacy, security and interoperability of information systems, as well as standards for establishing output standards (indicator standards) for medical information from existing information systems, and mechanisms for disseminating medical information through electronic media and websites. It is also necessary to develop non-technical standards such as functional standards for electronic medical records, certification standards for information systems, and functional standards for medical information systems, all of which need to be developed together.

Existing regulations on information security that are currently in effect are as follows;

Table V-15 Laws and regulations related to information security in Indonesia

Laws and regulations	Overview
GR 71/2019 on Implementation of Electronic System and Transaction	The health sector is a sector with strategic electronic data that must be protected, and the central government has designated an agency to oversee this data security. Medical information managers are required to create electronic documents and their backups and connect them to a specific data center for data security purposes.
GR 46/2014 on Health Information System	Security of medical information must be implemented in accordance with security standards. Maintaining the security and confidentiality of medical information is done by the Minister by prescribing standards and restrictions on the access rights of medical information users in compliance with the National Cyber Security. Each medical information manager shall maintain the security and confidentiality of medical information in the following ways; ・ Maintaining and storing medical information, and performing regular backups ・ Build a system to prevent medical information failure.
Ministry of Health Reg. 46/2017 on National e-Health Strategy	The results of the 2013 e-Health assessment revealed a lack of reference to national e-Health standards, indicating that they need to be strengthened.

Source: Compiled by survey team

６） Data use

Regulations on data use indicate that the use of medical information must comply with regulations regarding confidentiality of information and intellectual property rights. However, no regulations have been identified that specifically regulate the use of data in the digital health sector.

Table V-16 Laws and regulations related to data use in Indonesia

Laws and regulations	Overview
PP 46/2014 on Health Information System	The use of medical information shall be carried out for the direct or indirect benefit of supporting the management, implementation, and development of developments in the health care sector. The use of medical information shall be in accordance with the provisions of the law and shall comply with the provisions on confidentiality of information and intellectual property rights. Parties who create derivative products from medical information with the intention of being traded must obtain permission from the owner of the information in accordance with the provisions of the law, except for data that is already considered public information. However, no specific regulations on the use of data in the digital health sector have been identified.

Source: Compiled by survey team

B－５． Future Prospects in the Digital health Market

With the spread of COVID-19 infection and other factors, interest in the following areas is increasing.

（１） Remote medicine

The Ministry of Health is building Indonesia's own national telemedicine platform to promote telemedicine in the country. The Ministry of Health, in collaboration with Sarjeet Hospital and Gadjah Mada University, developed the Telemedicine Indonesia (TEMENIN) application in 2017 and has been conducting demonstrations in remote areas of the country. TENEMIN is a D to D platform for use between public medical facilitys and has functions such as tele-radiology, tele-electrocardiography, tele-ultrasound, and tele-consultation. Doctors at puskesmas and primarycare facility can consult specialists at higher level medical facilities, and the specialists support the diagnosis. At present, TEMENIN is collaborating with 174 lower-order medical facilities and 63 higher-order medical facilities[191]. However, TEMENIN is not well known and is still in its infancy.

In addition to TEMENIN, P-Care, a telemedicine platform developed by BPJS Kesehatan, is being used intensively by primary medical facilities such as Puskesmas. By using this application, primary medical facilities can directly access BPJS Kesehatan's server, register patient information, and share data with referral medical facilitys. It will also be possible to preview visitor information and the number of registered patients. The benefits of using the application for medical facilities include reduced work hours due to easier understanding of patient information, improved accuracy and speed of diagnosis due to patient records, and faster patient referrals due to online referrals[192].

Telemedicine, which is currently commonly practiced in Indonesia, can be broadly classified into two types. One is that the patient's symptoms and complaints are sent to the doctor via e-mail and the doctor makes a diagnosis. Another is that the patient and doctor directly interact via video call for treatment. Telemedicine includes not only online consultation services and online medical treatment, but also remote diagnosis, in which patient data such as radiology and electrocardiography are sent to a remote hospital for diagnosis, and data linkage of patient information between medical facilities.

（２） Digital health Platform

It is a digital platform that takes advantage of the increasing penetration of smartphones and the Internet, which in turn improves user convenience in accessing medical services such as digital pharmacies and online medical care. Indonesia's leading healthcare platform, Halodoc, in collaboration with BPJS Kesehatan, has teamed up with more than 1,400 hospitals and healthcare companies to build a nationwide alliance with the aim of improving the patient's hospital visit experience. The partnership is expected to shorten the waiting time at pharmacies after appointments and provide cashless consultation by linking to insurance benefits.

These digital platforms are being developed not only by start-ups but also by large private hospital groups, which are launching their own telemedicine services in the wake of COVID-19. For example, Siloam Hospital has partnered with Aido Health to launch a telemedicine service in April 2020[193]. Pondok Indah Hospital Group and Mitra Keluarga Hospital Group have also followed this trend and started remote consultation services[194].

191 TEMENIN. https://temenin.kemkes.go.id/list_rs/
192 BPJS Kesehatan. https://pcarejkn.bpjs-kesehatan.go.id/
193 Siloam Hospital. 2021. Available at: https://www.siloamhospitals.com/informasi-siloam/liputan-media/siloam-hospital-luncurkan-layanan-rawat-jalan-online
194 Pondok Indah Hospital. 2021. https://www.rspondokindah.co.id/rspi/public/en/pages/telemedicine-rs-pondok-indah-group; Mitra Keluarga Hospital. 2021.

（３） Electronic medical record (EMR)

There is a growing demand for electronic medical record systems that encompass patient records, appointment management, accounting systems, staff management, consumable inventory management, and financial reporting.

（４） Sharing of medical information (EHR)

The government aims to provide universal health coverage throughout Indonesia, with a focus on data exchange among health care providers. The platform can take many forms, including websites, online discussion forums, and social media.

（５） Mobile Health

Smartphone and tablet applications are changing the way patients interact with health care providers and the way health care providers provide consultations, monitor health status and medication intake, and streamline administrative functions such as appointments, prescriptions, and billing.

（６） Wearable device

Wearable devices that measure vital signs are widely used in conjunction with smartphones and video technology for diagnosis and treatment management. An example of a portable electrocardiograph for pregnant women, called TeleCTG, allows midwives to perform fetal heart rate tests remotely. In this way, wearable devices are bringing about significant improvements in the delivery of medical services in remote areas. Currently, the majority of purchasers of TeleCTG are local governments.

（７） AI

AI is being used to reduce work load in routine back-office tasks in the medical industry, such as transcribing doctors' notes using voice recognition technology. Data science is also being used for clinical data, contributing to the realization of personalized medicine for patients.

（８） Cloud computing

Cloud computing is in the early stages of revolutionizing electronic medical records. This technology will improve efficiency by removing silos and eliminating duplication in record management systems. It can also provide vast amounts of aggregate data for research purposes[195].

https://www.mitrakeluarga.com/promo/detail/lebih-mudah-konsultasi-dokter-telekonsultasi

[195] MTP Connect & Asia Business Link, "Digital Health in Indonesia," 2020,

B－６. Future Challenges in the Digital Health Market

Growth in the digital health market is still in its early stages due to issues such as clarification of regulations regarding data security, implementation of telemedicine, etc., and development of digital health infrastructure. Improvements in the implementation of telemedicine, data linkage, and operations are expected to lead to the correction of regional disparities.

（１） Low Adoption Rate of Electronic Medical Records

To meet the increasing demand for medical services in the wake of the COVID-19 disaster and after the end of COVID-19, there is a growing need for a comprehensive electronic medical record that integrates operational processes within hospitals. However, according to a report by the Ministry of Health, only 52% of health institutions have functional electronic medical records. The main reasons for this are the lack of qualified human resources and the limitation of hospitals to invest in software[196].

（２） Data Security and Privacy Protection

With the rapid development and emergence of new medical technologies, risks such as patient data security and privacy protection, data loss, erroneous data entry, connectivity issues, and violation of medical ethics have been identified. It is also not clear how insurance reimbursement will be integrated into the platform[197].

（３） Legislation on Telemedicine

Regulations on e-Health based on the Ministry of Health Regulation No. 46/2017 on the National e-Health Strategy do not provide details on the reliability of the business model of e-Health applications, service standards, workflow, patient safety, data protection, quality assurance, guidance and supervision. Looking at the current regulations on telemedicine institutions and medical practices through telemedicine, the Indonesian government is aware of the development of information technology in terms of digital health. It is expected that by improving and strengthening regulations and policies related to e-Health business, Indonesia will be able to develop telemedicine and ensure the safety and security of patients while attracting quality investors from home and abroad.

https://www.mtpconnect.org.au/images/Digital%20Health%20in%20Indonesia.pdf
[196] Manajemen Informasi Kesehatan, Universitas Gadjah Mada. SIMRS dan Strategi Pengadaannya. 2019. Available at: https://mik.sv.ugm.ac.id/2019/07/17/simrs-dan-strategi-pengadaannya/
[197] Jakarta Post. 2020. https://www.thejakartapost.com/academia/2020/08/28/digitizing-health-care-is-the-new-normal.html

（４） Cooperation between Public Insurance Systems and Digital Health

Currently, telemedicine services are not covered by public insurance, and patients who want to use their insurance to receive medical care must go to a primary health care provider. Therefore, private companies are trying to overcome this problem by developing their own products, and telemedicine application developers and insurance companies are increasingly offering their own insurance products. It is suggested that telemedicine reimbursement system and insurance reimbursement need to be established as a system in the future.

（５） Reducing Regional Disparities in the Digitalization of Healthcare

Although government initiatives to digitize healthcare have been revitalized, most of the efforts are concentrated in the capital and other urban areas. The government has collaborated with 11 private companies to release telemedicine applications in response to COVID-19, but their adaptation is limited only to the DKI Jakarta region.

Although the central government supports local governments through institutional support, supervision, and funding for general health service activities, the situation is that the funds provided are mostly allocated to offline activities rather than subsidizing and promoting digital health development. In addition, local governments have not specifically provided for regional programs and budgets for digital health deployment in their strategic planning documents.

C. Perspective of JICA

C－１. Status of JICA Support

In Indonesia, many projects related to communicable diseases and maternal and child health have been implemented. In addition, there is a relatively wide support for improving the quality of healthcare and human resource development related to information and ICT. The following is a list of projects completed since 2015.

Table V-17 JICA projects in the field of health care in Indonesia

Technical Cooperation	・ Project to Strengthen Intensive Care Capacity Using Remote Technology in the Epidemic of Novel Coronavirus Infections (October 2021 - September 2022) ・ Project on Improving the Quality of Maternal and Child Health Programs Using the Maternal and Child Health Handbook under Decentralization (October 2018 - October 2023) ・ Strengthening Pharmaceutical and Food Safety Project (July 2016 - July 2021) ・ Ecological survey of flying foxes and their involvement in rabies-related and other viral infections (August 2015 - July 2020) ・ Project for the discovery of novel anti-malarial and anti-amoebic drug lead compounds using Indonesia's biological resource diversity (April 2015 - March 2020) ・ Nursing Practice Capacity Enhancement Project (October 2012 - October

	2017)
Official Development Assistance Loans	・ Proactive Response to Novel Coronavirus Infections and Expenditure Support Program Loan (2020/08)
Official Development Assistance Grants	—
Public-Private Partnerships	・ Dissemination and Demonstration Project on the Introduction of Electronic Medical Records in Antenatal Care and the Strengthening of the Community Healthcare Collaboration System (Mitra Corporation, June 2018 - June 2021) ・ Research on the business of producing and selling anti-mosquito clothing to combat dengue fever (SDGs business) (Teijin Frontier Limited and Earth Chemical Co., Ltd. joint venture, April 2019 - July 2021) ・ A Case Study of Ultrasound Microscopy for Improving the Quality of Cancer Testing and Expanding Opportunities for Medical Examinations (Honda Electronics Co., Ltd., July 2018-August 2019) ・ Basic research on promoting the introduction of mobile ultrasound systems to improve initial medical care in rural areas (Japan Sigmax Corporation, under contract negotiation) ・ Preparatory survey for a sanitation project aimed at reducing oral infections through the habitual use of disinfectant gel (BOP business collaboration promotion) (Mandom Corporation and Hakuhodo Inc. joint venture, August 2012 - July 2015) ・ Preparatory survey for a project to improve health and hygiene using circulatory waterless toilets (promotion of BOP business collaboration) (Joint venture between LIXIL Corporation and i-Incubate Corporation, November 2013 - September 2015) ・ Pharmaceutical Halal Response Project Preparatory Survey (BOP Business Collaboration Promotion) (Eisai Co., Ltd., April 2017-March 2019) ・ Project for Promotion of Endoscopic Diagnostic Technology for Lung, Trachea and Bronchus Cancer (FUJIFILM Corporation, January 2015 - July 2016) ・ Urological Laparoscopic Surgery Promotion Project (Olympus Corporation, November 2015 - February 2019) ・ Project to promote the use of a medication compliance support system for tuberculosis patients (Otsuka Pharmaceutical Co., Ltd., November 2015 - May 2018) ・ Project to Promote Tuberculosis Diagnosis Kits (Nipro Corporation, December 2017 - February 2022) ・ Information collection and confirmation survey on the possibility of utilizing private sector technologies in developing countries under COVID-19 in the field of health and medical care (strengthening measures against infectious diseases and improving nutrition) (October 2020 - March 2021) ・ Information collection and confirmation survey on matching of demand from developing countries and private sector technologies related to global healthcare and welfare (aging and nursing care) (June 2021 - March 2022)

Source: Compiled by survey team

Table V-18 JICA projects related to ICT in Indonesia

Technical Cooperation	・ Information Security Capacity Building Project (July 2014 - January 2017) ・ Cyber Security Human Resource Development Project (May 2019 - May 2024) ・ Survey on the use of sensor networks for immediate earthquake warning for local disaster prevention (September 2015 - October 2016) ・
Official Development Assistance Loans	—
Official Development Assistance Grants	・ Disaster Management Information System Enhancement Plan (June 2019)
Public-Private Partnerships	—

Source: Compiled by survey team

Table V-19 JICA projects related to COVID-19 in Indonesia

Technical Cooperation	・ Project to strengthen capacity for early warning and response to infectious diseases (June 2021-)
Official Development Assistance Loans	・ Proactive Response to Novel Coronavirus Infections and Expenditure Support Program Loan (2020/08) *Represented
Official Development Assistance Grants	—
Public-Private Partnerships	・ Information collection and confirmation survey on the possibility of utilizing private sector technologies in developing countries under COVID-19 in the field of health and medical care (strengthening measures against infectious diseases and improving nutrition) (October 2020 - March 2021) *Represented

Source: Compiled by survey team

C－２． Initiatives by International Organizations and Governments to Promote Digital Health

Start-ups, VCs, and private players are growing in the digital health sector in Indonesia, while on the public side, initiatives are being taken by both international organizations and the government to promote digital health development.

（１） Initiatives of International Organizations

１） Policy Advocacy and Knowledge Sharing

There are a number of policy advocacy and knowledge-sharing initiatives aimed at building digital infrastructure, environment, and governance for digital health. These include the Asian Development Bank (ADB), the UK government, the United Nations

Development Programme (UNDP), the Australian government (DFAT), and the Asian e-Health Information Network (AeHIN).

Table V-20 List of Initiatives by International Organizations (Policy Advocacy and Knowledge Sharing)

Institutions, programs, etc.	Overview
Asian Development Bank (ADB)	In order to enable the health sector in developing countries to leverage existing IT governance to promote digital health, the Digital Health Information Governance Architecture Framework (HIGAF) is being promoted[198].
British Government	It has conducted a series of workshops on telemedicine and digital health, and is assisting the Ministry of Health to develop regulations and practices for providing safe and quality digital health services[199].
Digital health promotion organization AeHIN (established by WHO)	Promote capacity building by providing member countries in Asia with medical information infrastructure, including governance, architecture, program management, standardization, and interoperability of digital health[200].
Australian Government	The Indonesia-Australia Digital Forum is being promoted. The forum is a series of discussions involving Australian and Indonesian governments, hospitals, and healthcare professionals on the role of digital health in the future delivery of healthcare services in Indonesia and the potential for bilateral cooperation[201].
UNDP	UNDP has signed a MoU with the Indonesian Telemedicine Association (ATENSI) to collaborate on advocating for digital health services and improving the regulatory ecosystem for telemedicine. The focus of the MoU is on (1) evidence-based practice, (2) advocacy to the Indonesian government, and (3) capacity building[202].

Source: Compiled by survey team

[198] ADB. Transforming Health Systems through Good Digital Health Governance. 2018. Available at: https://www.adb.org/sites/default/files/publication/401976/sdwp-051-transforming-health-systems.pdf
[199] Jakarta Post. 2020. https://www.thejakartapost.com/news/2020/11/05/indonesia-uk-join-to-develop-telemedicine-during-pandemic.html
[200] AeHIN. https://www.asiaehealthinformationnetwork.org/
[201] The Australian Embassy. 2018 https://indonesia.embassy.gov.au/jakt/iadf2018.html
[202] UNDP. 2020. https://www.id.undp.org/content/indonesia/en/home/presscenter/pressreleases/2020/UNDP-and-ATENSI.html

２） Development of Digital Health Platform for Use in the Public Sector

Efforts are also being made to develop digital health platforms as a means for the public sector, including national and local governments, to better manage healthcare resources, supply chain logistics, and policy making. This effort is being undertaken by international organizations such as World Bank and UNDP.

Table V-21 List of Initiatives by International Organizations (Platform Development)

Institutions, programs, etc.	Overview
World Bank	SIAP Data Innovation is an open-source online tool to enhance the collection, management, and analysis of geocoded regional data to help communities, local governments, and national governments understand the socioeconomic impacts of COVID-19 and accelerate recovery[203]. The "Indonesia COVID-19 Observatory" is a data collection platform that aims to understand the impact of COVID-19 in near real time and reflect it in the policy making process[204].
UNDP	The SMILE application is used to monitor the distribution of COVID-19 vaccine from the provincial level to each health service facility throughout Indonesia. The SMILE application is being used to monitor the distribution of COVID-19 vaccine from the provincial level to each health service facility throughout Indonesia[205].

Source: Compiled by survey team

３） Promotion and Funding of Local Digital Health Entrepreneurs and Companies

There are also initiatives aimed at promoting and funding local entrepreneurs and communities, and bringing development benefits to the community, using funds from platforms, awards, incubators and accelerator programs. The ADB, World Bank, the British government, the U.S. government, and the German federal government, among others, are engaged in this type of initiative.

[203] The World Bank. 2020. https://blogs.worldbank.org/opendata/how-digital-data-helped-indonesia-respond-covid-19
[204] The World Bank. 2020. https://www.worldbank.org/en/country/indonesia/brief/indonesia-covid-19-observatory
[205] The UNDP. 2021. Available at:
https://www.id.undp.org/content/indonesia/en/home/presscenter/pressreleases/2021/Indonesian-Communication-and-Information.html

Table V-22 List of initiatives by international organizations (support for digital health companies)

Institutions, programs, etc.	Overview
ADB	In order to promote open innovation and to provide incubator and accelerator programs for medical technology-related start-ups in developing countries, SDB operates the following programs; １） ADB-AIM Hackathon It is a digital idea contest to crowdsource digital solutions to address COVID-19 in developing member countries[206]. ２） ADB Ventures ADB Ventures is ADB's impact technology investment platform, which provides VC investment and technical assistance to support early-stage technology projects that can have an impact on the Sustainable Development Goals (SDGs), such as in the health sector. The initial ADB Ventures investment fund has a 17-year term and a $12 million technical assistance program[207].
World Bank and the Wharton School	In collaboration with UN Women and UNDP, they promote the SDGs&Her initiative. This is a contest to recognize small-scale women entrepreneurs who support the UN Sustainable Development Goals (SDGs), including the health sector. Among the winners is a project that uses a digital health platform to develop community health[208].
British Government	Through UK Digital Access, it aims to improve digital access for communities in Kenya, Nigeria, South Africa, Brazil and Indonesia[209]. Through this initiative, in 2020, the British Embassy in Indonesia and the non-profit Common Room Network Foundation implemented a 3.5 billion rupiah (US$247,981) project to provide Internet access to the Ciptagelar community in Sukabumi, West Java. The project is designed to promote digital literacy. The project aims to provide Internet access to the Ciptagelar community and to provide up-to-date and reliable information on COVID-19 in order to improve digital literacy[210].

206 ADB. 2020. https://www.adb.org/news/adb-aim-launch-global-hackathon-digital-ideas-respond-covid-19-crisis
207 ADB. 2020. https://www.adb.org/news/features/adb-ventures-bottom-line-help-developing-asia-meet-sdgs
208 The World Bank. 2020. https://www.worldbank.org/en/who-we-are/news/campaigns/2020/sdgs-and-her-initiative
209 UK Aid. 2021. https://devtracker.fcdo.gov.uk/projects/GB-1-204963
210 IDN Financials. 2020.
https://www.idnfinancials.com/news/34353/british-embassy-launches-project-improve-internet-access-west-java

Institutions, programs, etc.	Overview
U.S. Government	Through its Digital Development Awards, the organization funds projects and activities across all regions that use technology to improve digital ecosystems and development effectiveness. In 2020, a consortium led by Chemonics International implemented the project "hrh2030. In 2020, the consortium led by Chemonics International won an award for the project "Strengthening Information Systems for Human Resources in Health Care in Indonesia. In 2020, a consortium led by Chemonics International won the award for "Strengthening the Information System for Human Resources in Health in Indonesia," a project that provides real-time data for strategic use and supports the development of policies to address the challenges of human resources in health.
Federal Government of Germany	Through the DeveloPPP platform, GIZ is promoting private sector activities to address development issues in developing countries[211]. Using the funds from this platform, in 2020, the Japan International Cooperation Agency (GIZ), in collaboration with Thirona, Fullerton Health Indonesia, IDBH Senso, and the Faculty of Medicine of the University of Indonesia, introduced a digital screening platform using the AI software CAD4COVID-XRay and SAM (Screening-Analytics-Management) to enhance the COVID-19 screening capability[212].

Source: Compiled by survey team

（２） Initiatives of Domestic Institutions

１） Government Initiatives

The Indonesian government, through the Ministry of Health and the Agency for Health Care and Social Security (BPJS Kesehatan), has been promoting the digitization of the health care system. Furthermore, the Ministry of Health Regulation 82/2013 requires all hospitals to operate electronic medical records. The Ministry of Health has comprehensive platforms such as Hospital Management System (SIMRS GOS, E-Rekam Medik, and ASPAK), Public Knowledge and Services (Applicasi NCC 119, SehatPedia, Temenin), Referral System (Sinarap, Sisrute), Quality Management (KARS) A comprehensive platform has been developed for these systems[213]. The Medical and Social Security Agency has developed JKN Mobile, a

211 DeveloPPP. https://www.developpp.de/en/
212 Delft Imaging. 2020. https://www.delft.care/strengthening-covid-19-screening-capacity-in-indonesia/
213 Kementerian Kesehatan. Kebijakan Digitalisasi Rumah Sakit. 2020.

mobile application that allows users to access a variety of health insurance information, and VEDIKA, a digital claims verification platform that users can use to bill for inpatient and outpatient services[214]. The government's COVID-19 task force has integrated 21 telemedicine services into a digital call center called Sociomile. When a patient's condition worsens, the doctor contacts the task force, which dispatches a medical professional to verify whether the patient has been exposed to COVID-19. On the other hand, in order to provide the public with information related to COVID-19, each local government has set up a website to display the latest case distribution maps, latest news, health care education, etc. In April 2020, the Ministry of Communications and Information released PeduliLindungi, a mobile application that can track COVID-19 contacts and notify the user when they are located in a risk zone. This has been updated with the ability to notify users of their vaccination status and certificate information[215].

２） Other Initiatives

Organizations, forums, and events have emerged to disseminate information, promote the development of new solutions, and act as a bridge between companies and governments to promote supportive policies and regulations.

Table V-23 List of other initiatives

Institutions, programs, etc.	Overview
Indonesian Telemedicine Alliance (ATENSI) [216]	It is a forum for Indonesian medical professionals engaged in digital-based medicine and telemedicine, and its members include academics and representatives of health tech companies. It collaborates with public stakeholders such as the Ministry of Health, and international organizations such as UNDP. The following are some of ATENSI's initiatives. ・ Development of a regulatory sandbox for digital health innovation (2020, Ministry of Health) ・ Provision of telemedicine services to COVID-19 patients undergoing self-quarantine (2021, Ministry of Health) ・ Recruitment and training of COVID-19 volunteers by DocQuity (2021, Ministry of Health) ・ Developing a Regulatory Sandbox for Digital Health Innovation

[214] Deloitte. 21st Century Healthcare Challenges: A Connected Approach. 2020. Available at: https://www2.deloitte.com/id/en/pages/life-sciences-and-healthcare/articles/ehealth-publication-Indonesia.html

[215] Kompas. 2020. Available at: https://tekno.kompas.com/read/2020/03/29/18020057/aplikasi-peduli-lindungi-untuk-melacak-covid-19-sudah-bisa-diunduh?page=all

[216] Aliansi Telemedik Indonesia. 2021. https://atensi.or.id/

Institutions, programs, etc.	Overview
	(2020, UNDP) As of Febuary 2022, ATENSI has 37 member companies and is strengthening its corabolation with telemedicine companies. The breakdown is as follows 【Telemedicine】 Aido Health, Alodokter, AVShunt Indonesia, Halodoc, CallMyDokter, Good Doctor, KakiDiabet Indonesia, KlikDokter, KlinikGo, Lekasehat, Link Medis Sehat, Milvik, Naluri Life, Sifa.id, Teman Diabetes, Varises Indonesia, YesDok, Digidoc, Get Well 【Home Healthcare】 Homecare24, Medi-Call, Okedok, Perawatku, ProSehat 【Doctor-to-Doctor Platform】 Aveecena, Docquity, Doctor to Doctor 【Healthcare Information】 Dokter Sehat, Hello Sehat, Vaskular Indonesia 【Healthcare E-commerce, Digital Pharmacy】 Emedis.id, GoApotik, and 【Remote monitoring of pregnant women】 Hallobumil, Teman Bumil 【Other】 Multi Sinar Adamar (Inventory Management), Trustmedis (Electronic Medical Records), Sehati TeleCTG (Remote CTG)
HealthTech.id [217]	The organization was founded by medical facilities, investors, insurance companies, pharmaceutical companies, medical devices and other healthcare-related start-up companies and currently has 80 members. It holds regular meetings with stakeholders and makes recommendations for policy making in the field of medical technology.
IndoHCF	As part of PT IDS Medical Systems Indonesia's (idsMED Indonesia) Corporate Social Responsibility (CSR), the company held its first annual event in 2017, the Indonesia Healthcare Innovation Awards[218]. The event was attended by various stakeholders including institutions, local governments, individuals, and academics who have successfully innovated

[217] Asosiasi HealthTech Indonesia. 2021. https://healthtech.id/
[218] Indo Healthcare Forum. 2021. https://indohcf.com/

Institutions, programs, etc.	Overview
	to improve healthcare services in Indonesia.

Source: Compiled by survey team

VI. Hypothesis building for JICA's Supporting Measures in the Field of Digital Health

VI. Hypothesis building for JICA's Supporting Measures in the Field of Digital Health

１. Approaches to Support

The objective of this project is to examine the specific support measures of JICA to partner governments and private companies (including Japanese, local and third countries) with collaboration and co-creation with various partners in order to promote the digitalization of the health sector and the development of the digital health market to solve healthcare issues including COVID-19. In order to achieve this objective, in this survey, we first developed macro-level (high-abstract level) policy hypotheses through desktop research, and then verified these hypotheses through PoC activities and interviews to related parties in order to compile concrete final policy proposals. In constructing the hypotheses, we first reorganized the issues and needs of the target countries and the market environment of the companies and their solutions based on the perspectives of the target countries, companies, and JICA as described in the previous chapter. In addition, we created and utilized a digital health architecture as the environment surrounding digital health in each country, and analyzed what gaps exist between the challenges of the target countries andthe companies, or what kind of players can effectively intervene through co-creation. Based on these analyses, and consistent with the perspectives and interests of JICA as a development donor, we examined hypotheses for measures that could add value to the digital health ecosystem at the macro level by connecting the challenges faced by the target countries and the solutions of private companies (including Japanese, target countries, and third countries).

The digital health architecture is a representation of the overall structure of digital health that organizes the complex relationships among various players from the perspective of data and systems. First, the horizontal axis shows three major categories, including "companies that provide solutions," "target countries where governments, medical facility, research organizations, etc," and "donors, VCs, that play a role similar to JICA in the digital health ecosystem". Company solutions are mainly described along the patient journey from prevention to follow-up. On the vertical axis, the objectives are placed from the bottom to the top of the digital health structure: "collection," "integration and storage," "utilization, processing, and analysis" of information, and "improvement of well-being" through a series of these activities. The supply layers corresponding to these objectives were organized into "devices," "networks," "cloud data centers," "platforms," " contents and applications" and "services". Each classification is divided into two major groups: customer contact and infrastructure. In addition, the digital health architecture is supported by the lowest layer, which is "policy strategy, rules (laws, regulations, systems, etc.), and organizational human resources. Finally, each layer can be divided into competitive and collaborative areas. The competitive area is led by private companies with technologies and solutions, and JICA is expected to co-creation with private technologies in this area. JICA is expected to co-creates with the private sector in this area. On the other hand, the collaborative area is expected to be supported by the public sector, including governments and development donors, and the status of this area in each country will have a significant impact on the development of the digital health ecosystem.

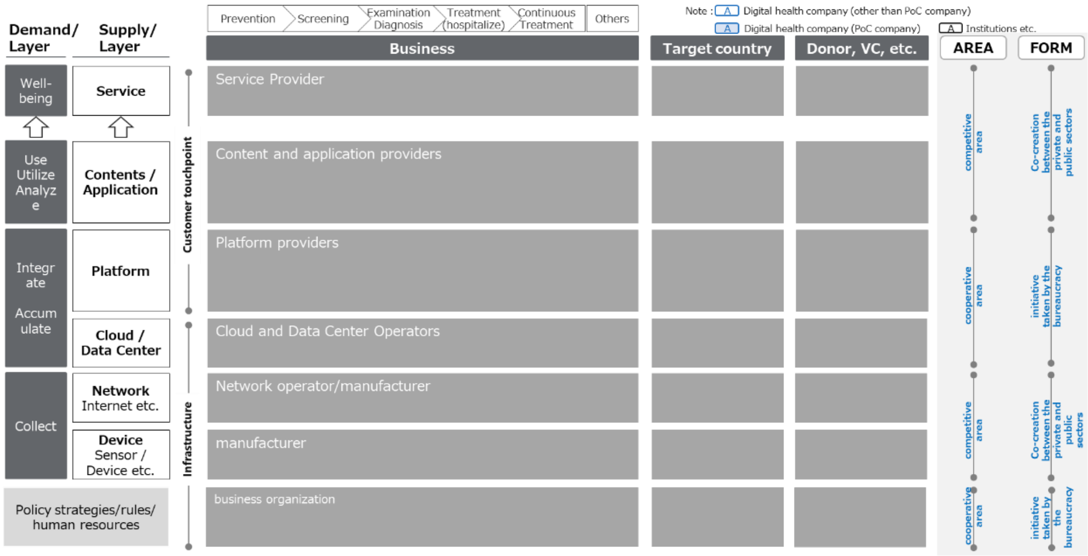


Figure VI-1 Framework for Digital Health Architecture

Source: Compiled by survey team

2． Hypothesis of JICA's supporting measure

2－1． Brazil

In Brazil, as mentioned in the previous chapter, the population is growing steadily, but the birthrate is declining and the population is aging. With the aging of the population, NCDs such as cardiovascular diseases, respiratory diseases, and diabetes are the top health care issues in terms of disease structure, and the quantity and quality of medical services for these diseases will need to be improved.

In order to meet these medical demands, Brazil has a national unified health care system, SUS. Under the SUS, all citizens can receive all medical services, from primary health care to highly advanced medical care, free of charge at public medical facilities and private medical facilities under contract with the government. The national health insurance system and health care delivery system are relatively mature compared to those of Kenya and Indonesia. In addition, the national health care sector is being digitized, with the SUS playing a central role in DATASUS, which is responsible for the storage and management of medical information of all Brazilian citizens. For example, the Connect SUS program (2020), which aims to establish and strengthen information linkages among different medical regions, including primary medical facilities, and between public and private medical facilities, and the National Health Data Network (RNDS) (2020), which is a nationwide medical information interoperability platform to realize Connect SUS, have been implemented. These medical information infrastructures are expected to be connected to all 27 states in Brazil by 2023. This shows that the country is forming a foundation for addressing future healthcare issues through the use of digital technology.

On the other hand, Brazil is still facing a situation where the disparity between the rich and the poor is still causing unequal health services. Brazil has long been ranked as the most unequal country in Latin America, and the World Bank's Gini coefficient, which measures inequality, reached a record high of 0.674 in the first quarter of 2021[219]. In addition, the fact that about 25% of the population, who are generally the wealthy, are less satisfied with public medical services, and that they have private health insurance in addition to the SUS universal health insurance, suggests that the gap between the rich and the poor is causing disparities in the medical services themselves.

In order to fill these gaps, there are high expectations for digital health. The shortage of medical human resources is considered to be one of the causes of the gap in the quality of medical services, and the response to COVID-19 has hit the medical human resources that were originally in short supply, especially in public medical facilities, leading to a further decline in quality. According to a survey conducted by medical facilities, there is a high demand for remote and non-contact technologies such as online medical treatment and online health consultation to improve the shortage of human resources, as well as for ICT technologies for data linkage and improvement of doctors' diagnostic capabilities.

Brazil's digital health market is expected to continue growing even under the COVID-19 pandemic, with more than 50 investment deals worth more than US$ 200 million in 2021, and a growth rate of 7%. There is a wide range of digital health solutions, from that contribute to the maintenance and improvement of daily health, to pre-diagnosis and triage, online medical care, and in-hospital information management systems. In recent years, solutions to support the daily activities and safety of the elderly have also been seen, and it is expected that technologies to meet the medical demands of the aging population will be expected.

However, it has been pointed out that digital health companies and startups, which are important players in solving healthcare issues, continue to face challenges in raising funds

[219] https://www.americasquarterly.org/article/inequality-is-brazils-achilles-heel/

for R&D and business development. As noted in the Global Innovation index report, the economic risks associated with innovation are higher in Brazil than in developed countries due to political, macroeconomic, and social uncertainties. Innovation sector entrepreneurs point out that banks are not interested in lending due to the lack of guarantees against risks.

The following figure shows the digital health architecture in Brazil, which shows the environment surrounding the above issues and companies in the target countries. In the cooperative area, among the most notable players in the Brazilian digital health sector are the innovation hubs in medical facilities and universities that have been created over the past five years. In addition to public universities, technology institutes, and R&D organizations, recent examples include the Brazilian Industrial Research and Innovation Company (Embrapii). In the innovation scenario, there are incubators, technology parks, private investors, companies, and systems such as the National Industrial Learning Service (Senai) and its Innovation Institute, and the Brazilian SME Support Service (Sebrae). In the health care industry, Brazil has developed an extensive system of public laboratories, including the Oswaldo Cruz Foundation (Fiocruz), the Adolfo Lutz Institute, and the Butantan Institute. This system has made Brazil an important center for epidemiological research and has played an important role in addressing the COVID-19 crisis. Furthermore, incubation programs and investment funds targeting the healthcare sector have been established, confirming that the innovation hubs are driving the digital health market mentioned above and contributing to solving healthcare issues.

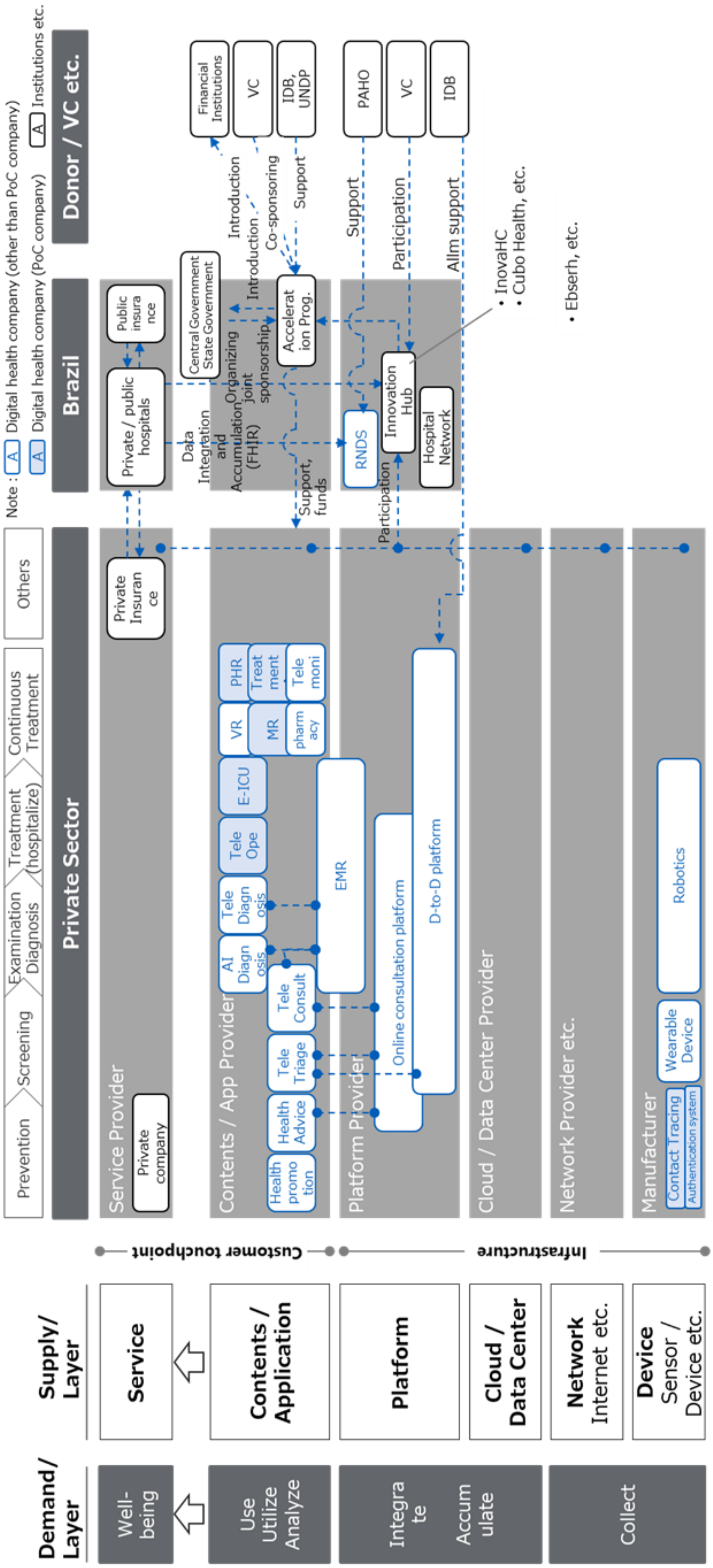


Figure VI-2 Digital health architecture in Brazil

Source: Compiled by survey team

As for JICA's efforts in the health sector in Brazil, as an ODA graduate transition country, JICA has not provided any paid or grant aid in the recent past. However, as stated in the Basic Policy for ODA (2) of the Policy for Country-Specific Development Cooperation with Brazil, the priority areas of ODA are to provide assistance in areas that promote economic growth, including the expansion of human resources, as well as to improve the investment environment and strengthen industrial competitiveness, and to provide technical assistance, etc., in collaboration with private sector funds. In particular, the government is focusing on market expansion through collaboration with the private sector, and in Brazil, there have been several smart healthcare diffusion projects implemented through private sector collaboration. In addition, the "Open Innovation Challenge TSUBASA (Transformational Start Ups' Business Acceleration for the SDGs Agenda)" was held jointly with IDB Lab, a member of the Inter-American Development Bank Group, with the aim of discovering and supporting Japanese start-ups working on business in Latin America and the Caribbean. (Transformational Startups' Business Acceleration for the SDGs Agenda). The program matches Japanese solutions in various fields with the needs of Latin America and the Caribbean, and in the field of healthcare, there is the possibility of supporting technological collaboration aimed at developing the private market in Latin America and the Caribbean.

Furthermore, in JICA's issue-specific project strategy (Global Agenda): 6. Health and Medical Care, measures against NCDs and aging are expected to be taken in collaboration with local governments, universities, and private companies to deploy Japanese technologies in developing countries, and to return those technologies to domestic technological development. The strategy is consistent with measures to address the aging population and the disease structure of NCDs in Brazil.

Based on the above, the following hypotheses are formulated at the macro level for consideration of measures that can add value to the Brazilian digital health ecosystem as JICA, by connecting the issues faced by the target countries and the solutions of private companies (including Japanese, target countries, and third countries).

Hypothesis: **In order to improve the quality of medical care caused by economic disparity and other factors, JICA encourage the expansion of the digital health market for measures against specific diseases in Brazil and the introduction of private-sector digital health solutions to medical facilities through the co-creation of Japanese and local companies, centered on local innovation partners.**

The hypothesis is built on the following arguments constructed from the above information.

- **Correction of healthcare disparities between the rich and the poor:** Brazil has a universal health insurance system, and the healthcare sector is being digitized. On the other hand, the gap in healthcare services between the rich and the poor is an issue, and digital health technology is expected to be used in public medical facilities where healthcare personnel tend to be in short supply.
- **Utilization of digital health solutions from Japan, a country with advanced issues:** In the case of Brazil, the conditions for private companies with digital health technologies to enter the Brazilian market are relatively good, as the country has a well-developed healthcare system and a medical information infrastructure is being formed. In addition, since NCDs and other healthcare issues associated with the declining birthrate and aging population are among the top issues in Brazil, there is a high possibility that Japanese companies, especially those that are advanced in issues related to the aging population, will be able to develop digital health solutions that are easy to do business with and in which Japanese companies have an advantage.
- **Partnerships with local innovation hubs**: Although the digital health market is growing, there are many obstacles to overcome in terms of funding, development, and business scale for the startups that are driving this market. In contrast, in Brazil, innovation hubs play an important role in supporting the business development and financing of startups with digital health technologies in the digital health architecture. By collaborating with these existing local partners, it is possible to promote the development of the digital health ecosystem in an agile manner while utilizing the vitality of the private sector.

Based on this hypothesis, the following JICA's supporting measures were extracted. These ideas will be developed, revised, and concretized (hypothesis verification) through PoC activities and interviews with related parties to finalize the proposed measures (described in detail in Chapter VIII).

- Through the partnership with Innova HC, which aims to promote a medical innovation ecosystem in hospitals, Japanese innovations (e.g., technology of startup companies) will be tested and improved, and solutions will be introduced to address medical issues such as those arising from the disparity between the rich and the poor in the region.
- Forming an innovation partnership with Ebserh, Brazil's largest network of public university hospitals, to promote the spread of ICT technologies across the board, including PoC and development of digital health technologies for public hospitals.
- Participate in the CUBO Innovation Hub, a hub for Brazilian startups, and implement the JICA (Reverse) Innovation Challenge targeting medical issues in South America or Japan.

- Matching Japanese doctors with Brazilian doctors (public hospitals and Nikkei hospitals), and supporting disease countermeasures for aging and NCDs by utilizing digital health tools (including e-learning tools for doctors) from Japanese and Brazilian companies.
- Co-creation of NCDs and other clinical research networks/bio-health/CROs with Japanese pharmaceutical companies and other healthcare companies using AI and other digital health solutions and medical data sets to help improve the quality of treatment in the country, including accessible and affordable medicines.

etc.

２－２． Kenya

In Kenya, as mentioned above, the population in 2019 is 52,573,000 (males: 49.6%, females: 50.4%), and although the population growth rate is growing steadily at 2.3%, the population pyramid shows a trend of high fertility and high mortality. This is thought to be due to the fact that the maternal and child related indicators, U5MR, NMR, and MMR, are much higher than the SDG target values (U5MR: 25, NMR: 12, MMR: 70). Although the fertility rate is projected to decrease continuously in the future, the number of births is expected to increase up to 1.2 times between 2018 and 2035 due to population growth. As a result, infectious diseases, which have been the main cause of death in the past, and NCDs, which have been on the rise in recent years, as well as the improvement of U5MR, NMR, and MMR will continue to be important healthcare issues.

The country's health system is also vulnerable. As shown in the results of the aforementioned survey of medical facilities, there is a shortage or absence of medical specialists in the examination and diagnosis process, and a shortage of medicines in the continuous treatment and follow-up process. Other challenges include capacity building of the medical workforce, low public health insurance coverage, and low public funding as a percentage of total healthcare expenditure. In Kenya, there are two main types of medical facilities: public and private, and most of these issues are found in public institutions. Although DHIS II, the core statistics for medical information, covers all medical facilities, its introduction in private medical facilities has been limited (see details below). As for EMR, private medical facilitys have made progress, but public medical facilitys have not yet adopted it. Furthermore, the information system for connecting communities to primary medical facilitys is not yet in place, and will be developed as e-CHIS (see details below).

Although statistics on public healthcare utilization by the population were not obtained, people working in the informal sector, who are estimated to be the primary users of public healthcare, accounted for 83% of the total working population in 2019[220]. This situation calls for continued efforts to improve the overall health system that supports public health institutions in a country with such a large population.

The government has also positioned the use of ICT in the healthcare sector as one of its priority policies to address these medical issues and to strengthen the healthcare system. With the establishment of the e-Health Unit within the Ministry of Health in 2020, the Kenyan government has begun to promote e-Health and telemedicine. The National e-Health Policy 2016-2030 seeks to create an enabling environment for sustainable adoption, implementation and efficient use of e-Health products and services at all levels of the health sector. From now on, as part of the creation of better environment, e-CHIS, electronic medical record system at the community level, will be established in the future. The background to the establishment of the e-CHIS is that the recording of community health services provided by community health volunteers is largely paper-based, which is not only inefficient but also subject to transcription errors and other data quality problems. The process of reporting this information from the local to the national level is also largely paper-based, which compromises both the accuracy of the data and the timeliness of the reporting. In addition, the lack of human resources has exacerbated these problems, and the Ministry of Health hopes to improve these problems by establishing an e-CHIS.

In Additiona, the Ministry of Health also aims to improve health services at the primary health care provider level and to strengthen referral function from the community to higher-level medical institutions through the establishment of the Primary Healthcare Network (PCN). In particular, the network encourages the use of digital health technology to improve access to a variety of health care services, pointing to the high importance of health care innovation to improve access to affordable and quality health care at the community and medical facility levels for the establishment and sustainability of the PCN. The importance of this has been pointed out. The Ministry of Health is currently implementing a pilot project in Isiolo County with funding from Johnson & Johnson, but according to interviews with the Ministry of Health, there is not enough funds to scale up the project.

However, the policies and systems in the field of digital health have just started, and the infrastructure and systems for the use of digital health are not yet in place, especially in hospitals, due to the low penetration of telecommunication infrastructure in rural areas, and insufficient establishment and dissemination of standards, laws, and regulations related to digital health. In comparison with the maturity of the digital health environment in Brazil, which is the target of this survey, it can be seen that the infrastructure and systems for utilizing

[220] P13The Informal Economy in Kenya, 2021 The Federation of Kenyan Employers

digital health technology in the national health system are still immature in Kenya[221].

On the other hand, looking at the private market, a gap is beginning to emerge between the public and private sectors in the adoption of digital health. Kenya's digital health market is expected to grow at a CAGR of 6.0% in USD terms from 2019-2024, expanding from USD 150 million today to USD 180 million by 2024, with high growth expected beyond 2024. IFC, the U.K., Germany, and other countries are among the countries that are expected to see the highest Internet access rates in Sub-Saharan Africa (84%), the emergence of 4G and 4G LTE services in 2020, government-approved universal 4G coverage, and an increase in personal smartphone usage (51%). IFC, UK, Germany, and other countries are providing start-up support to the growing digital health market in Kenya. The technology types of digital health in Kenya include online emergency calls, mainly in urban areas, and drug tracing to prevent counterfeit drugs.

However, most of the current digital health solutions are mostly mHealth, which uses mobile information terminals, due to the infrastructure limitations mentioned above. In addition, as mentioned above in IV.B-6, there are financial constraints and technical challenges surrounding interoperability and infrastructure requirements. As a result, there has been little development in technologies that require data linkage and high-capacity communication between various points, such as PHRs and regional coordination systems. It has also been pointed out that, with the exception of a few solutions, most of the digital health in Kenya is still in the pilot stage, making it difficult to expand the scale of business. The main reasons for this may be financial constraints and technical issues surrounding interoperability and infrastructure requirements on the hospital side. Particularly on the financial side, there is a lack of funds and liquidity to pay for the cost of using the solution for the general public, or in the case of public utilities, to pilot the solution or implement it on a large scale. In addition, the lack of health insurance coverage for telemedicine and other services also poses a challenge in terms of sustainability.

The following figure shows the digital health architecture in Kenya, which shows the environment surrounding the above issues and companies in the target countries. In the competitive area, the main feature is that there are many private companies which provide digital health solutions (customer contact point) for users such as medical practitioners and patients, and

[221] According to the report of the JICA Information Collection and Verification Study on Startup and Entrepreneurship Support (2021), it was confirmed that "there is a lack of collaboration and community among the players that make up the ecosystem, such as the absence of an organization that supervises intergovernmental support across the board, and there are issues such as the business content of entrepreneurs nurtured in incubators not meeting the requirements of VCs and the lack of commercialization.

a private sector platform has also been established through mobile payment. This can be attributed to the fact that other donors in the same area are actively supporting the private sector through acceleration programs. On the other hand, in the collaborative area, no specific co-creation system with these private technologies or infrastructure for data utilization could be confirmed.

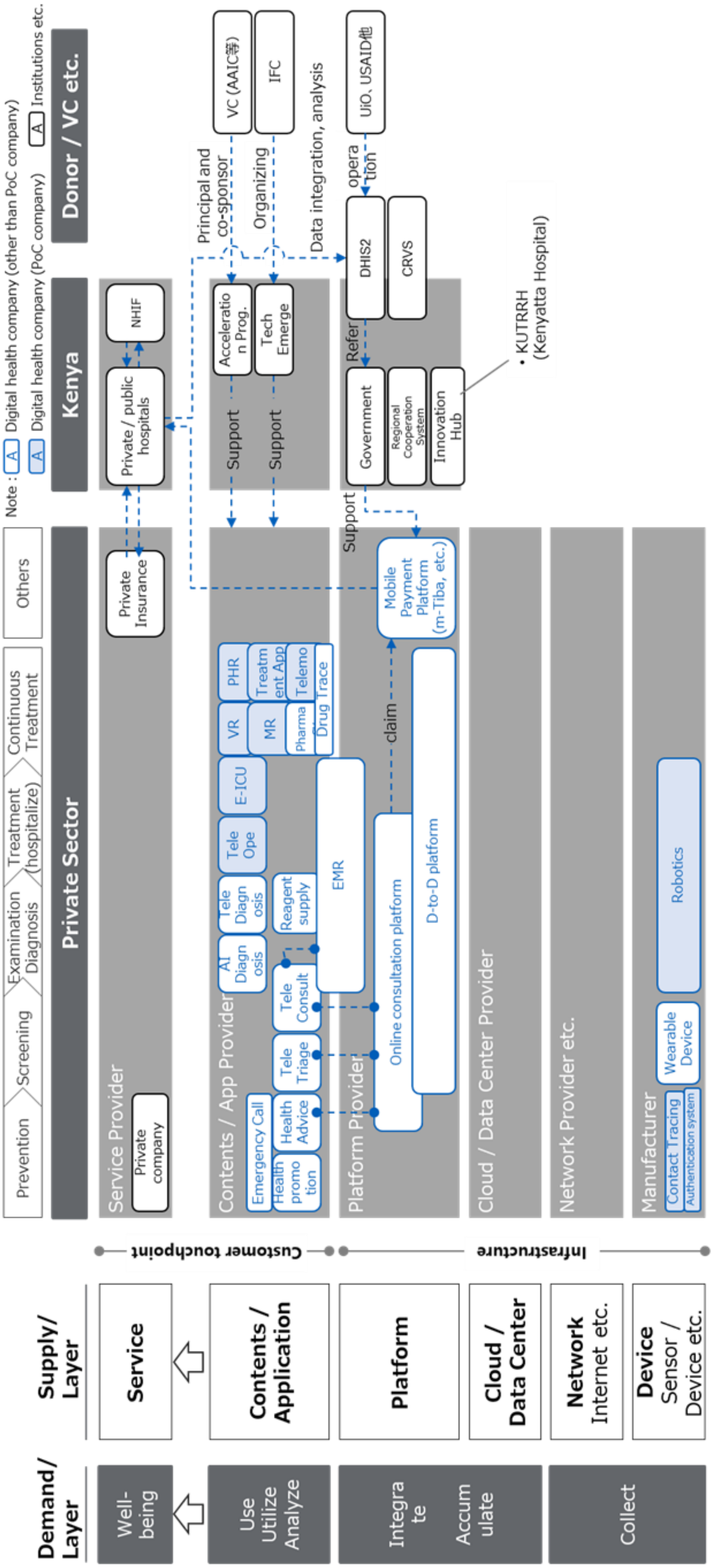


Figure VI-3 Digital health architecture in Kenya

Source: Compiled by survey team

In Kenya's Country Development Cooperation Policy, in the field of health and medical care, cooperation has been set up for the correction of inequalities in health services toward UHC, securing of health budgets and planned expenditures by county governments that are substantially responsible for health administration, realization of UHC especially under decentralization, and health system strengthening. In particular, for the achievement of UHC, JICA's project strategy by issue (Global Agenda: 6. Health Care) has set a cluster to be focused on, "To ensure access to health services through the development and improvement of health security systems, while increasing national commitment to policy and institutional It is also in line with the cluster to be focused on in the "Improving access to health care services through the development and improvement of health security systems by increasing national commitment, providing advice on policies and systems, coordination with service providers, and financial support.

Among the three target countries, Kenya has been implementing a wide range of projects, including technical cooperation, financial cooperation, and private sector collaboration, with a focus on health system strengthening, as healthcare is considered a priority area. One of the projects related to digital health is the Health Sector Policy Loan for Achieving Universal Health Coverage (Phase 2). The project supports the implementation of high-priority policies to achieve UHC, such as strengthening health financing and health service delivery capacity, but also includes the promotion of computerization of health information systems and strengthening of data analysis capacity. The Kenyan Ministry of Health has been working on the integration of health information systems, suggesting that building information infrastructure is an important component of health system strengthening**.**

Based on the above, the following hypotheses were formulated at the macro level for considering measures that could add value to the Kenyan digital health ecosystem as JICA, by connecting the challenges faced by the target countries and the solutions of private companies (including Japanese, target countries and third countries).

Hypothesis: **In order to achieve UHC and strengthen the health system, JICA supports the government and public medical facilities by introducing appropriate digital health technologies at the primary care level and by building a foundation that enables private companies and start-ups with these technologies to enter the market.**

The hypothesis is built on the following arguments constructed from the above information.

- **Strengthening primary care services through the use of digital health technology:** Primary health care services play an important role in Kenya's health system, especially in addressing maternal and child health and infectious diseases. As the Kenyan government has announced the establishment of e-CHIS and the promotion of digital health technology in PCNs[222], there is a high demand for the introduction of digital health technology especially at the primary care level as a mean to achieve UHC.

- **Building a foundation for public institutions to utilize digital health:** While the private sector is rapidly developing digital health, public institutions have yet to catch up with digitization. As the gap between the private and public sectors in terms of medical services is widening, it is important to create an environmental infrastructure (systems, structures, information systems, etc.) to utilize digital health technology in public medical facilities, which are used by most of the population. However, there has been no distinctive support from other donors in this area. If the infrastructure is established, it will contribute to the achievement of UHC and the strengthening of health systems, and may also attract private investment, leading to the development of private companies with ICT technologies.
- **Providing opportunities for co-creation between the public and private sectors:** The fact that national systems and regulations for digital health are not yet established or unclear is a hindrance to private sector innovation and market entry. As a neutral donor in the digital health field, we can provide opportunities to promote co-creation between the public and private sectors in terms of systems, regulations, and market matching.

Based on this hypothesis, the following JICA's supporting measures were extracted. These ideas will be developed, revised, and concretized (hypothesis verification) through PoC activities and interviews with related parties to finalize the proposed measures (described in detail in Chapter VIII).

- Support the construction of a medical information network (Digital Health Platform: DHP) among public and private medical facilities by developing and linking medical facility information infrastructure such as EMR and DHISII.
- Strengthen the referral system based on the PCN concept from complex community-level primary medical facilities to high-level medical facilities by utilizing digital health technology.
- Support the promotion of digitalization of medical information mainly at the community level, such as e-CHIS.
- Form a platform for Public Private Development Dialogue in the field of digital health to share institutional, legal and technical knowledge.

[222] The Kenyan Ministry of Health believes that community health is a fundamental component of UHC, and that the use of information systems and medical ICT technologies, especially at the primary care level, which are at the forefront of generating the data needed to inform public health responses and resource allocation, play a very important role in achieving UHC (from the National Community Health Digitization Strategy).

- Within the platform for public-private co-creation, pooling medical facilities that have a track record of collaboration with JICA or are capable of introducing digital health technologies, and connecting companies with technologies that contribute to solving medical issues to support the scale of existing businesses.

etc.

２－３． Indonesia

Indonesia is the fourth most populous country in the world, and although the population is expected to continue to grow, the rate of population growth is declining, and the population pyramid is showing a trend of low fertility and aging. In terms of disease structure, the proportion of NCDs has been increasing since 2000, and is expected to increase further in the future.

As the largest island nation in the world, geographical unevenness in medical services is a serious problem. Against the backdrop of the concentration of medical education institutions in urban areas and regional disparities in medical infrastructure, medical professionals such as doctors, nurses, and midwives are generally concentrated in urban areas, leaving patients in remote areas without access to appropriate medical services. The above situation, in which the proportion of NCDs is increasing as a disease structure, also suggests that there is an ever-increasing need for doctors who specialize in NCDs in particular.

In terms of companies, the digital health sector has been growing rapidly in Indonesia over the past five years, as it has in Brazil and Kenya. Revenue in the digital health sector is estimated to increase at a compound annual growth rate (CAGR) of more than 60%, from $85 million in 2017 to $973 million in 2022. Online medical practice accounts for the largest share of the digital health market in Indonesia, followed by digital pharmacy. The number of users of telemedicine services is believed to be more than 2 million, and is expected to increase by 67% YoY in 2020, indicating the high demand for telemedicine in the country.

However, although laws and regulations related to the use of data in Indonesia are in place, there are still no regulations regarding the protection of personal information specific to the digital health field, and no detailed regulations regarding information security have been confirmed. In addition, telemedicine services are not covered by public insurance, and patients who want to use their insurance to receive medical care need to go to a primary medical facility. Therefore, private companies are trying to overcome this problem by developing their own products. Telemedicine application development companies and insurance companies each offer their own insurance products, and the availability of insurance coverage has a significant impact on the spread of telemedicine.

The following figure shows the digital health architecture in Indonesia, which shows the environment surrounding the above issues and the situation of companies in the target countries. In the competitive area, there are many local private companies that provide online medical services, and electronic medical records are spreading to a certain extent. However, as platforms in the collaborative area, PHRs that allow medical institutions and patients to share and cross-reference data, regional collaboration systems that enable medical institutions to connect and share patients’ medical data, and doctor-to-doctor platforms that enable communication and collaboration among doctors (TEMENIN, a telemedicine program by the Ministry of Health) are concentrated in urban areas and have not spread to the national level, including rural islands.

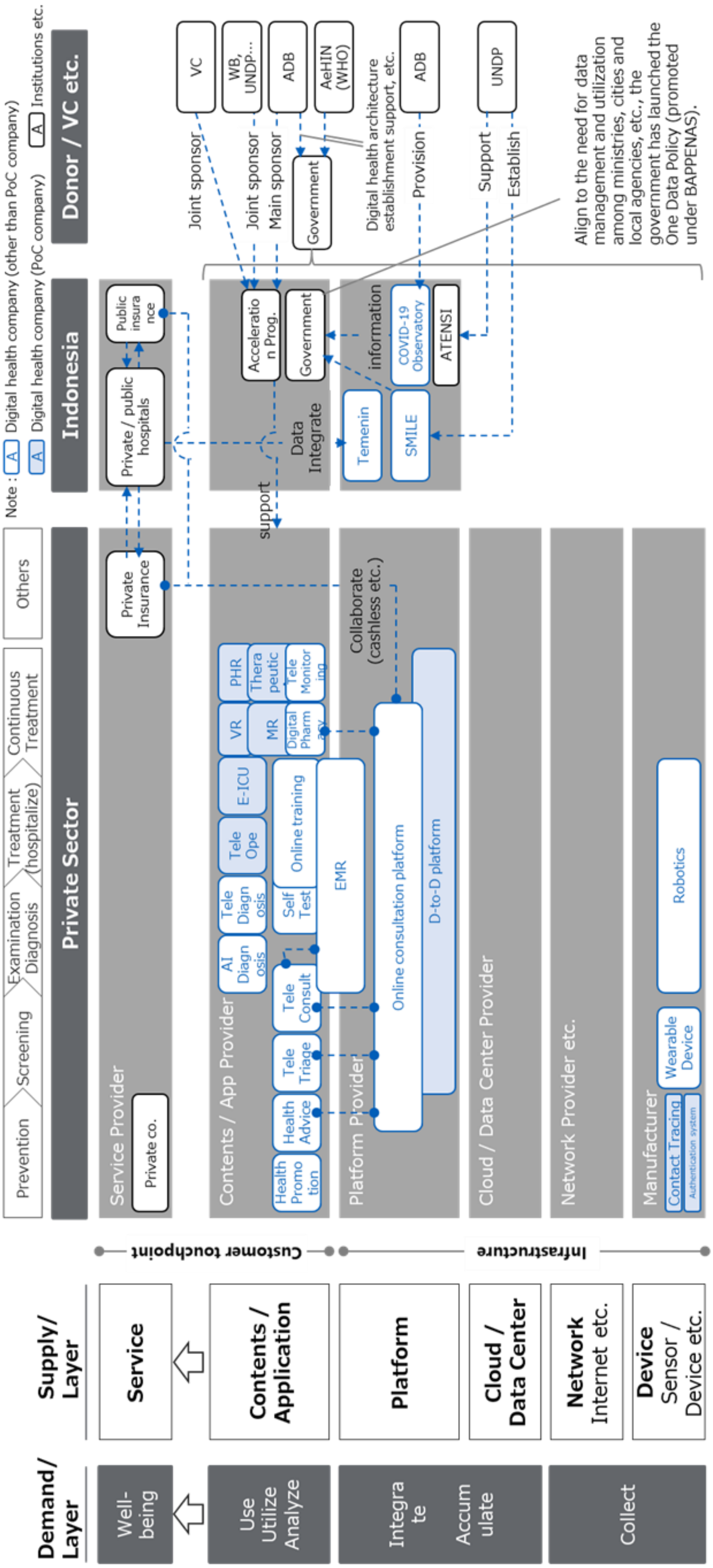


Figure VI-4 Digital health architecture in Indonesia

Source: Compiled by survey team

According to the Country Development Cooperation Policy for Indonesia, supporting the development of rural areas as well as major cities in order to improve the quality of life in order to realize a safe and just society has been set as a priority area of the basic policy of ODA, and JICA is focusing on correcting regional disparities. For example, from 2021, JICA is implementing the "Project for Strengthening Intensive Care Capacity Using Remote Technology under the Epidemic of Novel Coronavirus Infection". In this project, pilot activities for remote ICU services are underway at the University Hospital of Indonesia in West Java and Hasanuddin University Hospital in South Sulawesi. In addition, since 2018, JICA has been implementing the "Project on Improving the Quality of Maternal and Child Health Programs through the Use of Maternal and Child Health Handbooks in Decentralization", in which the digitalization of maternal and child health handbooks is also being considered. This is in line with JICA's Global Agenda: 6. Health and Medical Care, which aims to strengthen the system to continuously provide high-quality services from pregnancy to delivery and until the child turns five years old. It is expected that digital health technology will be utilized in the field of maternal and child health handbook, which has been supported for a long time.

Based on the above, the following hypotheses are formulated at the macro level to consider the JICA’s supporting measures that can add value to the Indonesian digital health ecosystem by connecting the challenges faced by Indonesia and the solutions of private companies (including Japanese, target countries, and third countries).

Hypothesis: **In order to realize the improvement of medical services in remote areas, JICA supports the Indonesian government in building a system and structure that enables the introduction and promotion of telemedicine-specific innovations at the national level, based on existing JICA project partners and technologies.**

The hypothesis is built on the following arguments constructed from the above information.

- **Correcting the uneven regional distribution of doctors:** In Indonesia, the shortage of medical personnel on remote islands is a priority issue. Especially in remote islands, primary medical facilities are not able to provide sufficient services, and it will be necessary to deal with the increasing number of NCDs, etc. Therefore, there is a high need for the introduction of information collaboration technology to support cooperation with doctors (and specialized doctors) and digital health technology to deal with these issues.
- **Strengthening of telemedicine system construction and implementation:** The government has been implementing telemedicine programs through temenin, but these programs have yet to spread due to various issues. Promote the introduction of

telemedicine in the nation by creating institutions that focus on issues specific to telemedicine, such as building health insurance and other systems, strengthening the implementation system of doctors, and collaborating with companies.

- **Development of existing digital health projects:** In the case of Indonesia, there are already existing JICA projects using digital health in the healthcare sector. Scaling up these projects with local partners and technologies will lead to agile and sustainable development of the country's digital health ecosystem and increase JICA's presence in the digital health field.

Based on the above hypothesis, the following ideas for JICA's supporting measures were extracted. These ideas will be developed and concretized (hypotheses will be verified) through PoC activities and interviews with related parties, and the proposed measures will be finalized (described in detail in Chapter VIII).

- Support the introduction of digital health technology for initial disease screening and diagnosis at primary medical facilities in remote areas such as remote islands.
- Promote coordination of patient information among doctors by connecting university groups, including those in remote areas, and medical association networks.
- Co-creation with the Ministry of Health, Ministry of ICT, hospitals, private companies, universities, etc. to build a community and center of excellence to promote digital health innovation such as telemedicine.
- Support for the establishment of a system to deal with regulations that are a particular obstacle to the introduction of telemedicine, such as the lack of a digital health category in Indonesia's medical device certification.
- Provide technical support in terms of policies and systems to ensure that telemedicine is covered by medical fees because telemedicine is not coordinated with the Indonesian BPJS universal health insurance system and the national social security system,
- Introduce new digital health technologies into existing projects, such as the use of AI technology in the Maternal and Child Health Handbook project and telemedicine collaboration in other fields with partners in the Tele-ICU project.

etc.

VII. PoC in Brazil, Kenya and Indonesia

VII. PoC in Brazil, Kenya and Indonesia

1. PoC proposal and selection

1－1. Selection Process Overview

The project was open to the public, and PoC partner companies were selected through the first and second rounds of screening. After the public seminar, the first screening was conducted, and a meet-up session was held for the companies that passed the first screening and local medical facilities. During the meet-up session, corporate pitches are also conducted to local medical facilities, and after listening to the interest from the medical facilities, the Japanese companies were matched with the local medical facilities. The matched Japanese companies and local medical facilities held a workshop as their option, and submitted their joint proposals for the second round of screening. In the second round of screening, interviews were conducted between JICA and the Japanese companies, and finally two companies from Brazil, two companies from Kenya, and three companies from Indonesia were selected. The selection process is illustrated below.

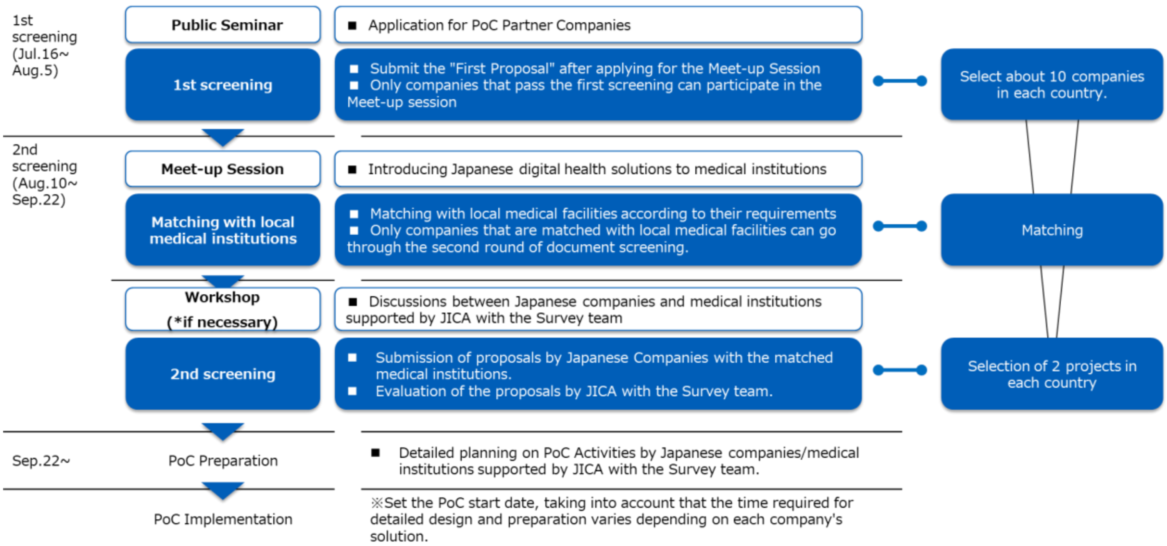


Figure VII-1 Flow of the selection process

Source: Compiled by survey team

Local medical facilities in this selection process refer to the facilities in each country where the online questionnaire survey and follow-up interviews were conducted in this project. In addition, medical facilities that did not complete the online questionnaire survey and follow-up interviews, but separately showed interest in the Project during the selection process, were invited to attend the local seminars and were interviewed individually about their interest.

１－２． Public seminar

On Friday, July 16, 2021, a seminar open to the public, "Challenges to Medical DX in Developing Countries: Opportunities for Local PoC Implementation through Co-Creation with JICA," was held online, and participation in this seminar was made a mandatory requirement for PoC applications. The purpose and outline of the project were explained to the participants, and the recruitment of private companies to be the partners for the PoC was explained. In addition, information was provided on the general situation of the healthcare sector in Indonesia, Kenya, and Brazil, trends in Covid-19 measures, and digital health needs based on the results of a questionnaire survey of local medical facilities. In addition to inviting companies directly from the survey team, the information was widely publicized by posting information on the websites and mailing lists of JICA, Japan Medical Venture Association, United Nations Forum, and Washington DC Development Forum. The number of viewers on the day of the seminar, excluding the management staff, was 62. At a later date, the seminar was recorded and distributed to the participants with seminar materials and application guidelines.

１－３． First screening

The first screening was based on document review, and the following 3 documents were submitted.

① Confirmation of interest in PoC (target country, target medical facility, and target issues)
② Proposal for PoC target technologies and services
③ Draft of presentation materials on PoC target technologies and services for the meet-up session

As a result, applications from 7 companies in Brazil (7 products), 7 companies in Kenya (7 products), and 14 companies in Indonesia (15 products) were submitted.

The following first screening criteria were established, and the submitted applications were evaluated and scored by the STI/DX Office of the Governance and Peacebuilding Department of JICA and the survey team.

Table VII-1 Evaluation items for the first screening

Evaluation Points	Detailed Items	Points
Resolvability of the problem	The implementation policy is based on accurate recognition of current problems.	5
	The proposed technology/service has the potential to contribute to solving problems in the target country and target medical facility.	5
	The proposed technology/service is recognized as relevant to COVID-19 measures.	5
	Use cases are clearly stated.	5
Competitive advantage	Competitive advantage compared to other products and services in Japan and the target country is demonstrated.	5
Adequacy of the PoC plan	The items to be verified are clear.	5
	The demonstration method for the items to be verified is simple and feasible in the target country and field.	5
	It is possible to quantitatively measure and evaluate the effects after PoC.	5
	The proposed technology/service is highly feasible, taking into account the local ICT situation and telecommunications infrastructure conditions.	5
	Risks to be considered in PoC implementation and their solutions are discussed and organized in advance.	5
Adequacy of schedule	PoC detailed design and PoC implementation is appropriately scheduled.	5
	Necessary preparations such as localization, customization, etc. are well taken care of.	5
Adequacy of operating structure	The responsible person is clearly indicated, and the system for implementing the PoC is sufficiently organized.	5
	The responsible person has the necessary language skills for PoC implementation.	5
	Has a local subsidiary or local partner company in the target country or neighboring countries.	5
Feasibility of commercialization	The business scheme of the target technology/service is clearly indicated.	5
	Prospects for business development and expansion in the target country and neighboring countries after PoC.	5
Stability as a corporation	Has experience in sales and implementation of products and technologies in Japan.	5
	Has experience in sales and implementation of products and technologies overseas.	5

Source: Compiled by survey team

As a result of the screening, the top 10 or so companies were selected from among the applicants from each country. 7 companies from Brazil, 7 companies from Kenya, and 11 companies from Indonesia passed the first screening. For details on the companies that applied for the first screening and their solutions and scores are referred to Appendix 9.

１－４． Meet-up session

In order to provide an opportunity for the companies that passed the first screening to introduce their solutions to medical facilities in each country, online local seminars were held in each country on the schedule shown below. At the meet-up sessions, the JICA STI/DX Office explained about the JICA Global Healthcare Initiative and JICA DX, and the survey team gave an overview of the project. Then, the companies that passed the first screening made pitches to introduce their solutions to the local medical facilities.

Table VII-2 Schedule of meet-up session

	Date and time (Japan time)
Indonesia	August 10, 2021, 12:00~14:20
Kenya	August 10, 2021, 19:00~20:45
Brazil	August 11, 2021, 20:00~21:45

Source: Compiled by survey team

After the meet-up session, the local medical facilities were requsted to submit Expression of Interest (EoI) for the survey team to understand their interest in the products of Japanese companies, and EoIs from 5 facilities in Brazil, 6 facilities in Kenya, and 5 facilities in Indonesia were submitted. The list of medical facilities submitting EoI and companies expressing interest are referred to Appendix 10.

Based on the results of the medical facility's EoI and the Japanese company's confirmation of interest in implementing the PoC (Document 1), a "match" was made if both parties were interested. If a match was made, each company was notified and a workshop was set up as necessary for joint proposals. In addition, in cases that only a medical facility expressed interest, the survey team notified the company of their interest and set up a workshop for the company that wished to have a conversation with the medical facility.

１－５． Second screening

For the second round of screening, the following 8 items were submitted as documents.

① Business development plan in the target country
② PoC implementation method (Problem solving verification)
③ PoC implementation method (Technical verification)
④ PoC implementation method (Business feasibility verification)
⑤ PoC implementation schedule
⑥ PoC implementation system
⑦ PoC budget planning
⑧ Joint proposal agreement for PoC with local medical facilities (*Optional submission)

As a result, applications from 5 companies (5 products) in Brazil, 5 companies (5 products) in Kenya, and 8 companies (8 products) in Indonesia were submitted. For details on the companies applying for the second screening and their solutions and scores are referred to Appendix 11.

On September 16, 17 and 21, 30-minutes screening interviews were held with each applicant company. The following secondary screening criteria were established, and the proposals were evaluated and scored by the JICA STI/DX Office, JICA field offices, JICA Human Development Department, and the survey team. As mentioned document "⑧Joint proposal agreement for PoC with local medical facilities" it could be submitted only if the agreement was reached by the deadline, and additional points were given as follows.

Table VII-3 Evaluation items for the second screening

Evaluation Items	Evaluation Points	Detailed Items	Points
Business Development Plan 30 points	Feasibility of Business Development	Have a hypothesis for business development after the PoC in the target country, such as understanding the market environment, setting target customers, and growth strategy.	10
	Development Impact	Contribute to the resolution of important issues in the medical field in the target country. Socioeconomic impact is expected.	10
	Risk Analysis	There are no laws or regulations that may be in conflict with the PoC implementation. If there are, the solution is clearly indicated.	6
		Have a hypothesis on the main disincentive/risk in business development.	4
PoC Implementation Plan 50 points	Adequacy of Objectives and Methods	The purpose of the PoC implementation is clear, specific, and feasible.	9
		The purpose, method, contents, and evaluation criteria for "verification of problem solving" are clear, specific, and feasible.	12
		The purpose, method, contents, and evaluation criteria for "technical verification" are clear, specific, and feasible.	12
		The purpose, method, contents, and evaluation criteria for "business feasibility verification" are clear, specific, and feasible.	12
	Adequacy of Schedule	Appropriate and detailed schedule has been proposed to implement the PoC for 3 months by the end of February 2022.	5
PoC Implementation Structure 20 points	Adequacy of Operating Structure	The responsible person of the Japanese company in the target country is clearly indicated, and the system for implementing the PoC is sufficiently organized.	8
		The responsible person of the medical institution in the target country is clearly indicated, and the system for implementing the PoC is sufficiently organized.	8
		The responsibilities and roles of the workforce are clearly indicated.	4
Other 5 points	Other	A cooperation agreement has been obtained from the medical facility where the PoC will be implemented.(Points will be added if agreement has been obtained.)	5
		Total	105

Source: Compiled by survey team

２． Results of Selection

After considering the balance of companies and diversity of solutions in the three target countries, 2 companies in Brazil, 2 companies in Kenya, and 3 companies in Indonesia were selected. OUI Inc. scored high in the three target countries, but was selected only in Kenya. Because they targets a limited area of pediatric ophthalmology in Indonesia, and it is difficult to actually use the product in Brazil due to local regulations. Their proposal for PoC in Kenya was evaluated as the most realistic and effective for future development.

２－１． Brazil

Table VII-4 List of selected companies and PoC implementing medical facilities in Brazil

Company	Local Medical Facility	Solution
Techlico. Inc	Unimed Juiz de Fora	Rehamaru (Rehabilitation system using Mixed Reality)
ICHIGO LLC	Hospital das Clínicas da Faculdade de Medicina da Universidade de São Paulo （HCFMUSP）	Teleradiology / Telepathology IT Platform Service

Source: Compiled by survey team

２－２． Kenya

Table VII-5 List of selected companies and PoC implementing medical facilities in Kenya

Company	Local Medical Facility	Solution
OUI Inc.	Ushirika Medical Clinic City Eye Hospital	Smart Eye Camera
Melody International Ltd	Nairobi Women's Hospital	Mobile Fetal Monitor iCTG

Source: Compiled by survey team

２－３． Indonesia

Table VII-6 List of selected companies and PoC implementing medical facilities in Indonesia

Company	Local Medical Facility	Solution
MITAS Medical Inc.	North Smatera University Hospital	Remote consultation service to ophthalmology using a smartphone-based mobile slit lamp
Precision Inc.	Harapan Kita Mother and Children Hospital	AI Clinical decision support
Allm Inc.	Indonesian Society of Pediatric Cardiology	Join

Source: Compiled by survey team

３． Assessment of PoC

３－１． Brazil

（１） Techlico Inc.

１） Overview of PoC Target Solutions

A rehabilitation system for higher brain dysfunction, including stroke and dementia patients, using MR technology (Rehamaru), is a content and analysis software developed based on the goal of making rehabilitation fun and effective.

Rehamaru uses MR technology to implement brain-related rehabilitation, which has traditionally been carried out with paper and pencil, in a three-dimensional way. Since the rehabilitation needed by patients is to support their return to the three-dimension of daily life, there is a great potential demand for rehabilitation in a three-dimensional space.

Also, by using Rehamaru, it is possible to quantify and automatically accumulate data such as rehabilitation records and effectiveness measurement results. In particular, the acquisition of eye movement history is important data for understanding the progress of a patient's rehabilitation, but until now it has been necessary for medical personnel to visually observe the patient's eye movements. Rehamaru system can quantitatively measure eye movements and automatically store the data. (For details of the PoC, please refer to the appendix 12.)

２） Medical facilities where PoC is conducted

Hospital Unimed Juiz de Fora (HUJF), which was selected through a PoC selection process, is a medical facility managed by the Juiz de Fora branch of Unimed, a major private insurance company in Brazil, and has a rehabilitation center in the facility.

３） Issues of target country

The number of occupational thearapist is insufficient in Brazil. The annual number of strokes in Brazil is about 700,000, which is more than double the number of 300,000 in Japan. On the other hand, the number of therapists per 10,000 population in Brazil is 9.7, and it seems sufficient compaired with that the number of therapists per 10,000 population in Japan is 7.9. However, the number of occupational therapists per 10,000 in Brazil is 0.8, which is far less than the number of occupational therapist per 10,000 in Japan of 5.1. Compared to physical therapists, occupational therapists provide rehabilitation of cognitive functions. Given these circumstances of therapists in Brazil, there is a possibility that rehabilitation of cognitive functions is not sufficiently performed.

In addition, according to an online questionnaire survey conducted for this project among medical facilities in Brazil, more than half of the medical facilities that responded indicated that patient follow-up including rehabilitation was insufficient and that there was a shortage of technicians including therapists.

Also, although this is not limited to Brazil, paper-based rehabilitation generally has the problem that patients tend to get bored and drop out of the program. In order to achieve therapeutic effects, it is important to keep patients from getting bored and to be able to provide continuous rehabilitation.

４） Purpose of PoC implementation

The solution to the issues of lack of follow-up to patients and lack of therapists, especially in the rehabilitation of cognitive functions, is to use ICT to improve their work efficiency and treat more patients with limited number of occupational therapists.

Rehamaru is a solution that focuses on cognitive functions, and by using ICT, it is possible to automatically execute rehabilitation, quantify objective data, and automatically store the data. With the introduction of Rehamaru, the workload of occupational therapists, who used to have to attend to patients during rehabilitation, take visual measurements, and record data manually, can be reduced. In addition, by improving the work efficiency per occupational therapist, it will be possible to provide rehabilitation to more patients.

In this PoC, the company will verify and confirm the effects of the introduction of Rehamaru, the infrastructure environment for considering business development, and the possibility of commercialization. The verification will be conducted from the 3 different perspectives of resolving local medical issues, related infrastructure, and business feasibility, and will include measurement of results based on specific verification methods, comparative analysis between initial assumptions and results, and suggestions obtained from the analysis, which will lead to development after this PoC.

５） Verification perspective 1: Resolving local medical issues

(a) Verification details

This study aims to verify whether the introduction of Rehamaru contributes to the improvement of work efficiency and rehabilitation effectiveness of occupational therapists in Brazil. The following hypotheses will be used as the main basis for the verification.

- In normal rehabilitation, it was not possible to know quantitative changes over time, but by understanding the quantitative data, it will be possible to provide guidance on the condition and future rehabilitation.
- Improve the efficiency of work per occupational therapist and contribute to resolving the shortage of therapists
- Higher patient motivation
- Improve the effectiveness of treatment for patients

(b) Verification method

Patients admitted to the HUJF will be divided into two groups, an intervention group that will receive rehabilitation with Rehamaru and a non-intervention group that will receive regular rehabilitation, and the effect of Rehamaru will be measured. Patients will be selected and assigned to each group randomly. The background, purpose, and content of the demonstration will be explained to the patients in advance, and written consent will be obtained for the handling of data and personal information. In addition, an occupational therapist will be assigned to each group, who will be in charge of the above target patients.

Table VII-7 Methods of testing hypotheses (Techlico Inc.)

Hypothesis	Verification Method	KPI
In normal rehabilitation, it was not possible to know quantitative changes over time, but by understanding the quantitative data, it will be possible to provide guidance on the condition and future rehabilitation.	Questionnaire	· Find out what the benefits of rehabilitating are.
Improve the efficiency of work per therapist and contribute to resolving the shortage of therapists	Questionnaire	· Identify the number of patients served by a therapist and the time spent per patient in the intervention group versus the non-intervention group.
Higher patient motivation	Questionnaire	· Percentage of drop-out rate between intervention group and non-intervention groups
Improves the effectiveness of treatment for patients	Questionnaire	· Analyze the effects of Rehamaru using the MMSE[223], a battery for assessing cognitive function.

Source: Compiled by survey team

(c) Verification results, analysis

In preparation for the implementation of the PoC, Techlico Inc. localized Rehamaru and completed the transfer of related equipment and materials to Brazil, but the implementation team-up at HUJF was not in place, and as a result, the PoC was not implemented until the end of the implementation period. With the global outbreak of COVID-19 Omicron strains since December 2021, the city of Juiz de Fora, Minas Gerais, where HUJF is located, has also experienced a rapid increase in COVID-19 patients, and this is the reason why JUJF has given top priority to COVID-19 patient care. In order to accommodate COVID-19 patients, general medical services, including rehabilitation, were suspended in principle, and the Rehabilitation Center, where PoC was scheduled to be conducted, was temporarily shut down. In addition, the HUJF management board decided to temporarily suspend collaboration with parties outside HUJF, such as this PoC, while COVID-19 patients are being treated. This background made it difficult to verify the hypothesis through PoC implementation.

[223] Abbreviation for Mini-Mental State Examination, MMSE is a type of testing method used to screen cognitive functions, and it enables to score and evaluate cognitive abnormalities, focusing on tasks such as naming objects explaining words, etc.

(d) Implications from the PoC

Although the PoC could not be implemented, the communication with HUJF during the preparation period showed a high interest in rehabilitation for higher-order functional disabilities from the medical facilities. Techlico Inc. will consider the possibility of continued collaboration in the future.

６） Verification perspective 2: Related infrastructure

(a) Verification details

Verify that there are no problems in the related infrastructure, such as communication infrastructure, when introducing Rehamaru. The verification is mainly based on the following hypotheses.

- Necessary facilities, equipment, and infrastructure are available
- Necessary and sufficient ICT literacy of users

(b) Verification method

Techlico Inc. will verify that there are no technical problems in communicating with HUJF through this PoC and in setting up the related equipment and systems.

Table VII-8 Method of testing hypotheses (Techlico Inc.)

hypothesis	Verification method	KPI
Necessary facilities, equipment, and infrastructure are available	Confirmation through PoC	・ Have a PC with a camera and be able to use online meeting tools such as Zoom
Necessary and sufficient ICT literacy of users	Confirmation through PoC	・ Able to operate PC, operation terminal and HoloLens

Source: Compiled by survey team

(c) Verification results, analysis

As described in the verification perspective 1, this PoC was not implemented, so the verification results could not be confirmed and analyzed through the PoC.

(d) Implications from the PoC

Although we were not able to confirm the environment through the PoC, the environment required for Rehamaru is fine as long as it is capable of sending and receiving emails and using online meeting tools such as Zoom. During the PoC preparation period, communication has been conducted through e-mails and multiple online meetings with the HUJF side, so it seems that HUJF has sufficient environment. In addition, Rehamaru is a system that can be operated by those who do not have a high level of ICT literacy, so it is not a problem if they can operate a PC, operation terminal, and HoloLens.

７） Verification point 3: Business feasibility

(a) Verification details

In a situation where there is a shortage of occupational therapists, there is a potential demand for improving the work efficiency of therapists. Based on the results obtained from this PoC, Techlico Inc. will examine whether the rehabilitation services provided by Rehamaru have the potential to be commercialized in Brazil.

(b) Verification method

In relation to the study of local commercialization and business models, Techlico Inc. interviewed Unimed Juiz de Fora, the Juiz de Fora branch of Unimed, a major private insurance company, about the general situation of the local healthcare system, insurance coverage for rehabilitation, and the business potential of rehabilitation from the perspective of an private insurance company. Techlico Inc. will also discuss the possibility of future collaboration with Unimed Juiz de Fora's medical and welfare equipment distributors and local partner companies.

(c) Verification results, analysis

Since the hearing with Unimed Juiz de Fora was planned to be discussed based on the results of the verification of the effectiveness of Rehamaru through this PoC, specific discussions were not possible due to the fact that the PoC was not implemented.

(d) Implications from the PoC

Techlico Inc. was not able to conduct concrete verification through interviews with Unimed Juiz de Fora and local companies. However, based on desktop research during the PoC preparation period, the shortage of occupational therapists in Brazil is a major problem as mentioned above. Techlico Inc. believes that there is a potential demand for increasing the efficiency of work and the number of patients that can be treated with limited medical resources.

８） Local laws and regulations

In order to start the PoC, the survey team checked whether there was a risk that the content of the PoC would conflict with local laws and regulations. A local law firm conducted a legal check and identified the following local laws and regulations and legal concerns for the PoC to be conducted by Techlico Inc.

- In this PoC, the provision of solutions for the purpose of rehabilitation itself does not fall under the scope of Brazilian physician practice, nor does it fall under the scope of physical and occupational therapist practice.
- On the other hand, if an accident occurs, such as the death of a patient, and it is determined that the solution provided by the company was the cause of the accident, the company that provided the solution may be held criminally, civilly, or administratively liable.
- It is possible to stipulate a disclaimer of liability between HUJF and Techlico Inc.. However, a memorandum of understanding is not sufficient, and a written contract that stipulates the disclaimer must be exchanged. The disclaimer does not apply to civil lawsuits with patients and their families.

the role of Techlico Inc., which provides solutions for rehabilitation in PoC activities, does not fall under medical treatment in Japan, nor does it fall under the legal scope of medical treatment in Brazil. On the other hand, according to the local law firm, the PoC activity itself for the purpose of rehabilitation of patients falls under the medical practice in Japan and is within the legal scope of the doctor's practice in Brazil, which is a common and exclusive practice of physical and occupational therapists.

In Brazil, the term "medical practice" does not exist, but is defined by profession, such as the practice of a doctor or the practice of an occupational therapist, and the authority and responsibility of each is defined by individual laws. Physician's acts are regulated by the Physician Act (Act No. 12,842/2013). Rehabilitation is included in the legal scope of practice of physicians, but it is not listed in the exclusive scope of practice of physicians as defined by the Clause 4 in the law, and is therefore the subject of activities of other professionals such as physiotherapists and occupational therapists. On the other hand, the acts of physiotherapists and occupational therapists are regulated by Resolution No. 8/19 of the Federal Federation of Physiotherapists and Occupational Therapists (COFFITO). The resolution stipulates in 2Article I that "the technical and methodological planning, programming, direction, coordination, implementation and supervision of physiotherapy and occupational therapy for health purposes at the primary, secondary and tertiary prevention levels are the exclusive fields of activity of physiotherapists and occupational therapists."

Although the provision of the solution itself does not constitute a therapeutic act, the possibility of criminal, civil, or administrative liability on the part of the company providing

the solution in the event of an accident caused by the solution cannot be denied. It is necessary not only to ensure the safety of the solution itself, but also to provide doctors and occupational therapists who will actually use the solution with sufficient guidance on how to use it and how to respond to emergencies.

Regarding tele-rehabilitation by physiotherapists and occupational therapists, COFFITO issued resolution 516 on March 20th in 2020, stating that tele-rehabilitation will be allowed during the COVID-19 disaster. However, at present, tele-rehabilitation by physicians, physical therapists, and occupational therapists is only allowed on a temporary basis during the COVID-19 disaster, and a separate law on tele-rehabilitation after the end of COVID-19 is needed.

９） During PoC preparation

Rehamaru Operation Manual　　　　Rehabilitation Menu

Source: Compiled by survey team

１０） General comments

In urban areas in Brazil, there is sufficient infrastructure for the introduction of Rehamaru, and local procurement of related equipment is generally considered to be no problem, but issues remain in the establishment of the PoC and project implementation team-up in Brazil. In Brazil, the number of COVID-19 patients and deaths is high compared to the rest of the world, and the burden on medical facilities is high because of the repeated spread of infection. In the case of COVID-19 in Brazil, there is a need to deal with patients infected with COVID-19 and patients under normal care. Until the situation of COVID-19 in Brazil settles down, it is necessary to explore the possibility of continuous collaboration in the future under such unstable conditions.

It was also difficult to communicate with the local people when Techlico Inc. were preparing for the PoC. Because of the 12-hours time gap, email-based communication often required a 1round trip in 2 days, which was time consuming. In addition, there were many cases where communication in English did not go smoothly, requiring translation into Portuguese or interpretation each time. When communicating with Brazil, it is good to use Portuguese as much as possible, and although it is a minor point, it is important to include interpreters and translators in the implementation team.

（２） ICHIGO LLC

１） Overview of PoC Target Solutions

ICHIGO LLC provides a system and related equipment (iCOMBOX) that allows remote radiologists to respond to remote radiological diagnostic support between different medical facilities that are not connected by a system. iCOMBOX includes a DICOM standard radiology image viewer system, reporting system, other related systems, and iCOMBOX, which is a network communication device. iCOMBOX does not require a special line and can be installed relatively easily by using a general broadband line. In addition, reports via iCOMBOX can be linked with PACS already installed in medical facilities, which enables efficient collaboration among facilities. Radiological image data and patient information to be communicated are automatically anonymized to ensure safety. (For details of the PoC, please refer to Appendix 12.)

２） Medical facilities where PoC is conducted

Hospital das Clínicas da Faculdade de Medicina da Universidade de São Paulo (HCFMUSP), which was matched through the PoC selection process, was selected as the PoC implementation site. In addition, HCFMUSP is a tertiary care facility affiliated with the Faculty of Medicine of the State University of São Paulo, the largest public university in Brazil, and is one of the core hospitals in Brazilian healthcare. In the radiology department of HCFMUSP, an innovation hub called InovaHC has been established, where active research and PoC between industry, government and academia are being conducted.

３） Issues in the target countries

Brazil has the world's 5-largest area and the world's 6-largest population and is the country with the largest area and population in the Latin American region. The number of physicians in the country as a whole has reached a certain level, but in this vast country, physicians are unevenly distributed, especially in urban areas, and there is a disparity in access to medical care between urban and rural areas. The southeastern part of the country, where the major cities of Sao Paulo and Rio de Janeiro are located, accounts for 10.9% of the country's land area, but about half of the country's doctors are concentrated there. The number of doctors per 1,000 people in the north, where many indigenous people live, is less than half the number of doctors per 1,000 people in the southeast, and the0.6 number of specialists per 1,000 people is even lower.

４） Purpose of PoC implementation

It is necessary to correct the disparity in access to medical care caused by geographical limitations by introducing remote diagnostic imaging technology that connects medical facilities in large cities with those in rural areas.

When the COVID-19 infection started to spread in Brazil in the beginning of 2020, HCFMUSP had tried to establish a remote diagnostic imaging support system with 50 medical facilities in Brazil that are collaborating with HCFMUSP. However, there were problems with the operability, convenience, and security of the system that we attempted to introduce at that time, and HCFMUSP have not been able to implement it to date.

Since there is a high demand for remote diagnostic imaging support in the local market, this PoC will verify and confirm the effects of introducing iCOMBOX, the infrastructure environment for considering business development, and the possibility of commercialization. The verification will be conducted from the 3 different perspectives of resolving local medical issues, related infrastructure, and business feasibility, and will include measurement of results based on specific verification methods, comparative analysis between initial assumptions and results, and suggestions obtained from the analysis, which will lead to development after this PoC.

５） Verification perspective 1: Resolving local medical issues

(a) Verification details

In order to establish a remote diagnostic imaging support network using iCOMBOX, ICHIGO LLC will first verify whether iCOMBOX is an easy-to-use solution for users. The verification is mainly based on the following hypotheses. For users, requesting remote image diagnosis and sending and receiving diagnosis results via iCOMBOX is easy to operate.

(b) Verification method

The number of operator is 2, one of whom is assigned as the “requesting person” and another is the “radiologist.” Since it takes time to select another medical facility other than HCFMUSP to implement PoC, to obtain permission to implement PoC in the facility, and to set up iCOMBOX, the following 2 patterns of PoC sites were planned.

- Pattern1: iCOMBOX is installed and operated at different points in HCFMUSP.
- Pattern2: iCOMBOX is set up and operated both in HCFMUSP and in the homes of HCFMUSP affiliated doctors.

Table VII-9 Method of testing the hypothesis (ICHIGO LLC)

Hypothesis	Verification Method	KPI
For users, requesting remote image diagnosis and sending and receiving diagnosis results via iCOMBOX is easy to operate.	recording Questionnaire	・ Time required for request operation ・ Time required for diagnostic operation ・ Ease of use ratings from users

Source: Compiled by survey team

The iCOMBOX will be installed at each location of the Requesting Person and Radiologist, one for sending requests and one for reading. The requesting unit will be connected to the existing PACS in HCFMUSP for image acquisition. In addition, the iCOMBOX is connected via the Internet to the center server for management and relay (iCOM SERVER), which was established in Brazil by ICHIGO LLC. This creates a network that transmits radiological images taken at the HCFMUSP and diagnostic reports created in the HCFMUSP and at the doctor's home via the Internet.

During the PoC implementation period, the actual radiological images taken at HCFMUSP, such as CT and MRI images, will be used for communication. The system linkage information related to the communication within HCFMUSP will be obtained from HCFMUSP in advance, and the necessary settings will be made on iCOMBOX in advance before sending it to the site. At the site, the iCOMBOX will only be turned on after the LAN cable has been wired. As for the Internet, the Internet connection line used by HCFMUSP will be used as it is. In the case of the pattern2, the Internet connection line used at the doctor's home will be used for the Internet, and the Internet router and iCOMBOX will be connected by wire.

After the units are installed at the above 2 locations, ICHIGO LLC will follow up on the installation from Japan using Teams, the remote access tool "TeamViewer," and a VPN connection.

(c) Verification results, analysis

The iCOMBOX set was sent to Brazil for the PoC, but it took longer than expected to clear customs in Brazil and the procedures for receiving the package at the site were very complicated, so it was not possible to receive the package and conduct the PoC during the PoC period.

The initial plan was for the person of ICHIGO LLC to travel to Brazil, carry the iCOMBOX, and set it up at the PoC site. However, due to the increase in the number of patients infected with COVID-19 in Brazil due to the spread of COVID-19 Omicron strains since around the end of

2021, ICHIGO LLC decided to cancel the trip to Brazil and instead transport iCOMBOX by air. Since the customs clearance procedures are related to the complicated tax system in Brazil and take time to complete, the package has not been received even after more than a 1month has passed since it was confirmed that the package was stuck in the local customs. This background made it difficult to verify the hypothesis through PoC implementation.

According to JETRO, the following information was obtained regarding import customs clearance procedures by international courier (courier) service for Brazil.

- Small import shipments arriving at international airports in Brazil are subject to the simplified taxation system (Regime de Tributacao Simplificada) if they fall under the 3,000less-than-dollar rule at customs inspection, and a flat 60percentage of the CIF amount is levied as a single tax. It is common for couriers to pay this single tax in advance, pick up the cargo, and deliver it to the shipper.
- However, if the customs inspection determines that the value, volume, quantity, type, content, or use of the subject cargo does not correspond to the regulations, the simplified taxation system will not be applied, and a normal import declaration (DI), which is not simplified, will be required. In such cases, a "DI declaration" mark (carimbo) is stamped on the courier's air waybill, and the consignee has no choice but to separately request a customs broker for import customs clearance, which often results in the consignee having to hire a customs broker and go through payment procedures, resulting in extra time and costs.
- Even if the invoice price is less than a 3,000-dollar amount, depending on the assessed value by customs, or the intended use and quantity, it will be a normal import procedure. In this case, the procedure must be done by a registered importer (RADAR), and if the consignee does not have a RADAR, customs clearance will be virtually impossible.

(d) Implications from the PoC

The iCOMBOX itself is positioned as a network communication device, so there is usually no need to go through any special prior procedures or obtain any permits for transportation or customs clearance. In the past, when iCOMBOX was shipped overseas, it was not stopped by customs as in this case, so this was an unforeseen situation for the company.

On the other hand, as mentioned above, there are detailed regulations for import procedures in Brazil, and furthermore, once a shipment is stopped at customs, the procedures for receiving the shipment are extremely complicated and require the use of a specialized company. In addition, the necessary measures vary depending on the decision of the customs, so it is necessary to check with a specialized company before shipping to Brazil.

６） Verification perspective 2: Related infrastructure

(a) Verification details

For this PoC, we will build a new data center in Amazon Web Service (AWS)'s Brazil region to verify the performance of communication in Brazil.

- Data communication through iCOMBOX and iCOMSERVER can be carried out smoothly.

(b) Verification method

To measure the communication speed, CR, MRI, CT, MG, PET and ES images are sent each 10 times in the morning, afternoon and evening. Each data is sent, and the arrival time of data from iCOMBOX for transmission request to iCOMSERVER and from iCOMSERVER to iCOMBOX for reading is measured and evaluated from the record log on the iCOMSERVER side.

Table VII-10 Method of testing the hypothesis (ICHIGO LLC)

Hypothesis	Verification Method	KPI
Data communication through iCOMBOX and iCOMSERVER can be carried out smoothly.	Recording	・ Time required for request operation ・ Time required for diagnostic operation

Source: Compiled by survey team

(c) Verification results, analysis

As mentioned above, it was not possible to verify the results using iCOMBOX and iCOMSERVER during the PoC implementation period, which made it difficult to measure and analyze the results.

(d) Implications from the PoC

Communication with iCOMSERVER set up in Brazil could not be confirmed, but since iCOMBOX and iCOMSEVER are located in the same region of Brazil, no major technical problems are expected to occur.

７） Verification point 3: Business feasibility

(a) Verification details

Based on the results obtained from this PoC, we will verify whether the remote diagnostic imaging support network provided by iCOMBOX has the potential to be commercialized in Brazil.

(b) Verification method

The following aspects will be confirmed mainly through interviews with HCFMUSP.

- Potential use cases for iCOMBOX implementation
- Proposed specific schemes for billing methods (charging diagnostic fees), cost sharing, etc., with a view to future commercialization
- Desired technical support from ICHIGO LLC to HCFMUSP, and whether or not support can be obtained from the IT department within HCFMUSP.
- Formulation of a plan to expand the remote diagnostic imaging network using iCOMBOX, and understanding the scale of the 50-hospital network centered on HCFMUSP

(c) Verification results, analysis

Since the hearing with HCFMUSP was planned to be based on the results of the verification of the effectiveness of iCOMBOX through this PoC, specific discussions were not possible due to the fact that the PoC was not implemented.

Although no concrete discussions have been held, HCFMUSP recognizes that there are significant issues in telemedicine collaboration, especially with medical facilities within the HCFMUSP network, and has expressed high interest in iCOMBOX that enables telemedicine. HCFMUSP's intention is to introduce iCOMBOX to other medical facilities on a trial basis as a post PoC phase, and to establish a remote image diagnosis support network system using AI in the future.

(d) Implications from the PoC

The top referral hospitals in Brazil, such as HCFMUSP, are aware that there are challenges in collaborating with their affiliated medical facilities, and there is a great demand for the establishment of a telemedicine network infrastructure in Brazil. In addition, since Brazil's top referral hospitals have a large network or are affiliated with a large network, if companies can collaborate with the core medical facilities in the network, it will be easier for them to develop their business.

８） Local laws and regulations

In order to start the PoC, we checked whether there was any risk that the content to be implemented in the PoC would conflict with local laws and regulations. As a result of the legal check by the local law firm and the confirmation of local laws and regulations and legal concerns in the PoC to be conducted by ICHIGO LLC, it was confirmed that there were no major concerns.

- In this PoC, since the target of the solution is not a patient, it does not correspond to the actions of a doctor or other person in Brazil.

・ Since there is no possibility of patient death or other accidents caused by this PoC, there is no possibility of criminal, civil, administrative, or other liability on the part of the company.

９） During PoC preparation

patientid	modality	studydate	series	images	studyinsuid
case_101_02	CT	20120419	3	81	1.2.392.200036.9132.1.201.1100201239.02.03
case_102_02	CT	20081122	1	36	1.2.392.200036.9132.100.143.20081122201536748.02.03
case_103_02	CT	20120421	5	915	1.2.392.200036.9132.1.201.1100196592.02.03
case_104_02	CT	20130212	6	761	1.2.392.200036.9132.1.201.1100932074.02.03
case_105_02	CT	20140118	8	1994	1.2.392.200036.9132.1.201.1101815579.02.03
case_106_02	CT	20090608	5	1075	1.2.392.200036.9132.100.143.2009060801973607.02.03
case_107_02	CT	20131011	6	1305	1.2.392.200036.9132.1.201.1101573733.02.03
case_108_02	CT	20131227	10	2018	1.2.392.200036.9132.1.201.1101770295.02.03
case_109_02	CT	20121024	10	904	1.2.392.200036.9132.1.201.1100683163.02.03
case_110_02	CT	20140117	3	656	1.2.392.200036.9132.1.201.1101812919.02.03
case_01_02	MR	20140718	22	799	1.2.392.200036.9132.1.201.1102272475.02.03
case_02_02	MR	20140707	11	331	1.2.392.200036.9132.1.201.1102250413.02.03
case_03_02	MR	20140718	11	335	1.2.392.200036.9132.1.201.1102279689.02.03
case_04_02	MR	20140723	11	334	1.2.392.200036.9132.1.201.1102127282.02.03
case_05_02	MR	20140723	13	739	1.2.392.200036.9132.1.201.1102143883.02.03
case_06_02	MR	20140801	10	324	1.2.392.200036.9132.1.201.1102315561.02.03
case_07_02	MR	20140729	6	69	1.2.392.200036.9132.1.201.1102257614.02.03
case_08_02	MR	20140422	13	495	1.2.392.200036.9132.1.201.1102038683.02.03
case_09_02	MR	20140807	13	356	1.2.392.200036.9132.1.201.1101881897.02.03
case_10_02	MR	20130821	14	674	1.2.392.200036.9132.1.201.1101439136.02.03

Sample of data used to measure communication speed

Source: Compiled by survey team

１０） General comments

Especially through the discussion with HCFMUSP, it was felt that there is a high potential demand for telemedicine in Brazil. HCFMUSP is also interested in tele-surgery using surgical robots and high-capacity lines, and has confirmed that there is also a demand for more advanced telemedicine other than conventional telemedicine, such as tele-advisory, tele-consultation, and tele-imaging/pathology. On the other hand, there are a lot of institutional challenges to doing business in Brazil, and the barriers to entry seem to be high. In addition to the fact that ICHIGO LLC was not able to clear customs this time, there is the issue of the complicated tax system in Brazil. According to an interview with the JETRO Sao Paulo Office, each administrative district of the government, state, and city in Brazil has its own tax system, which is a complicated structure. As a result, the tax and general affairs departments in companies have a heavy workload to conduct business in Brazil. Even at the PoC stage, it is important to find a local partner company in advance and establish a collaboration team-up.

３－２． Kenya

（１） OUI Inc.

１） Overview of PoC Target Solutions

Smart Eye Camera (SEC), a smartphone-attached medical device. This is a product that makes it possible to diagnose almost all anterior eye diseases as inexpensively and easily as with existing slitlamps by using the camera and light source of a smartphone and implementing the "light shape" and "magnifying and imaging" mechanisms necessary for

diagnosis.

OUI Inc. have completed the registration of medical devices in Japan (2016) and European Union (2016), and CE marking. In Kenya, where the PoC have conducted this time, the registration of the local medical device was completed by PPB on the September 8, 2109.

With the introduction of SEC, medical professionals in rural areas will be able to take ophthalmic images with SEC and transmit the data to ophthalmologists in urban areas via smartphones. (For details of the PoC, please refer to Appendix 12.)

２） Medical facilities where PoC is conducted

Coast General Teaching and Referral Hospital (CGTRH), a public tertiary care hospital, and Ushirika Medical Clinic (UMC), a private primary care hospital, were matched through the PoC selection process. However, CGTRH is currently in the process of developing its ophthalmology department, and informed that collaboration during this PoC period is no longer possible. As a result, City Eye Hospital (CEH), a private medical facility, was newly selected as the PoC implementation partner instead of CGTRH, and the PoC was conducted by connecting the 2 bases of CEH and UMC.

CEH is a private medical facility that provides eye care in and around Nairobi, and UMC is a private primary health care provider that provides medical care to the poor in Kibera Slum, the largest slum in East Africa, located in Nairobi, the capital of Kenya.

３） Issues of target country

According to the International Agency for the Prevention of Blindness (IAPB), there are about 4 million population suffering from visual impairment [224] and about 320,000 population suffering from blindness in Kenya as of 2020[225]. The number of ophthalmologists is about 120[226], which is about 0.22 ophthalmologists per 100,000 population, which is lower than the number of ophthalmologists per 100,000 population in Japan, which is about 11. The causes of blindness are cataract in 43%, trachoma in 19%, and glaucoma in 9%. Both cataract and trachoma are diseases of the anterior segment of the eye that can be diagnosed by the SEC, and with appropriate treatment and surgery, blindness can be prevented or treated[227].

[224] Population (2020) 53.8 million multiplied by blindness (CRUDE) 0.60%. https://www.iapb.org/learn/vision-atlas/magnitude-and-projections/countries/kenya/
[225] Population (2020) 53.8 million multiplied by all vision loss (CRUDE) 7.50%. https://www.iapb.org/learn/vision-atlas/magnitude-and-projections/countries/kenya/
[226] https://www.iapb.org/learn/vision-atlas/magnitude-and-projections/countries/kenya/
[227] Karimurio, African Program in Kenya, Community Eye Health Vol 13 No. 36 2000

In the field of ophthalmology in Kenya, social issues such as the shortage of ophthalmologists and ophthalmic equipment in relation to the size of the population and the uneven distribution of ophthalmologists are prominent, and access to ophthalmic care is limited, especially in rural areas. These restrictions on access to specialized medical care may hinder the early detection and treatment of ophthalmic diseases that are preventable and treatable.

４） Purpose of PoC implementation

In order to improve the limited access to specialized ophthalmology care due to the shortage of ophthalmologists and medical equipment, collaborate with ophthalmologists and medical professionals at CEH and UMC to verify the establishment of a remote diagnosis model that connects primarycare facilities and higher-level medical facilities with the SEC and its dedicated application.

In addition, UMC is providing primary health care to the residents of Kibera slum, the largest slum in East Africa. The establishment of tele-diagnosis model that can provide poor Kibera residents with opportunities for appropriate examination, diagnosis and treatment of preventable eye diseases. It is expected to benefit those who cannot access medical care for economic reasons.

In this PoC, we will verify and confirm the effects of the introduction of the SEC, the infrastructure environment for considering business development, and the possibility of commercialization. The verification will be conducted from the perspectives of local medical issues, related infrastructure, and business feasibility, and will include measurement of results based on specific verification methods, comparison and analysis of results with initial assumptions, and suggestions obtained from the analysis.

５） Verification perspective 1: Resolving local medical issues

(a) Verification details

The following hypotheses will be tested to determine whether it is possible to provide appropriate eye care services to patients in a primary health care facility that does not have a resident ophthalmologist and only staff with no knowledge of ophthalmology, thereby promoting the prevention and treatment of eye diseases among patients with UMC.

- Even at a primarycare facility without ophthalmologist, medical personnel can take photographs of the patient's eyes using SEC and send the data to ophthalmologist at a higher-level medical facility in remote area for consultation.
- An ophthalmologist in remote area can make a diagnosis based on the data and send the diagnosis and treatment to primarycare facility.

(b) Verification method

UMC staff will use the SEC to photograph the patient's eye and send the data to the CEH ophthalmologist via SEC app, so that the CEH ophthalmologist can diagnose the patient from a professional standpoint. The following KPIs will be checked to (a) hypothesis described in the validation details. Since the data will be uploaded to the cloud, the OUI Inc. check whether the data is properly uploaded and is sufficient quality for diagnosis.

VII-1 Methods for testing hypotheses (OUI Inc.)

Hypothesis	Verification Method	KPI
Even at a primarycare facility without ophthalmologist, medical personnel can take photographs of patient's eyes using SEC and send the data to ophthalmologist at higher-level medical facility in remote area.	Recording	・ Number of data that could be uploaded to cloud
The ophthalmologist in remote area, can make a diagnosis based on data and send the diagnosis and treatment to the primarycare facility from remote area.	Recording	・ Percentage of data of sufficient quality to make an appropriate diagnosis

Source: Compiled by survey team

(c) Verification results, analysis

During the PoC implementation period, one outreach activity was conducted in collaboration with CEH and UMC on January 24, 2022. In this outreach, the SEC was used to examine about 150 residents and collected data for 94 patients. The results according to the KPIs described above and their analysis are as follows.

(i) Number of data that could be uploaded to the cloud

The SEC was handed over to UMC in November 2021, just after the PoC started, and online training was conducted. In November, we visited UMC and gave a tutorial on how to use SEC directly to the UMC staff. After 30 minutes training, the UMC staff was able to take eye videos at diagnostic level.

Due to technical problems such as the local communication infrastructure, we were not able to upload the videos we took. However, after much consideration, we were able to solve

the problems and the videos were successfully uploaded to the cloud server. The technical issues and their cause analysis will be described in detail in the verification perspective (2) below.

On the other hand, UMC staff did not enter patient IDs in SEC application, so there was still an operational issue that the data did not match the patients in the cloud. The UMC had to manually enter this information later.

On January 24, 2022, CEH staff visited UMC to conduct eye screening of patients. In the post-intervention interviews, the participants commented that the SEC made it possible to use a slit light instead of a torch light, which greatly improved the accuracy and efficiency of the diagnosis.

(ii) Percentage of sufficient quality data to make appropriate diagnosis

Approximately 90% of the uploaded data were of low quality and did not reach a diagnostic level, such as images with less information due to the angle of the SEC being applied from angle rather than from the front, or images where the eye was not included in the captured image in the first place.

The reason for this is that most of the images taken were from the ice screening conducted by CEH and UMC, and since CEH staff were in the field and conducted the screening jointly, there was little practical need for UMC to take images with sufficient quality, and therefore, insufficient care was taken when taking the images. This may be due to the fact that the UMC did not need to take sufficient quality images.

In addition, since the UMC staff was able to take pictures without any problem during the on-site training when OUI Inc. visited UMC in November 2021, it is possible that the staff forgot the points when taking pictures, such as the need to point the camera from the front, due to the time that has passed since the training. This was also the reason why the staff forgot to take precautions when filming, such as pointing the camera at the front.

(d) Implications from the PoC

Although they were able to capture images of sufficient quality during the initial training, they did not perform well during screening. This may be due in part to the staff's lack of understanding of what constitutes a good image. It is important to gradually improve the results by showing reference images and providing a lot of individual feedback. In addition, before the next screening, the staff will be given another training session on the imaging method online.

On the other hand, when providing training to staff, it is important to have some kind of incentive to motivate them. One of the specific ways to provide incentives is to create a lecture course on how to use the SEC and to develop it in a way that gives points to Kenyan medical staff to renew their qualifications.

Another issue not related to the above hypothesis and KPIs was that CEH's commitment and involvement was weak and did not respond in a timely manner as a result of discussions with UMC. The fact that the imaging images from the UMC side were not up to diagnostic standards may have been one of the main reasons for the weak response from the CEH. Therefore, one of the solutions is to improve the imaging skills of the UMC staff so that they can take ophthalmologic images of a quality that would be acceptable to ophthalmologists of higher medical facilitys. In addition, busy ophthalmologists at high level medical facilities may face high time and psychological hurdles to promptly diagnose and describe the diagnosis results from scratch for each reading request. It is also important to provide ophthalmologists with a template of answers for diseases that they are likely to encounter in order to increase the involvement of high level medical facilities.

６） Verification perspective 2: Related infrastructure

(a) Verification details

To technically verify that there are no problems in the related infrastructure, such as communication infrastructure, when introducing SEC. The verification is mainly based on the following hypotheses.

- Uploading videos from the dedicated app can be done smoothly.

(b) Verification method

The results were recorded in terms of table below when the videos were uploaded from the primarycare facilities via dedicated application.

VII-2 Methods for testing hypotheses (OUI Inc.)

Hypothesis	Verification Method	KPI
Uploading videos via dedicated app can be done smoothly.	Recording	・ Number of data that could be uploaded to cloud

Source: Compiled by survey team

(c) Verification results, analysis

(i) Uploading videos via dedicated app can be done smoothly.

As mentioned above, at the beginning of PoC, there was a problem in uploading data via dedicated application to the cloud and uploading continued to be impossible. As a result of interviewing a local company that develops cloud-based applications for healthcare in Kenya, they pointed out the possibility of a problem with the location of the cloud server.

From December to January, we changed the configuration of AWS, which was being used as the cloud server for the SEC app. And restructured the routing so that images taken in Kenya using the SEC app would be transferred from that location to the cloud server in Japan via the nearest AWS server, and the data would be uploaded successfully from UMC.

(d) Implications from the PoC

Since there are no cloud regions in Kenya, any cloud-based solution will need to go through the nearest country or regional region. Since the physical distance between these regions can cause problems in uploading data, it is important to consider the most appropriate cloud region geographically when considering entering a new market in another country.

With regard to the region of cloud servers, an important point of discussion is the relationship with Data Protection Act enacted in Kenya in 2019. In particular, the setting of cloud server regions outside of Kenya is not clearly defined in the Data Protection Act, and the interpretation and concept of this is still unclear, requiring careful consideration.

On the other hand, when we interviewed several local companies that have already developed cloud-based healthcare applications, they told us that they have established governance systems for information management and security systems, and have set up cloud servers outside of Kenya with a system in place to explain these systems. In the future full-scale demonstration, we will also verify how cloud data should be used in compliance with local regulations, in cooperation with local lawyers and advisors.

７） Verification point 3: Business feasibility

(a) Verification details

In order to develop SEC in Kenya, examine the purchase intention and sales price through interviews with local medical professionals who are actual potential customers. Also discuss the local manufacturing system based on the interviews.

(b) Verification method

We visited ophthalmologists and medical professionals in Kenya and conducted demonstrations of SEC, usability hearings, and interviews about their intentions to

purchase SEC and their sense of price. In addition to the existing iPhone-compatible model, we also evaluated the usability of the SEC universal model currently under development, which is compatible with other iPhone models and Android, and the direct imaging model, which enables diagnosis of the fundus.

(c) Verification results, analysis

The current iPhone-compatible model, which is only compatible with iPhone 7 8and SE2, poses a high initial hurdle in Kenya, where the iPhone is not widely used. As a result of the interviews, there was a high level of interest in the SEC universal model that is also compatible with Android.

In addition to the existing SEC for diagnosing frontal eye, we found that there was a great need to diagnose retina and other fundus parts as well. Ophthalmologists and medical staff who are usually skilled in diagnosing fundus were able to diagnose the optic nerve papillae of fundus with almost no problem on the first visit. Many people commented that if the existing anterior segment model and fundus model could be sold as a set, it would be very easy to use and they hoped for early commercialization.

There was a large discrepancy between the price assumed by ophthalmologists and the sales price in Japan. In addition, considering the purchasing power of primary medical facilitys, further cost reduction is considered necessary.

(d) Implications from the PoC

Since there is a high potential demand for SEC and the prototypes mentioned above, it is possible to increase the appeal of SEC as a solution by lowering the hurdles to implementation for local users, such as equipment design and affordability.

On the other hand, from the perspective of business feasibility and sustainability, there is room for reconsideration of equipment pricing, and a review of the production system, including local production, is considered necessary.

８） Local laws and regulations

In order to start the PoC, we checked whether there is a risk that the contents to be implemented in the PoC will violate local relevant laws and regulations. The legal check was conducted by a local law firm, and the following local laws and regulations and legal concerns were identified for the PoC to be conducted by OUI Inc.

- Although there is no clear definition of the category of medical treatment in the local laws and regulations, devices used on patients are treated in the same way as medical devices such as CT and MRI, and tests using such devices can be interpreted as part of medical treatment.

- According to Health Act (No. 12 of 2017), only qualified medical practitioners in Kenya are allowed to perform medical practices, and the medical facility where the PoC will be implemented will be required to perform the tests and analyze the test results for the patients. In the event that the test data obtained using the device is incorrect and affects the diagnosis of the local medical professionals, and as a result, the patient is harmed in some way, the company that provided the solution cannot deny the possibility of being held liable for third party or criminal liability.

In order to avoid the risks mentioned above, the local law firm suggests that PoC should be conducted based on thorough informed consent to the patient and the signature of the consent form. Informed consent should be given in accordance with the following principles at a minimum

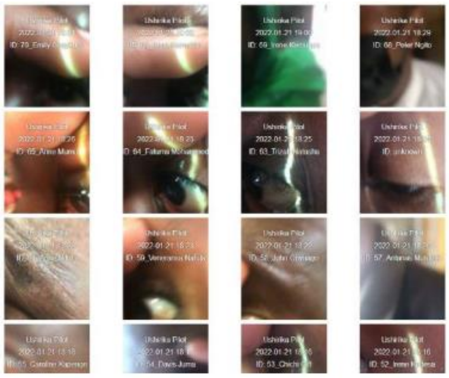
- Information and disclosure: Necessary information is disclosed to the patient.
- Competency: Patients have the ability to understand the information they are given.
- Comprehension: The patient actually understands the information given
- Voluntary: Allows for voluntary decision-making on the part of the patient
- Decision-making: The patient actually decides whether or not to proceed with the procedure.

9） During PoC implementation

User training

User training

Eye screening



Records in eye screening

Source: Compiled by survey team

１０） General Comments

Since OUI Inc. had completed the local medical device registration before the PoC, it was relatively easy to obtain approval for the PoC implementation in the medical facility where the PoC was to be implemented, and as a result, the PoC preparation and implementation were relatively smooth. Many of the problems identified during the implementation period can be expected to be improved by improving the users' photography skills, etc., and it is thought that the continuous use of the system in the future will contribute to solving local medical issues.

On the other hand, it remains a challenge to establish an implementation system that enables effective remote consultation among medical facilities. Ophthalmologists, who are scarce in number, are already busy providing medical care at the higher-level medical facilities to which they belong, and in order to provide remote consultation from primary medical facilities, it is necessary to consider a scheme that is realistic and sustainable for both the higher-level hospitals and primary medical facilities in terms of workload, incentives, and payment methods.

From a technical standpoint, cloud region setting is an important issue for solutions that are based on cloud servers. Although local laws and regulations are unclear regarding the use of regions outside of Kenya, there is a need for accurate interpretation of current laws and flexible responses to future changes in telemedicine laws and regulations.

（２） Melody International Ltd

１） Overview of PoC Target Solutions

The iCTG is a compact, lightweight, and mobile version of a delivery monitoring device. Furthermore, it is a medical device that can transmit the measured fetal heart rate and uterine contraction signals using data communication networks such as the Internet and has been approved as a medical device. Medical professionals can obtain the measured data via internet and use it for diagnosis. Since the device has a built-in battery, it can also be used in places where are no power source.

By attaching 2 transducers to surface of the pregnant woman's body to measure fetal heart rate and labor waveforms, it is possible to monitor fetal heart rate and uterine contraction strength non-invasively. This device is waterproof and can be rinsed and disinfected directly after each test, which is superior to other equipment in terms of infection control. (For details of the PoC, please refer to appendix 12)

２） Medical facilities where PoC is conducted

Nairobi Women's Hospital, which was matched through the PoC selection process, was found to require time for internal approval of the PoC implementation, so UMC, which had interest in iCTG, was selected as the PoC implementing facility. UMC is a private primarycare provider located in Kibera Slum, the largest slum in East Africa, where access to appropriate and regular prenatal checkups is limited.

３） Issues in the target countries

In Kenya, MMR has remained above the SDG target level, and appropriate medical approach for pregnant woman has become urgent issue. In addition, Kenyan government has made strengthening maternal and child health services as priority measure, and there are high hopes for improving MMR. However, the real problem is that many medical facilities do not have obstetricians and other specialists, making it difficult for pregnant women to access appropriate medical care.

In addition, most of the currently prevalent delivery monitoring devices are not easily affordable for primarycare facilities, and because they are large and wired, their

availability is limited in terms of facilities and space.

４） Purpose of PoC implementation

Introduction of iCTG in primarycare facilities and the ability of obstetricians and nurses in remote areas to monitor measured perinatal and fetal data and the health status of pregnant women are expected to contribute to solving issues such as the shortage of medical specialists and limited access to appropriate medical care in the region.

In this PoC, it is difficult to verify the effect of introducing iCTG for collaboration with high level facilities because PoC is implemented only at UMC, which is a primary medical facility. Instead, we will collaborate with UMC to verify and confirm the effects of iCTG implementation within the primary medical facility, as well as the infrastructure environment and commercialization potential when considering future business development. In the verification, we will set the contents of verification from the viewpoint of solving local medical issues, related infrastructure, and business feasibility. We will measure the results based on specific verification methods, compare and analyze the results with our initial assumptions, and summarize the suggestions obtained from the analysis, which will lead to the development after this PoC.

５） Verification perspective 1: Resolving local medical issues

(a) Verification details

The following hypotheses will be tested to determine whether the introduction of iCTG is useful in collecting appropriate data and understanding the health status of pregnant women within primarycare facilities.

- The measured perinatal and fetal data can be appropriately checked by health care providers in the primarycare institution and is useful for understanding the health status of pregnant women.

(b) Verification method

We will introduce iCTG to UMC, primarycare institution, to share information on pregnant women via internet, and check the usability of iCTG. iCTG will be used to treat pregnant women visiting the UMC without setting a target number of measurements during the PoC period.

VII-3 Method of testing hypotheses (Melody International Inc.)

Hypothesis	Verification Method	KPI
The measured perinatal and fetal data can be appropriately checked by medical personnel within the primarycare institution, and is useful for understanding the health status of pregnant women.	Recording. Questionnaire	・ Percentage of measurements conducted that yielded data useful for understanding health status.

Source: Compiled by survey team

In order to investigate whether iCTG is useful for medical treatment, we first provided training on how to use the iCTG to local supporters from Melody International Inc. During the PoC implementation period, the training by the local supporters was conducted about once a month, and the measurement data were periodically checked in the checkup room of UMC.

According to the preliminary interview with the UMC, they conduct antenatal checkups for about 10 patient every Thursday, and Non Stress Test (NST) is conducted once a month. NST conducted by PoC is based on the fetus heart rate data from 28 week and is performed in 40 minutes per measurement as the same time duration in Japan. In addition, it is assumed that the measurement data from the iCTG can be used for early detection of urgent pregnant women who need to be transported to a higher-level medical facility. A questionnaire survey will be conducted to ascertain whether it is useful for local clinical officers and nurses to assess the health status of the patients, including those in the field.

(c) Verification results, analysis

At the beginning of february in 2022, after the completion of user training, data measurement using iCTG was conducted for 4 pregnant women at UMC. The results of the validation according to the KPIs mentioned above and their analysis are as follows.

(i) Percentage of measurements conducted that yielded data useful for understanding health status.

Although we expected to measure data for 40 minutes per measurement, we were actually able to collect only about 5 minutes of measurement results. Therefore, we were not able to collect data of sufficient quality to understand the health status of the pregnant women who were measured.

Although pregnant women visited the clinic for the antenatal checkup at UMC in late January 2022, the UMC staffs were not able to check the data in the cloud because the user training was not completed at that time, and the internet was not stable and data communication did not take place. A local supporter who was scheduled for training visited UMC later in the day to measure the four pregnant women. Initially, two antenatal checkups were expected, but since the PoC started later than expected, the number of monitoring during the PoC implementation period was only this time, and the total number of pregnant women to be measured was four.

According to the UMC, it took about 10 minutes to prepare the conventional delivery monitoring system, but it took about 20 minutes to prepare the iCTG. Since the iCTG is designed to be used in a simple manner, we assume that the reason for this comment was that the users were not familiar with the preparation and use of the iCTG. In addition, if we assume that it takes 20 minutes preparation per pregnant woman, it will take about 200 minutes just for the preparation to measure all the pregnant women in the antenatal checkup, which is visited by about 10 pregnant women per day. Since it was not possible to make the pregnant women wait for almost three hours, the number of measurements during the PoC period was only four.

(d) Implications from PoC

Since the number of pregnant women to be measured was small, and it was difficult to collect the initially expected data in all four cases, we could not obtain sufficient information to determine whether the introduction of iCTG would contribute to the understanding of the health status of the pregnant women to be measured.

As a background to the difficulties in data collection, there is a possibility that the data was not properly uploaded to the cloud due to a problem in the local communication infrastructure and due to the waiting time of pregnant women. iCTG itself can transfer data to the monitors using Blootuth, but a problem may have occurred when uploading the data to the cloud. The iCTG itself can transfer data to the monitor by Blootuth, but there may have been a problem in uploading the data to the cloud.

In addition, there is a possibility that the users such as medical officers and nurses were not familiar with iCTG. We believe that more appropriate data collection can be solved by thorough training of the users. In addition, at the final meeting with UMC, the clinic requested that the number of devices, which was only one in the PoC, should be increased.

Thorough user training and increased proficiency are also expected to reduce the time required for related preparation and testing and increase the number of pregnant women that can be measured per testing equipment, thereby improving testing efficiency at primary medical facilitys.

6） Verification perspective 2: Related infrastructure

(a) Verification details

Technically verify that there are no problems in the related infrastructure, such as communication infrastructure, when introducing iCTG. The verification will be mainly based on the following hypotheses.

- Have necessary infrastructure in place at the destination facility.
- Enables smooth measurement of fetal data (40minute measurement transmission data, 20KB) by doctors, nurses, and pregnant women

(b) Verification method

At the primary care facility, when the data was transferred from the iCTG to the monitor and uploaded to the cloud, measurements were taken from the perspective of the table below, and the results were recorded. Melody International, Inc. checked the quality of the uploaded videos and confirmed that the data was properly measured and uploaded.

VII-4 Method of testing hypotheses (Melody International Inc.)

Hypothesis	Verification Method	KPI
Have necessary infrastructure in place at the destination facility.	Recording Questionnaire	・ Availability of relevant infrastructure available in the facility.
Enables smooth measurement of fetal data (40minute measurement transmission data, 20KB) by doctors, nurses, and pregnant women	Recording Questionnaire	・ Was it possible for the medical staff to upload the measured data smoothly?

Source: Compiled by survey team

(c) Verification results, analysis

(i) Availability of relevant infrastructure available in the facility.

Since iCTG communication is very light in terms of data volume (20KB), it was assumed that stable communication would be possible even in areas with poor communication

environment, but in reality, at the beginning of the PoC, there were times when the Internet was not stable and information could not be uploaded to the cloud. The iCTG enables data upload from the iCTG to the cloud with 3G or 4G local SIM inserted to iCTG, but during the PoC period, this Internet communication was considered unstable. This issue has been resolved, but drastic improvement of the communication instability will be an issue for further study.

(ii) Was it possible for the medical staff to upload the measured data smoothly?

Only when the test was conducted by UMC medical personnel only, the data was not uploaded properly, and the result cannot be denied that the problem was not only the local communication infrastructure but also the proficiency of the users.

We have confirmed that the data that was skipped by the local supporters on a test basis at the time of introduction was uploaded without any problem. On the other hand, measurements taken at the 1first antenatal check-up by UMC medical staff only, have not been able to upload the information to the cloud.

Later, when the local supporters followed up to measure the data for the second time, it was confirmed that the data of 4 pregnant women had been uploaded. However, it was not the 40 minutes of measurement data we had originally expected, but only about 5 minutes.

(d) Implications from the PoC

It was unclear whether the cause of the failure to properly upload the measured data to the cloud was a problem with the local communication infrastructure or a human error. If the communication infrastructure is weak, it will be necessary to strengthen the communication environment at the primary medical institution. However, it may be difficult for a single medical institution to improve the communication infrastructure, since it is thought that there are significant problems in terms of the number, placement, and stability of communication base stations in the vicinity. On the other hand, if the problem is caused by human error, it can be solved for a certain degree by providing appropriate and sufficient training to users in advance.

As for the problem that most of the measured data are within 5minutes, the shortage of medical personnel at UMC may be the cause. Many medical facilitys in Kenya have a shortage of medical personnel compared to the number of patients, and UMC is no exception. As a result of the shortage of personnel, it is suggested that the measurement time may be shortened because only the heartbeat is heard or it is measured in combination with conventional methods.

７） Verification point 3: Business feasibility

(a) Verification details

With shortage of obstetricians, there is a potential demand for improving the quality of

perinatal care provision and access to care in primary healthcare institutions. On the other hand, through this PoC, it was found that in many cases, the first condition for implementing a pilot project in Kenya is to have a local medical device registered. Therefore, we will first complete PPB registration as the first step toward commercialization. In the following, we will examine the feasibility of local medical device registration with a view to commercialization in Kenya.

(b) Verification method

Verify whether iCTG can be registered as a local medical device through interviews with the PPB. To introduce the iCTG as an official medical device in medical facilitys in Kenya, PPB registration will be conducted through Mediquip, a local distributor.

(c) Verification results, analysis

As a result of the hearing with PPB, medical devices are categorized into Class A to D according to the risks of device. The period for registration is as follows. According to the local distributor information as of late February 2022, iCTG will be classified as Class B.

Class A: 0 to 90 days
Class B: 0 to 180 days
Class C: 1 year to 1 year and a half
Class D: 1 year to 1 year and a half

For devices from Japan, the U.S., Canada, EU countries, and South Africa, the review period can be shortened on the condition that the device has been in use in the country for at least one 5 years and has been accident-free. However, it is not clear how much the period can be shortened.

As of the completion of PoC, PPB registration process through Mediquip has not yet started. According to interviews with other Japanese companies that have already completed PPB registration, although there are many local distributors, it is important to find a local company that is familiar with PPB registration. Depending on the ability of local company, the registration period will be greatly affected. In addition, some local companies may try to force you into an exclusive contract as a sales agent after PPB registration, so it is important to choose local agent carefully.

(d) Implications from the PoC

In many cases, the higher-level medical facility, the more likely it was that the PPB registration of the target device would be required prior to the implementation of PoC or negotiations for commercialization. In the case of local commercialization, there is a possibility that PPB registration will be required even before the feasibility study.

On the other hand, if we can collaborate with a higher-level medical facility through PPB registration in PoC and commercialization, we will have a higher possibility of deploying iCTG to primary and secondary medical facilitys that have a referral relationship with that medical facility.

８） Local laws and regulations

In order to start the PoC, we checked whether there is a risk that the content to be implemented in the PoC will violate local laws and regulations. The local law firm conducted a legal check and identified the following local laws and regulations and legal concerns in the PoC to be conducted by Melody International Inc.

- Although there is no clear definition of the category of medical treatment in the local laws and regulations, devices used on patients are treated in the same way as medical devices such as CT and MRI, and tests using such devices can be interpreted as part of medical treatment.
- According to Health Act (No. 12 of 2017), only qualified medical practitioners in Kenya are allowed to perform medical practices, and the medical facility where the PoC will be implemented will be required to perform the tests and analyze the test results for the patients. In the event that the test data obtained using the device is incorrect and affects the diagnosis of the local medical professionals, and as a result, the patient is harmed in some way, the company that provided the solution cannot deny the possibility of being held liable for third party or criminal liability.

In order to avoid the risks mentioned above, the local law firm suggests that PoC should be conducted based on thorough informed consent to the patient and the signature of the consent form. Informed consent should be given in accordance with the following principles at a minimum

- Information and disclosure: Necessary information is disclosed to the patient.
- Competency: Patients have the ability to understand the information they are given.
- Comprehension: The patient actually understands the information given
- Voluntary: Allows for voluntary decision-making on the part of the patient
- Decision-making: The patient actually decides whether or not to proceed with the procedure.

９） During PoC implementation

e

Kibera Slum

UMC

User training

Antenatal checkup

Source: Compiled by survey team

１０） General Comments

In Kenya, many medical practitioners believe that Kenyans were used for clinical trials in the past when companies from developed countries commercialized new drugs and medical devices, and they tend to be reluctant to accept products other than those that have been approved for local use in accordance with Kenyan domestic rules. In addition, according to interviews with local medical facilities, the rules regarding the use of unregistered devices in the obstetrics field are particularly strict, as the obstetrics field has a high mortality rate in Kenya and is one of the priority medical fields for the government. Since this was Melody International's first attempt to conduct a PoC and verify business feasibility in Kenya, the company did not register any medical devices in advance. As a result, it took some time to obtain approval for implementation in the medical facility during the PoC preparation phase.

In order to register a medical device in the local market, it is necessary to contact a local distributor. However, it is necessary to be cautious when selecting a distributor, as they often offer favorable contract terms. Although it depends on the level of the medical device, the simplest medical device registration is approved within 90 days.

３－３． Indonesia

（１） MITAS Medical Inc.

１） Overview of PoC Target Solutions

MITAS Medical Inc. provide a portable slitlamp that can be attached to a smartphone to capture images of frontal eyes, and a dedicated application for the slitlamp (MS1). MS1 will enable collaboration between ophthalmologists at primarycare facilities and higher level medical facilitys in remote areas and support the provision of remote eye care services at primary medical facilitys. (For details of the PoC, please refer to the appendix 12.)

２） Medical facilitys where PoC is conducted

Rumah Sakit Universitas Sumatera Utara (University Hospital of North Sumatra: USU), which was matched through the PoC selection process, was selected as the medical facility to implement the PoC. In addition, USU is a secondary care facility located in Medan, North Sumatra, and one group hospital and four primarycare facilities in the region, which have referral relationships with USU, are also considered as PoC implementing institutions. In addition, the five facilities were selected as the medical institutions to implement this PoC based on the introduction and proposal from USU.

３） Issues in the target countries

Indonesia is geographically a vast country with more than 13,000 islands, five times the size of Japan. As of 2016, there are 2,877 ophthalmologists[228] in Indonesia, which is about 1.0 ophthalmologist per 100,000 people, or about 11 ophthalmologists per 100,000 people in Japan, suggesting that access to eye care is limited.

However, according to the Indonesian Association of Ophthalmologists (Perhimpunan Dokter Spesialis Mata Indonesia atau: PERDAMI), there are 41 ophthalmologists in Medan city where the PoC was conducted. According to the Central Statistics Office of Medan City in 2020, the population of Medan City is 2,435,252, which means that the number of ophthalmologists per 100,000 people in the region is about 1.7. Even in urban areas, which are the fifth most populous in Indonesia, the number of ophthalmologists is insufficient. Even in urban areas, the fifth most populous in Indonesia, there is a shortage of ophthalmologists.

The USU was collaborated in this PoC is a public secondary facility that covers about 30 primary facilities in Medan, North Sumatra, but the number of ophthalmologists in USU is not sufficient. However, some patients with ophthalmologic symptoms come directly to USU instead of the primary facility, or return to USU after their symptoms worsen, leading to congestion of outpatients in medical facility. This situation may lead to increase risk of COVID-19 infection or

[228] Olly Congga, SMECeyecaresystem:Profileanditsreleiminatingavoidable blindnessinIndonesia, 2019

even blindness due to worsening symptoms.

４） Purpose of PoC implementation

In response to the above local medical issues, introducing MS1 to primary medical facilitys and enabling remote consultations on ophthalmology from doctors in the primary medical facilitys to ophthalmologists in USUs could compensate for the shortage of human resources for ophthalmologists in primary medical areas, especially in rural areas. In addition, it could reduce the congestion of outpatients in USUs and improve their productivity as higher level medical facilitys. In addition, for public and private primary health care institutions, online consultation with an ophthalmologist could provide appropriate eye care to patients, resulting in reduced blindness and medical costs. In addition, this MS1-based system may also help reduce the risk of COVID-19 infection as a secondary effect by reducing patient travel to the USU and outpatient mix.

In this PoC, we will verify and confirm the effects of the introduction of MS1, the infrastructure environment for business development, and the possibility of commercialization. The verification will be conducted from the perspective of solving local medical issues, related infrastructure, and business feasibility. We will measure the results based on specific verification methods, compare and analyze the results with our initial assumptions, and summarize the suggestions obtained from the analysis, which will lead to the development after this PoC.

５） Verification perspective 1: Resolving local medical issues

(a) Verification details

The following hypotheses will be tested to determine whether the introduction of MS1 will contribute to the improvement of the quality of ophthalmic diagnosis in primary health care institutions in Indonesia and to the improvement of productivity of ophthalmologists in USU, the referral center.

- Most ophthalmology patients can be treated at primary medical facilitys
- Tele-diagnosis is more efficient than face-to-face consultations and can improve the productivity of eye care delivery

(b) Verification method

The MS1 and smartphone sets were placed at the USU and group hospital1 facilities, which are the PoC implementing medical facilitys, and at 4 primarycare facilities (public: 2, private: 2). In addition, the system for remote diagnosis was introduced to 4 ophthalmologists at USU, and the necessary instructions and accounts were provided to the participants at each facility.

Of the patients who visited the primary facility, those who complained of ophthalmic symptoms were classified into two groups: one group was given a normal ocular examination by a doctor at the facility without using the MS1, and the other group was given a remote consultation with an ophthalmologist at a higher-level medical facility using the MS1, video recording of the ocular region, and a dedicated application. The data measured in these different groups were compared, and the following KPIs were confirmed to verify the veracity of the hypothesis described in (a) Contents of verification.

VII-5 Methods for testing hypotheses (MITAS Medical, Inc.)

Hypothesis	Verification Method	KPI
Most ophthalmology patients can be treated at primary medical facilitys	Recording	・ Percentage of cases judged to be able to be handled by primary medical facilitys ・ Agreement rate of diagnosis and referral decisions between primary care physicians and USU ophthalmologists
Tele-diagnosis is more efficient than face-to-face consultations and can improve the productivity of eye care delivery	Recording	・ Average time spent by USU ophthalmologists on face-to-face consultations and teleconsultations, respectively

Source: Compiled by survey team

On USU side, the ophthalmologist filled in the judgment based on the questionnaire and video information uploaded from the primary medical facility via a dedicated application, and saved the data via the same application. The primary medical facility that conducted the primary examination confirmed the results returned via the dedicated app and communicated them to the patient.

We also recorded the time taken for each of the above series of steps, with and without MS1, as well as the time taken to upload the data with the dedicated application.

(c) Verification results, analysis

During the PoC period, which is approximately less than 2 months from the middle of December 2021 to the beginning of February 2022, there were approximately 150 remote consultations at the primary medical facility side. The results of the verification in accordance with the KPIs mentioned above and their analysis are as follows.

(i) Percentage of cases judged to be able to be handled by primary medical facilitys

Based on the results of the respective diagnoses at the primary health care institution and the USU, it was determined that about 70 percent of the cases of patients presenting to the primary health care institution could be handled at the primary health care institution level, a relatively low result.

(ii) Agreement rate of diagnosis and referral decisions between primary care physicians and USU ophthalmologists

Comparing the results of diagnosis and referral decisions made by physicians at primary medical facilitys with those made by ophthalmologists at USU, the overall agreement rate for diagnosis results was 57.9%, and the agreement rate for referral decision results was 46.9%, indicating that discrepancies in results occurred in about half of the cases. By disease, there was a marked difference in the results of referral decisions, especially for some diseases. Specifically, for cataracts, which are diseases of the inside of the eye, the agreement rate41.7 for diagnosis and the agreement rate8.8 for referral decision was %, and for keratitis and corneal ulcers, which are diseases of the surface of the eye but require detailed ocular information for diagnosis and treatment decisions, the agreement rate42.9 for diagnosis and the agreement rate for referral decision was low at 28.6%.

VII-6 Agreement Rate of Diagnosis and Referral Decision Results (MITAS Medical, Inc.)

Disease	Match rate (diagnostic results)	Match rate (referral decision results)
Refractive error	88.2	78.9
Cataract	41.7	8.8
Keratitis and corneal ulcers	42.9	28.6
Winglet	50.0	50.0
Conjunctivitis	66.7	46.2

Source: Compiled by the survey

Approximate 30 percent of cases that were difficult to treat at the primary medical facility level, many of the diseases that ophthalmologists would normally want to be referred, such as cataracts and keratitis, were missed by conventional examinations at primary medical facilitys and were judged to require no referral, which may have been the cause of the difference in the rate of cases judged to require referral.

(iii) Average time spent by USU ophthalmologists on face-to-face consultations and teleconsultations, respectively

The average time spent by the ophthalmologist on USU side for face-to-face consultation (anterior segment) was 12 minutes and 22 seconds, and the average time spent for remote consultation was 2 minutes and 49 seconds. In addition to the time spent directly examining the eye, the face-to-face consultation requires time for the patient to move around in the chair, time for questioning, and time for explaining the results of the examination, whereas the remote consultation requires only time for the patient to check the uploaded video and fill in the examination results. It seems that the time required for remote consultation was shorter than that for face-to-face consultation.

(d) Implications from the PoC

These results suggest that the introduction of MS1 in primary facility will contribute to the improvement of the quality of ophthalmic diagnosis in primary health care institutions and the productivity of ophthalmologists in top hospitals in Indonesia. Remote consultation using MS1 is expected to reduce the number of cases that may have been missed at the level of primary medical facilitys in the past, and lead to early diagnosis and prevention of serious diseases, based on the results of appropriate examinations based on the expertise of ophthalmologists.

In addition, since the average time per case1 for remote consultation is shorter than that for face-to-face consultation, the number of cases that can be handled by one ophthalmologist increases, which is thought to contribute to improving the productivity of ophthalmologists. If the ophthalmologist's proficiency with MS1 improves, the average time required for a remote consultation may be further reduced. In addition, compared with face-to-face consultations, remote consultations can be performed during gaps between outpatient visits and surgeries, and the risk of COVID-19 infection is reduced because of the non-face-to-face nature of the consultation.

６） Verification perspective 2: Related infrastructure

(a) Verification details

We will technically verify that there are no problems in the related infrastructure such as communication infrastructure when MS1 is introduced. The verification will be mainly based on the following hypotheses.

- Uploading videos from the dedicated app can be done smoothly.
- Uploaded videos have sufficient quality for accurate diagnosis

(b) Verification method

The USU checked the quality of the uploaded videos and confirmed that they were diagnosable.

VII-7 Methods for testing hypotheses (MITAS Medical, Inc.)

Hypothesis	Verification Method	KPI
Uploading videos from the dedicated app can be done smoothly.	Recording	・ Percentage of cases that could be uploaded within minutes
Uploaded videos are of sufficient quality for accurate diagnosis	Recording	・ Percentage of cases with sufficient quality for accurate diagnosis

Source: Compiled by the survey

(c) Verification results, analysis

(i) Uploading videos from the dedicated app can be done smoothly.

The percentage of cases that could be uploaded within minutes was 95.2%. Most of the cases were uploaded within a 3 minute, but there were cases where it took longer to upload the images when the images were taken with a native smartphone camera application outside of the dedicated application. In addition, one of the PoC sites, a medical facility that takes a long time to travel from Medan, had a higher percentage of cases that took a long time to upload compared to the other PoC sites, which may have been affected by the Internet infrastructure due to the geography of the remote area.

(ii) Uploaded videos are of sufficient quality for accurate diagnosis

The percentage of cases with sufficient quality for accurate diagnosis was 92.0%. Most of the uploaded videos were of sufficient quality to make an accurate diagnosis in most cases, but there were some cases that were unclear. Some of the unclear cases were due to reflection of light from the outside world on the ocular surface, and some primary care facilities had more than one photographer, which may indicate inadequate training for the users.

(d) Implications from the PoC

Of the problems confirmed this time, the upload problems in rural areas may be caused by the communication infrastructure. On the other hand, most of the problems are thought to be caused by operational problems such as inadequate explanation to users or insufficient proficiency in using MS1, rather than technical problems.

The upload time can be improved by providing thorough instructions to the medical facilitys in advance to use the dedicated application for taking and uploading images, since the dedicated application is designed to prevent the size of images from becoming too large.

As for the quality of the uploaded videos, we believe that the main problems identified this time can be improved by reiterating to users the recommended shooting environment and precautions to be taken when shooting MS1.

７） Verification point 3: Business feasibility

(a) Verification details

In the situation where there is a shortage of specialists in ophthalmology, there is a potential demand for improving the quality of ophthalmology care provision in primary medical facilitys and improving the productivity of ophthalmologists in higher-level medical facilitys such as USU. Based on the results obtained from this PoC, we will examine the possibility of commercializing the ophthalmology teleconsultation service provided by MS1 in Indonesia.

(b) Verification method

After dividing the target customers into the 4types of private primary medical facilitys, the Ministry of Health, patients, and private insurance companies for each payer, we conducted desktop surveys and questionnaires to the target customers as necessary, in addition to the information confirmed in the verification perspectives (1) and (2), to confirm the demand and verify the possibility of commercialization.

(c) Verification results, analysis

(i) Private primary medical facilitys

As for the private primary medical facilitys, there is no significant difference in the level of technology between them and the public primary medical facilitys, and there is potential demand for the provision of quality-assured medical care by medical specialists. In this PoC, one of the 2 institutions was a private primary medical facility, and when the results of this 2institution were extracted, the concordance rate between the primary medical facility physicians and USU ophthalmologists was about 53.8%. On the other hand, the agreement rate for cataract, pterygium, and conjunctivitis was 0%. On the other hand, when we interviewed doctors at private primary medical facilitys, we received opinions on both the advantages and disadvantages of MS1 and identified areas for further improvement before commercialization. As advantages, the efficiency and simplicity of the MS1, which is portable and does not require a power source, and the ability to take detailed images of the anterior segment were highly evaluated. On the other hand, there were concerns about too many medical questionnaire items in the dedicated application, the time it takes to take and send videos, and the time it takes to receive the diagnosis results, forcing patients to wait. there were also some opinions from the interviews that medical equipment costing more than 100,000 yen is too expensive for private primary medical institutions.

(ii) Ministry of Health

It is thought that there is a potential demand for remote ophthalmology consultation services by MS1 in public primary medical facilitys as well as in private primary medical facilitys. The PoC was conducted at two public primary medical facilitys in addition to a private primary medical facility. Extracting the results of the PoC implementation at these 2institutions, it was found that more than half of the cataract cases found at the public primary care institutions were missed by the primary care doctors.

In terms of efficiency of healthcare delivery, the study confirmed the possibility of increasing the number of patients per ophthalmologist in the USU, which is a top-tier healthcare institution, which is expected to improve the productivity of the limited number of ophthalmologists in Indonesia as a whole and to improve access to specialty care.

It is also estimated that the economic[229] loss due to cataracts is equivalent to 68,8trillions of rupiah (≈48 100 million US dollars), and the economic loss due to blindness and severe visual impairment is equivalent to trillions of rupiah (59100 million US dollars) per year84.7, so improving the quality of eye care is expected to have an appealing effect on the government, as it may have no small impact on the overall economy of Indonesia.

On the other hand, interviews with doctors at public primary medical facilitys confirmed the advantages and disadvantages of the MS1 and revealed areas for improvement for commercialization. The advantages were that it was easy to use and operate, that ophthalmology services could be provided at the primary medical facility level even in the absence of an ophthalmologist, and that it was practical for early detection of cataracts. There was also a comment that it could lead to Puskesmas Accreditation[230], a governmental certification system. In addition, it is a modern solution that appeals to patients, and patients appreciate the fact that they do not have to go to a higher-level medical facility. On the other hand, it took some time to get used to using the system, and it was difficult to adjust the environment to be suitable for shooting, such as blocking out the outside light. There were also some complaints about the time spent waiting for the video transmission and diagnosis.

[229] dr.Aldiana Halim, SpM(K), MSc THE ECONOMIC CONSEQUENCES OF VISUAL IMPAIRMENT AND THE IMPACT OF CATARACT SURGERY IN GAINING ECONOMY IN INDONESIA, 2020

[230] In accordance with Article 57 of Regulation Reg 43/2019 by the Ministry of Health, Puskesmas is required to obtain and renew its accreditation every three years. The purpose of the accreditation system is to foster the development and continuous improvement of primary medidcal institutions. In addition, if a puskesmas is not accredited, the medical services provided will not be covered by the public insurance.

In addition, the USU praised the MS1 as a device that can examine the anterior segment of the eye in detail. However, the disadvantages of the MS1 were that it took time to log in and that the USU was too busy teaching students and residents and working at other clinics to have time for reading. USU management also pointed out that the system was not financially sustainable because there was no payment for ophthalmologists who read remotely from primary care institutions.

(iii) Private insurance company

Cataracts are covered by the BPJS but its coverage for surgical operation methods are limited, so some private insurance packages also provide coverage for cataracts. Even taking into account that drug costs are incurred when preventing progression, if cataracts can be detected early and prevention of severe disease can be initiated, treatment costs could be greatly reduced.

(d) Implications from the PoC

Although the potential demand for MS1 was confirmed, it is necessary to examine the demerits received from each facility and take necessary improvement measures before commercialization. Many of the disadvantages mentioned above are not technical issues, but rather due to the level of proficiency of the users, the large number of questions to be answered, and the busy schedule of the ophthalmologists who provide consultations. These non-technical problems are expected to be improved by providing necessary training to users, simplifying the operation, and setting consultation hours.

On the other hand, the suggestion that it takes time to log in is thought to be due to the fact that it took time to receive the security code required for login, and since this is a technical problem with the communication infrastructure and equipment, improvement measures need to be taken.

Finally, since the payment mechanism for inter-facility telemedicine, including tele-consultation service for ophthalmology using MS1, has not been established in the current insurance system, it is expected to be difficult to receive insurance reimbursement within the existing system in terms of feasibility study for public medical institutions that expect payment from the government. On the other hand, the Ministry of Health has already started some pilot activities to make telemedicine services eligible for reimbursement under the BPJS nationwide, and future developments need to be monitored.

８） Local laws and regulations

In order to start the PoC, we checked whether there was a risk that the content to be implemented in the PoC would conflict with local laws and regulations. The legal check was conducted by a local law firm, and the following local laws, regulations, and legal concerns were identified for the PoC to be conducted by MITAS Medical.

- If the role of the company is only to propose solutions, it does not constitute a local medical practice.
- There are no clear regulations regarding the responsibility of the company that provided the solution in the event of an accident, such as the death of a patient, during the PoC implementation period. However, there is a possibility that the affected patients may be held criminally or civilly liable.

In order to avoid the risks mentioned above, the local law firm suggests that PoC should be conducted based on the patient's signature on the consent form. It is also important to agree on the exemption with the medical facility where the PoC will be conducted and exchange a written document in advance.

９） During PoC implementation

Examination

Examination

Examination

Examination

Source: Compiled by survey team

１０） General comments

The results of the PoC showed that there is a gap between the judgment of ophthalmologist in higher-level medical facility and General Practitionor at primary medical facilities. The establishment of a system that enables access to specialized medical care at primary medical facilities through telemedicine is considered to be an important initiative from the perspective of equalizing medical care.

However, there are some barriers to commercialization, including the local system. As described in A-6. Overview of the Insurance System, insurance reimbursement models differ depending on the level of the medical facility. This complicates the revenue sharing among facilities when they share the workload for a patient. Under the current system, it is difficult to see the benefit of participating in teleconsultation services for higher level medical facilities. Although the current system remains problematic for public medical institutions, the Ministry of Health is working on pilot activities for BPJS coverage of telemedicine services, and it is necessary to follow the regulation changes in the future. In the case of private medical institutions, since inter-facility telemedicine is based on a contract between facilities, revenue sharing is relatively easy to organize, and therefore, there is room for consideration as a candidate for the introduction of MS1.

（２） Precision Inc.

１） Overview of PoC Target Solutions

Precision Inc. provide an AI electronic medical questionnaire for patients to fill out before their visit to the hospital. By inputting symptoms and other information into the electronic medical questionnaire from a smartphone or tablet device, a draft of the medical record is automatically created, which is expected to reduce the workload of medical professionals such as doctors and nurses. According to the company's past case studies, it is possible to reduce the time required for doctors to prepare medical records by about one-third.

In addition, when the medical textbook called Current Decision Support (CDS) provided by the company is used in combination with the electronic medical questionnaire, AI predicts possible diseases based on keywords entered in the electronic questionnaire. CDS is a solution that contributes to the equalization of diagnosis and treatment among doctors at different medical facility levels and in different regions.

Although CDS is a medical textbook supervised by about 2,000 doctors in Japan, it was difficult to localize it during the PoC implementation period, so only the AI electronic medical questionnaire is the target solution in this PoC. (For details of the PoC, please refer to appendix 12)

２） Medical facilitys where PoC is conducted

RSAB Harapan Kita Women and Children Hospital (HKWCH), which was matched through the PoC selection process, was selected as the PoC implementing medical facility. HKWCH is a tertiary public medical facility specializing in maternal and child health care located in DKI Jakarta.

３） Issues in the target countries

The number of doctors per 1,000 population in 2018 was 0.4, and nurses/midwives was 2.4, which is below the EAP average (physicians: 1.61 person, nurses/midwives:2.7 1 person) and the SDG Index (medical personnel4.45 per 1,000 population), and there is a shortage of medical personnel in Indonesia as a whole.

In addition, doctors and other medical personnel are unevenly distributed in urban areas, and there are regional disparities in access to medical services. In particular, the Maluku-NTT-Papua region, where many islands are scattered, has the lowest number of doctors, although about 40% of the population lives in this region.

Due to the shortage and uneven distribution of medical personnel, it is considered to be difficult to receive appropriate medical services at the right time, especially in rural areas. In addition, this disparity in medical care between regions hinders the prevention, early detection, and early treatment of diseases, which may lead to the risk of serious illness.

In addition, since the human resources of medical personnel are limited, there is a concern that the number of patients and the workload that 1each medical personnel has to deal with will increase. As the workload increases, the efficiency and productivity of medical care itself may be affected in no small way.

４） Purpose of PoC implementation

The introduction of AI electronic medical questionnaires has the potential to contribute to solving local medical issues such as increased workload of medical personnel. In addition, the introduction of CDS in the future after this PoC may contribute to eliminating the disparity in medical care between regions caused by the shortage and uneven distribution of medical personnel, and to the equalization of medical care.

In this PoC, we will first verify and confirm the effects of the introduction of AI electronic medical questionnaires, which is the target solution of this project, as well as the infrastructure environment and the possibility of commercialization when considering business development. The verification will be conducted from the perspective of solving local medical issues, related infrastructure, and business feasibility and will include measurement of results based on specific verification methods, comparison and analysis of results with initial assumptions, and suggestions obtained from the analysis.

In this PoC, outpatients with cleft lip and palate who visit HKWCH were targeted. As a background, there has been an exchange of physician personnel between Indonesia and Japan in the treatment of cleft lip and palate, so the medical treatment of cleft lip and palate is similar in Indonesia and Japan. With this background, it was thought that this PoC could be localized for Indonesia without major changes by slightly modifying and translating the AI electronic medical questionnaire that has already been introduced in Japan.

５） Verification perspective 1: Resolving local medical issues

(a) Verification details

We will verify whether the application of AI electronic medical questionnaires in medical

practice contributes to the collection of information from patients and the improvement of work efficiency of doctors and nurses. The verification will be based on the following hypotheses.

- Able to chart cleft lip and palate in an outpatient setting using AI electronic medical questionnaire
- Using AI electronic medical questionnaires will reduce workload.

(b) Verification method

Based on the information provided by the target facility, patients attending or hospitalized at the facility will be selected. The physicians will be full-time doctors in the target facility. The background, purpose, and content of the PoC will be explained to the target patients in advance, and a written agreement on the handling of data and personal information will be obtained.

We will use questionnaires to check the impressions and satisfaction levels of doctors and nurses who have actually used the medical records created by the AI electronic medical questionnaire.

VII-8 Method for testing hypotheses (Precision Inc.)

Hypothesis	Verification Method	KPI
Able to chart cleft lip and palate in an outpatient setting using AI electronic medical questionnaire	Questionnaire	・ Is it possible to enter the information in more than 10% of patients and is the draft of the medical record properly prepared?
Using AI electronic medical questionnaires will reduce workload.	Questionnaire	・ Is there a high level of satisfaction with the reduction of workload from doctors and nurses who are users?

Source: Compiled by the survey

Regular weekly meetings were held with the HKWCH side, and preparation was proceeded for the PoC implementation through the following STEP 1 to 3 processes.

- STEP 1: Hearing the needs of the HKWCH side
- STEP 2: Propose to HKWCH the content of the AI electronic medical questionnaire to be used in the PoC, referring to the paper medical questionnaires used in children's hospitals in Japan
- STEP 3: Organize necessary requirements etc. from HKWCH

In the first meeting with HKWCH in STEP 1, we confirmed the requirements of HKWCH based on the electronic medical questionnaire translated into English and found out that HKWCH uses two types of paper medical questionnaires to check not only the patient's own information but also the information of the patient's parents. It was confirmed that the overall operation flow was similar to that of the admission and discharge support center in Japan.

In STEP 2, we proposed the contents of the electronic medical questionnaire to be used in this PoC to the HKWCH side. Precision Inc. contacted two Japanese doctors working at a pediatric hospital in Japan and interviewed them about the content and flow of the questionnaire for cleft lip and palate in Japan. The questionnaires obtained during the interviews were translated into English and proposed to HKWCH as a draft electronic questionnaire. We also made a sample video for patients to understand about cleft lip and palate surgery and proposed it to HKWCH.

The doctor in charge of HKWCH told us that the Maternal and Child Health handbook is also used in Indonesia and that it is difficult to input data into the electronic questionnaire because the handbook is currently in paper form and requested us to create an electronic handbook. However, due to the limited time for this PoC, we decided to continue discussing the above requests from the hospital side after the PoC. Through these discussions, we reflected the revision instructions from HKWCH and completed the electronic medical questionnaire. In addition, questions on symptoms of new coronavirus infections can now also be asked in the screening. The content of the video was prepared by a doctor in Japan who treats cleft lip and palate, and once it was translated into an English video, it was also translated into the local language.

(c) Verification results, analysis

We started using the AI electronic medical questionnaire from the beginning of February 2022 at actual medical sites. For some patients, a trial was conducted to have them enter the information at home before coming to the hospital, enabling them to check the information before visiting the hospital. During the PoC implementation period, the medical records of 7 patients were created as a result. The verification results and their analysis in accordance with the KPIs mentioned above are as follows.

(i) Is it possible to enter the information in more than 10% of patients and is the draft of the medical record properly prepared?

Although the number of patients was insufficient, it was possible to enter data into the electronic medical questionnaire from all patients. We conducted a questionnaire survey to 3 doctors who used the medical records generated by the AI electronic medical questionnaire, and 2 doctors answered that the information obtained from the electronic medical questionnaire was sufficient (4 points of 5), while 1 doctor answered 3 points of 5. The same questionnaire was given to one nurse who also used the medical records, and the results showed that they were in the process 3 points of 5.

(ii) Is there a high level of satisfaction with the reduction of workload from doctors and nurses who are users?

When the above 3 doctors and 1 nurse were asked whether the electronic medical questionnaire could reduce their workload, only 1 physician responded 4 points of 5, remaining 2 doctors and 1 nurse responded that 3 points of 5.

Some comments such as the accuracy of the Indonesian translation, loading speed, and the need for simplification due to patients' confusion over the number of options were received, and the results were generally positive, although some issues remain.

Doctors who used the system commented that it reduced the workload of nurses who had to spend time on medical interviews and inputting the results and improved the quality of medical care.

In addition, the video explanation of the surgery was highly evaluated by the doctors and nurse. They said that if the patients could understand in advance the not-so-common cleft lip and palate disease and its general treatment process, it would improve their understanding of the detailed explanation by the doctors. Also, inspired by this video, some people thought that if there was a video explaining how to use the electronic medical questionnaire, it would make it easier for patients to fill out the electronic questionnaire and increase the percentage of patients who fill out the questionnaire in advance.

(d) Implications from the PoC

We started the PoC in February 2022 and have been implementing it for about a 2week, and we will continue to collaborate with HKWCH while solving each issue one by one as we have received opinions and improvements from users as mentioned above during the PoC.

６） Verification perspective 2: Related infrastructure

(a) Verification details

Technically verify that there are no problems in the related infrastructure such as communication infrastructure when introducing AI electronic medical questionnaires. The verification will be based on the following hypotheses.

-Facilities　Necessary facilities, equipment, infrastructure, etc. are available (facility side)

-. Necessary and sufficient ICT literacy on the user side (facility side, patient side)

(b) Verification method

For the following hypotheses, we confirmed the status of the related infrastructure through PoC implementation.

VII-9 Method for testing hypotheses (Precision Inc.)

Hypothesis	Verification Method	KPI
Necessary facilities, equipment, infrastructure, etc. are available (at the target facility).	Confirmation through PoC	・ Necessary facilities, equipment, and infrastructure environment are in place.
Does the user side have sufficient ICT literacy? (Facility side, patient side)	Confirmation through PoC	・ Understands and can use the application without problems.

Source: Compiled by survey team

(c) Verification results, analysis

(i) Necessary facilities, equipment, and infrastructure environment are in place.

The necessary facilities, equipment, and infrastructure environment were in place. Initially, the connection speed was slower than in Japan, suggesting the possibility that the AI electronic medical questionnaire could not be fully utilized, but this was improved by making the website lighter. The web browser used was almost compatible with Precision's software.

(ii) Understands and can use the application without problems.

Patients were able to understand and use the application without any problems, and the AI electronic medical questionnaire, which was prepared in Indonesian translation, was fully usable without any major problems.

(d) Implications from the PoC

The AI electronic medical questionnaire was found to be technologically feasible and effective enough to be used in the medical field in Indonesia to facilitate communication between doctors, nurses and patients.

７） Verification point 3: Business feasibility

(a) Verification details

In a situation where there is a shortage of medical professionals, there is a potential demand for reducing the workload of medical professionals and improving their productivity. Based on the results obtained from this PoC, we will examine the possibility of

commercializing the AI electronic medical questionnaire in Indonesia.

(b) Verification method

After the implementation of the PoC, interviews will be conducted with users and companies with knowledge of the business environment in Indonesia to investigate their opinions of the proposed solution and to examine the possibility of commercialization in the country.

(c) Verification results, analysis

Based on the general labor cost, the local labor cost is about 1/5 of the Japanese labor cost, so the service unit price could be lower than in Japan. However, assuming that the fixed costs such as server maintenance cost would not change much, there was a concern about whether profitability could be expected.

In order to confirm the feasibility of the project, we interviewed doctors at HKWCH and found out that medical costs in Indonesia vary depending on the disparity between the rich and the poor, and that medical costs are expensive for the wealthy and especially for foreign patients such as Japanese. In addition, there is medical care for the wealthy and medical care for remote islands, suggesting that AI questionnaires may be useful for communication, especially in remote island medical care.

In addition, a Japanese company that is knowledgeable about the business environment in Indonesia suggested that it is important to consider collaborating with medical facilitys that have an extensive network for future development in the region. In the case of the private sector, conglomerates often have hospital chains, and among public universities, the University of Indonesia is the most well-known and has a large network. He suggested that collaboration with the University of Indonesia would be a good idea when creating e-textbooks in the future.

(d) Implications from the PoC

In order to consider monetization, it is necessary to carefully examine the differences between Japan and the local market in terms of prices.

In addition, since there are many private and public medical facilitys and academic societies with large networks in Indonesia, it is necessary to carefully examine the partners that match the demand for solutions such as AI electronic medical questionnaires and CDS, and that can be expected to expand significantly horizontally and vertically through collaboration.

８） Local laws and regulations

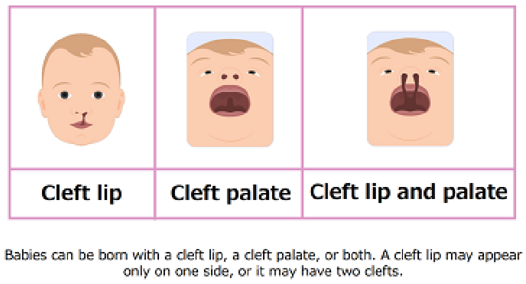
In order to start the PoC, we checked whether there was any risk that the content of the PoC would conflict with local laws and regulations. The legal check was conducted by a local law firm, and the following local laws and regulations and legal concerns were identified for the PoC to be conducted by Precision Inc.

- If the role of the company is only to propose solutions, it does not constitute a local medical practice.
- There are no clear regulations regarding the responsibility of the company that provided the solution in the event of an accident, such as the death of a patient, during the PoC implementation period. However, there is a possibility that the affected patients may be held criminally or civilly liable.

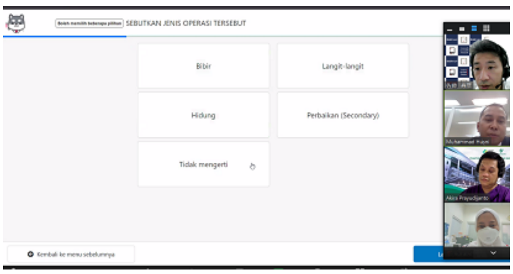
In order to avoid the risks mentioned above, the local law firm suggests that PoC should be conducted based on the patient's signature on the consent form. In addition, it is also important to agree on the exemption with the medical facility where the PoC will be conducted and exchange a written document in advance.

９） During PoC implementation

Screen of explanation video for patients



Screen of explanation video for patients



Meeting with HKWCH

Medical questionnaire

Source: Compiled by survey team

１０） General Comments

Since this PoC was conducted within a limited period of time, the PoC was only for verifying the effectiveness of the AI electronic medical questionnaire for the specific disease of cleft lip and palate. HKWCH has also expressed a desire to link the AI electronic medical questionnaire with the paper-based maternal and child health handbook introduced at the hospital, and it is hoped that the AI electronic medical questionnaire can be further validated and commercialized while expanding its scope.

（３） Allm Inc.

１） Overview of PoC Target Solutions

Allm Inc. provides a communication application (Join) for medical professionals that allows them to display DICOM-standard medical images by such as MRI and CT on their smartphones and share them via chat. Join is the first application in Japan to be covered by insurance as a medical device program, and has already received approval from PMDA in Japan, FDA in the U.S., and CE in Europe. Its advanced security features enable secure handling of medical images and other data. The system can be used not only for communication within the same medical facility, but also for a wide range of other purposes such as collaboration between medical facilities.

In addition, the use of Join has been confirmed to improve the efficiency of work among medical personnel, shorten the time required to start treatment for patients, and reduce unnecessary transportation.[231] In addition, the use of Join has been confirmed to improve operational efficiency among medical professionals, shorten the time required to start patient treatment, and reduce unnecessary transportation.

In this PoC, we have adopted a simple technical specification called the FileGateway method, which can be introduced at a lower cost and in a shorter period of time than the conventional Join method, with a view to future local commercialization. By adopting the FileGateway method, it will be possible to complete the service on the Web without the need to install a server at the target medical facility. (For details of the PoC, please refer to Appendix 12)

[231]Ministry of Internal Affairs and Communications (MIC), "Research and Study on the Realization of a Secure Information Collaboration Model in the Medical Field Using Mobile Terminals and Cloud Technologies in 27Fiscal Year 2009

２） Medical facilities where PoC is conducted

8 medical facilities were selected from the medical facilities affiliated with the Indonesian Pediatric Cardiac Society (PERKANI), which were matched through the PoC selection process. Most of these 8 facilities are tertiary care facilities that are members of PERKANI, and many of the top referral facilities are in the field of cardiovascular medicine in Indonesia.

３） Issues in the target countries

As mentioned in the other PoC section in Indonesia, there is a shortage of medical personnel in Indonesia, especially doctors, and the limited medical personnel are concentrated in urban areas in the vast country. Due to the uneven distribution of medical personnel, it is difficult for rural areas and islands to access the necessary medical care.

On the other hand, cerebrovascular diseases are responsible for 35% of all deaths in Indonesia, and while this percentage is increasing every year, the demand for more specialized and advanced medical care is also increasing. The same is true in rural areas, and the demand for specialized medical care that is more difficult to access is expected to increase in the future.

In response to this shortage and uneven distribution of medical personnel, telemedicine using ICT is attracting attention as a solution to the need for more efficient use of existing resources. However, the introduction of telemedicine requires a large infrastructure and cost burden, and it will take time for it to spread. Although DICOM-standardized images cannot be viewed on SNS, the handling of patient information on SNS should be avoided from the perspective of patient privacy and data security. In addition, general SNSs do not have functions such as managing communication by case or linking with archiving systems for medical image data, and are not designed for actual use in the medical field, so they are not highly convenient tools for medical professionals.

４） Purpose of PoC implementation

To address the above local medical issues, Allm Inc. believes that it is possible to build an environment that can provide appropriate medical care even in rural areas through communication among doctors who are unevenly distributed by utilizing Join, a communication application among medical professionals, and building a telemedicine collaboration network using smartphones, which many doctors already have.

By establishing an environment in which doctors and healthcare workers in rural areas can consult with specialists in remote areas, especially in specialized medical care such as cardiovascular disease, where joins can easily demonstrate their strength, it is expected to contribute to improving access to specialized medical care in rural areas.

In addition, by using Join, patient information can be handled more securely than with general SNS. Furthermore, because Join supports the DICOM standard, it can share and view images taken by medical devices such as CT and MRI, unlike general SNS, thus supporting more efficient and effective collaboration among medical professionals.

In this PoC, Allm Inc. will verify and confirm the effects of the introduction of Join, the infrastructure environment for considering business development, and the possibility of commercialization. The verification will be conducted from the 3 different perspectives of resolving local medical issues, related infrastructure, and business feasibility, and will include measurement of results based on specific verification methods, comparative analysis between initial assumptions and results, and suggestions obtained from the analysis, which will lead to development after this PoC.

５） Verification perspective 1: Resolving local medical issues

(a) Verification details

Allm Inc. will examine whether the introduction of Join will contribute to the improvement of cooperation among doctors and the productivity of doctors in Indonesia. The verification will be based on the following hypotheses.

- The newly introduced File Gateway method is effective for cooperation among doctors.
- Simultaneous introduction of Join to multiple facilities in cooperation with academic societies such as PERKANI, rather than individual hospitals, is effective in improving cooperation among doctors.

(b) Verification method

Join will be introduced to smartphones from doctors participating in the PoC, and the infrastructure for cooperation within PERKANI will be constructed. Currently, free SNS such as WhatsApp is used as the basis for cooperation within PERKANI, but there is no function to send DICOM images necessary for consultation, and a secure communication environment that can withstand medical information is not in place. Therefore, in this PoC, a mobile telemedicine system based on chatting will be introduced to enable the sharing of a large number of DICOM images and medical information necessary for medical consultation and sharing, as well as complex information such as text, images, voice, and video.

Table VII-11 Method for testing hypotheses (Allm Inc.)

Hypothesis	Verification Method	KPI
The newly introduced File Gateway method is effective for cooperation among doctors.	Questionnaire	・ Confirm the usefulness of Join through a questionnaire to the doctors who use it.
Simultaneous introduction of Join to multiple facilities in cooperation with academic societies such as PERKANI, rather than individual hospitals, is effective in improving cooperation among doctors.	Confirmation through PoC	・ Make sure it is practical to work with societies that do not have a budget.

Source: Compiled by survey team

In order to operate the medical collaboration network using smartphones, regular meetings were held for briefing, training, and progress confirmation for the doctors who are the users of the network. At the regular meetings, we reached a consensus on the schedule, issues, and desired outcomes of this PoC.

(c) Verification results, analysis

(i) The newly introduced File Gateway method is effective for cooperation among doctors.

Through this PoC, the following results could be obtained. Join has strengths in communication accompanied by CT and MRI images in situations dealing with acute diseases such as heart disease and stroke. Although Join can share medical images obtained from ultrasound equipment as long as they are DICOM-standardized, many of the ultrasound equipment used in Indonesia are not DICOM-standardized.

However, in the FlieGateway system, when uploading images that do not conform to the DICOM standard, the images need to be converted to the DICOM standard, and this conversion process was a major frustration.

Furthermore, PDF, PNG, JPEG, etc. can be shared through the File Gateway, but videos cannot be uploaded through the File Gateway, and this point was also dissatisfaction for the users. There were also requests to upload files such as Microsoft Power Point.

On the other hand, there were many opinions that the system was effective for case discussion. This is due to the fact that the information is shared by physician societies rather than by hospitals, so it is assumed that the usage scenarios are not treatment policies that require immediate decisions or sending patients, but rather case consultation and sharing.

(ii) Simultaneous introduction of Join to multiple facilities in cooperation with academic societies such as PERKANI, rather than individual hospitals, is effective in improving cooperation among doctors.

In collaboration with the academic society, Allm Inc. was able to establish a collaborative network with 8 medical facilities in this PoC. It was also confirmed that the File Gateway method does not require a server to be installed in each individual hospital, but rather can be installed in multiple facilities on a web basis in a relatively simple manner, making it easy to demonstrate its features when collaborating with academic societies.

(d) Implications from the PoC

Compared to the conventional Gateway method, in which a Gateway server is installed in the hospital and images can be automatically uploaded to the Join, the FileGateway method requires more time and effort, including analog processing, which is a major barrier to its use. It is necessary to reconsider the policy for the future deployment of Join in Indonesia.

In addition, some medical facilities do not have file-compatible archiving systems, and there seemed to be a high level of interest in applications that could support various file formats other than medical images used in the facilities. However, it remains to be seen to what extent the Join communication tool will be able to meet this demand.

There are also requests for improvements in image searchability and viewability, and the user interface and user experience will need to be improved through ongoing discussions with PERKANI.

Linkage with physicians' societies is considered to be highly effective from a long-term perspective, as it enables simultaneous linkage with multiple medical facilities. In the conventional Gateway method, the system is deployed only within a medical facility where it is installed, so it will inevitably take time to expand the system to a wider area. However, the combination of the File Gateway method and academic societies has potential for deployment in regions such as Indonesia, where there are many remote islands and medical care is unevenly distributed.

On the other hand, from the perspective of business development, Allm Inc. believes that the FileGateway system will lose its advantage. Although academic societies are organizations that receive profits from companies, it is difficult for them to pay for services and actively use services from within their limited overall operating budgets. Therefore, Allm Inc. concluded that it should not position medical societies as direct customers, but rather as network builders.

６） Verification perspective 2: Related infrastructure

(a) Verification details

When introducing Join, technically verify that there are no problems in the related infrastructure such as communication infrastructure. The verification is mainly based on the following hypotheses.

- Image uploading from the dedicated app is smooth and easy.

(b) Verification method

Table VII-12 Method for testing hypotheses (Allm Inc.)

Hypothesis	Verification Method	KPI
Image update from the dedicated app can be done smoothly.	Confirmation through PoC	・ Properly upload files that comply with DICOM and other standards supported by Join

Source: Compiled by survey team

(c) Verification results, analysis

(i) Image update from the dedicated app can be done smoothly.

No notable problems were found in the communication environment. On the other hand, there were several medical facilities where the PoC was conducted that used medical equipment that did not support the DICOM standard. The main barrier to uploading non-DICOM standard images to Join was the need to convert the standard to analog format.

According to interviews with doctors who have used the system, even the in-house electronic medical record systems installed in tertiary care facilities often do not have vendor-neutral specifications that support the file formats of different equipment and systems, resulting in poor file compatibility. In an environment where the infrastructure for data standardization and utilization within the hospital is not in place, there are many cases where an application such as Join that assumes international standards such as the DICOM standard cannot properly upload files.

(d) Implications from the PoC

In reality, the problem is not the performance or function of the File Gateway itself, but the fact that the File Gateway does not work due to the fact that the medical facility is forced to import images that cannot be originally uploaded by Join due to problems with the facility. However, it is necessary to be aware of the possibility that this is the current situation in Indonesia and Southeast Asia.

７） Verification point 3: Business feasibility

(a) Verification details

Based on the results obtained from this PoC, we will examine the possibility of commercializing the communication application between medical professionals provided by Join in Indonesia.

(b) Verification method

The results of questionnaires to doctors who used Join will be conducted to confirm the responses from users. In addition to the information confirmed in verification perspectives 1 and 2, desktop surveys and other surveys were conducted as necessary to confirm demand and verify the possibility of commercialization.

(c) Verification results, analysis

The effectiveness of the File Gateway and the use of it by medical societies both proved to be difficult to develop and monetize. For the future development, the following story strategy is necessary.

- Continue to promote the use of PERKANI, but only as an awareness and advertising activity.
- Expand the network of PERKANI members to the medical facilities to which they belong, aiming for the possibility of securing revenue from the facilities.
- Aim to budget for MOH.

(d) Implications from the PoC

In addition to external factors such as the countless islands, the world's 4-largest population, and the rate of smartphone penetration, Allm Inc. was able to have concrete communication with PERKANI, which has a strong interest in telemedicine, which gave Allm Inc. the impression that the potential for telemedicine in Indonesia is very large.

However, as a result of the actual on-site operation of Join in this PoC, even the top referral hospitals for cardiology that are members of PERKANI were insufficiently developed in terms of infrastructure such as medical equipment used. Despite the fact that the PoC was conducted in the suburbs of a major city around Jakarta, the equipment used in the cardiovascular field was mostly ultrasound equipment, not CT or MRI, and many of them did not conform to the DICOM standard. In order to cope with this situation, there is room for reconsideration, such as the development of Join products that are compatible with standards other than DICOM, or changing the target diseases in the first place.

For example, although the number of CTs and MRIs is small at present, the company may approach hospitals that have the potential to introduce them, given the future economic growth and market expansion potential in Indonesia, or expand the File Gateway function to increase its share in the large number of Bottom of the Pyramid (BOP) markets. In the case of the former, it could be CT or MRI. In the former case, the target would be large hospitals that can install CTs and MRIs, while in the latter case, the target would be small and medium-sized hospitals to primary medical facilities. As a private-sector company, Allm Inc. cannot survive as a business without generating revenue, so it is necessary to determine the value to be provided and create a cash point.

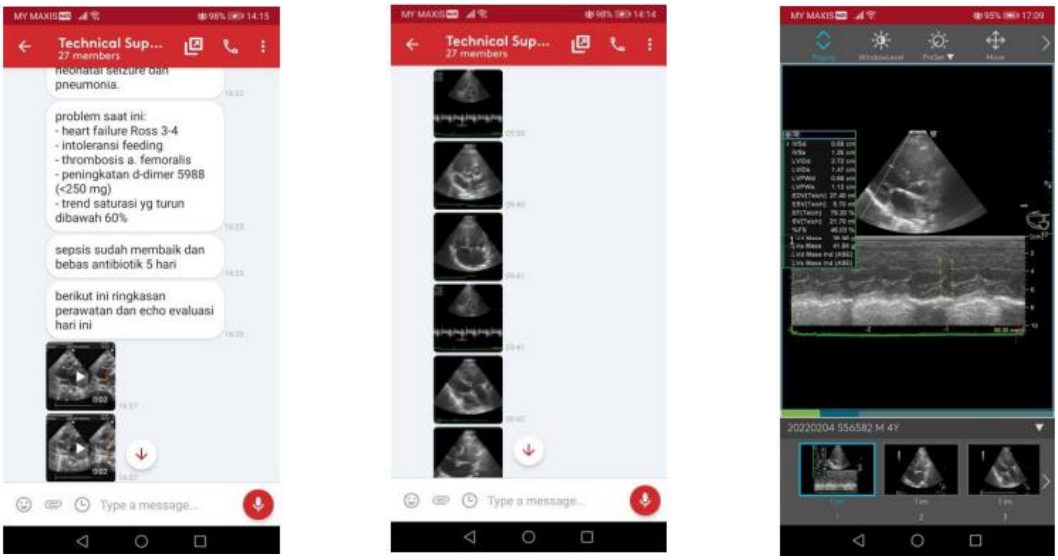
８） Local laws and regulations

In order to start the PoC, we checked whether there was a risk that the contents to be implemented in the PoC would conflict with local laws and regulations. A local law firm conducted a legal check and identified the following local laws and regulations and legal concerns in the PoC to be conducted by Allm Inc.

- If the role of the company is only to propose solutions, it does not constitute a local medical practice.
- Join is a communication tool between doctors, not a direct solution for patients. There is no current law that clearly stipulates the liability of the company providing the solution in the event of an accident such as a patient death.

While the relevant risks are not clear as described above, a suggestion from a local law firm is that it is important to agree on a disclaimer of possible risks between the company and the medical facility where the PoC will be implemented and to exchange a written document in advance.

９） During PoC implementation



Fegistration of case studies

Source: Compiled by survey team

１０） Sohyo (General Council of Trade Unions of Japan)

From the perspective of network building, it is meaningful to cooperate with academic societies such as PERKANI, but from the perspective of commercialization and monetization, it is more realistic to approach individual medical facilities that have ability to pay. One idea is to first collaborate with an organization that has a network such as an academic society, and then proceed with specific discussions with individual medical facilities participating in that organization.

However, there are some critical issues that need to be resolved before such a network can be established. For example, there are many medical devices that do not support the DICOM standard, an international standard, and electronic medical record systems in medical facilities do not have enough functions for archiving systems such as PACS to ensure file compatibility. In many cases, the infrastructure required to use Join is inadequate, but it may be necessary to consider commercialization by proposing solutions to the overall problem while also proposing solutions from other companies, such as iCOMBOX by ICHIGO LLC.

VIII. Final Proposal of Supporting Measure

VIII. Final Proposal of Supporting Measure

１． Verification of the hypothesis of the supporting measure

The hypotheses of the measures developed in Chapter IV were verified through interviews with stakeholders and PoC activities to see whether they are appropriate as measures that contribute to the sustainable and self-sustaining development of the digital health market by demonstrating added values to the target country government and private companies (including Japanese, target countries, and third countries) in the areas where the interests of the target country, companies, and JICA overlap, and with collaboration and co-creation with other stakeholders in mind. In addition, we verified the appropriateness of the proposed measures based on the hypothesis through interviews with related parties and PoC activities. Survey team also developed, revised, and concretized the policy ideas based on the hypothesis. One of the constraints in the hypothesis testing was that due to the spread of COVID-19 mutant strains (e.g., Omicron strains), some of the team members were unable to travel from Japan and conduct sufficient interviews with related parties.

１－１． Brazil

In Brazil, the following hypothesis was derived in Chapter VII: "In order to improve the quality of medical care caused by economic disparity, the digital health market in Brazil will be expanded and private digital health solutions will be introduced to hospitals and other facilities through the co-creation of Japanese and local companies with local innovation partners. The validity of this hypothesis is discussed in Chapter VII. The validity of this hypothesis was verified through the PoC activities and interviews with the following parties[232].

Table VIII-1 List of organizations conducting interviews (Brazil)

Interviewee	Category	Organization
InovaHC	Innovation Hub in the University Hospital of Sao Paulo	・ As a hub for collaboration between academia and the private sector, etc., advisory services for start-up companies, support for introduction and dissemination of technologies to medical facilitys, etc., and support for business expansion ・ In this survey, we will focus on the local medical facilitys that are participating in the PoC by Medical

[232] The20221 survey team members traveled to Sao Paulo for about2 a week, but due to the spread of the infection, the survey was limited to their stay in Sao Paulo, making it difficult to interview the Ministry of Health, local medical facilitys, subordinate medical facilitys, local venture capitalists, and other related parties.

Interviewee	Category	Organization
		Intelligence, LLC.
Ebserh	A public corporation that centrally manages all university hospital40 facilities in Japan.	・ Promote management, human resource development, and DX initiatives for national university hospitals under the Ministry of Education
NTTD Brazil (Everis)	Companies participating in the Innovation Hub (CUBO)	・ Provides business consulting, strategy, digital transformation, and IT development services
Mindify	Local Startup Company	・ Providingsolution to automate medical protocols into web forms using AI. [233]
FUJIFILM	How to enter the Brazilian market Japanese manufacturers	・ In Brazil, the company sells medical equipment, mainly endoscopes.
Canon Medical Systems do Brasil	How to enter the Brazilian market Japanese manufacturers	・ Sales of CT, MRI and other medical equipment in Brazil
Mitsubishi Corporation (Brazil)	In the Brazilian market Japanese trading company	・ Main businesses are mining-related, machinery-related, energy-related, chemicals, and lifestyle-related industries.
Santa Cruz Japanese Hospital	Japanese private hospitals in Brazil	・ Provides medical services at Hospital Israelita Albert Einstein, Children's Hospital, State Hospital, etc.

Source: Compiled by survey team

In this survey, we first interviewed the local innovation partners whose core positions in the country's digital health ecosystem were confirmed in the desktop survey. InovaHC, one of the leading innovation partners in Brazil, is an innovation hub that was established in 2018 as part of the Institute of Radiology (InRad) at the University Hospital of São Paulo. InovaHC is an

[233] Company website: https://www.mindify.net/english

innovation hub established as part of the Institute of Radiology (InRad) at the University Hospital of São Paulo. Specifically, as a hub for collaboration between academia and the private sector, it plays a wide range of roles, including joint development of medical device-related solutions with large companies, provision of PoC opportunities and advisory services to start-up companies, support for introduction and dissemination of technologies to medical facilitys, and support for business expansion.

Through the interviews, it was confirmed that what InovaHC is particularly emphasizing is the complex collaboration with various companies that have products and technologies to address issues in the medical field. For example, InovaHC is collaborating with a major medical device company to research remote diagnostic imaging support using AI, and in the future aims to link information with other medical facilitys such as the university's network in order to correct disparities in access to medical care between regions. However, in order to achieve this, technologies from other companies were required that could enable remote diagnostic imaging to be performed even in the fragile infrastructure of regional hospitals. Against this backdrop, InovaHC focused its attention on Medical Chigo, a limited liability company with image transmission technology, and participated in this survey as a PoC partner. The results of the hearing suggest that the complex collaboration of such technologies may lead to the improvement of the quality of medical care in the country. In addition, InovaHC has been searching for technologies on its own, but as it is costly and time-consuming to reach the required technologies, there is a high need for a role in connecting various cutting-edge technologies that Japan possesses in the future.

We also interviewed Ebserh, which centrally manages university hospital40 facilities across the country and plays an important role in reducing regional disparities. Ebserh is implementing joint programs with companies and research and development, as well as the use of medical big data to improve the efficiency of medical treatment processes, support decision-making by doctors, reduce the risk of medical errors, and promote preventive medicine. It is independent from the Ministry of Education and the Ministry of Health, and has a quick decision-making process, so it has started to use digital technology even before the spread of COVID-19. Ebserh's public network has a high potential to reduce healthcare disparities by introducing digital health technologies nationwide. InovaHC is not included in the network.

According to NTTD Brazil, which participates in CUBO as a maintainer, CUBO is an innovation hub with about250 a dozen startups and about30 a dozen major companies. In CUBO, there are several maintainers such as NTT DATA. In CUBO, there are several companies called maintainers, such as NTT DATA, and maintainers have the right to invest in startups and collaborate with them on technology, as well as to present a specific problem and solicit new solutions from startups participating in CUBO. Participating startups have solutions not only in the healthcare sector, but also in diverse areas such as finance, education, and logistics. Therefore, it is expected that collaboration with CUBO will be beneficial to gather open innovation for complex cross-sectoral issues, rather than issues specific to healthcare in Brazil.

In order to confirm the voices of local companies supporting the Brazilian digital health market, we also interviewed Mindify, a local start-up, and confirmed that innovation hubs such as CUBO have become the center of the digital health market. Mindify is interested in expanding its business not only to the Brazilian market but also to the Japanese market. Although it is impossible to generalize from the results of Mindify's interview, there is an impression that startups in Brazil have advanced digital health technology and tend to develop their business not only in their home market but also in the global market. This suggests that the maturity of innovation hubs in Brazil is high in terms of nurturing startups, and that innovation hubs have a significant influence on the digital health ecosystem.

In addition, in order to verify the hypothesized need for support for Japanese companies entering the Brazilian market, interviews were also conducted with Japanese private companies in the healthcare sector that have already entered the Brazilian market. According to FUJIFILM, they are conducting joint research using endoscopes with InovaHC, a company they met through their existing business network, and it was confirmed that teaming up with a local partner representing Brazil would be an advantage in future business development. In addition, Canon Medical Systems do Brasil is collaborating with InovaHC in the development of AI for MRI, and InovaHC is the largest network of medical facilitys in Latin America, with the largest number and highest quality of research facilities and researchers. In addition, when medical facilitys and companies collaborate, InovaHC acts as an intermediary and the collaboration procedures and processes are clear such as discussion and planning of collaboration contents, cost demarcation, schedules etc. and exchange of collaboration agreement etc., making it easy to collaborate. In this way, it can be said that innovation partners play an important role for Japanese companies in overcoming institutional challenges unique to Brazil, especially in the early stages of entering the Brazilian market, verifying local adaptability and business potential, and expanding their business.

As a result of testing the validity of the hypothesis, it can be said that collaboration with the innovation partners proposed in the hypothesis is expected to have a high impact on the autonomous development of the digital health market and ecosystem. In collaboration with innovation hubs such as InovaHC, it is highly likely that co-creation will be realized not only with medical facilitys but also with various stakeholders such as companies, start-ups, research institutions, and government agencies. As for the direction of providing support mainly to private companies in the field of digital health, in the case of Brazil in particular, digitalization of medical services is progressing not only in private medical facilitys but also in public institutions. In the case of Brazil, digitalization of medical services is progressing not only in private medical facilitys but also in public institutions.

In addition, the hypothesis was that the direction of the policy was to encourage companies to enter the market, especially in Brazil, but the results of the interviews suggest that it is highly significant to target start-ups, small and medium-sized companies, etc. that have digital health technology among the companies. However, the results of the interviews suggest that it is highly significant to target start-ups and small and medium-sized enterprises (SMEs) that have digital health technology. The Japanese companies that were the target of the interviews in this survey are already conducting joint research with InovaHC, etc. by utilizing their own business networks. However, relatively small and medium-sized companies and start-ups have yet to collaborate with InovaHC. As mentioned in Chapter VII, the results of this PoC activity showed that companies needed to confirm detailed items such as finding local partners, confirming laws and regulations, and concluding contracts, which required time and cost. In this sense, establishing a collaboration system with innovation partners in advance as a neutral party will enable agile solutions to issues that arise in the medical field. In addition, for many companies, the fact that a framework has already been established with a highly trusted local partner will motivate them to consider market development, and can be seen as a value that only JICA can provide.

On the other hand, as a point that was not sufficiently discussed in the hypothesis, in order to reflect the improvement in the quality of medical care caused by the economic disparity related to the target country's perspective and JICA's perspective, it is important for innovation partners to select partners that have the potential to develop into the country's medical issues. For example, in the case of CUBO, from the perspective of local companies, market expansion with an eye on the Japanese market is expected to be a higher incentive than solving problems in Brazil, and it may not be highly compatible with the objective of improving the quality of medical care in Brazil. Therefore, partners who can seek solutions from the medical issues in the field are expected to have a higher affinity. Furthermore, although the hypothesis was that the technologies expected from Japan to improve the quality of medical care would be in the area of diseases related to aging, many people would rather see the use of cutting-edge technologies (such as remote surgery and other 5G applications in the medical field) in a variety of disease areas. Therefore, in collaboration with Japanese companies, it is expected that they will provide support for the introduction of cutting-edge technologies with a view to utilizing them.

１－２． Kenya

As for the direction of JICA's policy in the field of digital health, which is the subject of this survey, Kenya is expected to "introduce appropriate digital health technologies at the primary care level to achieve UHC and strengthen the health system, and to build a foundation to enable private companies and start-ups with these technologies to enter the market (e.g., institutional In Chapter VII, the hypothesis was formulated that "the government and mainly public medical facilitys should raise the level of the healthcare system. The validity of this hypothesis was verified through the PoC activities and interviews with the following parties.

Table VIII-2 List of organizations conducting interviews (Kenya)

Interviewee	Category	Organization
Ministry of Tresury and Planning, Vision 2030	Social Policy Division, Medium- and Long-term Planning Bureau, Ministry of Finance and Planning	・ Kenya National Policy Making Body
Ministry of Health (Directrate General of Medical Service and Prevention)	Health Care and Prevention, Ministry of Health	・ Overall coordination of technical work within the Ministry of Health.
Ministry of Health (Policy and Planning)	Department of Planning within the Ministry of Health	・ Undertake work related to policy formulation within the Ministry of Health.
Ministry of Health (e-Health)	e-health division within the Ministry of Health	・ Work related to e-health within the Ministry of Health (e.g., formulating laws (e-health Bill)).
Ministry of Health (ICT)	ICT Technology Division within the Ministry of Health	・ Responsible for ICT-related technology within the Ministry of Health.
Ministry of Health (Primary Health Care)	Primary Health Care Bureau within the Ministry of Health	・ Perform primary health-related work, mainly in primary health care facilities within the Ministry of Health.
Ministry of Health	Primary health care section	・ Section in charge of services ranging

Interviewee	Category	Organization
(Division of Primary Health Services)	in the Ministry of Health	from community health to primary health care within the PHC bureau
National Hospital Insurance Fund (NHIF)	A state-owned company of the Kenyan government that provides public health insurance	・ Provide health insurance to Kenyan citizen subscribers and their dependents (spouses and children).
The Council of County Governors	National Governors Association of Counties	・ Non-partisan organization established under the Intergovernmental Relations Act (IGRA 2012), 19Art. ・ The Governor's Council is made up of the governors of the 47counties.
PPB (Pharmacy and Poisons Board)	Medical Devices and Drugs Regulatory Authority, Government of Kenya	・ It regulates the manufacture and trade of medical devices, pharmaceutical spare parts, and poisonous substances in the country.
Kenya Association of Private Hospitals	A hospital association composed mainly of private hospitals	・ Improves working conditions, provides educational opportunities, legal support, and professional liability insurance for private hospitals and other institutions.
Metoropolitan Hospital	5Next level private hospital in Nairobi	・ Same as on the left.
Nairobi Women's Hospital	Private hospital specializing in women in Nairobi	・ Same as on the left.
DPHK (Development Partners for Health in Kenya)	Donor Coordinating Agency	・ Coordinating body for donors (international organizations, bilateral organizations, international NGOs, etc.) working in Kenya, with regular monthly meetings and various coordination activities
The International Finance Corporation (IFC)	International Development Finance Institutions	・ Support digital health startups through the Tech Emerge program.
Surgipharm	Local pharmaceutical company dealing with healthcare-related products	・ One of the largest pharmaceutical companies in the country, with branches in Nairobi and Mombasa

Interviewee	Category	Organization
PSI (Population Services International (PSI))	A duly registered international non-profit organization	・ He has worked on a wide range of medical topics including HIV/AIDS, reproductive health and family planning, non-communicable diseases, malaria, diarrhea, pneumonia, and malnutrition.
My Dawa	Local Startup	・ Provide electronic prescriptions and improve patient access to various medicines.
Daktari Afrika	Local Startup	・ Diagnostic services by cardiologists are provided remotely through private non-profit hospitals.
Asia Africa Investment & Consulting (AAIC)	Strategy Consulting & Investment Fund	・ Established a healthcare fund based in Kenya that specializes in medical care and invests in local companies. ・ Provides consulting services for Japanese companies in the areas of overseas market entry strategy planning, new business development, and market research.

Source: Compiled by survey team

First, in order to understand the current situation of private hospitals in the field of digital health, we interviewed the Kenya Association of Private Hospitals (KAPH). According to KAPH, the use of digital health solutions has become widespread in recent years because private hospitals have the funds to build systems and train their staff. The main area of digital health technology is telemedicine, such as online medical treatment conducted by medical professionals through mobile apps and communication platforms, and in recent years, online medical treatment by psychiatrists and psychologists has also been expanding. However, according to interviews with Nairobi Women's Hospital and Metoroplitan Hospital, although many services and payments, including insurance premiums, have been digitized, each is an independent system and inefficient. On the other hand, according to KAPH On the other hand, according to KAPH, most of the public medical facilitys have not yet been digitized, and under-declaration of income is still occurring due to paper-based systems, and the infrastructure necessary for the introduction of digital health technology is not yet in place. One of the risks associated with such a delay in digitalization is that fragmented patient data may lead to repeated wrong medical procedures and increased financial burden for patients. In addition, even if the data is collected, the interoperability of the system was pointed out, as it is not possible to exchange data between healthcare data management systems, which prevents the referral higher medical facilitys from properly diagnosing the symptoms. The results of the interviews suggest that there is a gap between public and private medical facilitys in Kenya due to the delay in digitalization, and this may have an impact on the quality of medical services. The results of the interviews suggest that the establishment of a data infrastructure for medical facilitys and data collaboration among medical facilitys are essential for the effective use of digital health technology.

We interviewed the Assistant Director General of the Ministry of Health and the Department of Planning regarding the introduction of digital technology in these public medical facilitys, and they reported that the Ministry of Health has been promoting digital health (e.g., establishment of data centers) as part of its action plan, using development policy loans from the Japanese government. He reported that the Japanese government has been promoting digital health (e.g., establishing a data center) as part of its action plan, using development policy loans. The District Health Information Software 2 (DHIS 2)[234] uses the Internet to monitor disease statistics in all medical facilitys and public health facilities, and to provide information on preventive medicine, HIV/AIDS, and other diseases. DHIS 2 uses the Internet to monitor and track disease statistics, preventive vaccinations, HIV/AIDS and other public health measures, and COVID-19. On the other hand, DHIS 2 has not yet been fully implemented in private medical facilitys, and in general, different electronic medical records and other systems are used by different medical facilitys, and different health insurance payment systems are used by different insurance institutions. In order to strengthen the health system, improve efficiency in medical facilitys, and enhance the quality of services, the Ministry of Health is developing a DHP to integrate payment systems and Electronic Health Records (EHR) to enable seamless sharing of medical data as a nation, both public and private. The DHP is based on the Health Act 2017, which is based on the integration of information, and aims to be a platform where individual digital technologies developed by various stakeholders, including the private sector, can be utilized. It will be possible to realize a common nationwide electronic medical record that will allow citizens to access their medical data at any medical facility with only information such as national ID and birth certificate number. Currently, the Ministry of Health is in the process of formulating an e-health law to implement the DHP, and plans to set up data centers where IT infrastructure and personal information protection will be ensured, as well as pilot projects to check data operability in Nairobi and Machakos County. Thus, the hearing from

[234] DHIS2 is an open source web-based platform used as a health management information system (HMIS).

the Ministry of Health confirmed that the creation of a medical information infrastructure for the centralized management of data is being addressed as a matter of utmost importance.

The importance of DHPs was also pointed out in a hearing held by NHIF, which manages the national health insurance. According to NHIF, In recent years, an e-claim system has been introduced in all certified medical institutions, enabling the linkage of Benefits (services), Provider (certified medical institution), and Member (insurance subscriber). NHIF certifies all public medical institutions from primary to tertiary level and private medical institutions at the secondary level and above, but there remain many facilities that are not certified for primary level private medical institutions. The NHIF has introduced these digital technologies, but the payment for medical services through digital health technology is within the scope of the DRGs, which requires coordination with the EMR of each medical facility. It is also important to link basic personal information on the platform, such as social security information and family register information, in order to curb medical fraud. Therefore, NHIF would like to cooperate with the DHP promoted by the Ministry of Health to realize data linkage with various organizations. In this regard, the Department of E-health of the Ministry of Health also hopes to establish a centralized platform like the DHP for all health insurances, including NHIF, to enable the sharing of data that can be used to verify the identity of patients when they are uninsured. This suggests that improving the payment function of the NHIF through DHPs is also an important position in promoting the use of universal health insurance.

The AAIC, which has been investing in local private companies with digital health technology, confirmed its expectations for the improvement of NHIF functions through the DHP. Currently, there are many inefficiencies in health insurance, especially in the field of NHIF, such as lack of online payment and timely payment to medical facilitys. Universal health coverage is one of the most affordable insurance for many Kenyans and they mainly receive their health services from public health institutions. Therefore, it is considered that enhanced data linkage between medical institutions and NHIF will improve these services and expand the healthcare market.

In terms of the future development of the DHP, according to the Department of Planning of the Ministry of Health, they have already analyzed the gaps in the digital sector initiatives.202112 Through the Intergovernmental Forum (a forum organized by the Ministry of Health several times a year with the participation of county government health officials to promote coordination between the central and local governments), the current situation has been shared with the county governments. As the DHP covers many modules (patient information, drug information, insurance information, human resource information, DHIS as output, etc.), the Ministry of Health believes that it is essential to first share the results of these analyses with a wider range of stakeholders, and to build consensus and initiative through repeated consultations. We believe that it is important to share the results of these analyses with a wider range of stakeholders to build consensus and initiative for further discussions. Until now, each stakeholder has developed their own digital technologies without having a platform for information integration, and the lack of such integration has become a bottleneck in improving the efficiency and quality of healthcare services. Therefore, the stakeholders include the public sector such as the central government, county governments, NHIF, and public health institutions, as well as representatives of private organizations such as Kenya Healthcare Federation (KHF) and Health Nurses Network (HENNET), service providers, private insurance companies, and tech companies. Service providers, private insurance companies, and tech companies. According to KAPH, there is currently a mismatch between digital health technology developers and users, mainly healthcare institutions, due to the lack of a joint forum for developers and innovators. The lack of a joint forum for developers and innovators has been cited as a reason for this mismatch. In order to solve the existing problems faced by developers and to improve the system through feedback from users, it is presumed that promoting communication between various stakeholders, especially developers and users, will be important in the promotion of DHP.

In addition, we interviewed the Department of Primary Health Care within the Ministry of Health about the possibility of introducing digital health technology in primary health care, which was presented in the hypothesis. Currently, the digitalization of community health care is being carried out by major company in Isiolo according to MOH's request, with financial support from a major health care company and technical cooperation from the ICT Division of the Ministry of Health, to introduce DHIS II to the community health level, revise the health worker education curriculum, and introduce smartphones and tablets. These activities are also being carried out by the Department of Planning, Ministry of Health. It was confirmed that these activities are also part of the DHP initiative led by the Department of Planning, Ministry of Health. Currently, there is some progress on pilot activities to establish a Primary Healthcare Network (PCN) to connect communities to higher level medical facilitys. In the Kenyan health system, both the referral system to higher levels and the referral system to lower levels are important, and the establishment of a PCN will further strengthen the existing referral system. The PCN is expected to further strengthen the existing referral system. However, since referrals themselves are currently paper-based and limited, we believe that the use of digital technology is important to make this happen. Thus, even in the field at the community level, as a framework for DHP, we are actively working on digitization at the level of primary health care institutions, and among other things, the use of digital health technology to support communication in new networks is expected.

As a result of the above interviews, the direction of support for the introduction of digital health technology targeting the government and mainly public medical facilitys, which was the central axis of the hypothesis, will contribute to the improvement of public medical services, the achievement of UHC, and the development of the digital health market in the target country, although not directly. It is also expected to contribute to the development of the digital health market in the country, although not directly. From the interviews with stakeholders, it was confirmed that in general, public institutions in Kenya are lagging behind in digitalization, which creates a further quality gap with private healthcare services. Public institutions, such as the Ministry of Health, are already aware of these issues and are eagerly working on the introduction of DHIS2, including the establishment of a surveillance system (mSoS[235]), and the establishment of a DHP, utilizing the support provided by Japan to date. The DHP in particular is expected to play an important role in the smooth payment of NHIF to medical facilitys, and the creation of such an infrastructure is essential to the goal of achieving UHC. In addition, the improvement of the environment for medical information infrastructure and insurance systems is likely to contribute to the development of private digital health technologies and the promotion of demand for the use of these technologies.

In the hypothesis, specific approaches and target areas were not sufficiently considered for the creation of institutional and system infrastructure, but through the verification hearings, it was confirmed that there is a high need for opportunities for public-private co-creation through dialogues and other means for the creation of infrastructure. The Ministry of Health recognizes that the first important step is to share the bottlenecks in the country's digital architecture that have been identified so far in the DHIS2 and DHP initiatives with various stakeholders and to discuss them with them. This is also a desirable direction for the private sector. In the past surveys, it has been confirmed that unestablished or unclear national systems and regulations for digital health have hindered innovation and market entry by the private sector, and by creating opportunities to promote co-creation between the public and private sectors, we believe that we can further encourage the creation of infrastructure.

On the other hand, with regard to the use of digital health technology for primary health care as hypothesized, although it is expected that digital technology will be used for referral systems, etc. in line with the new PCN framework, it could not be fully confirmed at this hearing how exactly it will be introduced. As for PCNs, a pilot project is currently underway with the support of Italy, the World Bank, UNICEF, etc., with the goal of establishing at least1

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one PCN in each sub-county. Although the introduction of digital health technology at the level of primary health care institutions is considered to be highly effective, the new PCN concept itself is still in the trial stage and digitalization is still in the beginning stage, so it is necessary to continue to discuss how to introduce digital health technology.

Finally, the survey also interviewed IFC and AAIC, both of which are engaged in support and investment activities focusing on the private tech market in Kenya. IFC believes that while the World Bank's IDA and IBRD are engaged in public sector development, their role in promoting the private market is important, and they are supporting private tech companies through their techemerge The IFC supports private tech companies through its techemerge program. AAIC is also looking forward to JICA's investment partnership in the same way. As for the possibility of JICA's direct financial support to these private markets, it is necessary to consider what kind of added value JICA can provide to the digital health market, as many other donors and foundations are making similar efforts.

１－３． Indonesia

As for Indonesia, the hypothesis for the direction of JICA's policy in the field of digital health, which is the subject of this survey, is as follows: "In order to improve medical services in remote areas, the Indonesian government will support the creation of a system and structure to introduce and promote innovations specialized in telemedicine at the national level, based on existing JICA project partners and technologies. In Chapter VII, the hypothesis that "the Indonesian government will support the creation of institutions and systems to introduce and promote innovation in telemedicine at the national level based on existing JICA project partners and technologies to improve medical services in remote areas" was derived. The validity of this hypothesis was verified [236] through the PoC activities and interviews with the following parties.

Table VIII-3 List of organizations conducting interviews (Indonesia)

Interviewee	Category	Organization
Gadjah Mada University	National University of Indonesia, headquartered in Yogyakarta	・ Supporting various initiatives of the Ministry of Health in the field of medical informatics and digital health
Halodoc	Local digital health start-up (Doctor to Patient)	・ Indonesia's largest provider of online medical consultation and drug

[236] In this study, due to the spread of COVID-19 infection, it was not possible to travel to the site and remote interviews were conducted through local staff.

Interviewee	Category	Organization
		delivery services to patients
Docquity	Local Digital health Startup (Doctor to Doctor)	・ Support for consultation and collaboration among physicians, including continuing medical education and medical conferences at medical facilitys and national medical associations through a dedicated network of physicians
Officials from medical facilitys in the eastern region of Indonesia	(Medical professionals working in remote areas who participated in this survey for the hearing)	Hearing participants ・ Doctor in Sorong City, West Papua Province ・ Doctor in a mental medical facility in Southwest Sumba Regency, East Nusa Tenggara/NTT Province ・ Doctor in Puskesmas in Raja Ampat Regency, West Papua Province ・ Doctor in Puskesmas in Raja Ampat Regency, West Papua Province ・ Doctor in Puskesmas in Asmat Regency, Papua Province ・ Doctor and Head of Puskesmas in Siau Island Regency, North Sulawesi Province
UNDP	International Organizations Focusing on Digital Health in Indonesia	・ UNDP has signed a MoU with the Alliance for Telemedicine in Indonesia (ATENSI) to promote telemedicine services, and is providing support for policy formulation.
ATENSI	Indonesia Telemedicine Alliance	・ Develop regulations related to telemedicine, remote services for COVID-19, and conduct webinars to promote project telemedicine.
Association of Health-tech Indonesia	Association for Healthtech Businesses and Professionals	・ In collaboration with the Ministry of Health,1) a regulatory sandbox for

Interviewee	Category	Organization
		digital health startups related to business model development and interoperability, and2) support for the digitization of healthcare institutions. ・ Supporting capacity building of medical professionals in collaboration with the Ministry of Information and Communication

Source: Compiled by survey team

First, we interviewed medical facility personnel working on remote islands in the eastern region of Indonesia about the challenges of providing medical services on remote islands and expectations for telemedicine. Many of the medical professionals mentioned that the medical challenges in remote areas are the limited number of medical personnel (especially doctors and pharmacists) and the inability of patients to access the nearest medical facilitys. To solve these problems, D to D and D to P telemedicine technologies are expected to be beneficial for medical facilitys in remote areas. However, some medical facilitys face infrastructure problems such as lack of reliable access to electricity and networks (cell phones and Internet networks), and most patients and community members do not have cell phones to receive telemedicine services. However, some of the physicians in the discussion do use social media platforms such as WhatsApp to discuss their patients' symptoms with other health care providers. These doctors are aware of the risks of data security and therefore believe that the option of adopting telemedicine services that allow for safer and more secure data exchange is desirable. Regarding the issue of infrastructure, a program in the Ministry of Information and Communication (Kominfo) is working on Internet connectivity throughout Indonesia, and it was found that the infrastructure and other conditions vary from one remote area to another, and the needs vary.

In addition, through discussions with medical personnel, we learned that in order to provide a full range of medical services from diagnosis to treatment, these remote islands need to (1) strengthen laboratory capacity (e.g., blood tests for liver and kidney function and other complications to identify chronic diseases in patients are not available), (2) deploy medicines (e.g., acute respiratory infectious diseases, hypertension, malaria, etc. are not available), and (3) securing transportation to higher level medical facilitys that can provide treatment (e.g., there is no transportation such as ship or plane transport to refer patients to

the nearest hospital or Pushkessma) were also identified as essential. Even if more advanced medical treatment and diagnosis can be provided by the introduction of telemedicine, it is suggested that in order to improve the health status of the residents of remote islands through subsequent treatment and follow-up, it is necessary to consider measures to deal with these improvements in parallel with the introduction of telemedicine technology.

In order to improve the medical environment in such remote areas, the Indonesian government has also launched a telemedicine platform, TEMENIN, in 2017. According to the interview, TEMENIN mainly covers 4 areas: teleradiology, tele-ultrasound, tele-electrocardiography, and tele-consultation. It is basically a D to D service used between medical facilitys (GPs to specialists, etc.) and has telemedicine programs in rural areas, mainly in partnership with 136 radiologists, 186 cardiologists, 136 obstetrician/gynecologist, and 377 general practitioner. Gadjah Mada University, in collaboration with the Ministry of Health and the National Planning and Development Agency, assisted in the implementation of TEMENIN in 3one primary health care institution and one upper referral health care institution in West Papua Province. According to Gadjah Mada University, in addition to the above-mentioned issues reported by the medical staff in the remote islands, TEMENIN is facing (1) unclear payment mechanisms and (2) insufficient capacity of medical staff. Among them, regarding (1), the payment mechanism is currently twisted between Puskesmas (using capitation tax) and hospitals (reimbursement system based on diagnostic groups), and as a solution, applying a mechanism to add capitation fee for Puskesmas is being considered. The Ministry of Health and the National Health Insurance/BPJS are planning pilot projects in 5 regions of Indonesia to try out the new payment mechanism in 2020, but due to limited human and financial resources, the implementation is being postponed. (2) Lack of capacity of healthcare professionals in Indonesia includes lack of clinical expertise due to the absence of doctors, as well as lack of knowledge and experience in the use of digital technology. As described above, the introduction of telemedicine has not been verified yet, although efforts have been made, because there are still peripheral issues such as differences in the systems among medical facilitys that collaborate with each other, and even if they are connected remotely, there is still a lack of capacity to actually respond by using digital technology.

In this hearing, private companies that are developing telemedicine solutions in Indonesia also strongly pointed out issues related to systems and regulations. DocQuity, a company that provides a platform for doctors to consult and collaborate with each other, hopes to solve the uneven distribution of medical services in the region, as the number of medical specialists in Indonesia is relatively small and most doctors tend to live in the capital or urban areas. However, with regard to the development of telemedicine services in remote areas, Indonesia's regulatory framework is a fundamental issue, and the government is strongly advocating the need for the development of regulations to make telemedicine a reality, including regulations on personal information protection and electronic medical records. Regulations on personal information protection have not yet been finalized by the National Legislative Program (Prolegnas) and are still in the process of being developed. Regulations related to electronic medical records are still under discussion for revision within the Ministry of Health. Furthermore, in order to enable doctor-to-patient telemedicine services, the Law on Medical Practice (Law/UU No. 29, 2004) [237]needs to be amended, but it is not easy to amend the law and is expected to take some time. Similarly, halodoc, which provides online medical consultation and drug delivery services to patients, pointed out that the development of these regulations is the most serious challenge for the introduction of telemedicine. They are also attempting to collaborate with BPJS again, but noted that it is difficult to expand service coverage because the payment mechanism is unknown at different levels of medical facilitys. Thus, it can be inferred that although the private sector is willing to introduce telemedicine to remote areas, undeveloped regulations and unclear payment systems are hindering its advancement.

It was confirmed that UNDP and the UK government[238] are working with the Ministry of Health to develop a roadmap to solve the complex challenges of telemedicine in these regulations and systems. According to UNDP, it has signed an MoU with the Indonesian Telemedicine Alliance (ATENSI), a forum for Indonesian healthcare professionals who use digital technology and telemedicine, to promote telemedicine services, and developed a Blueprint for Digital Health Transformation Strategy 2024[239] with the Ministry of Health in December 2021. In particular, telemedicine services including Doctor-to-Patient online consultations at first-line healthcare providers (FKTPs), which include primary medical institutions such as Puskesmas and community health centers, is planned to improved by 2023 and to be expanded by 2024, including in remote areas. The transformation Roadmap in the Blueprint for Digital Health Transformation Strategy is divided into 3 major activities, among which the expansion of telemedicine technology is mentioned as "development of medical technology ecosystem," indicating that the government is also focusing on telemedicine. The UNDP is currently developing a roadmap for the implementation of this blueprint, with a focus on telemedicine (to be completed by the end of March,2022). The UNDP is currently developing a roadmap for the implementation of this

[237] Regarding the regulation of doctors versus patients, the current Medical Service Act requires doctors to perform physical examinations (inspection, palpation, percussion, and auscultation) to establish a diagnosis, which cannot be done by individual doctors unless the patient goes to a medical facility.

[238] The UK government signed a Memorandum of Understanding (MoU) on health cooperation with the Indonesian government during the 20206year. According to UNDP, the UK government's telemedicine efforts have not been directly coordinated to date.

[239] https://dto.kemkes.go.id/ENG-Blueprint-for-Digital-Health-Transformation-Strategy-Indonesia%202024.pdf

blueprint, focusing on telemedicine, and it is expected that the development of telemedicine in Indonesia will be promoted in accordance with the strategies in the roadmap. In Indonesia, the government has just begun to move in earnest toward the realization of telemedicine, and support for the implementation of these policies will be required in the future.

Finally, we interviewed the Indonesian Healthtech Association (AHI), which provides a forum for digital health startups to collaborate in Indonesia. AHI that had established 2018 works with the Ministry of Health to (1) sandbox regulations related to business model development and interoperability for digital health startups, and (2) support the digitization of medical facilitys. In addition, in collaboration with the Ministry of Information and Communication, it is developing human resources for digital health and capacity building for medical professionals. According to the hearing, with regard to (1), the Ministry of Health established a new Digital Transformation Division in 2021 and is actively working on the broad dissemination of digital health technologies, including the introduction of a regulatory sandbox system. Specifically, in urban areas, AHI provides capacity building sessions mainly through video conferencing and other educational technology platforms dedicated to health education, such as microlearning and e-libraries. On the other hand, AHI also supports training and capacity building for health workers in remote areas using floating hospitals (e.g., the floating hospital developed by UNAIR) that can go to remote areas, as trainers need to meet and talk with health workers in person. The interview with AHI suggests that it is important to accelerate efforts to introduce telemedicine by utilizing regulatory sandboxes to test new approaches in the future.

From the above, it was reconfirmed from the interviews with many people involved that the provision of inadequate medical services in remote areas, which was the central issue in the hypothetical target country, is regarded as a serious medical issue for the entire country. In particular, the introduction of telemedicine is expected to be a solution to the shortage of doctors in remote islands. Against this background, telemedicine programs such as TEMENIN have been implemented mainly by the Ministry of Health, and the Blueprint for Digital Health Transformation Strategy 2021122024 was formulated by the Ministry of Health with the support of UNDP. One of the characteristics of Indonesia is that the efforts to promote telemedicine, which were previously undertaken by different stakeholders, are now beginning to move as a more integrated effort. The hypothesized direction of support by the Indonesian government is to support the creation of systems and structures to introduce and promote telemedicine-specific innovations at the national level. The direction of the support is highly significant to promote the development of the country's digital health sector.

On the other hand, although the hypothesis indicated that the approach should be based on existing JICA project partners and technologies, the results of the verification suggested from the interviews that a broader partnership is needed to realize the introduction of telemedicine, especially to remote islands in Indonesia. The reason for this is that there are a wide range of problems that need to be solved in order to introduce telemedicine technology to medical facilitys in remote islands and for residents to actually receive consistent medical services, from medical treatment to medical care. Throughout the interviews, the introduction of telemedicine in remote areas can be broadly divided into the following areas: insurance coverage, payment mechanisms, regulations for such as personal information protection and EMR/medical practice etc., infrastructure, human resource development, and the development of pharmaceutical logistics, laboratories, and a treatment system that is accessible to residents in order for them to receive a full range of services using telemedicine technology. In addition, in order for residents of remote islands to receive a series of services using telemedicine technology, it is necessary to develop pharmaceutical logistics, laboratories, and a treatment system that is accessible to residents. For these issues, each party concerned has been working on modifying the existing regulations and introducing new systems by conducting pilot project, but the implementation has been stalled due to human and financial resource constraints. In order to overcome the challenges in realizing telemedicine in remote areas, it is necessary to collaborate with various stakeholders who are working on these issues, and it is also suggested that it is necessary to collect information and data through demonstration experiments and to review the existing framework in order to implement the new technology and medical service provision model of telemedicine in society. In addition, it is necessary to collect information and data through demonstration experiments and to review the existing framework in order to implement the new technology and medical service delivery model of telemedicine in society.

２. Finalizing the Supporting measure

In order to finalize the proposed measures, the feasibility of the measures and the procedures and issues for introducing the measures were sorted out, and opinions were exchanged with JICA personnel. We focused on the areas where the interests of the target countries, companies, and JICA overlapped, and on the proposed measures that would contribute to the sustainable and autonomous development of the digital health market by demonstrating the added value to the target country governments and private companies (including Japanese companies, target countries, and third countries) with the collaboration and co-creation with other stakeholders in mind.

In final measure proposal, the current status of the issues to be solved by the measure proposal and the desired state, the value that JICA can provide and the impact of the

measure, and the partners involved by each measure proposal as described in the "Approach to Support" section and the possibility of collaboration and co-creation with them were organized.

Table VIII-4 Items to be considered for supporting measures

Main issue	What is the problem that the measure wants to solve?
Gap between current situation and what want to achieve	What is the current state of the issue (as is), what is the ideal state (to be), and what are the gaps?
JICA value proposition/strengths	What are the strengths and assets that are unique to JICA?
Possible clients	Who exactly will you provide value to?
Possibilities for collaboration and co-creation	Who and what kind of co-creation will be created by the measures?
Ultimate beneficiary	Who in the medical and peripheral fields will benefit from the measures?

Source: Compiled by survey team

２－１． Brazil

As for the proposed measures for Brazil, the following measures are finally proposed as a result of the above verification.

（１） Support for collaboration with InovaHC to implement digital health technology to solve medical issues

Overview

This initiative will establish a collaboration system and implementation framework with InovaHC, a local innovation hub, to agilely verify and improve the technologies of Japanese start-up companies to address issues faced by the medical field, introduce ICT solutions that contribute to solving local medical issues, and support Japanese companies to enter the Brazilian market. We will also support Japanese companies to enter the Brazilian market.

Background of selection and significance of implementation

This survey is based on the hypothesis that, in order to improve the quality of medical care caused by economic disparities, the expansion of the digital health market for measures against diseases specific to Brazil and the introduction of private digital health solutions to hospitals, etc.

will be encouraged through the co-creation of Japanese and local companies, centered on local innovation partners. As a result of the verification, it was found that the digital health technology has a significant impact on the healthcare market. As a result of the verification, it was determined that InovaHC of Sao Paulo Hospital, which has digital health technology, the largest network in Brazil, and high level of willingness to accept Japanese companies, would be highly significant as a local partner for solving issues in the medical field in Brazil and for Japanese companies to enter the Brazilian market. InovaHC is highly motivated to accept Japanese companies. InovaHC aims to address these issues through the development and demonstration of digital health technology, and the ICT technology verified here can be disseminated to many medical facilitys through InovaHC's largest medical network in the country. The ICT technology verified here will be able to spread to many medical facilitys through InovaHC's largest medical network in Japan. In addition, in terms of collaboration with various stakeholders, which is the subject of this survey, the collaboration with InovaHC is not limited to medical facilitys, but also includes private companies, research institutes, and government agencies, and is expected to lead to multifaceted co-creation with various actors.

InovaHC would like to consider the introduction of new solutions using digital health technology owned by Japanese companies to address the issues currently faced by the medical field, but the number of Japanese companies entering the Brazilian market is limited and they are not able to reach out to the market sufficiently. InovaHC is interested in solutions that can be remotely linked to the 50 facilities in its network, especially those that require advanced technology and equipment, such as remote surgery, in addition to remote consultation between doctors and remote image diagnosis. They are also interested in collaborating with Japanese telecommunication companies, as there is a lack of telecommunication infrastructure in Brazil to enable such collaboration between facilities in remote areas. In the future, InovaHC hopes to quickly solve the problems in the field by introducing the latest technologies and technologies related to the aging society that Japanese companies possess in a timely manner. In the future, InovaHC hopes to solve the problems in the field by introducing the aging-related technologies and the latest technologies of Japanese companies in a timely manner, and therefore, a platform and a framework for cooperation between Japanese companies with digital health technologies and the Brazilian medical field are needed to realize this. JICA has a track record of supporting many Japanese private companies, especially in the healthcare sector, through private sector collaboration schemes centered on research work, and has connections with private companies that have digital health technologies developed through this research, as well as experience in procedures for demonstration experiments with InovaHC. There is a high possibility that these assets can be utilized. In addition to InovaHC and Japanese start-up companies, which will be the main partners, this measure is expected to lead to a wide range of co-creation, including the spread of digital health technology through InovaHC's hospital network, collaboration with companies participating in InovaHC, and collaboration with doctors and researchers in the medical field. It is expected to contribute to the development of the ICT market and the digital health ecosystem, as well as to the improvement of medical services for patients.

Policy Outline	・ We will establish a collaboration system and implementation framework with InovaHC, a local innovation hub, to agilely verify and improve the technologies of Japanese start-up companies to address medical issues faced by hospitals, introduce ICT solutions that contribute to solving local medical issues, and support Japanese companies to enter the Brazilian market. Support
Main issue	・ Improving disparities in the quality of medical services
Gap between the current situation and what to achieve	・ Current situation (as is) : Although Japanese companies would like to consider introducing new solutions using their digital health technologies to address the issues faced by the medical field in Brazil, the number of companies operating in the Brazilian market is limited and they are not able to reach out sufficiently. Similarly, Japanese companies are also interested in the Brazilian market, but are hesitant to expand their business because they do not know what kind of regulations and business practices exist. ・ Objective : To quickly solve the problems faced by the medical field in Brazil by introducing aging-related technologies and the latest technologies owned by Japanese companies in a timely manner. ・ Gap: There are no platforms or frameworks for collaboration between Japanese companies with digital health technologies and Brazilian medical facilities.
JICA value proposition/strengths	・ JICA has a track record of supporting many Japanese private companies, especially in the health care sector, through private sector partnership schemes centered on research work. ・ We have connections with private companies with digital health technologies developed in this research and have experienced procedures to conduct demonstration experiments with InovaHC.
Possible clients	・ InovaHC University Hospital of Sao Paulo ・ Japanese companies and startups

	・ Doctors and researchers in the medical field
Possibilities for collaboration and co-creation	・ Social implementation of digital health technology with InovaHC ・ Business collaboration with Japanese startups ・ Spread of digital health technology through InovaHC's hospital network ・ Collaboration with companies participating in InovaHC
Ultimate beneficiary	・ Patients receiving improved medical services through ICT technology introduced through demonstration experiments, etc.

The detailed proposal for the implementation of the measures is as follows. This measure is highly feasible, as it is consistent with JICA's policy and the local partner, InovaHC, has high intentions for future collaboration.

Consistency with JICA policy	➢ This measure is consistent with JICA's Global Agenda 6. clusters to be focused on in health care and "strengthening core hospital diagnosis and treatment. In addition, Brazil's measures against NCDs and aging population are expected to be implemented in collaboration with local governments, universities, and private companies to deploy Japanese technologies to developing countries, and to return these technologies to domestic technological development. ➢ This measure is in line with JICA's Global Agenda 15 . "Promoting Digitalization", which is based on the principle of "Increasing the effectiveness of development and solving problems by promoting digitalization in each area and field of development (cross-sectoral mainstreaming of DX). (Cross-sectoral mainstreaming of DX)." This is consistent with "Implementation of new problem-solving approaches (development of new approaches)", which states that JICA will strategically address DX and promote issues that address the achievement of results in new areas and approaches through the use of digital technology. ➢ This measure also falls under the basic policy of ODA in the Country Development Cooperation Policy for Brazil, which states: "Assistance in areas that promote economic growth, including the expansion of human resources, with an eye to

	collaboration with private sector funds, such as the development of an environment for improving the investment environment and strengthening industrial competitiveness, and technical assistance.
JICA Support Form	Support for demonstration experiments by Japanese companies through information collection and confirmation surveys, etc.
Counterpart	InovaHC, University Hospital of Sao Paulo
Project Site	University Hospital of Sao Paulo
Implementation period	March 2022 - March 2024
Inputs and activities	Personnel: Consultants (agreement coordinators, demonstration experiment accelerators) Funds: Demonstration experiment support funds
Possibility of collaboration with existing projects	・ Information collection and confirmation survey on support for countermeasures against novel coronaviruses by global digital health ・ Tsubasa project
Future actions	・ Conclusion of Consensus Agreement ・ Establishing a demonstration framework with InovaHC ・ Establishing medical issue themes with InovaHC ・ Collaborate with the Ministry of Economy, Trade and Industry (METI) to identify Japanese companies for the Health Care Innovation Hub and Tsubasa project and create a pooling list of Japanese health tech companies. ・ Support for PoC implementation by Japanese companies that match the theme of medical issues

The following figure shows the digital health architecture of this initiative. In particular, by partnering with InovaHC, which plays an important role in the platform in cooperative area, the technologies and solutions of companies in the supply layer, which have not been connected individually in the architecture until now, will be able to complement each other or create a synergistic impact through inovaHC, based on the common goal of solving medical issues in the field. In addition, co-creation with a number of private companies that have cutting-edge technologies in competitive fields and solutions that do not exist locally in Japan to address the challenges of public healthcare in Brazil is a support that only the government can provide and is highly significant in terms of strengthening the country's digital health architecture. The significance of this project is high in terms of strengthening the country's digital health architecture.

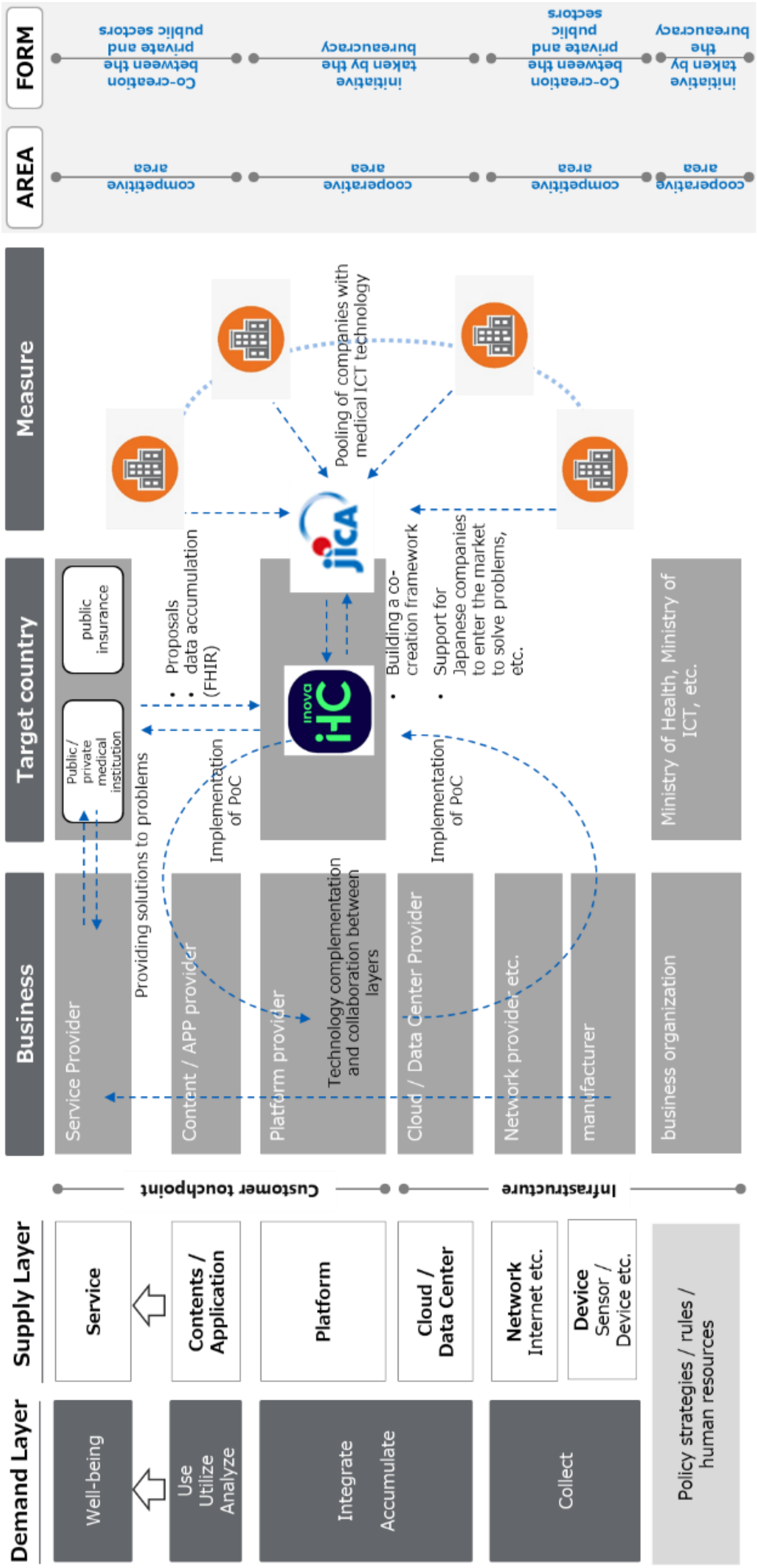


Figure VIII-1 Proposed Final Measures in Digital Health Architecture (Brazil)

Source: Compiled by survey team

Finally, the five-year (2022-2026) concept of Brazil's final proposal envisages the establishment of solutions to health issues in the field through demonstration experiments of new digital health technologies in the year 1 and 2, and the spread of the demonstrated and improved digital health technologies to subordinate medical institutions and regional hospitals in the year 3 to 5. As HCFMUSP, the parent organization of InovaHC, has a network of 50 medical institutions, the demonstrated and improved digital health technology is expected to be deployed vertically and horizontally in the network.

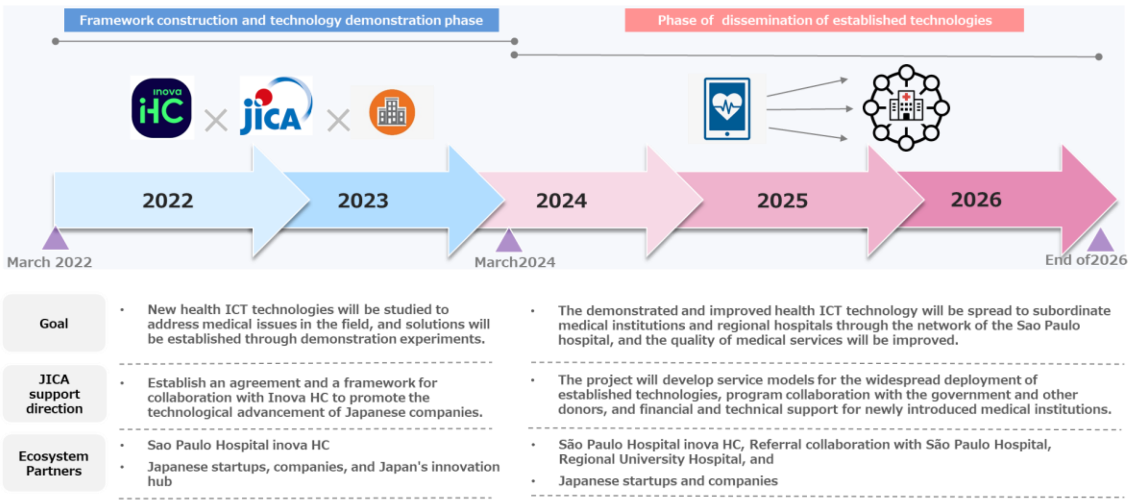


Figure VIII-2 Five-Year Roadmap for Proposed Measures (Brazil)

Source: Compiled by survey team

２－２. Kenya

As for the proposed measures for Kenya, the following measures are finally proposed as a result of the above verification.

（１） Support for conducting stakeholder dialogues to build a digital health platform

Overview

In order to build a digital health platform as stated by the MoH, this measure will promote dialogue between policy making/regulatory government agencies (MoH, Ministry of Finance, Ministry of Information, etc.), health administration implementing agencies (MoH, county governments), public/private medical facilitys, public/private insurance institutions, and private tech companies, and will provide lateral support for building a medical information infrastructure for the introduction of digital health technologies. Provide lateral support for the establishment of medical information infrastructure for implementation.

Background and significance of implementation

In order to achieve UHC and strengthen the health system, this survey has examined the measures to be taken by the government and mainly public medical facilitys, based on the hypothesis that the government will raise the level of medical care by introducing appropriate digital health technologies at the primary care level, and by creating an infrastructure that enables private companies and start-ups with such technologies to advance (e.g., by building systems and structures). As a result of this survey, we found that in Kenya, the number of private companies and start-ups that have the potential to enter the market has increased. As a result of the verification, a gap in the quality of medical services between public and private medical facilitys is beginning to emerge due to the delay in digitalization in Kenya. The promotion of the Digital Health Platform (DHP) was determined to be the highest priority support in this survey. In Kenya, the use of digital health technology is recognized as an important means of strengthening the health system, and the data linkage infrastructure between patient data and the NHIF is expected to play an important role in achieving UHC by enabling smooth payments to medical facilitys. In addition, the development of medical information infrastructure, insurance systems, and other environments will be essential for the development of private digital health technologies and the promotion of demand for the use of these technologies.

The Kenyan Ministry of Health is currently considering the establishment of a DHP that will serve as a foundation for sharing health and medical information, as the interoperability of health and medical information (disease information, medical services, PHR, insurance-related information, information on medical supplies, health human resources, etc.) is weak and information sharing is difficult. However, the DHP, which will cover a wide range of information such as patient information, drug information, insurance information, and human resource information, will require consensus building and initiative building among the parties concerned, as it is necessary to integrate the situation where each of these parties is developing and operating their own digital technologies. JICA has been cooperating with the Kenyan health sector for more than half a century and has built strong relationships with Kenyan stakeholders by being a major donor in the field of health system strengthening for UHC. It is likely to contribute highly to building DHPs from effective dialogue. In addition to the Ministry of Health, the County Government, NHIF, and public and private health institutions, which are the major clients of this measure, it is also expected to collaborate with private health institutions, private insurance institutions, tech companies, Kenya Healthcare Federation (KHF), HEALTH NGOS NETWORK (HENNET) In addition to the private healthcare institutions, collaboration with private healthcare institutions, private insurance institutions, tech companies, Kenya Healthcare Federation (KHF), HEALTH NGOS NETWORK (HENNET), and others is expected, and comprehensive co-creation in the digital health ecosystem that has not been tackled by other donors can be expected. Ultimately, this measure will lead to more efficient operations at medical facilitys and improved services for users of medical facilitys.

Policy Outline	・ Environment development and technical support for the establishment of a digital health platform: Support for the formation of dialogues to coordinate various stakeholders
Main issue	・ Health system inefficiencies due to lack of health information sharing among health administrators/health service providers
Gap between the current situation and what you want to achieve	・ As is : Weak interoperability of health-related information (disease information, medical services, PHR, insurance-related information, drug consumables information, health human resources information, etc.) makes information sharing difficult. ・ To be : To build a foundation DHP that will enable the sharing of health information to improve the efficiency and quality of health services. ・ Gap: Each of the parties involved in handling patient information, drug information, insurance information, human resource information, etc. are developing and operating their own digital technologies, and opportunities for consultation do not exist.
JICA value proposition/strengths	・ More than half a century of cooperation in the health sector in Kenya ・ Strong relationships with Kenyan stakeholders through being a major donor in the area of health systems strengthening aimed at UHC
Main Clients	・ Ministry of Health ・ County Government ・ NHIF ・ Public and private medical facilitys
Possibilities for collaboration and co-creation	・ Central government, county governments ・ NHIF ・ public medical facility ・ Private medical facilitys, private insurance institutions, tech companies ・ Kenya Healthcare Federation (KHF) ・ HEALTH NGOS NETWORK (HENNET) and others
Ultimate beneficiary	➢ Direct beneficiaries

	・ Department of Health, County Government: Enables accurate and immediate aggregation of medical information. ・ Public and private medical facilitys: Information coordination within hospitals will be possible, which will lead to more efficient medical practices. ➢ Indirect beneficiaries ・ Residents using medical facilitys (patients, etc.): Reduction of waiting time and explanation time to medical facilitys, and improvement of convenience when changing medical facilitys

The detailed proposal for the implementation of the measures is as follows. The proposed policy is consistent with JICA's policy, and the strong will of the Kenyan Ministry of Health (MOH), which will be the counterpart of JICA, to implement the DHP has been confirmed. Therefore, it is important to determine the implementation scope through further discussions.

Consistency with JICA policy	➢ This measure is in line with JICA's Global Agenda:6. Health Care cluster of focus: "To ensure access to health care services through the development and improvement of health care coverage systems by providing policy and institutional advice, coordination with service delivery, and financial support, while increasing national commitment. ➢ This measure is part of JICA's Global Agenda:15 "Promoting Digitalization. This policy is consistent with JICA's Global Agenda: "Promote digitalization to provide a basis for developing countries to reap the benefits of economic and social digitalization and reduce the disparities and safety risks associated with digitalization. This is consistent with the above. In particular, it is positioned as a side support for the implementation of information and communication infrastructure development (hardware support). ➢ This measure is in line with the Kenya Country Assistance Plan and will facilitate measures to achieve UHC.
JICA Support Form	・ Dispatch of experts in the field of digital health (Assumed to be a person who defines DHP requirements from a neutral standpoint with a high level of expertise, such as having the necessary knowledge of information linkage between systems

	and knowledge of linking digitized information to medical service improvement.) ・ Support for organizing workshops and forums
Counterpart	・ Planning Department, Ministry of Health, Kenya
Project Site	・ Ministry of Health, Kenya (Nairobi)
Implementation period	・ July 2022 - June 2026
Inputs and activities	・ Personnel: Expert (digital health field) IT coordinator experience ・ Funding: WS and forum support for DHP construction
Possibility of collaboration with existing projects	・ Health Sector Policy Loan for Achieving Universal Health Coverage (Phase2) ・ Project to Strengthen Accountability in County Health Service Management (Study Subject)
Future actions	・ Confirmed the results of the digital health gap analysis with the Ministry of Health ・ Selection of dialogue stakeholders based on stakeholder analysis ・ Conducting gap analysis WS on digital health architecture (forming the initiative of various stakeholders, formulating specific implementation plans, etc.)

The following figure shows the digital health architecture of this initiative. In Kenya, the supply layer of contents and applications is a competitive area that has been activated mainly by local start-ups, but the information platform, which is the core of the digital health architecture, is not yet mature. This measure supports the construction of DHP, which is expected to be tackled by the government as a cooperative area to address the same issue. This will enable interoperability between the various layers in the fragile digital health architecture, which until now has lacked vertical coordination, to achieve seamless medical and health information coordination and improved medical services for patients. Especially in this measure, since there are companies and parties involved in the digital health architecture with different systems and interests, it is important to have a bird's eye view of their roles and relationships through the digital health architecture and to integrate them as a platform.

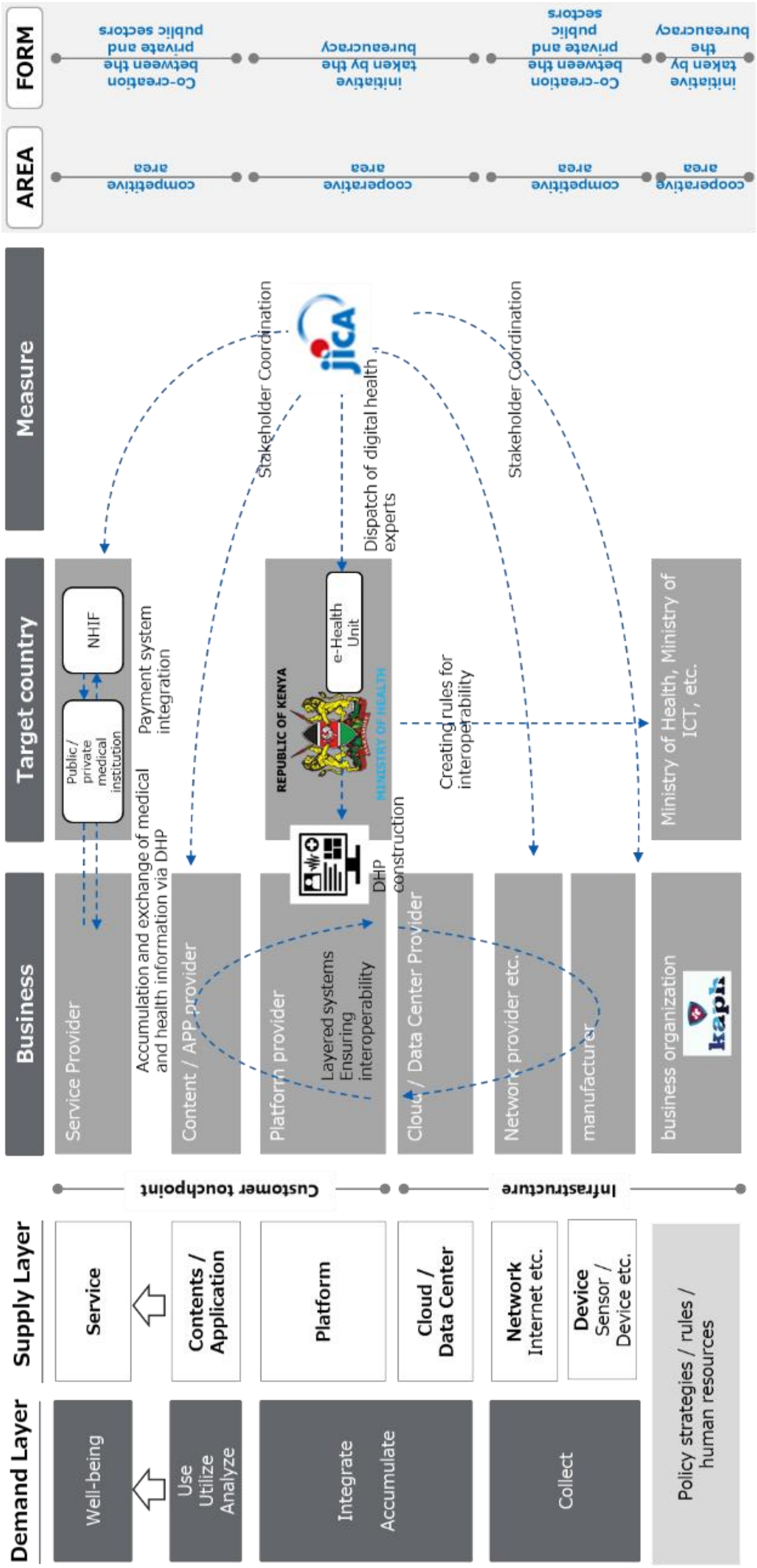
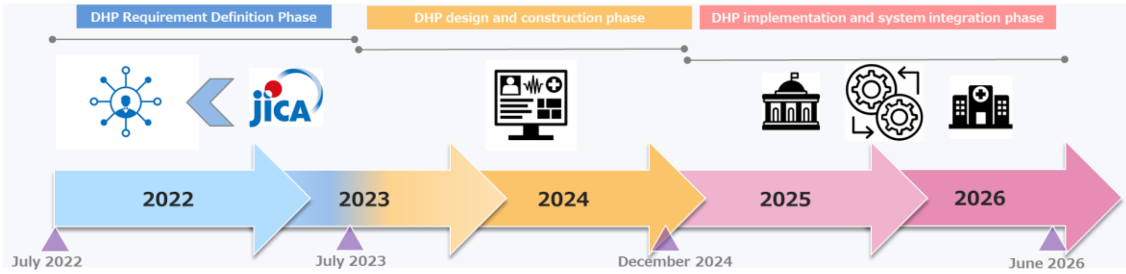


Figure VIII-3 Proposed Final Measures in Digital Health Architecture (Kenya)

Source: Compiled by survey team

Finally, the five-year (2022-2026) concept of Kenya's final proposal is as follows. Iin the first year, DHP requirements will be defined in consultation with various stakeholders; in the second and third years, DHP requirements will be defined and program design will be implemented. The implementation of the DHP in the forth and fifth year will enable interoperability between health insurance and other systems, and strengthen the health system.



Goal	• Consultations with various stakeholders to identify needs and define requirements for the DHP.	• Based on the requirements definition, the DHP is constructed, including requirements definition and program design related to the design of the DHP.	• The introduction of DHP will strengthen the health system by enabling interoperability between systems with health insurance and other systems.
JICA support direction	• Facilitate dialogue and consensus building among stakeholders.	• Provide technical and financial support to promote digitization and build DHPs in medical institutions.	• Provide technical support for the full-scale introduction of DHP, including development of implementation and maintenance operation guidelines, user training, etc.
Ecosystem Partners	• Government agencies, including the Ministry of Health • Medical institutions, private sector, NPOs, etc.	• Ministry of Health, NHIF, medical institutions • Private companies involved in digitization	• Ministry of Health, NHIF, medical institutions • Other donors who are implementing the system, etc.

Figure VIII-4 Five-Year Roadmap for Proposed Measures (Kenya)

Source: Compiled by survey team

２－３. Indonesia

As for the proposed measures for Indonesia, the following measures are finally proposed as a result of the above verification.

（１） Support for establishment and strategy implementation as a center of excellence [240] specializing in telemedicine

Overview

Co-creating with players related to various issues for the introduction of telemedicine in remote areas, andestablishing a center of excellence specializing in telemedicine that provides evidence for deployment of digital health solutions through PoC, JICA will support the implementation of the Indonesian government's telemedicine strategy.

240 It refers to an organization or group that brings together top-level human resources, know-how, and tools in a particular domain.

Background and significance of measures

In this survey, we have examined the proposed measures based on the hypothesis that the Indonesian government will underpin the creation of institutions and systems to enable the introduction and promotion of telemedicine-specific innovations at the national level, based on existing JICA project partners and technologies, in order to realize the improvement of medical services in remote areas. As a result of the verification, it was judged that in order to newly implement telemedicine in remote islands in Indonesia, it is essential to promote the social implementation of new systems and medical service models (i.e., to establish a center of excellence) through demonstration experiments for each issue and to support the implementation of the government's telemedicine strategy. In Indonesia, regional disparities have emerged. In Indonesia, telemedicine is an effective tool in remote areas where regional disparities occur, but the conditions for introducing telemedicine are complex, and it is difficult to realize telemedicine in remote islands without solving these issues. By providing data and other evidence on each issue through small-scale pilot project of new service models, as has been done in the PoC project of this survey, there is a high possibility that the system will be improved and new models will be established. In addition, since there are currently no players who can play such a role, the implementation of this measure is considered highly significant.

As mentioned above, in Indonesia, the use of telemedicine in remote islands faces challenges such as insurance coverage, payment mechanisms, regulations, infrastructure, human resource development, and in order for residents of remote islands to receive a series of services using telemedicine technology, they need to develop pharmaceutical logistics, laboratories, and access to transportation for residents. As a result, the implementation of telemedicine has been slow. In order for telemedicine to be implemented in remote islands, pilot projects have been planned to establish new technologies and regulations, especially by utilizing the regulatory sandbox system, but implementation has been delayed due to lack of resources. JICA is expected to play a role in supporting the implementation of Indonesia's newly formulated digital health and telemedicine strategies, given its experience in ICT-related projects such as tele-ICU using Japanese technology, as well as its track record and relationships with key stakeholders including the Ministry of Health. In addition to the Ministry of Health and the private sector with ICT technology, this measure will also include the UNDP, ATENSI (regulation), BPJS, GMU (payment mechanism), Indonesian Healthtech Association (AHI) (interoperability, human resource development), etc., depending on each issue. There is potential to contribute to the development of the digital health ecosystem through multifaceted co-creation. Ultimately, telemedicine is expected to improve medical services for remote islanders, who have been slow to respond.

Policy Outline	・ Establishing a center of excellence that specializes in telemedicine and provides evidence for social implementation through PoC, we will support the implementation of the Indonesian government's telemedicine strategy by co-creating with players related to various issues for the introduction of telemedicine in remote areas.
central issue	・ Correcting disparities in medical services in remote islands
The gap between the current situation and what you want to achieve	・ As is : To introduce telemedicine to remote islands, there are issues such as (1) insurance coverage, (2) payment mechanism, (3) regulation, (4) infrastructure, (5) human resource development, and in order for residents of remote islands to receive a series of services using telemedicine technology, there are issues such as pharmaceutical logistics, laboratory development, and mobile access for residents, which prevent the implementation of the strategy. ・ To be : Telemedicine will be implemented in remote islands. ・ Gap: Pilot projects to establish new technologies and regulations for telemedicine have not been implemented.
JICA value proposition/strengths	・ Track record of numerous projects in Indonesia in the health care sector and building relationships with key stakeholders ・ Experience with remote ICU and other ICT related projects
Main Clients	・ Ministry of Health
Possibilities for collaboration and co-creation	・ Regulation: Ministry of Health, UNDP, ATENSI ・ Payment mechanisms: BPJS, Startup, GMU ・ Capacity: Indonesian Healthtech Association (AHI) ・ Technology and business collaboration: Japan and local startups ・ Existing project counterparts: University Hospital of Indonesia, West Java, and Hasanuddin University Hospital, South Sulawesi
ultimate beneficiary	・ Patients in remote islands and remote areas

For the Center of excellence, it is necessary to first set up the problem areas (medical human resource development, payment mechanism, etc.) to be demonstrated with telemedicine as the main theme. In addition to digital health technologies, other ICT technologies (e.g., fintech, pharmaceutical supply chain) should also be assumed to be utilized in the verification if necessary. According to the results of the interviews, mobile networks and the Internet are prerequisites, but since there are medical facilitys on remote islands that have secured these environments to some extent, these medical facilitys will be considered for the verification experiment.

Consistency with JICA policy	➢ This measure is in line with JICA's Global Agenda:6. Health Care cluster of focus: "To ensure access to health care services through the development and improvement of health security systems by providing policy and institutional advice, coordination with service delivery, and financial support, while increasing national commitment. Consistent with the "Health and Human Development Fund (HDFF)". ➢ This measure is part of JICA's Global Agenda:15 "Promoting Digitalization. This policy is consistent with JICA's Global Agenda: "Promote digitalization to provide a basis for developing countries to reap the benefits of economic and social digitalization and reduce the disparities and safety risks associated with digitalization. Consistent with ➢ This policy is in line with the country's development cooperation policy for Indonesia: "To support the development of rural areas as well as major cities to improve the quality of life in order to realize a safe and just society.
JICA Support Form	・ Technical cooperation projects ・ Support for demonstration experiments through information collection and confirmation surveys, etc.
counterpart	・ DX Department, Ministry of Health, Indonesia
Project Site	・ Jakarta, West Papua Province, etc.
Implementation period	・ July 2022 - December 2024 (Blueprint for Digital Health Transformation Strategy Target Year)
Inputs and activities	・ Personnel: center of excellence operation secretariat, local collaboration coordinator ・ Funds: Demonstration experiment support funds
Possibility of collaboration with existing projects	・ Project for Enhancing Intensive Care Capacity Using Remote Technology in a Novel Coronavirus Epidemic ・ (1) Information collection and confirmation survey on support for countermeasures against novel coronaviruses by global digital health

Future actions	・ Consultations with the Ministry of Health (e.g., agreement on issue areas where empirical data is required) ・ Problem area mapping and pilot technology selection for telemedicine [Human Resource Development] Introducing AI diagnostic technology from Japanese startups and strengthening Doctor to Doctor diagnostic capabilities [Payment mechanism] Verification of inter-agency payment mechanism using TEMENI with BPJS and GMU [Regulation] Feasibility of Halodoc's D-to-P service and verification of the implementation model for remote islands, etc. ・ Agreements with collaborative partners and implementation of pilot projects

In addition, in Indonesia's digital health architecture, this measure is positioned as shown in the figure below. In Indonesia, as mentioned above, although TEMENIN and others exist in the platform layer for telemedicine utilization, they have not been sufficiently disseminated and utilized. This is due to weaknesses in the policy strategy, rules, and organizational human resource layers that support the digital health architecture in Indonesia with regard to telemedicine. This initiative will strengthen the platform of the digital health architecture by establishing a center of excellence that brings together the most advanced technologies on the theme of telemedicine through collaboration with the private sector in competitive areas. The center of excellence will not only conduct PoC on telemedicine technology for remote areas, but will also work on collaborative areas led by the public sector, which is the layer of government strategy, regulation, institutional development, and organizational human resource development, to develop the entire digital health architecture.

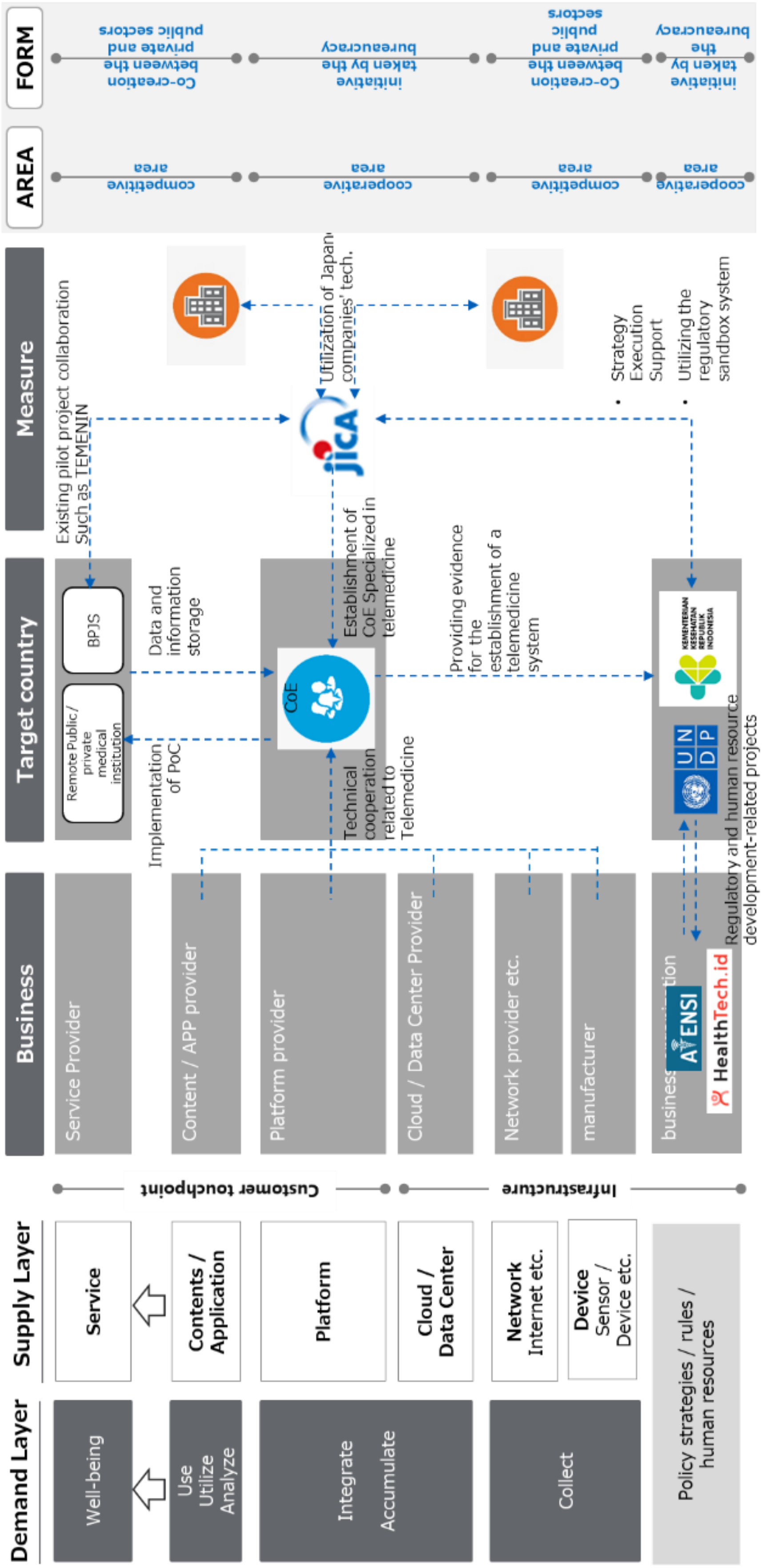


Figure VIII-5 Proposed Final Measures in Digital Health Architecture (Indonesia)

Source: Compiled by survey team

Finally, the five-year (2022-2026) concept of Indonesia's final policy proposal is shown in the table below. It is assumed that in the year 1 to 3, the issues related to the introduction of telemedicine in remote areas will be examined and the system will be developed in accordance with the government strategy. From the year 4 to 5, telemedicine services will be launched for residents of remote islands under the established telemedicine system, and that health service disparities in remote areas will be improved.

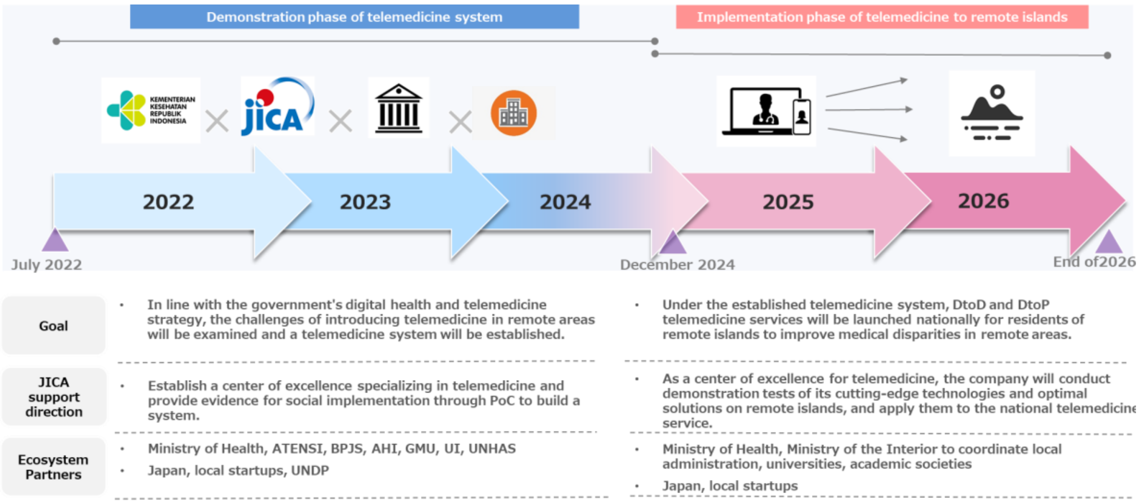


Figure VIII-6 Five-Year Roadmap for Proposed Measures (Indonesia)

Source: Compiled by survey team