The promotion of value-based healthcare through digital transformation

American Medical Devices and Diagnostics Association

Digital Health Committee

Research Project Report

Executive summary

- Maintaining a universal health insurance system and providing high-quality medical care requires transitioning from the current fee-for-service-based system for health insurance to value-based healthcare (VBHC). Healthcare digital transformation (DX) is essential in this process.
- Linking and sharing data such as personal health records (PHR) and medical information allow for early diagnosis and the prevention of disease aggravation, leading to an improvement in healthcare value. These actions can also promote research and development and technology assessment, while helping to solve social problems (e.g., by reducing social costs such as expenses for medical care and nursing and eliminating labor shortages in clinical settings).
- To link PHR and other medical information, it is necessary to establish a platform and policy for shifting data ownership and management into the hands of individuals.
- It is necessary to create an environment that will ensure the international interoperability of PHR and other medical information, so that people can benefit from world-class medical technology at the highest level.
- Reasonably evaluating the value of digital health technology is difficult in current fee-based medical systems. Enabling evaluation from new perspectives specific to digital health technology—such as burden reduction for healthcare professionals, the equalization and optimization of technology, rapid development, and product improvement—will require establishing a new system for evaluation with reference to foreign cases and the utilization of the system for medical expenses combined with treatment outside insurance coverage.
- Collaboration among stakeholders and the healthcare DX schema, as well as knowledge-sharing, is essential for implementing healthcare DX amid significant environmental changes and advances in technology. An information-sharing and discussion platform for government and industry should be prepared for that purpose.

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Introduction

Given the declining birth rate in Japan, healthcare DX should be promoted to extend Japan's healthy life expectancy, improve operational efficiency in clinical settings, and ensure the efficiency and effectiveness of medical service provision. Healthcare DX is designed to manage information and data generated during processes related to healthcare, medical services, and nursing (e.g., prophylaxis, consultation, examination/treatment/prescription, medical certificate preparation, medical fee claim, collaborative care, collaborative local medical service, and research and development) through an optimal platform, as well as the externalization and standardization of systems and data and the tasks performed by personnel involved in healthcare, medical services, and nursing. It is also intended to promote an awareness of preventive medicine and ensure the provision of high-quality medical services. Japan was ranked 29th in global digital competitiveness in 2022 (according to an IMD survey) and is falling behind the rest of the international community on digitalization and DX. Government promotion of digitalization in the medical field is urgently needed.

The government established a headquarters for healthcare DX promotion in the cabinet secretariat in October 2022. This headquarters is fostering the establishment of a platform that will enable the optimization of service and its quality improvement through healthcare DX to improve medical services covered by health insurance and optimize medical care. This headquarters has established a system to address tasks interdepartmentally without the need for vertical government administration and has created a policy emphasizing the need for collaboration between the medical and industrial communities.

The American Medical Devices and Diagnostics Manufacturers' Association (AMDD) is mainly comprised of Japanese subsidiaries of US manufacturers of medical devices and *in vitro* diagnostics (IVD) and of Japanese manufacturers of medical devices and *in vitro* diagnostics (IVD) serving US markets. The AMDD aims to achieve high-quality medical care and sound medical financing through the introduction of high-value medical technology. To this end, the organization is seeking to implement VBHC. The AMDD considers that this will require a wide range of digital technology applications in the medical field as well as the management and distribution of medical devices and IVD. The promotion of healthcare DX is a core pillar of AMDD activities.

The AMDD Digital Health Committee initiated a research project in the context of the government's commitment to promoting healthcare DX. This committee aims to create a better society through the digitalization of medical and societal systems utilizing medical, information, and communication technologies. It proposes to foster these systems by referring to advanced cases inside and outside the country.

This proposal consists of the following.

Section 1 Overview of elements and direction of discussion on healthcare DX, which discusses the necessity of healthcare DX from the perspective of VBHC pursued by AMDD, the direction of future advances in medical devices and technology, the mapping of stakeholders who are assumed to cooperate with AMDD for the implementation of healthcare DX, and issues related to work style reform starting in 2024.

Section 2 Necessity of policies for shifting data ownership into the hands of individuals and secondary use of data by companies , which discusses and introduces the cases how healthcare DX can contribute to improvements, such as increasing opportunities for medical care utilizing real-time data, ensuring appropriate medical care by making a solid platform for sharing medical information, promoting companies' research and development/technology assessment opportunities by increasing access to medical information, and contributing to work style reform of healthcare professionals via the use of medical information.

Section 3 Whole issue of digital health technology assessment and its perspectives, which focuses on how to evaluate digital health technology for promoting healthcare DX for inclusion in the health insurance system; and discusses issues related to assessment, including reducing burdens on healthcare professionals, fostering technology equalization and optimization, conducting assessments in line with rapid product development and improvement, and addressing problems specific to digital health technology (such as programmed medical devices) that are difficult to assess properly in the current medical fee system, with a presentation of foreign cases and proposals for the utilization of the system for medical expenses combined with treatment outside insurance coverage.

Section 4 Creation of a digital health environment that ensures user safety and security and efficient utilization, which identifies four principles (open and inclusion, pursuit of state-of-the-art and international compatibility, minimization of human load, and creation of an environment with safety and security) and three issues (architecture, laws and regulations, and implementation) that stakeholders should understand regarding the promotion of healthcare DX in the current situation, amid drastic environmental changes and in technological advances. This includes the need to establish codes for medical device logistics to ensure a stable supply of medical devices and IVD, which is currently recognized as an important issue.

In addition, the section proposes the necessity of an inclusive discussion involving all stakeholders on the effective and efficient implementation of multidisciplinary digital health technology and appropriate policy assessments.

This report, based on the specialized knowledge of medical domain, is expected to be referred to by government officials and members of the Diet in collaboration with the academic community and relevant industrial associations to support their discussions. This will result in a collaboration between government and industry in Japan, as well as with the US government and the US-based Advanced Medical Technology Association (AdvaMed), which will help enhance healthcare in Japan.

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Section 1: Overview of elements and direction of discussion on healthcare DX

This section discusses the necessity of healthcare DX in terms of the VBHC pursued by the AMDD, the future direction of medical device and technology advances, the mapping of stakeholders who are likely to cooperate with the AMDD in healthcare DX implementation, and issues regarding the work style reform starting in 2024.

1.1 Necessity of healthcare DX from perspective of value-based healthcare (VBHC)

The aging population and increasing medical costs due to advances in medical technology are issues that affect the entire nation. However, the environment of medical settings is changing due to advances in digital technology that can facilitate outcome measurements. In addition, innovations have produced new beneficial functions for medical devices (various values). Voices, not only from Japan, but from many nations argue that medical reimbursement should be based on the benefits provided rather than what is done. In this context, the AMDD considers that the current fee-for-service system should be changed to a healthcare system centered on value (called "value-based healthcare," or "VBHC" in this proposal document) to maintain the universal health insurance system and provide better medical care.

In this document, "value" is defined as (1) the efficiency of a new technology (i.e., the extent to which patients or the medical system can receive a benefit, such as efficacy and safety, from a new technology, against a certain cost), (2) the efficiency of improvements in the system and the mechanism for medical fee claims and medical service provision, and (3) the concept of value used by patients and their families in their decision-making in clinical settings.

The following issues are key factors for VBHC implementation: (1) the creation of an environment where patients and their families can select the best medical technology option based on relevant information, (2) healthcare DX, (3) the development of a database for data visualization enabling the selection of the best medical technology option for healthcare providers and the promotion of clinical outcome assessments in terms of medical fee points (basic fee and technical fee), (4) a review of the pricing (reimbursement calculation) for medical devices and technologies with the proper evaluation of the value and efficiency of individual technologies, (5) distribution optimization and ensuring supply stability, (6) the creation of an environment that can reduce development costs through global harmonization in the pharmaceutical affairs system, the facilitation of evidence creation, and the realization of an efficient approval system through the joint use of regulations and research results.

In this research project, (2) healthcare DX is discussed from a wide range of perspectives.

Figure 1: Six pillars of VBHC implementation

1.2 Objectives of this proposal and issues regarding promotion of healthcare DX

This report is published by the AMDD, which aims to help promote a better society through the digitalization of healthcare/social systems by using the information and communication technology of medical devices and techniques. The report proposes a system for enabling this process, environmental arrangements, and activities for stakeholder collaboration.

Based on discussions with the Healthcare Information and Management Systems Society (HIMSS), a key academic society for medical information and healthcare digitalization, we speculate that healthcare DX will produce four changes. It will

(1) diversify the medical system by enabling early diagnosis, the prevention of disease aggravation, and VBHC

(2) enable changes in medical service provision (e.g., telemedicine, home care)

(3) lead to the sharing of medical information and the resolution of silos (e.g., eliminate barriers to sharing medical data among hospital staff and vendor lock-in)

(4) allow technical collaboration with nonmedical companies and organizations, and facilitate human resource acquisition to help promote healthcare DX

This research project identifies issues, presents successful cases, and offers proposals from the three viewpoints described below to promote above mentioned four significant changes.

1. Policies for shifting data ownership into the hands of individuals and secondary use of data by companies (in “Section 2 Necessity of policies for shifting data ownership into the hands of individuals and secondary use of data by companies”).

2. Digital health technology assessment and its perspectives (in “Section 3 Whole Issue of digital health technology assessment and its perspectives”)

3. Arrangement of digital infrastructure for user safety and security and efficient utilization (in “Section 4 Arrangement of environment for digital health to ensure safety and security of users and efficient utilization”)

1.3 Mapping of main stakeholders for healthcare DX

Many stakeholders (such as the government, academia, and industrial companies) are involved in healthcare DX. The main stakeholders and themes are mapped as follows:

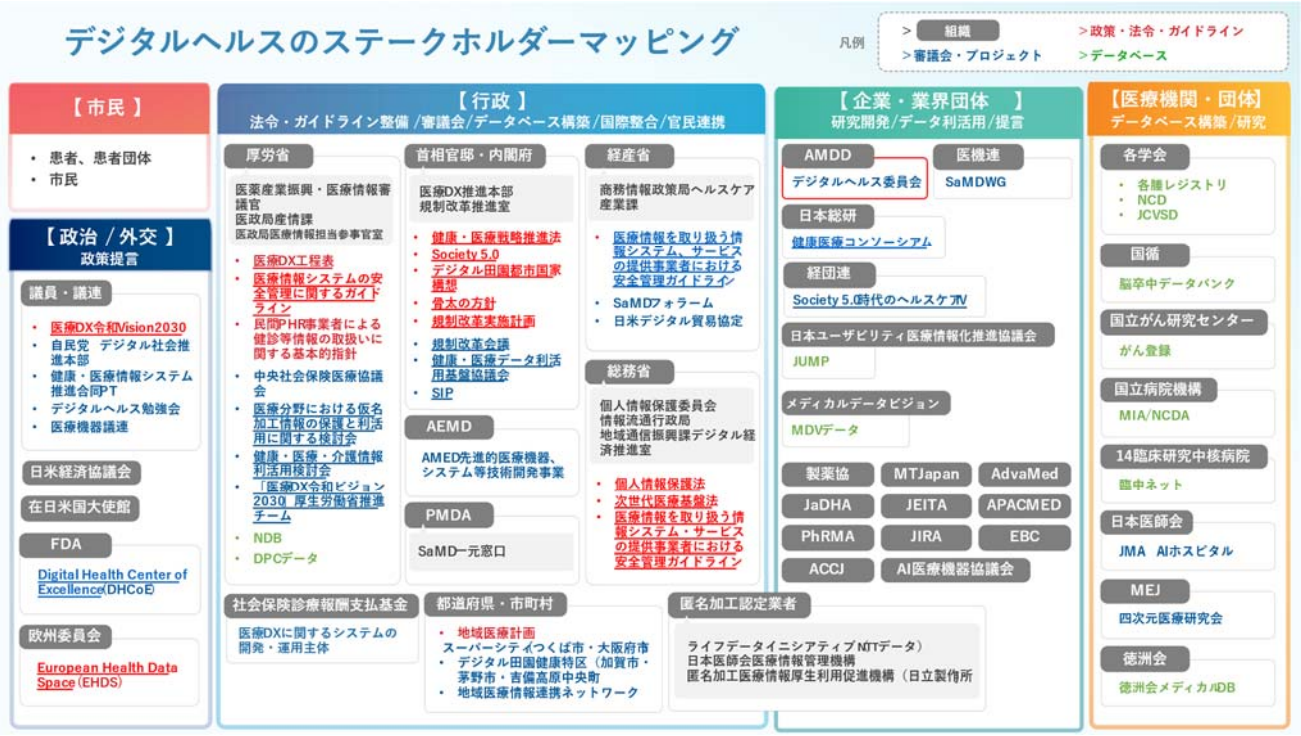

Figure 2: Mapping of stakeholders for healthcare DX

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Section 2 Necessity of policies for shifting data ownership into the hand of individuals and secondary use of data by companies

This section promotes the establishment of a system that will lead to the creation of new value through data utilization with contributing to users' health and medical care as essential elements. This section does not focus on the profit-making of member companies, as it is assumed that their profits can be obtained through fair competition under an established system.

The most significant issue in data utilization is involved in the challenge of mutual data use, in which data are used by individuals and also for medical purposes or in which multiple kinds of medical data are used for various medical purposes. This section describes the necessity of measures to shifting data ownership in the hands of individuals to solve the above-mentioned issue. In addition, the section discusses cases in which opportunities for research and development or technology assessment are lost due to a company's lack of access authorization, and cases that lead to potential disadvantages for patient, to emphasize the necessity of enabling the secondary use of data. Finally, cases are presented in which data are utilized in order to effectively employ limited resources as a way to address the reform of healthcare professionals' work style and emphasize the overall necessity for data utilization.

2.1 Necessity of linking and sharing healthcare data

The government has proposed Society 5.0 as a vision of an ideal society and has taken measures to realize it. In Society 5.0, all people and things are linked by the Internet of Things (IoT) and share knowledge and information so that new values can be produced to overcome the challenges mentioned above, particularly beneficial to health and medical care. The artificial intelligence (AI) analysis of big data (e.g., real-time data on physiological measurements, status of disease diagnosis and treatment, presence or absence of infection, living environment, and medical/family history) will enable real-time automatic health check-ups, leading to improved health and early disease diagnosis; and physiological and medical data sharing, leading to optimal treatment regardless of location, in addition to reduced social costs (e.g., medical and nursing costs) and the solution to labor shortages in clinical settings.

Various government agencies are advancing policies for establishing a platform for linking medical and health data, promoting networking, and encouraging utilization of information and communication technology (ICT). The ministry of internal affairs and communications (MIC) promotes networking and ICT utilization to resolve challenges (e.g., increasing medical and nursing

costs, the uneven distribution of medical resources) and improve services, emphasizing the promotion of ICT utilization. The ministry of economy, trade and industry (METI), which promotes the “provision of medical services utilizing technology at the highest level in the world” and “contributions to economic growth” as part of the “health/medical strategies” proposed by the cabinet in 2014, implements policies for advanced research and development and the creation of new industries scheduled from FY 2020 to 2024 (five years). The MHLW established its headquarters for data health reform in 2017. Based on the idea that the current scattered and disconnected nature of data does not produce benefits for academic–industrial collaboration, patients, and society, the MHLW has implemented an intensive reform plan and other plans inspired by the necessity of establishing a big data platform to handle a large amount of existing information related to health, medical care, and nursing.

This is but one example of the action being taken by various government agencies. Numerous other policies are being implemented to advance networking and data linking in many organizations. Although these measures vary, their main objective is to solve various problems through data sharing. The keyword for these policies is “data utilization” (i.e., how to utilize both existing data collected through various methods and data that will be collected in the future). What is the current situation regarding data utilization?

Data types can be classified in various ways. In this document, as one method, healthcare data are classified into the following types:

1. Data that are independently stored and managed by ordinary people (i.e., who are not healthcare providers) regardless of their intended use. These are called “personally used data” and include medical records (such as records of health checkups for nursing women, infants/children, schools, workplaces, and residents, as well as records of life-habit disease monitoring), test results, medication records, and healthcare data obtained from self-measurement.
2. Health/medical data that are utilized by healthcare professionals or under instructions from healthcare professionals to help with medical procedures. These are called “data on healthcare use” (e.g., data on a general practitioner’s diagnosis, post-operative follow-up, rehabilitation, nursing).

The inability of personally used data and data on healthcare use to be used mutually and the inability of diagnostic data and nursing data which having the same purpose (i.e., healthcare use data types) to be used mutually are an example of the challenges associated with these kinds of data. The former challenge is related to the mutual use of personally used data and data on healthcare use (i.e., related to points [1] and [2] above, as illustrated in Figure 1), and the latter is related to the mutual use of multiple kinds of medical data used for various medical purposes (i.e.,

related to point [2], as illustrated in Figure 2). This report discusses these challenges and their effects, and presents specific cases involving them.

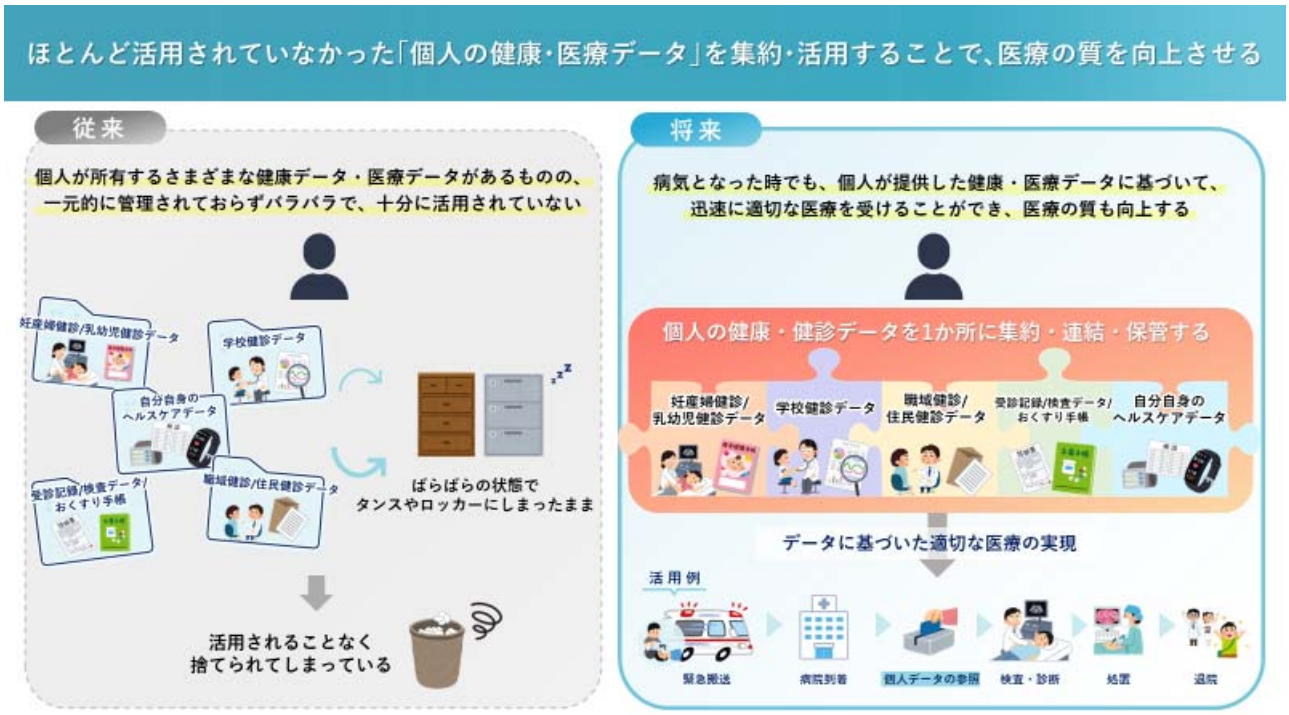

Figure 3: Challenge related to mutual use of personally used data and data on healthcare use (related to 1 and 2)

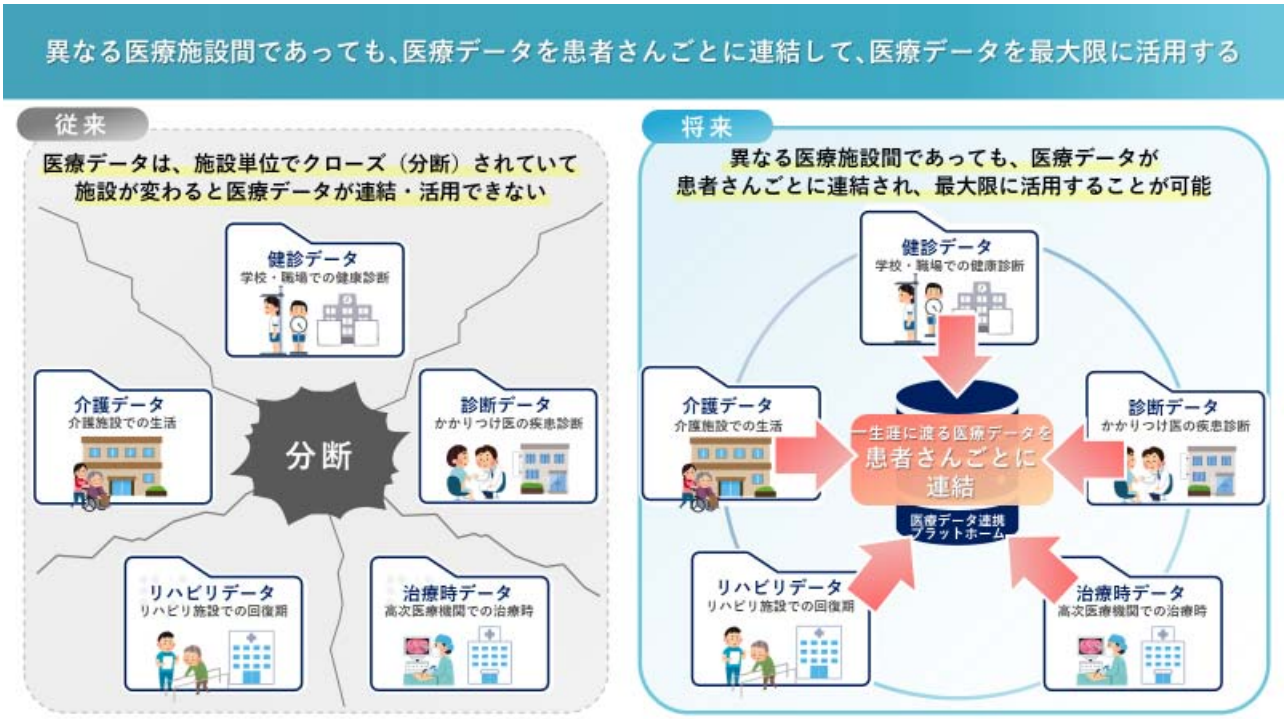

Figure 4: Challenge related to multiple kinds of medical data used for various medical purposes (related to 2)

2.2 Loss of opportunities to receive medical advice that would occur with personal data obtained in a real-time manner (case of "challenge related to [1] and [2]")

Data that can be classified as either personally used data or data on healthcare use include patient-reported outcomes (PRO). These data mainly include the EQ-5D (comprehensive quality of life scale), VAS Pain (disease-specific score), and PRO-CTCAE (used in oncology) and are increasingly being used for assessment in research, clinical trials, and clinical settings.

Data for personal use (can be obtained daily) including number of daily steps, heart rate, meal records, body weight; and data on healthcare use including blood pressure and other measurements made by medical devices such as a blood glucose meters are measured as PRO. Life-habit diseases are one of the areas that may benefit from the visualization of records and collaboration with a medical institution. A study involving 1,354 patients with Type 2 diabetes for whom patient monitoring technology was applied twice (in 2015 and 2017) to record their PHR data at an interval of three months found that HbA1c improved in patients for whom this patient monitoring technology was used more often during these periods. In addition, many cases have been reported that the recording, visualization, and sharing of personally used data that supported changes in patient behaviors and appropriate medical instruction also led to improvements in outcomes.

In addition to lifestyle-related diseases, relevant cases have also been reported in the field of oncology. A study titled "Symptom Monitoring With Patient-Reported Outcomes During Routine Cancer Treatment: A Randomized Controlled Trial" published in the *Journal of Clinical Oncology* found a change in the survival rate and health-related QOL (HRQL) in advanced solid tumor patients undergoing chemotherapy, with 12 common symptoms being reported by the patients on a web-based Symptom Tracking and Reporting (STAR) system utilizing a tablet PC. The results are summarized as follows:

- The one-year survival rates were 75% and 69% in the intervention and standard therapy groups, respectively.
- For serious symptoms, which were reported by 63% of patients who received the intervention during the study period, nurses performed frequent clinical procedures in response to e-mail alerts.
- Scientific research has shown that approximately half of patients' symptoms are overlooked by clinicians during cancer treatment.

- The survival rate was improved by PRO monitoring* due to an extension of the period during which patients could tolerate cancer treatment, a decrease in the number of ER** consultations, and the early discovery of recurrence.

  * PRO monitoring: continuous monitoring of various symptoms subjectively felt by patients

  ** ER: Emergency Room

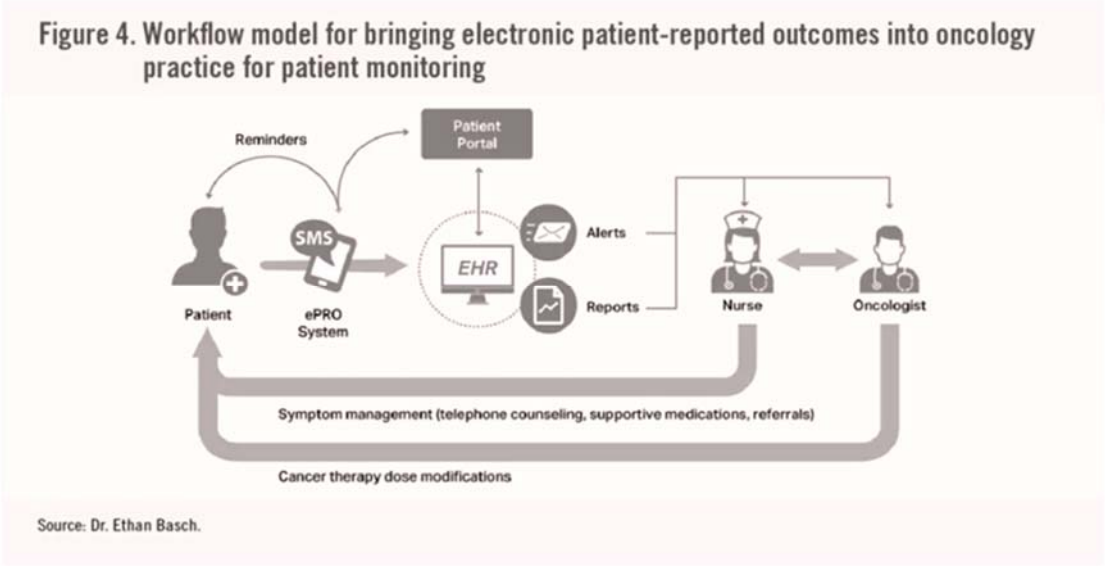

Figure 5: Example of workflow in PRO monitoring

As shown in these cases, linking personally used data and data on healthcare use that are employed mutually can lead to the visualization of records, which can help improve the quality of medical care. In addition, the utilization of techniques for the entry, viewing, and management of PRO data (mainly using a mobile application installed in a smartphone or tablet) for the treatment of various diseases resulted in an improvement of treatment adherence (i.e., patients' active participation), according to a study report. This study reviewed 11 studies evaluating mobile applications, and reported that improvements in treatment adherence were seen in seven studies. In addition, efficacy has been reported with the use of mobile applications in patients with asthma, coronary heart disease, and acquired immunodeficiency syndrome (AIDS). The positive effect of a patient support program in which nurses' support was combined with a mobile application for the treatment of psoriasis has also been reported.

In the current treatment trends, hospitalization periods tend to be shorter, and hospital visits and home care have been widely selected when possible. In addition, given the changes made in local medical care, hospitals, clinics, care facilities, and home care in response to the 2025 problem,* an

system for remotely monitor patient conditions and urgently respond them are urgently required to make the best use of limited medical resources, reduce medical costs while preventing disease aggravation, and build medical infrastructure that can help people to live healthy, safe, and secure lives which is the essential element. A system enabling the real-time utilization of PRO that can be applied in actual clinical settings is available. Further advancements in this system could accelerate the efforts for digital health and data health in Japan.

*2025 problem: Various difficulties associated with a hyper-aging society, where 1 in 3.9 people will be aged 75 or older in Japan in 2025, when the baby boomers will comprise the late elderly, defined as those aged 75 or older.

However, the real-time utilization of PRO faces challenges, including burdens on healthcare professionals. In addition, the system and environment for PRO utilization are not well-organized (e.g., no assessment based on medical fee points is available for PRO utilization). Furthermore, system standards vary among companies, depending on the main IT vendors in the region. It is necessary to establish a system based on a vision for the future (such as the efficient utilization of accumulated data).

For this purpose, it is necessary to establish the following:

(1) Clear definitions and standards for data entry
(2) Quality control system with periodic assessments of differences between devices and entry systems
(3) System for data integration into an external system (such as a vendor-independent electronic medical record system).
(4) Market systems with a platform for the development of a better medical services , leading to competition.

This section describes challenges and makes proposals regarding the mutual utilization of personally used data and data for healthcare. Data that are difficult to classify as either personally used data or data on healthcare use (such as PRO) may be produced indefinitely. This phenomenon is typical of intangible data. Although it is important to classify such data, it is more important to produce data that can be used for both purposes. It is thus necessary to establish a system in which data that can be used more frequently can be produced as a basis for new services and competition.

2.3 Loss of opportunities for medical care due to insufficiency of database (case of “challenges related to [2]”)

This section describes a case of joint replacement generally requiring post-operative follow-up as an example. After surgery, a digital device, including a product called the “TracPatch” (see Figure 6), can be used for remote monitoring to improve clinical outcomes and care efficiency, ultimately leading to cost reduction.

This product has two components that are attached to the leg of a patient who has undergone knee joint replacement. Before surgery, this patch is applied above and below the knee for baseline measurement. After surgery, patients often experience pain; therefore, they cannot move the leg as is required to help their recovery. The TracPatch can be used to monitor the leg’s range of motion, the appropriate amount of exercise, and the temperature of the surgical wound; the information can be used in follow-up examinations of disease status and to propose changes in the treatment plan. The patient can also use the application to report problems such as pain or to ask their doctor about recovery status and physical treatment plans. This product enables communication and monitoring of patient status without requiring the patient to visit a hospital. This may lead to a more rapid recovery. In addition, physicians can verify that the treatment is progressing as planned, reducing the need for follow-up visits.

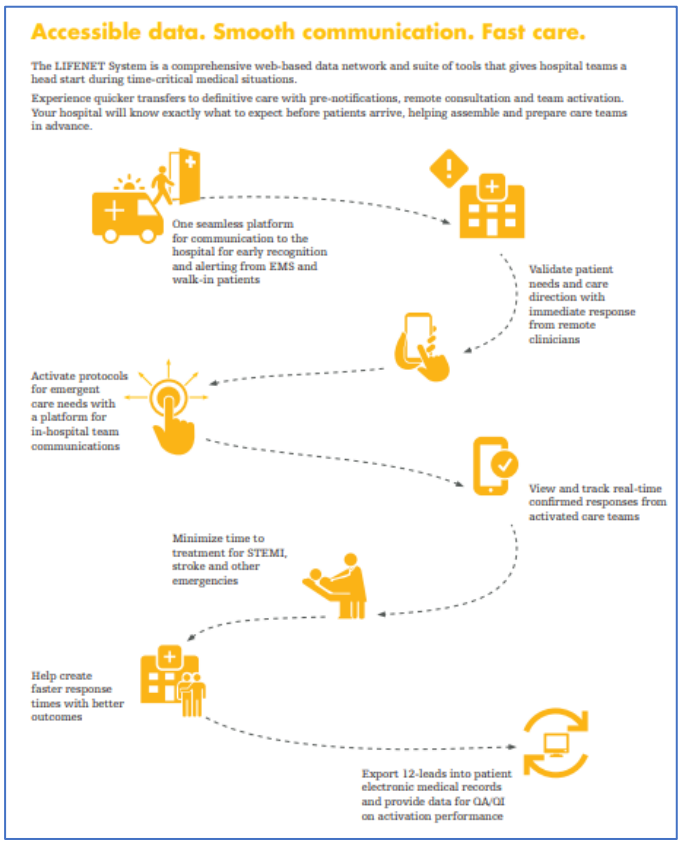

Figure 6: Example of model for optimization of post-operative outcome monitoring

However, other types of data on healthcare use face challenges (related to 2 above) is assumed to be caused by the partial optimization of information drawn from the electronic medical record

system, etc. in individual facilities and the limited coverage of the network for local medical care. The standardization of electronic medical record systems should be advanced in parallel with the standardization of operations/procedures for treatment, medical terms, formats of medical records, and other medical practices. Not enough has been done to enhance the collection and utilization of medical records across medical facilities because medical record vendors have developed and modified the systems designed and optimized to operate in individual medical facilities.

In the United States, the informatization of medical information is overseen by the Office of the National Coordinator for Health Information Technology (ONC). Japan has fallen behind in the establishment of an organization in charge of cross-sectional informatization for the future of our healthcare system. Given that the utilization of personally used data and data on healthcare use are involved by multiple government agency departments, which are further divided into more departments, it is difficult for companies and research facilities to identify contacts to whom they could offer opinions or ask questions. Efforts should be made to establish a system in which, for example, the digital agency serves as a control tower and information desk to respond rapidly to inquiries from stakeholders, including the key companies involved, and to perform overall control of data utilization.

As mentioned, it is necessary to shift data ownership and management into the hands of individuals and establish a system for the seamless handling of healthcare-related information obtained from electronic medical record systems in order to resolve challenges related to the mutual use of personally used data and data on healthcare use (challenges related to 1 and 2) and challenges related to other types of data on healthcare use, thus promoting the secondary use of healthcare data by companies and organizations. An image of the achievement of challenges related to the mutual use of personal data and data on healthcare use (related to 1 and 2, as shown in Figure 1) and challenges related to other types of data on healthcare use (related to 2, as shown in Figure 2) is illustrated in Figure 7.

Figure 7: Plan for enabling individuals to own and manage their data

As we mentioned about ONC, US measures and the background are briefly described below. In the United States, the right to have access to electronic PHR was defined in the HIPPA Act under the Clinton administration. Subsequently, under the Bush administration, healthcare IT initiatives were implemented to improve healthcare quality. Through these initiatives, which aimed to establish an environment in which people could access their own PHR, the ONC was established as an organization to promote healthcare IT. Under the Obama administration, the HITECH Act was enacted to reinforce efforts to promote healthcare IT. It offered subsidies/financing for infrastructure and privacy protection, with the Blue Button system established to encourage the provision of healthcare information to patients. Blue Button allows patients to download their healthcare data from a medical institution's portal site. This system, which was initially used by veterans and Medicare users, was adopted by private insurance users. However, this system provided only a system for downloading, without any standardization of data content or structure. In response, standard specifications for healthcare information and safe transfer methods were established to improve the system and create "Blue Button Plus." Subsequently, MyHealthData initiatives were prepared under the Trump administration, with Blue Button 2.0 created to improve patients' data access and control capacity. Blue Button 2.0 employs the fast healthcare interoperability resource (FHIR) as a standard protocol for healthcare information exchange and OAuth (open standard for authorization) as a tool to obtain authorization to access data.

A review of the implementation sequence for these US systems indicates what is required for access to healthcare data, including electronic medical record systems, and their utilization. An example of the standalone-type system (similar to the initial version of the Blue Button system) is shown on the left-hand side of Figure 8. The middle graphic illustrates a tether-type system similar to Blue Button Plus, which includes a portal for accessing and registering patient information. In these two systems, which include neither specifications for medical information exchange (standardized language) nor structures for data access authorization, data cannot be linked among different medical institutions. The graphic on the right illustrates the integrated-type system, similar to Blue Button 2.0. It is equipped with FHIR and OAuth, which allows for the control of information (i.e., input of information from different medical institutions and information output) for patients. Our issues to be addressed is insufficient standardization of healthcare information required to achieve this type of mutual interchangeability, which poses a challenge. The realization of a system like Blue Button 2.0 should initially be pursued in Japan.

The Japanese government, which aims to encourage the mutual use of health information and other data by local governments and residents via the My Number Card, has been sought to ensure that information on municipal health checkups, specific medical checkups, and prescriptions (noted on the health insurance claim form) can be provided by Mynaportal. However, the My Number Card is not fully distributed in the country. Although a system for online qualification confirmation is required in principal for health insurance medical institutions and pharmacies after April 2023, this requirement has not been fully met. Open-source, decentralized networks similar to Blue Button 2.0 should be established as soon as possible under the leadership of the government so that patients can access (and download) their health information data via the data portals of various medical institutions and control them. This type of network would help put healthcare data management and ownership in the hands of individuals.

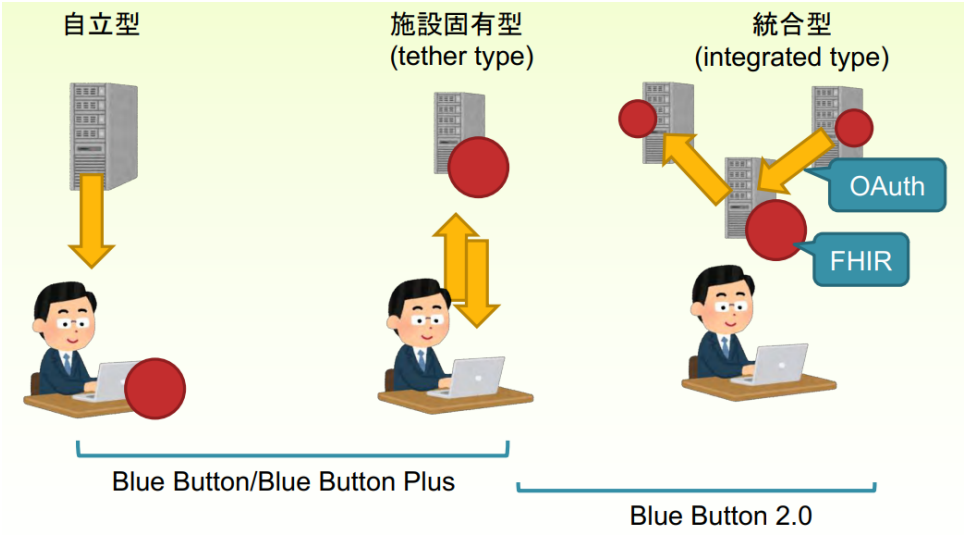

Figure 8: Blue Button 2.0 with standard specifications

2.4 Brief summary and challenges related to data privacy and their solutions.

We discussed and presented cases illustrating the challenges related to the mutual use of personally used data and data on healthcare use (related to 1 and 2) and challenges related to other types of data on healthcare use (related to 2) and proposed ideas how to shift data management and ownership into the hands of individuals. This requires a mechanism for the seamless handling of healthcare-related information obtained from an electronic medical record system. Shifting data management and ownership into the hands of individuals could enable the real-time utilization of peripheral data and data tracing over time.

Data utilization is associated with privacy issues. Appropriate data privacy protection is a critical challenge when putting data management and ownership into the hands of individuals. This challenge must be overcome for the system to be usable. However, excessive privacy protection is a barrier to data utilization. Therefore, a policy that both protects data privacy and encourages utilization is necessary. A proposal and example of how to do this are provided below.

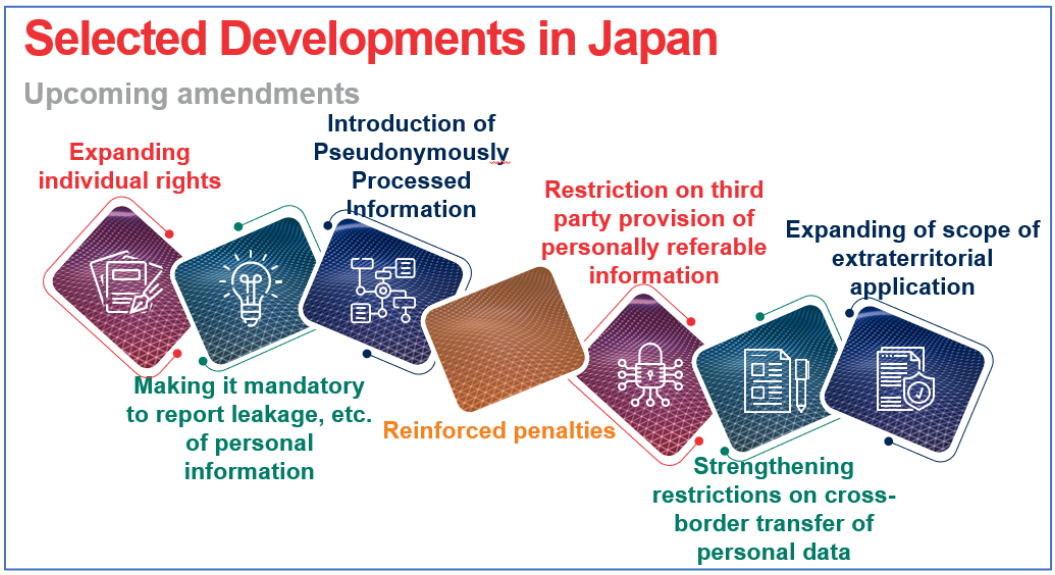

Figure 9: Current unorganized data privacy system in Japan

ApacMed, a medical device association located in the Asia-Pacific region, recently announced recommendations about how to provide access to high-quality data. ApacMed emphasized that data access can promote patients' understanding, accelerate access to the market, and support development based on needs. In the ApacMed meeting, the following were recommended as means of enabling effective data access:

- Development of specifications for health data and harmonized format

- Utilization of best practices developed by the International Standards Organization or other government agency and models for reference
- Development of practice codes and a voluntary framework to promote the reliable utilization of and access to health data

Japan's Personal Information Protection Commission updated five guidelines for the Japanese privacy system under the Act on the Protection of Personal Information in August 2021.
These guidelines include:

- General regulations
- Provision of personal information for a third party in foreign countries
- Obligation of review and recording of personal information provided for a third party
- Anonymized information
- Certified organization for personal information protection

In these revised guidelines, in which data privacy protection is significantly enhanced, ApacMed requires further modifications in the areas described below:

- Expansion of individual rights
- Requirement for reporting of data leakage
- Use of pseudonymized information
- Reinforcement of penalties
- More strict regulations on the provision of data that can identify individuals to a third party
- Avoidance of personal data leakage across the border
- Expansion of extraterritorial application

Under the "expansion of individual rights", a data subject can ask for data deletion in cases where

1. individual data are no longer necessary
2. significant data leakage occurs, or
3. the rights or profits of the subject may be violated.

In addition, the data subject can ask for the disclosure of individual data transfers. Furthermore, the requirement for reporting has been strengthened to make the following compulsory:

- reporting to the regulatory authorities
- notification to the data subject who will be affected

Data privacy is currently considered in many ways. However, policies for achieving both data-privacy protection and data utilization have been insufficient. The above proposal by ApacMed does not address every issue. However, regulations should be reorganized developing matrix management structure as soon as possible to establish a system that achieves both data privacy protection and actual implementation to prevent inappropriate privacy policies from hampering data utilization. Therefore, complete privacy protection is not necessary to pursue. Instead, it is important to clarify first the limitations and responsibility boundary points so that providers and users can understand both the responsibilities and risks of data utilization.

The MHLW announced its Digital Transformation (DX) Action Strategies in Healthcare for SaMD(Software as a Medical Device) on November 24, 2020, which set out a policy for developing enhanced structure for promoting the practical use of programmed medical devices. Reducing the hurdles to data utilization will accelerate this policy. Factors that hamper data utilization include the following:

1. the need to obtain consent from individuals to use their personal information
2. data integration difficulties due to differences in data format across electronic medical records
3. uncertainties regarding business models (e.g., medical fee claim) and regulations

However, data on healthcare use cannot be used mutually when patients receive checkups at multiple medical institutions, which leads to a shortage of the information required for diagnoses. In this situation, duplicate examinations may be necessary or diagnostic precision may be reduced. To solve this problem, data should be managed uniformly, data ownership should be shifted to the hands of individual patients, data utilization should be promoted, patient convenience should be improved, and medical costs resulting from unnecessary examinations should be reduced. In addition, given that a factor 2 above cannot be easily resolved, data that can be mutually used should be identified. We propose that a roadmap for the realization of the mutual use of data should be formulated, starting with data for which mutual use may be relatively easy (such as vital data obtained from health checkups and wearable devices), subsequently expanding this work.

The 5th Basic Science and Technology Basic Plan decided by Cabinet in 2016, describes Society 5.0 as the kind of society that Japan should pursue. In this society, all generated data are aggregated as big data to be analyzed by AI and are returned to the real world for use in economic development and the resolution of social challenges. As an example, to embody this, the revision of medical fees in April 2022 specified a policy by which health insurance would cover the costs of programmed medical devices, which encouraged manufacturers. However, Japan has few medium- or small-scale medical institutions with fewer than 400 beds (allowed under the medical law) and dedicated staff with IT expertise. Even where such dedicated staff are present, few medical institutions have

sufficient security measures to protect personal information due to their budget or knowledge level. Medical fee was revised that imposes a medical fee premium for medical record management systems at institutions with at least 400 beds that can submit a notification of the premium. In line with this revision, improvements in the IT security levels of medical institutions should be monitored so that policies can be reviewed and revised based on the monitoring results.

In addition, there is often no significant difference in medical fees between medical institutions that do and do not use programmed medical devices. Companies may therefore give up introducing such devices given the business risks involved. The evaluation measures for medical fees should be clarified in ways not limited to programmed medical devices. Encouraging their use requires incentives of many kinds (in addition to medical fees for medical institutions) from a macroscopic perspective. Furthermore, in addition to a system for medical fees for medical interventions using programmed medical devices, another medical fee system is required for the application of data obtained in clinical settings.

As mentioned, the contents and attributes of data items differ depending on the specifications of electronic medical record manufacturers, which prevents medical institutions from being able to utilize uniformly collected data without any processing. Thus, a public database should be prepared under the leadership of the government to collect data for use and uniform management, followed by processing for anonymization and standardization. Sufficient security measures should be taken for such a database, which would reduce the burden on medical institutions and promote its utilization by companies. The “future plan for shifting healthcare data management and ownership into the hand of individuals” described above with reference to Blue Button 2.0 and the establishment of a public database under the leadership of the government could help achieve this.

2.5 Loss of opportunities for research and development/technology assessment due to company’s lack of authorization to access data

The cost of new medical device development is increasing worldwide. Although insurance reimbursements covering those costs may have been expected in the past, these that meet the investment are often difficult to obtain amid the severe insurance financing situation. The introduction of new devices to the Japanese market may be abandoned when no recovery of the investment can be expected.

Data utilization in line with actual clinical settings may lead to significant optimization, cost reduction, and acceleration in the development of medical devices, for which huge costs are required. In particular, real-world data (RWD), in contrast to clinical trial data, can contribute

significantly to the early realization of innovative medical devices with low costs, increasing investment in the Japanese market and investment priority.

The utilization of RWD is expected to occur during various phases of product development. The utilization of RWD in the regulatory process is highly expected to accelerate the creation of evidence. The Pharmaceutical and Medical Devices Agency (PMDA) announced notifications called “Basic Principles on Utilization of Registry for Applications and Points to Consider for Ensuring the Reliability in Utilization of Registry Data for Application” as a measure to create an environment for the utilization of RWD, including data in databases (registries) managed by academic societies and other organizations.

Registry data employed for regulatory applications may be used for various purposes, such as external reference comparison and the supplementation of clinical studies. If data can be used instead of clinical studies, new medical devices and new indications can be rapidly provided to patients, leading to significant cost reduction. Given that applications for regulatory approval using RWD are increasing worldwide, use standards that are more flexible and in line with real-world conditions should be prepared with consideration given to the differences across database reliability levels and the need for international regulatory harmonization (as methods of handling personal information in Japan differ from those of other countries).

In Japan, many registries have been established through industry–government–academia collaboration. Although many registries developed under the leadership of academic societies are available, they pose several challenges, such as the requirement for patient consent, limited access for companies, and a limited availability of information. Therefore, these databases are not utilized extensively for the development of new products, algorithm improvement, or the submission of applications for regulatory approval. Although many other types of registries have been established for various purposes, no process for obtaining consent for company use has been designed, which often causes accumulated data to remain unused. In one case, for example, only opt-in data can be used because the patient’s consent for the submission of an application for regulatory approval is required even when consent has been obtained from the academic society that manages the data.

To address these problems, a scheme should be established to utilize the data extracted by processing, such as anonymization/pseudonymization, in such a way as to include only the information necessary for the submission of the application for regulatory approval. Registry data, which reflect the status of the clinical setting and include patient data that are more diverse than data drawn from clinical studies conducted under controlled circumstances, can be used for clinical development.

An example of the challenges posed by companies' lack of authorization to access data is provided below. This is a case in which utilization is prevented from improving an AI algorithm based on patients' RWD in program development.

The technology continuously records local field potential (LFP), a type of brain wave, provides an AI-programmed auto-adjustment of the intensity of stimulation to the deep part of the brain depending on the changes in the patient's condition related to treatment and other factors. This technology is expected to reduce the incidence and degree of adverse reactions related to the maintenance of the on-status and excessive stimulation. Patient monitoring data collected via IoT and remote monitoring system were used as training data in an effort to improve the quality of the algorithm in the research and development department. In the actual clinical settings, algorithm optimization of AI-programmed devices can be achieved using pseudonymized RWD information. The following problems arose in Japan case:

- Pseudonymized RWD information obtained from medical institutions can be used secondarily for research and development under the relevant regulations. However, data utilization is insufficient because of the absence of specific written procedures for pseudonymization in medical institutions
- There are no procedures for appropriate data processing in medical institutions using patient data obtained from medical devices equipped with an AI program used as training data
- The relevant regulations are unclear (e.g., the submission of raw data for quality assurance, which must be submitted in applications for regulatory approval, may violate personal information protection regulations)

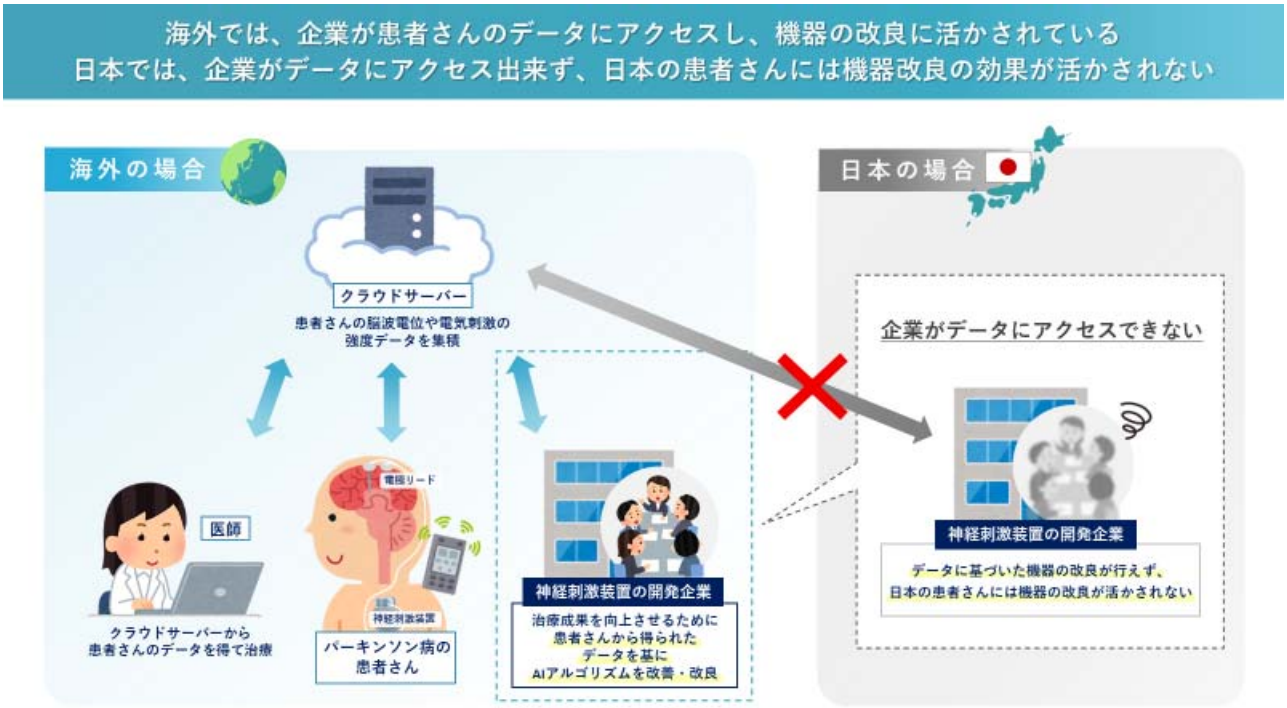

Figure 10: An example of challenges due to a lack of company's authority to access data

Companies cannot access data in Japan due to the complex regulations, as shown in Figure 10. Therefore, data from Japanese patients cannot be used for research and development or technology assessments to improve treatment performance.

The regulations at issue in this context include the prohibition of data provision to third parties specified in the Next Generation Medical Infrastructure Act (Paragraph 6 of Article 41 and Paragraph 1 and 2 of Article 42). In this regard, the following matters should be clarified: (1) the procedures for pseudonymization in medical institutions and (2) the fact that the use of raw data for quality assurance in the process of regulatory review (regarded as a part of research and development) is acceptable under the Personal Information Protection Law. Industry–government–academia collaboration should be conducted to achieve better results and foster utilization.

2.6 Data utilization with consideration for the work style reform

Japan has an excellent system for providing medical services, which is supported by the commitment of healthcare professionals, including physicians. However, they have reached a limit because of their excessive burden. Therefore, work style reforms for healthcare professionals are being discussed. An application of a regulation regarding the upper limit for extra work hours will be started in April 2024. Given that many physicians have exceeded this upper limit of working hours, the total supply of medical services will decline due to the application of this limit. Meanwhile, the

demand for medical services is expected to continually increase in most regions due to population aging at least until between 2030 and 2040.

As mentioned, the promotion of data utilization can lead to improvements in patient outcomes and the promotion of innovation by companies. Furthermore, it is likely to encourage work style reforms among healthcare professionals. As one case in point, an increase in the efficiency of healthcare operations through data utilization is described below.

In an Asset Performance System (APM), a sensor is attached to ultrasound diagnostic equipment (mobile type) to identify and display its location using a receiving system in a hospital. In a large-scale hospital with dozens of pieces of equipment of the same type, not all equipment is in operation at any one time; thus, some equipment may be redundant. This requires a system that could ensure a more efficient operation of the hospital's equipment and confirm that only what is necessary and sufficient is purchased.

In addition, a system called a "command center" could visualize the status of physicians and nurses (e.g., their location) as well as the status of bed usage, prospects for admission and discharge, and other issues. With this system, nurses in a ward with more than enough workers could be sent timely to a ward that lacks staff, or the operation of beds could be optimized based on the current bed situation and prospects for future admissions and discharge.

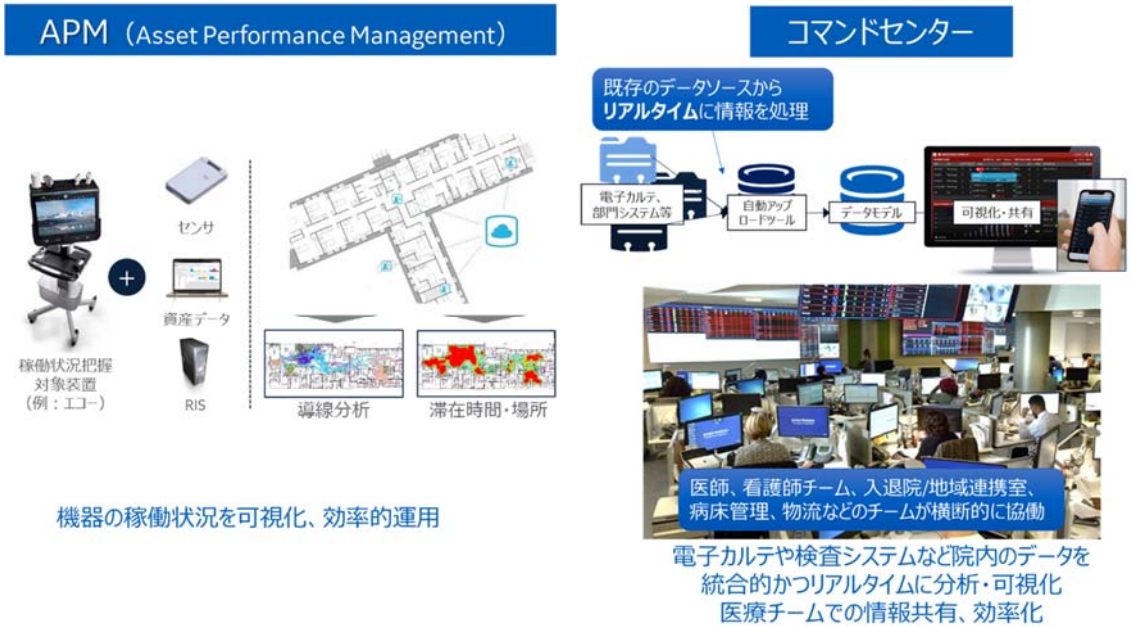

Figure 11: Efficient operation of medical assets and optimization of workflow

In such cases, the system does not perform optimization. Instead, data on status in the clinical setting are prepared for visualization. Based on the visualized data, the personnel in charge can

consider increasing efficiency for optimization. In these cases, data are utilized for the efficient operation of limited medical resources, in addition to work style reforms for healthcare professionals.

In addition, automation and optimization are expected for the processes of checking for medical fee claims and preparing draft symptom specifics. If the standardization of information in medical health records includes the integration of electronic medical health records and medical fee claims, computer processing can be refined to allow for the identification of items required to calculate medical procedure fees, making medical fee claim checks by physicians unnecessary. The attachment of symptom specifics may be required for techniques newly covered by insurance. In this case, the draft can be automatically prepared based on information drawn from electronic medical health records, leading to a significant reduction in the desk work burden on healthcare professionals. It is not difficult to imagine several scenarios based on the development of automatic writing systems.

The introduction of an additional system may be required as infrastructure to allow data utilization to contribute to work style reform for healthcare professionals. However, a dilemma often occurs when a new system cannot be introduced without a medical fee. Therefore, medical institutions should appreciate the value of data utilization (e.g., cost reduction for medical institutions and increased attractiveness due to an improved work environment, leading to new personnel acquisition) and take the appropriate measures. The AMDD and its individual member companies would like to support the efforts of medical institutions and personnel operating in various work areas.

2.7 For future

We have described issues surrounding data utilization, pointing out the necessity of a policy designed to shift data ownership into the hands of individuals, enable the secondary use of data by companies, and encourage data utilization with a consideration for work style reform. Important challenges, including issues regarding data handling difficulties such as data quality assurance and the transition of personally used data into data on healthcare use, will be discussed in detail in the future. This document does not describe the dilemma posed by the conflict between the necessity of classifying data types and the difficulties associated with this classification. This will also be discussed in the future.

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Section 3 Whole issue of digital health technology assessment and its perspectives

This section focuses on evaluating digital health technology (i.e., healthcare DX) for inclusion in the health insurance system.

First, the main issues related to digital health technology assessment/value assessment are summarized, covering the assessment method for digital health technology and various perspectives. Issues related to assessment are then discussed, including the reduction of burdens on healthcare professionals, technology equalization and optimization, assessments in line with rapid product development and improvement, and problems specific to digital health technology (such as programmed medical devices) that are difficult to assess properly in the current medical fee system. This is followed by a presentation of foreign cases, and a proposal for expansion of the scope for additional fee for a first-time patient without a referral and a system use for medical expenses combined with treatment outside insurance coverage.

This section focuses on the digital health technology specified in the PMD Act (i.e., that used for the diagnosis, treatment, and prophylaxis of human diseases in medical care). The term “digital health technology” may include any IT-related technology used in healthcare. However, this section excludes discussion of technologies used to share information in medical institutions or conduct optimization (such as electronic medical health records).

3.1 Digital health technology assessment/main challenges related to value assessment

3.1.1 Digital health technology assessment contributing to reduction of burden on healthcare professionals, etc.

While many digital health technologies offer high efficacy and safety for patients, some digital health technologies can reduce the burden on healthcare professionals and help equalize technology.

For example, a program for supporting diagnostic endoscopy equipped with AI can help equalize medical technology by increasing the accuracy of non-specialists and reduce the burden on healthcare professionals through the support provided by imaging interpretation.

Under the current medical fee system, assessments of medical techniques and equipment are performed for techniques that are found to have efficacy and safety levels higher than those of the

existing techniques. However, it is unclear how best to evaluate reductions in the burden on healthcare professionals and technology equalization. As will be mentioned later, the Central Social Insurance Medical Council has discussed only the current framework for the FY 2022 revision of medical fees.

3.1.2 Assessment in line with speed of product development and improvement

Medical devices have shorter development and improvement cycles than pharmaceuticals have. However, digital health technologies have even shorter cycles. Changes in line programs may lead to widely different performance levels.

It takes at least four to five months to re-evaluate existing medical technology/equipment to determine medical fees (points) by functional classification or technical fee for both special treatment materials and technical-fee included ones. In this situation, it is difficult to provide the benefits of new technologies to patients rapidly, and suppliers have few incentives for rapid development and provision.

3.1.3 Assessment of technology contributing to optimization of medical institutions and systems

Digital health technology often contributes to the optimization of medical institutions' operations and systems (e.g., reduction in medical costs), which reduces the burden on healthcare professionals.

As has been mentioned, for example, supporting imaging interpretation can help reduce the burden on physicians and advance optimization in medical institutions through the supporting function to prepare reports of the interpretation results. In addition, a software program for supporting the design of a surgery plan, which is expected to have high precision, can save time in surgery simulation. This technology can also contribute to data collection and management, as well as telemedicine.

The evaluation of medical institution and system optimization within the framework of the medical fee system includes the evaluation of many materials purchased by medical institutions (e.g., personal computers). It is thus natural for a certain framework to be considered necessary for the evaluations conducted in the medical fee system. According to a discussion in the Central Social

Insurance Medical Council for the FY 2022 revision of medical fees, materials that are not approved or certified as medical devices are not included in the medical fee system.

However, in the Japanese healthcare system, where there is strong demand for the optimization of medical costs, efforts should be made to introduce digital health technology that enables healthcare optimization. Therefore, an assessment framework for this type of technology in the medical fee system is necessary.

3.1.4 Assessment in Japanese health insurance system focused on fee-for-service

The government is promoting a form of “new technical fee” and “premium” mainly in the fee-for-service system in line with what it considers appropriate for medical institutions.

The rate of digital health technology adoption will not increase in medical institutions without a visible incentive, even if the government promotes it. According to a member of healthcare institution, new technology is typically introduced following a discussion with reference to the medical fee in the administrative office of the hospital, according to a person affiliated with a medical institution.

It is understandable that the difficulties to assess reductions in the burden on healthcare professionals and the optimization of medical institutions and systems in the current medical fee system. However, action must be taken given the relationship between medical fees and the initiatives of medical institutions, as well as the significant need to optimize medical costs in Japan.

3.2 Overall aspects of evaluation of digital health technology and its perspectives

The main aspects concerning the evaluation of digital health technology and its perspectives are summarized in Table 1.

		評価の視点					
		患者アウトカムの向上	医療者の負担軽減	技術の平準化	効率化（医療費）	効率化（院内の効率化）	データ収集（2次利用推進）
評価方法	技術料増点	○					
	機器加算/管理料	○	○		○		
	特定保険医療材料	○	○		○		
	アウトカム評価/成功報酬型	○	○	○			
	先行評価 (coverage with evidence development)	○	○				
	DPC機能係数		○	○	○	○	○
	施設基準の緩和		○		○	○	
	保険外併用療養	○（評価療養）		○（選定療養）			

（その他、医療機能評価機構の病院機能評価の項目に含めることも検討すべき）

Table 1: Overall aspects of evaluation of digital health technology and its perspectives

The main perspectives and elements concerning digital health technology evaluation are shown in the columns of Table 1. The items to be evaluated are shown in the rows, and the items for which evaluation method requires consideration are circled in the column.

For example, digital health technology that may contribute to improve patient outcomes may be evaluated in terms of a potential increase in the technical fee (e.g., surgery fee), the premium, or the management fee for medical devices or special treatment materials.

Among these aspects, the evaluation perspectives that should be considered deeper are discussed below, along with the relevant evaluation methods.

3.2.1 Reduction of the burden on healthcare professionals

If the reduction in the burden on healthcare professionals is assessed in terms of the technical cost in a conventional manner, the technical fee may be negative (rather than positive) from the viewpoint of the amount of money relative to the time consumed by healthcare professionals. In this situation, medical institutions make no effort to introduce such technology, and development incentives for companies are significantly reduced.

A discussion of the Central Social Insurance Medical Council for the FY 2022 revision of medical fees concluded that a program supporting the design of treatment plans cannot be evaluated only in

terms of a reduced plan preparation time (see below).

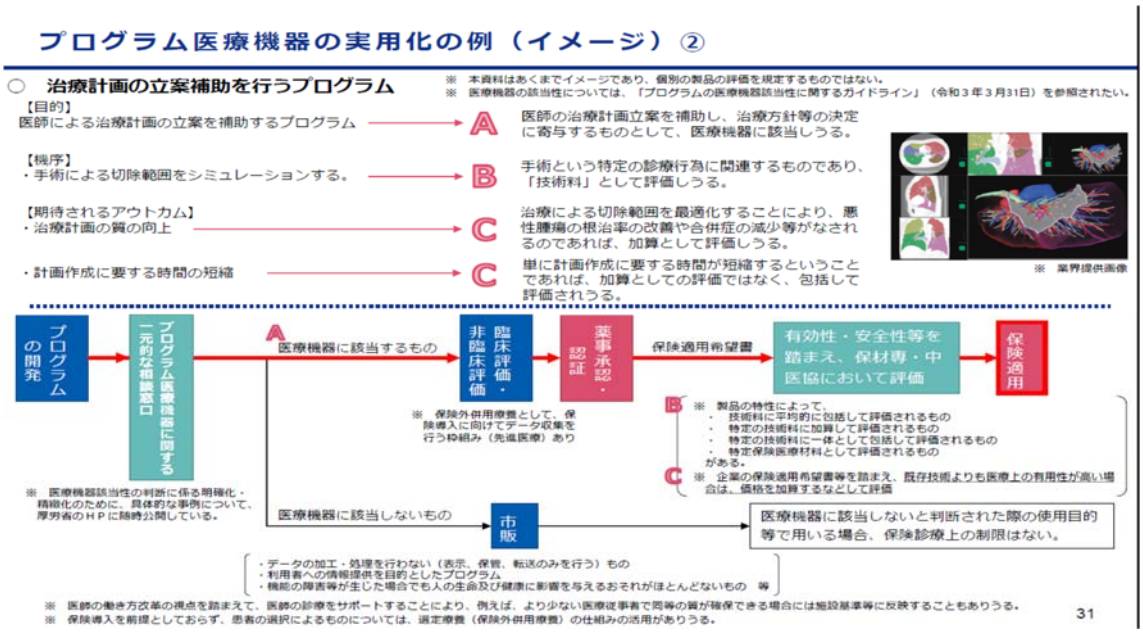

Figure 12: An example of practical use of programmed medical devices (from MHLW's materials)

Three effective methods of evaluating burden reduction for healthcare professionals are described below.

3.2.1.1 Evaluation as special treatment material

Digital health technology can be evaluated as a special treatment material to ensure that burden reduction for healthcare professionals is not linked with a reduction in technical fees. It is necessary to demonstrate that digital health technology, as a special treatment material, has certain clinical benefits. Even if the technical fee decreases, the total technical fee and price of the special treatment material may be positive.

In cases where digital health technology is evaluated as a special treatment material, a rule should be formulated to clarify the definition of the functional classification of special treatment materials and their costing methods. For example, while the functional classification of special treatment materials is defined as "a group of special treatment materials that resemble each other in terms of the structure, intended use, and clinical indications, and others," what "structure" means for

programmed medical devices is not clear.

3.2.1.2 Preliminary evaluation

A preliminary evaluation, as defined in this section, is a medical-fee-based evaluation of technology with a high likelihood of efficacy for which insufficient evidence has been accumulated, and it is performed in advance of the evidence collection period. In Europe and the United States, this is referred to as “Coverage with Evidence Development” and is a widely used process. In Europe, where evidence of efficacy was not required for the certification of medical devices for a long time, this kind of system was developed in a context where approved medical devices were not available for patients because they were not covered by health insurance (efficacy data are now required for all medical devices in Europe from the outset).

Table 2 presents a list of cases wherein the New Technology Add-on Payment (NTAP), a preliminary evaluation system under Medicare and public health insurance for the elderly in the United States, was applied to medical devices equipped with AI. For example, the NTAP was applied to technology that diagnoses diabetic retinopathy using AI.

Table 1. Selected AI devices that are reimbursed by US Medicare.

Manufacturer	Technology	Description	Payment mechanism	Year reimbursement granted
Digital diagnostics	IDX-DR	Deep learning algorithm to diagnose diabetic retinopathy from fundoscopic images in the outpatient setting	CPT	2020
viz.ai	Viz LVO	Radiological computer-assisted triage and notification software that analyzes CT images of the brain and notifies hospital staff when a suspected large-vessel occlusion (LVO) is identified	NTAP	2020
Rapid AI	Rapid LVO	AI-guided medical imaging acquisition system intended to assist medical professionals in the acquisition of cardiac ultrasound images.	NTAP	2020
Caption health	Caption guidance		NTAP	2021
viz.ai	Viz SDH	Radiological computer-assisted triage and notification software that analyzes CT images of the brain and notifies hospital staff when a suspected subdural hematoma is identified	NTAP	2022 (candidate)
Rapid AI	Rapid aspects	Computer-aided diagnostic device characterizing brain tissue abnormalities on brain CT images	NTAP	2022 (candidate)
AIDoc	Briefcase for PE	Radiological computer-assisted triage and notification software that analyzes CT images of the chest and notifies hospital staff when a suspected pulmonary embolism is identified	NTAP	2022 (candidate)
PROCEPT BioRobotics Corporation	The AQUABEAM system	Autonomous tissue removal robot for the treatment of lower urinary tract symptoms due to benign prostatic hyperplasia (BPH).	NTAP	2020

Table 2: Cases where the US NTAP is applied to medical devices equipped with AI (from NTAP materials)

As mentioned in the opening, digital health technology is developing rapidly and has a short

product cycle. Therefore, it may be preferable to evaluate the efficacy this type of technology in clinical settings based on real-world evidence (safety is essential). It is thus reasonable to use a preliminary evaluation system for digital health technology.

Digital health technology that is expected to reduce the burden on healthcare professionals has its own value. This reduction is expected to reduce accidents. This aspect should be evaluated based on real-world evidence rather than a framework such as a clinical study.

Advanced healthcare system includes the concept of preliminary evaluation. In advanced healthcare, evidence is accumulated in clinical settings for materials for which evidence of efficacy is insufficient for a determination of whether the materials are to be covered by health insurance. While the cost of the technology of advanced healthcare is paid by patients, the costs of other medical procedures are paid as medical expenses combined with treatment outside the scope of public health insurance coverage.

In addition, according to the interim report for regulatory reform promotion prepared by the regulatory reform promotion council in December 2022, a two-phase approval system will be introduced for Software as a Medical Device (SaMD). In this system, for software approved at the first phase based on evidence from nonclinical studies and other sources, “based on safety and efficacy, the cost is set to a price somewhat lower than the prices of existing products with a similar function covered by health insurance, or a flat price determined based on a newly added functional classification (functions similar to existing ones).” This is based on the concept used in the preliminary evaluation process.

Note that careful consideration is necessary regarding “a price somewhat lower.” If the cost is determined to be “a price somewhat lower ,” the reimbursement price set for the second stage approval by the challenge application and others should be determined without consideration of the price determined at the first phase. A system is required for this process.

3.2.1.3 DPC functional coefficients

The evaluation of digital health technology introduced to reduce the burden on healthcare professionals may be reflected in the diagnosis procedure combination (DPC) functional coefficient II, which includes six types of coefficients: data submission coefficient, efficiency coefficient, complexity coefficient, cover ratio coefficient, emergency healthcare coefficient, and regional

healthcare coefficient. Otherwise, a premium related to a reduced burden for healthcare professionals may be introduced in the system for the addition of basic hospitalization fees for the evaluation based on the functional assessment coefficient I.

3.2.2 Equalization and levelling of healthcare technology

Several techniques (such as a program for endoscopic diagnosis equipped with AI, which provides higher diagnostic accuracy than non-specialists can provide) can advance the equalization and levelling of healthcare technology.

In a discussion of the Central Social Insurance Medical Council for the FY 2022 revision of medical fees, it was pointed out that this type of technique can "lead to a mitigation of the standards of medical institutions, which require the presence of a specialist." This evaluation is clearly related to medical fees. However, many medical institutions do not have a standard that requires specialists. Therefore, this concept alone is insufficient.

Assessment methods that can further the equalization of medical technology are described below.

3.2.2.1 Outcome assessment/reward success type

The equalization of technology is expected to have a positive effect on outcomes in medical institutions that provide the technology required. Where a certain outcome level is achieved in a medical institution, an additional technical fee can be introduced via a kind of "outcome assessment/reward success" evaluation (i.e., "pay-for-performance").

Although outcome assessment is being increasingly adopted in other countries, there is a risk of cherry-picking (i.e., the selection of patients who are more likely to achieve a higher outcome in a medical institution). Therefore, the system design is not simple. In Japan, this type of assessment is included in a system for the management fee in a recovery rehabilitation ward and for preventive instructions for diabetic dialysis patients.

For example, in the evaluation of a program to support colonic endoscopic diagnosis, additional criteria can be set based on the rate of polyp removal, malignant polyps removed, and other factors in medical institutions subject to the evaluation. A premium should be introduced in medical institutions to achieve good outcomes without this AI support program. Nonetheless, when an AI

support program is regarded as useful, medical institutions actively seek to introduce it.

3.2.2.2 DPC functional coefficient

Similar to the system mentioned in the section on reducing the burden on healthcare professionals, certain benefits can be provided by the DPC system for medical institutions where digital health technology is introduced, contributing to the equalization of medical technology.

3.2.2.3 Selected treatment

The selected treatment system that requires copayment can be used for patients for whom digital health technology (which ensures a certain level of technique with high accuracy) is used. This measure was implemented to address the needs of patients who value a sense of security.

3.2.3 Optimization (of medical costs or in medical institutions)

As mentioned, it is difficult to evaluate optimization based on medical fees. However, given the importance of optimizing Japanese healthcare, a certain form of assessment method should be considered.

3.2.3.1 DPC functional coefficient

As with the system described in the section on reducing the burden on healthcare professionals and equalizing medical technology, DPC functional coefficients can be used to evaluate the introduction of a certain digital health technology, contributing to the optimization of healthcare.

3.2.3.2 Assessment of premium for medical devices/management fee

It is difficult to evaluate optimization in medical institutions. However, a certain benefit may be provided if medical costs are expected to decrease.

For example, a remote monitoring premium (150 points/month) was provided from 2018 for the

remote monitoring of CPAP. However, evidence provided by the Central Social Insurance Medical Council at the time of introduction indicates that no increase in patient efficacy or safety was observed.

As shown in Figure 13 below, a premium was given for remote monitoring based on the fact that the rate of CPAP use is comparable between patients who visit a hospital every month and patients who undergo remote monitoring and visit a hospital every three months. In this case, the medical cost payment frequency decreases from every month to every three months, and remote monitoring contributes to save the associated medical costs, and the savings are used for remote monitoring.

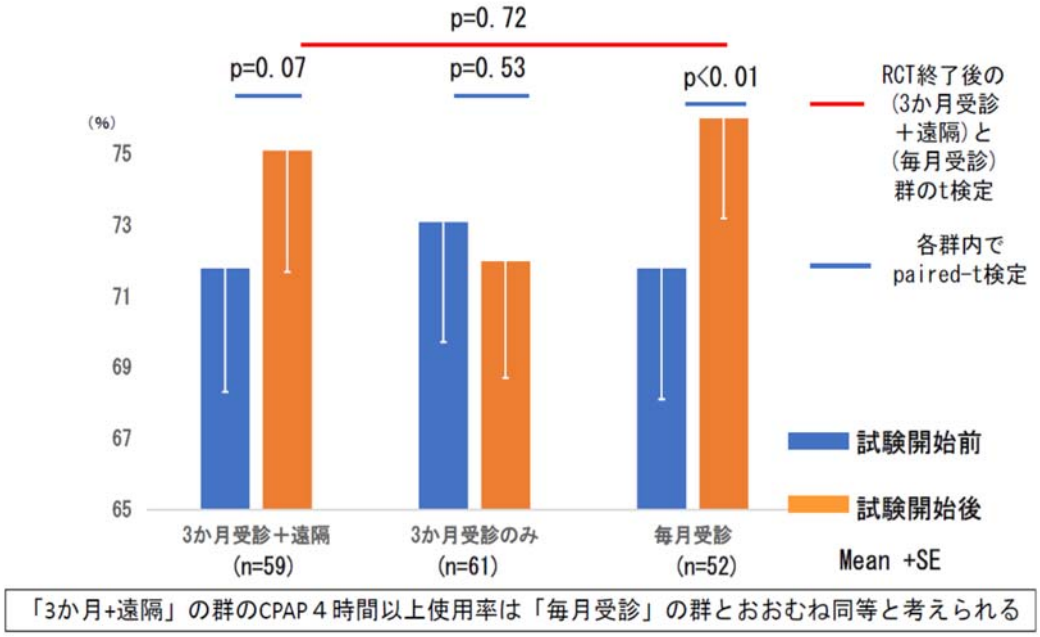

Figure 13: Change in the rate of CPAP use for at least 4 hours and comparison of the rate of CPAP use for at least 4 hours between [visit every 3 months + remote] group and [visit every month] group after RCT completion

If medical cost savings can be clearly shown, the amount of savings can be used to evaluate digital health technology.

3.2.4 Evaluation in line with speed of product development and improvement

Product improvement and development are much faster with digital health technology than with

conventional medical devices. Therefore, it is difficult to perform assessments based on the health insurance system. Therefore, the methods described below should be considered.

3.2.4.1 Preliminary evaluation

The preliminary evaluation mentioned above—used to reduce the burden on healthcare professionals—can also be used as part of an early authorization system.

Specifically, the conditional early approval system (such as a system used for regenerative products) may be employed for programmed medical devices so that early approval/insurance coverage can be achieved, with a re-evaluation performed based on additional data (e.g., RWD) collected during a certain period (utilizing a framework for the challenge application).

In this case, flexible operation is necessary so that re-evaluation for a challenging application can be performed multiple times.

3.2.4.2 Advanced medical care

In the absence of evidence warranting insurance coverage, patient access can be ensured with the System for Advanced Medical Care A, to which application can be made by a company before insurance coverage based on RWD after introduction to the clinical setting. At the time of implementation, the introduction process should be faster than that of the current advanced medical care system.

3.2.5 Other issues

In addition, the issues described below should be discussed.

3.2.5.1 Primary and secondary prophylaxis

The selected treatment system can be used with digital health technology for primary and secondary prophylaxis. Although it is necessary to differentiate this from “what is irrelevant to covered medical treatment,” medical devices used for prophylaxis for which regulatory approval

has been provided should be clearly positioned as the selected treatment, as it may be regarded as a mixed medical treatment. Note that the possibility of insurance coverage is limited to secondary prophylaxis, which is regarded as irrelevant to benefits for medical treatment or selected treatment, regardless of what evidence may be accumulated in the future.

Otherwise, an introduction may be considered for the health of residents under local governments and for insured people (to provide countermeasures against lifestyle diseases and metabolic syndrome, as well as to encourage exercise).

3.2.5.2 Continued development after product launch

If general-purpose devices such as the iPhone are used for program provision, there will be a cost for continued development via device updates. The convenient use of such general-purpose devices for patients is associated with high values. From this perspective, program provision using general-purpose devices should be evaluated.

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Section 4 Arrangement of environment for digital health to ensure safety and security of users and efficient utilization

This section makes a proposal based on four principles (open and inclusive, pursuit of state-of-the-art and international compatibility, minimization of human load, and arrangement of environment with safety and security) and three issues (architecture, laws and regulations, and implementation) that stakeholders should understand in order to promote healthcare DX from the perspective of a stable supply of medical devices and IVD as well as the introduction of innovative technology, amid drastic environmental changes and technological advances.

4.1 Four principles for arrangement of environment for digital health

In its digital reform policy, the Digital Agency specifies 10 basic principles for the formation of a digital society and three principles for the implementation of online-based administrative services defined in the Digital Procedure Act. In addition, the Cabinet established a headquarters for the promotion of healthcare DX in December 2022. The three principles of healthcare DX are as follows: “Digital first” (i.e., individual procedures and services are digitally completed in a consistent manner), “Once only” (i.e., the re-submission of information is unnecessary), and “Connected one-stop” (i.e., multiple procedures and services are performed on a one-stop basis). With reference to these principles, the AMDD proposes four principles for the creation of a digital health environment that will foster healthcare safety, security, and effectiveness.

4.1.1 Principle of open inclusion

The current system, which is closed and exclusive, has sought to ensure safety (e.g., security) by reducing the human load. By contrast, the open-inclusive principle seeks to foster “network externality” (i.e., increased value via the linking of data owned by medical institutions in Japan with those owned by local governments), as well as to reduce the human load and ensure security.

4.1.2 Principle of pursuit of state-of-the-art and international compatibility

Providing service at the highest global level requires fostering the utilization and linking of data. This should not be based on uniform and rigid pre-specified regulations but should be done using risk-based evaluation at the introduction stage, to ensure rapid review, flexible, and continuous improvement utilizing data. In addition, international compatibility should be ensured by examining the situation in foreign countries, so that their data can be utilized. In this manner, an effort should be made to establish a system that can take advantage of the global “network externality.”

4.1.3 Principle of minimization of human load

A system that places a heavy load for operation in the clinical setting is not acceptable. Therefore, it is necessary to establish a system that does not place the burden on healthcare professionals. "Once-only" processes and automation should be introduced for operations for which documentation, visual inspection, be resident, or onsite participation are required to reduce the human load and human error, with tasks being completed by digital processing only.

4.1.4 Principle of arrangement of environment with safety and security

The environment should comply with international standards to ensure security and privacy. In particular, data storage in on-premises/standalone environments can increase security risks. Therefore, an open system that uses a public cloud should be considered, as it may paradoxically increase safety.

4.2 Three steps for arrangement of digital health environment (arrangement of digital health architecture/arrangement of laws and regulations/implementation) and medical devices-specific challenges

Healthcare DX should be implemented based on four principles, and three steps—arrangement of digital health architecture, arrangement of laws and regulations, and implementation—and medical device-specific challenges should be shared.

4.2.1 Digital health architecture

Proceeding with healthcare DX and the social acceptance of digital health requires the arrangement of an "architecture" (an overall plan for linking digital health data with the associated systems and technology) and by fostering awareness of it, to ultimately achieve safe and effective utilization.

This "digital health architecture" is a basic concept reflecting the direction of a system for the "realization of goals via digital health in Japan." It defines "components constituting digital health, including stakeholders, system, and technology," the "relationship among components," and the "relationship between digital health and the external environment," which serve as a basis for specific policies.

The government established a headquarters for healthcare DX via Cabinet in 2022 and listed the social goals "to be realized via healthcare DX." In addition, the MHLW specified policy goals and a

schedule in 2021 in the form of a table titled “Data Health Reform Schedule.” However, the “Architecture” cross-section among stakeholders in healthcare DX has not yet been specified and shared. The “Proposal on the Promotion of Medical Data Utilization” published by the Japan Research Institute on February 12, 2023, points out that, “Although the objectives and directions of medical data utilization are currently specified, the overall design and comprehensive system structure has not been made public, with a common understanding among stakeholders being particularly insufficient,” and “an effort should be made so that stakeholders can share an awareness for the objectives of medical data utilization, and the government policy should specify the sharing of use cases from various stakeholder perspectives.”

In this report, noteworthy challenges and proposals are discussed from the perspective of the medical device and IVD industry for the realization of a standardized platform that would ensure international interoperability.

4.2.1.1 Necessity of arrangement of master data related to medical device logistics

The distribution of several tens of thousands of highly controlled medical devices is complex because of the necessity for the strict management of medical safety as well as the unique business practices and industrial structures involved. Difficulties in locating necessary treatment materials or obtaining the proper quantities can worsen in an emergency, such as a pandemic or earthquake. The AMDD is concerned about the potential for various future problems, such as a shortage of human resources, to impact the stable supply of medical materials.

The AMDD collaborates with NEC/Nippon Express in the “Smart logistic services” project of the Cross-ministerial Strategic Innovation Program (SIP) to devise a solution of these challenges. It performed a pilot test of a medical device information platform (PF) in FY 2021, followed by social implementation in FY 2022. The purpose of the medical information PF is to ensure a stable supply of medical devices by improving distribution efficiency, and enable the immediate availability of precise information on the location and amount of necessary medical devices in case of a pandemic or earthquake. Medical device companies are also pursuing the optimization of operations using RFID/barcodes, the visualization of inventory for distribution/lending, improvements in precision, and the development of new business models (such as cooperative logistics) by sharing information between players involved in medical device logistics for possible optimization (see Figure 13).

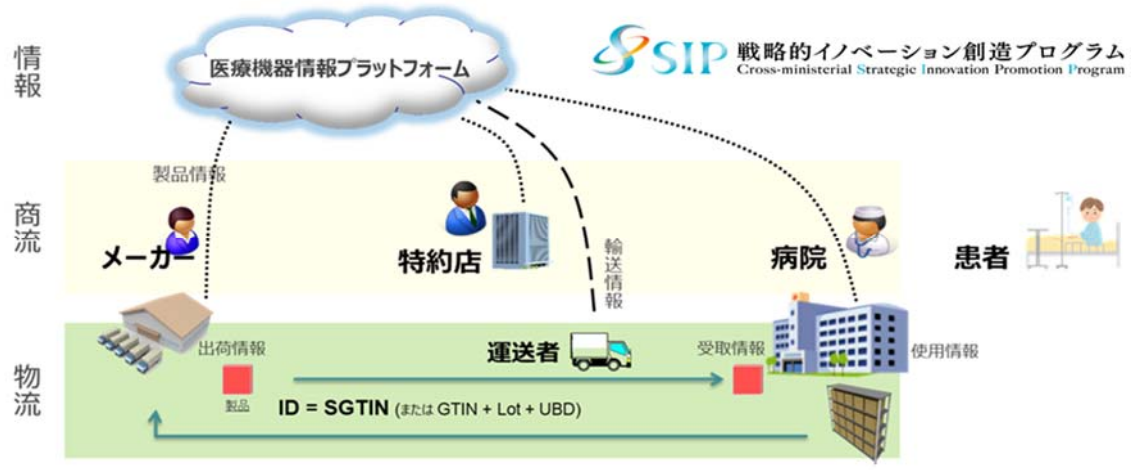

Figure 14: SIP Smart Logistics Program schema (from Cabinet Office materials)

The program highlighted the need for master data at the unified location of medical device distribution. In particular, the following two types of master data should be collected under the leadership of the government so that national unification and maintenance can be achieved intensively:

- **Medical institution code:** This code is currently managed and operated by the Regional Bureau of Health and Welfare. Therefore, modifications such as integration and transfer across regions cannot be made. This should be updated to the published **medical institution code** and turned into master data that can be used at the national level.

- **Medical device distributor code**: Neither the medical device distributor code nor master data that can cover branches, business offices, and warehouses at the national level are available.

4.2.1.2 Promotion of administrator function for safety management of medical information system in medical institutions

The FY 2022 medical fee revision specified that the requirements for a “review for an additional fee for a medical record management system” should include the assignment of dedicated personnel in charge of medical information system safety management in covered medical institutions with at least 400 beds and information security training for staff (at least once a year).

A higher level of medical digitalization may lead to the wide use of digital health products in online systems that cannot be connected to the in-hospital system. Medical institutions increasingly require

an arrangement of basic infrastructure (such as the maintenance of power supply and internet lines) and an understanding of the trends in state-of-the-art technology. However, medical institutions often engage in excessive or technically incorrect discussions that stress security reinforcement.

It is necessary to assign administrators in charge of the safety management of medical information systems who have sufficient knowledge and expertise in medical institutions, as well as to centralize safety management administrator functions in the regional medical collaboration promotion corporation (for small- to medium-sized hospitals) in order to facilitate partnerships with companies for the introduction of new technology and the arrangement of a safety environment. In addition, the government should specify policies and incorporate supportive measures into the digital health architecture.

4.3 Arrangement of laws and regulations

The establishment of a digital health architecture requires a change in the relationship between stakeholders and the legal system and the governance among the stakeholders. Laws and regulations must define the nature of governance and rules in the new era, and key legal definitions should be disseminated to stakeholders (including individuals, medical institutions, and companies):

- **Medical institutions** have an obligation to submit medical institution data and standardize procedures based on guidelines defined by the government on the premise that the data are owned by patients.
- **Companies** have an obligation to ensure safety in data utilization
- **Individuals** operate under the opt-out principle of healthcare data submission (whereby data are principally controlled at the time of utilization), and the data are owned and managed by them

4.3.1 Introduction of cases demonstrating the necessity of legal arrangement to ensure cyber security of medical devices

This section describes issues involving the cyber security and handling of personal information in digital health products unconnected to an in-hospital system and offers proposals for legal arrangements that would address such cases.

Medical institutions are often required to explain the security of online systems that use digital health products that are not connected to the in-hospital system (in compliance with ISO14971 and IEC62304) and handle personal information based on their own judgment. Specifically, the following requirements are observed:

・Response on the compliance with the “Guidance On Thoroughly Ensuring Cyber Security Of Medical Devices”

・Read the main text and supplementary volume of the “Guidelines on Safety Management of Medical Information System Version 5.2” before submitting materials prepared in line with an attached checklist and the Appendix (“Contents To Be Determined for Sharing Medical Information and Others with an External Agency”).

Given that a detailed response from each medical institution should be made in line with the notification issued by the MHLW and the content of the guidelines, the burden on companies is significant.

It is proposed that the implementation of a system based on the once-only principle (such as the arranged specification of standard medical information or system authorization) and its dissemination should be conducted under the leadership of the government.

4.4 Implementation

The presentation of a digital health architecture and the necessity of legal arrangements are discussed for the realization of a healthcare DX. First, an environment where patients can obtain the necessary information and conduct comprehensive discussions with stakeholders is necessary so that the stakeholders can participate aggressively and effectively in the implementation phase.

4.4.1 Arrangement of environment where options are provided for patients and their families in an appropriate manner

The achievement of VBHC requires an environment in which patients can select personally optimized medical techniques based on appropriate information, which reduces the burden by preventing duplicate examinations, prescriptions, and needless hospital visits. Specifically, reliable websites explaining diseases for patients and certification systems should be established in collaboration with the government and industry.

4.4.2 Investigation of challenges related to implementation of online medical care and its effectiveness

To promote patient access to medical care, the challenges and effectiveness of the implementation of online medical care should be investigated in a cross-sectional manner by stakeholders such as medical institutions and patients. Discussions should be conducted about whether it is appropriate to set the medical fees at the same level when the same outcomes are obtained, or what kind of system is necessary to arrange the appropriate environment for medical institutions and patients.

4.4.3 Digital health conference between government and industry

Collaboration among stakeholders (particularly the government and industry) is necessary to promote healthcare DX. The Basic Policies for Economic and Fiscal Management and Reform in FY 2022 specifies that "an effort itself for the solution of social challenges, as a source of the additional value creation is positioned as a growth strategy, with medium- or long-term investment and reform being performed in a well-planned and emphasized manner with government–industry collaboration to achieve solutions to challenges and economic growth." For healthcare DX, knowledge-sharing about technology and systems between the government and industry, continuous updating are necessary to pursue the principles—open-inclusive, pursuit of state-of-the-art, and international compatibility—as specified in Section 4.1.1, and to establish the use cases describing preferable options and a digital health architecture, which is the basis of the overall plan for healthcare DX promotion.

The MHLW minister, executive members of METI, and industry representatives have discussed the status of innovation progress presented by pharmaceutical and medical device industry (the public-private dialogue for the creation of innovative pharmaceuticals and medical devices). We propose the establishment of a "Digital Health Conference" to serve as a new platform for open and inclusive discussions on healthcare DX between the government and industry. The specific draft is summarized below.

[Objectives]

Industry side: Sharing advanced cases, challenges, and proposals

Government side: Collection of information on advanced cases and trends in foreign countries as well as verification of hypotheses specified in a policy agenda

[Composition]

・Given that cross-sectional challenges among government agencies are addressed as part of DX promotion in society as a whole, participation is expected from the Digital Agency, MHLW, METI, MIC, and Headquarters for Healthcare Policy in the Cabinet Office, on the government side.

・Cross-sectional participation from the medical device, pharmaceutical, IT infrastructure, cyber security services, and insurance industries is expected on the private side (with the industry associations serving as a contact point).

・As needed, healthcare professionals, academic personnel, payers, patient representatives, local government personnel, and staff members of private companies may be invited.

・The office will be operated by subcontracting on a private enterprise basis, ensuring neutral and efficient operation.

[Form]

・Digital Health Conference: Closed and mutual discussion and information sharing among members who are in a position to lead operations in both the government and industry.

・Digital Health Private–Public Dialogue: Representatives/executive members of member organizations are expected to participate in this dialogue. The discussion and presented outcomes are to be confirmed at the digital health conference, with an agreement on the direction of efforts. This discussion is expected to occur in closed sessions.

・For digital health conferences, a collaboration platform is expected to be utilized to enable timely and flexible online discussions, theme tracking, and information sharing.

[Frequency]

・Digital Health Conferences are held approximately four to six times a year

・Digital Health Private-Public Dialogue is to be held once every six months

[Expected output]

・Proposal for government policy such as the basic policy

・Proposal and joint statement for the establishment of the digital health architecture

・Provision of use cases (including advanced cases in the area of healthcare DX inside or outside Japan)

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