＜ Review ＞

The challenge to develop and implement artificial intelligence (AI) technologies in health and medical care in Japan

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Abstract

Since the statement by then Prime Minister Shinzo Abe in 2016, the development and application of artificial intelligence (AI) technologies in Japan has progressed rapidly. AI can be used and applied in several domains, of which health and medical care are among the most important and most emphasized. In this article, the history of the challenges to develop AI technologies in Japan is outlined and past achievements and future prospects for the research, development, and implementation of AI are reviewed and discussed, with a particular focus on the fields of health and medical care.

AI is clearly identified as one of the core technologies needed to promote science, technology, and innovation and to grow the economy of Japan. AI was first mentioned in the fifth phase of the "Science, Technology and Innovation Basic Plan," in which AI was regarded as an important part of realizing "Society 5.0." A specific vision for promoting the application of AI has then been presented in the "Integrated Innovation Strategy," an annual action program for realizing this basic plan. Additionally, in an annual strategy that presents a comprehensive set of initiatives for economic growth, AI has been described as a key measure for economic growth and productivity improvement in Japan.

In the "Artificial Intelligence Technology Strategy," which was formulated in 2017 by the Strategic Council for AI Technology, a council composed of three ministries (the Ministry of Education, Culture, Sports, Science and Technology, Ministry of Internal Affairs and Communications, and Ministry of Economy, Trade and Industry) relevant to AI, the priority areas specified included productivity, health, medical care, welfare, mobility, and information security. Subsequently, the "Social Principles of Human-Centric AI," which were formulated in 2019, described ethics and other issues that should be considered in the utilization of AI. In line with this strategy and these principles, the first "AI Strategy" was developed in 2019 by the Cabinet Office, and a framework for promoting AI throughout the government, including all ministries, was established. In this strategy, key areas in which social implementation should be achieved were designated. These areas included health, medical care, long-term care, agriculture, national resilience, transportation infrastructure and logistics, regional revitalization (smart cities), and manufacturing.

Because health and medical care have been defined from the beginning as a priority area in which to promote the application of AI, the Ministry of Health, Labour and Welfare began its efforts on AI quite early and has taken on a leading role. The process chart for accelerating the development of AI in the field of health and medical care was released in 2020, and priority areas were identified, including genomic medicine; support for diagnostic imaging; support for diagnosis and treatment; drug discovery and development; long-term care and dementia; support for surgical procedures; prevention; infrastructure for the development of AI; and improvement in the efficiency of operations for reimbursing medical fees. Of these priority areas, diagnostic imaging is the most advanced because it has the largest number of related research proj-

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ects, resulting in the completion of a database through collaboration among six related academic societies. With regard to other cases, the project to integrate data held by industry and academia on drug targets, efficacy, and toxicity and to build AI for drug discovery and the "AI Hospital System" project were conducted. The AI Hospital System aims at providing highly advanced medical services, improving the efficiency of medical care, reducing burden on medical personnel, and increasing the productivity of medical care.

I. Introduction

In recent years, artificial intelligence (AI) technologies, which can perform portions of human intellectual activities, have developed at an accelerating pace around the world. These technologies are expected to transform our society, not only by substituting for routinized tasks but also by supporting and enhancing human activities and decision-making. Governments and companies invest tremendously in the research and development (R&D) of AI technology as a driving force for realizing a sustainable society and as core technologies for industrial strengthening. Additionally, domains in which AI can be used and applied have expanded, and health and medical care are positioned as one of the most important and most focused-upon domains.

It is no exaggeration to say that the initiatives for AI in Japan began with the following statement by then Prime Minister Shinzo Abe on April 12, 2016, at the Fifth Meeting of the "Public-Private Dialogue toward Investment for the Future," which was established under the Japan Economic Revitalization Headquarters.

"R&D goals and a roadmap for industrialization of AI will be developed this year. To this end, the Strategic Council for AI Technology will be established to gather the wisdom of industry, academia, and government and to eliminate stove-piping" [1].

Since then, a whole-of-government approach to AI has intensified, and R&D has accelerated the implementation of AI in various fields to contribute to the development of science and technology and the economy. Although these efforts have not necessarily progressed as markedly as those in the United States and other developed countries, the steady and systematic development process in Japan may be useful for other countries.

In this article, the history of the challenges to develop AI technologies in Japan is outlined, and past achievements and future prospects for R&D and implementation of AI are reviewed and discussed, with a particular focus on the fields of health and medical care.

II. Role of AI in various policies of Japan

1. AI in science, technology, and innovation policies

On the basis of the Basic Act on Science, Technology and Innovation [2], the "Science, Technology and Innovation Basic Plan" has been formulated to achieve comprehensive and systematic promotion of policies to advance science and technology from a long-term perspective. The first plan was developed in 1995 and has since been revised every five years. AI technology was first mentioned in the fifth phase of the plan [3], which was formulated in 2016. In this plan, the concept of "Society 5.0" was first proposed as a future society for which Japan should aim. Society 5.0, defined as a human-centered society that balances economic development and the resolution of social issues through a system that integrates cyberspace (virtual space) and physical space (real space), denotes a new society following the hunting (Society 1.0), agricultural (Society 2.0), industrial (Society 3.0), and information (Society 4.0) societies [3]. Moreover, AI technology was regarded as an important part of realizing Society 5.0, and thus the promotion of the R&D of AI; development of human resources capable of utilizing AI; and resolution of ethical, legal, and social issues (ELSI), such as the influence of the advancement of AI on society and humans, were highlighted.

In addition to this basic plan, the "Comprehensive Strategy on Science, Technology and Innovation" has been developed annually since 2013. This strategy describes a long-term vision that includes an overview of science, technology, and innovation policy and a short-term action program that summarizes the policies to be implemented to realize this vision consistently with the basic plan [4]. AI was first indicated in the 2015 version of the strategy [5]. In the 2016 version of the strategy, it was then specified that with regard to AI, which is indispensable for realizing Society 5.0, relevant efforts that were introduced in the basic plan should be strengthened [6]. Other matters that were highlighted included establishing a system to promote AI-related R&D in an integrated manner, addressing ELSI related to AI, protecting intellectual property related to creation by AI, reviewing systems and rules for implementing

AI, and fostering social acceptance of the use of AI [6]. In the 2017 version of the strategy, it was reported that public and private investments in the R&D of innovative cyber-space infrastructure technologies, such as AI and the Internet of Things (IoT), had increased [7].

In 2018, when the "Comprehensive Strategy on Science, Technology and Innovation" was renamed to the "Integrated Innovation Strategy," AI was clearly identified as a key area where efforts should be particularly strengthened, and a goal and deadline were set for the implementation of AI by 2022 [8]. In the 2019 version of the strategy, it was specified that AI efforts would be based on the newly developed "AI Strategy" (explained later in this article), which was aimed at spreading AI to all people, industries, communities, and governments [9]. In 2020, the development of a consultation assistance system for COVID-19 using AI avatars and R&D on medical devices based on the use of AI technology were added as initiatives in the areas of health and medical care [10].

The 6th Science, Technology and Innovation Basic Plan was launched in 2021. From the 6th period, AI has been clearly positioned as a fundamental technology, and specific efforts related to AI, including R&D and human resource development, have been emphasized [11]. In the Integrated Innovation Strategy 2021, which was formulated in the same year, Behavioral Insights x Technology (BI-Tech), disaster prevention chatbots, and smart cities, among others, were newly added as specific examples of the application of AI [12]. Additionally, in the latest Integrated Innovation Strategy, it was indicated that efforts to address AI will be promoted on the basis of the AI Strategy as revised in 2022 [13].

2. AI in policies for economic growth

AI is expected to play an important role not only in the advancement of science, technology, and innovation but also in the economic growth of Japan. The Japanese government has developed an annual strategy that presents a comprehensive set of initiatives for economic growth since 2013 [14], and in the 2015 revision of the Japan Revitalization Strategy, reform of industrial and employment structures through IoT, big data, and AI was described as a key measure for economic growth and productivity improvement in Japan [15]. Subsequently, in the Japan Revitalization Strategy 2016, the concretization of the R&D and implementation of AI were cited as one of the key measures for economic growth [16].

It was clearly stated in the strategy for economic growth developed in 2017, named the Future Investment Strategy 2017, that the realization of Society 5.0 is key to breaking the long-term stagnation of economic growth in Japan [17].

To realize Society 5.0, policy resources in Japan are to be concentrated in five areas: extending healthy life expectancy, realizing a mobility revolution, next-generation supply chains, comfortable infrastructure and community development, and fintech; it was specifically stated that the use of AI would be promoted in each of these areas [17]. According to the Future Investment Strategy 2018, the direction of economic growth in Japan will be focused not only on the realization of Society 5.0 but also on the achievement of Sustainable Development Goals (SDGs), for which the following were identified as future focus areas: mobility systems, healthcare systems, sustenance of economic activity, public administration and infrastructure, and communities and small and medium enterprises (SMEs) [18].

The "Super City" concept, proposed for realizing futuristic lifestyles ahead of the rest of the world using AI, big data, etc., was presented as a new initiative in the "Action Plan of the Growth Strategy" [19] in 2019. In the 2020 edition of this action plan, it was then specified that various regulations should be reexamined in light of the implementation of digital technologies, including AI, in the near future and that demonstration projects should be implemented for this purpose, focusing on three areas: mobility, fintech, and architecture [20]. In the 2021 edition of the action plan, it was indicated that support must be provided for the implementation of AI and other important advanced technologies from the viewpoint of economic security [21]. Thus far, in the latest plan, called the "Grand Design and Action Plan for a New Form of Capitalism," it was specified that efforts for the implementation of AI will be promoted [22].

III. Overview of strategies to promote AI in Japan

1. Artificial Intelligence Technology Strategy

The "Strategic Council for AI Technology" was established on April 18, 2016, by the joint jurisdiction of the Ministry of Education, Culture, Sports, Science and Technology (MEXT); Ministry of Internal Affairs and Communications (MIC); and Ministry of Economy, Trade and Industry (METI) for promoting the R&D and implementation of AI technology. The council was initially intended to provide coordination among these three ministries, which have been promoting the R&D of AI technology at research institutes under their jurisdictions. Later on, the Ministry of Health, Labour and Welfare (MHLW); Ministry of Agriculture, Forestry and Fisheries; and Ministry of Land, Infrastructure, Transport and Tourism joined the council. In particular, because health and medical care have attracted attention as fields where AI technologies are being applied and implemented, the MHLW was encouraged to join the council

and, fully aware of the importance of AI, decided to actively participate.

The "Artificial Intelligence Technology Strategy" was devised on March 31, 2017. From this strategy, the "Industrialization Roadmap Projected by Fusion of AI and other related Technologies (Industrialization Roadmap)" was formulated, and "productivity"; "health, medical care, and welfare"; "mobility"; and "information security" were specified as priority areas that should be adopted for the time being as part of the industrialization roadmap [23]. Additionally, an action plan was developed on the basis of the "Artificial Intelligence Technology Strategy" on August 17, 2018, and specific goals for R&D were established. The goals related to health, medical care, and welfare were as follows [24]:

/to collect training image data necessary for the development of AI in cooperation with medical societies and provide these data to companies and other entities that develop AI

/to standardize interfaces for interconnecting data related to surgery to build a system that supports surgery using AI technology

/to develop techniques for analyzing the brain characteristics of healthy individuals and patients using big data on brain function and network analysis of brain activity

/to seek targets in drug discovery for idiopathic pulmonary fibrosis and other diseases by collecting information from medical records, omics analysis, literature, etc., and utilizing AI

/to improve the quality of care at medical institutions and long-term care facilities by measuring the daily functions of caregivers and patients using wearable sensors, etc., and analyzing the data using AI

/to develop, build, and implement an "AI Hospital System" using AI, IoT, and big data, which will provide highly advanced medical services; improve the efficiency of medical care; reduce the burden on doctors, nurses, and other medical personnel; and increase the productivity of medical care

2. Recommendations regarding the relationship between humans and AI

The "Advisory Board on Artificial Intelligence and Human Society" was established to discuss issues and directions that should be addressed in the future regarding the relationship between AI and human society to promote sound progress in the R&D and utilization of AI. Their first meeting was held on May 30, 2016, and their report was issued on March 24, 2017. The key issues extracted in this report were ethical, legal, economic, social, and R&D issues [25].

In 2018, a review conference on the Social Principles

of Human-Centric AI was established under the Strategic Council for AI Technology. The purpose of this conference was to discuss the basic principles of ethics and other issues that should be considered in the R&D and utilization of AI from a broad perspective by multiple stakeholders from industry, academia, and the government. Their first meeting was held on May 8, 2018, and the "Social Principles of Human-Centric AI" [26] were formulated on March 29, 2019. Among these principles, it was indicated that the basic philosophy for the utilization of AI was to respect the three values of dignity, diversity and inclusion, and sustainability, followed by the following seven principles [26]:

(1) human-centric principle;
(2) principle of education/literacy;
(3) principle of privacy protection;
(4) principle of ensuring security;
(5) principle of fair competition;
(6) principle of fairness, accountability, and transparency; and
(7) principle of innovation.

3. AI Strategy

The AI Strategy expert meeting was established as one of the expert meetings for promoting and strengthening innovation policy under the Integrated Innovation Strategy Promotion Council; the first of these meetings was held on September 5, 2018. Although the Artificial Intelligence Technology Strategy has thus far been promoted jointly by three ministries, i.e., MEXT, MIC, and METI, the Cabinet Office has taken the lead in developing and promoting a new strategy for AI, given that many other ministries have also become involved in AI.

On June 11, 2019, the first AI Strategy (AI Strategy 2019 [27]) was developed. The purpose of this strategy was to specify the environment and measures conducive to the effective future utilization of AI for contributing to the solution of global issues through the realization of Society 5.0 and to overcome the issues facing Japanese society. The following strategic objectives were devised for this strategy [27].

/Strategic Objective 1: For Japan to develop a base of human resources which leads the world in being aligned with the needs of the AI era and to become a country that attracts human resources from around the world. Additionally, to build a mechanism to achieve this objective on a sustainable basis

/Strategic Objective 2: For Japan to become a frontrunner in the application of AI to real-world industry and to achieve strengthened industrial competitiveness

/Strategic Objective 3: For a series of technology systems to be established in Japan that will realize a "sustainable

society that incorporates diversity" and to implement a mechanism to operate them

/Strategic Objective 4: For Japan to take a leadership role in building international research, education, and social infrastructure networks in the AI field and to accelerate AI-related R&D, human resource development, achievement of SDGs, etc.

Specific initiatives, including for education reform, reconstruction of the R&D system, social implementation, development of data-related infrastructure, AI era digital government, support for SMEs and venture companies, and ethics, were developed, and main and specific objectives were established for each initiative [27]. Additionally, key areas in which to achieve social implementation were identified, including (1) health, medical care, and long-term care; (2) agriculture; (3) national resilience (to disasters); (4) transportation infrastructure and logistics; and (5) regional revitalization (smart cities) [27].

The main objectives of the field of health, medical care, and long-term care are to maintain an environment in which people feel assured that they can receive the most advanced and effective treatments and high-quality long-term care regardless of location and to reduce the burden on medical and long-term care providers [27]. Specific objectives for health, medical care, and long-term care are as follows: (1) provision of a data infrastructure for the utilization of AI in the health, medical care, and long-term care fields; (2) promotion of AI technology development in medical fields, in which Japan is known to have strengths, and reduction of the burden on healthcare workers through utilization of AI in medical treatment; (3) promotion of the introduction of AI/IoT technology to the field of prevention and long-term care and reduction of the burden on care workers through the use of AI/IoT for long-term care; (4) formation of the leading medical AI market and medical AI hub in the world; and (5) education in training facilities and training centers on the use of AI for medical professionals and recurrent education for healthcare workers [27].

On June 11, 2021, AI Strategy 2019 was revised, and AI Strategy 2021 [28] was developed in light of changes in the environment, such as delays in digitization during the COVID-19 pandemic and the establishment of the Digital Agency in September 2021. Amendments from AI Strategy 2019 were to include Strategic Objective 0 (for Japan to establish a system and technical infrastructure that can protect the lives of people and their property to the maximum extent possible against pandemics and large-scale disasters and to ensure proper and sustainable operation of the infrastructure) and to add "manufacturing" to the key areas for social implementation.

On April 22, 2022, AI Strategy 2022 [29], a major revision of the previous strategy, was formulated. In this revision, although the purpose of the strategy and strategic objectives remained unchanged, the framework of the initiatives was reconstructed. First, the establishment of AI for national resilience, AI for planetary resilience, and resilient and responsible AI were decided upon as main objectives corresponding to Strategic Objective 0. Second, the main and specific objectives regarding social implementation were changed significantly. Objectives previously stipulated for each key area, such as health, medical care, and long-term care, were changed to objectives that are common to all areas, including improvement in the reliability of AI, enhancement of data to support the utilization of AI, efforts regarding human resources, information sharing with regard to technology, rules for data handling, promotion of the utilization of AI in governments, and fusion with fields in which Japan is known to have strengths [29].

The major actions for health, medical care, and long-term care described in AI Strategy 2022 were as follows [30]:

/evaluation of the availability of public databases for the development of AI;

/improvement of the environment in which patient data are used in the R&D of medical devices that apply AI;

/development of a tool that assesses the likelihood of child abuse using AI, to be made available at child guidance centers across the country;

/drug discovery target search using AI to analyze omics and clinical information, in addition to whole-genome information;

/implementation of high-quality clinical research, investigator-initiated clinical trials, etc., aimed at the development of innovative medical devices;

/development of AI for microbiome analysis to accelerate personalized diabetes prevention;

/implementation of prevention and long-term care field verification projects and support through building a network of AI start-up businesses in the same field; and

/information gathering and risk management using AI to support decision-making in response to infectious diseases.

IV. Actions to apply AI to health and medical care

1. Overview of approaches to promote AI, led by MHLW

The MHLW began its efforts on AI quite early. The expert panel on the promotion of the use of information and communications technology (ICT) in the fields of health and medical care was established, and their first meeting was held on November 19, 2015. This panel recommended the formulation of AI-based techniques for pathological diagnosis and the development of AI-based technology for

standardizing information contained in electronic medical records [31].

The expert panel on the promotion of the use of AI in the fields of health and medical care was then established for clarifying the effectiveness of the use of AI for patients and the public and discussing necessary measures to promote the development of AI and to ensure the quality and safety of services that use AI. Their first meeting was held on January 12, 2017, and their report was published on June 27, 2017. In this report, priority areas for the development of AI in the fields of health and medical care were identified: genomic medicine; support for diagnostic imaging; support for diagnosis and treatment; drug discovery and development; long-term care and dementia; and support for surgical procedures [32].

Subsequently, the consortium for accelerating the development of AI in the fields of health and medical care was established to further develop in the directions set forth in this report. Their first meeting was held on July 23, 2018; their documentation [33] summarizing discussions among the consortium and outlining future directions was published on June 28, 2019; and their process chart [34] was released on June 18, 2020.

The consortium discussed the roadblocks to develop AI in terms of stages of development, which included an institutional review board; informed consent; annotation/ labeling; transfer, standardization, and anonymization of data; computation and data storage in the cloud; validation in clinical settings; review and regulatory approval by the Pharmaceuticals and Medical Devices Agency; and commercial development and update [33,34]. The consortium also formulated a bird's-eye view of the areas where AI can be expected to be developed and utilized in the fields of health and medical care, long-term care, and welfare [33,34]. It was then specified that the burden of data entry, standardization of electronic medical records, human resource development, and quality assurance and evaluation of AI need to be considered. Medical safety, infrastructure for the development of AI, and improvement of the efficiency of operations for reimbursing medical fees were also newly identified as additional areas to be addressed in AI research and implementation [33,34].

The specific initiatives outlined in the process chart developed by the consortium are listed in Table 1 [34].

2. Recent trends in R&D related to the application of AI to health and medical care

R&D on AI in the fields of health and medical care is conducted mainly in research programs subsidized by the MHLW and the Japan Agency for Medical Research and Development (AMED) under the jurisdiction of the MHLW and other ministries. The research program on medical

Table 1 List of specific initiatives outlined in the process chart [34]

(1) Genomic medicine /Implementation of whole-genome analysis on cancer and rare and intractable diseases
(2) Support for diagnostic imaging /Construction of databases of images by relevant academic societies /Provision of training data of images to manufacturers of medical devices and development of programs to support diagnostic imaging using AI
(3) Support for diagnosis and treatment /Construction of knowledge database on rare and intractable diseases and development of AI /Investigation of the usefulness of medical safety data analysis using AI /Implementation of support for diagnosis and treatment using AI for common diseases /Implementation of support for diagnosis and treatment using AI for rare diseases
(4) Drug discovery and development /Construction of database for discovery of drug targets and development of AI /Construction of databases containing data on efficacy of drugs owned by companies and empirical knowledge related to structural optimization and development of AI technology that can be used for compound optimization /Development of AI that can be applied to drug development and achievement of efficient drug development using AI
(5) Long-term care and dementia /Identification of issues related to support for the design of care plans using AI /Development of systems to assist in coping with patients with dementia using AI /Research for development of systems to support interpersonal interaction and community development for elderly with dementia using AI /Establishment of a base to support the process of developing, introducing, utilizing, and improving robots to assist caregivers
(6) Support for surgical procedures /Collection, integration, and deposition of data related to surgical procedures
(7) Prevention /The basic concepts and issues regarding the direction of the personal health record should be organized, and a process chart should be formulated. Then, initiatives will be developed on the basis of the process chart.
(8) Infrastructure for development of AI /Review of criteria for security needed in cloud environment for developing AI /Identification and promotion of cloud environments that fulfill those criteria
(9) Improvement of the efficiency of operations for the reimbursement of medical fees /Development of a new system for review and payment of medical fee claims and development of AI for review /Operation of a new system and implementation of AI in review

ICT and artificial intelligence was launched in 2016 at the MHLW and AMED, respectively [35]. (In 2021, the research program of AMED was renamed to the research project for medical–engineering collaboration and implementation of artificial intelligence.)

In the review for this study, research projects conducted in the research program on medical ICT and artificial intelligence and the research project for medical–engineering collaboration and implementation of artificial intelligence that have been completed by 2021 were searched using the MHLW Grants System (https://mhlw-grants.niph.go.jp/) and the AMED funding for innovation database (AMED-find) (https://amedfind.amed.go.jp/amed/index.html). As a result, ninety-one projects (including fifty-one projects by the MHLW and forty projects by AMED) were identified. Thirty of the research projects (33%) were conducted for a period of one year, twenty-two projects (24%) for a period of two years, thirty-nine projects (43%) for a period of three to four years. More than half of the research projects required a short period of one to two years to produce research results. With regard to research funds allocated to each research project, more than half of the projects by the AMED had a research fund of more than 100 million yen each, whereas more than half of the projects by the MHLW had a research fund of less than 30 million yen each. This shows that AMED has conducted research projects with larger budgets than those of the projects by the MHLW.

Table 2 presents the numbers and percentages of research projects with respect to their main research purposes. In total, thirty-five projects (38.5%) addressed the development and application of AI, and thirty-nine projects

(42.9%) prepared the data and infrastructure necessary for promoting the development and application of AI. Approximately half of the research projects by AMED were aimed primarily at the development and application of AI, whereas approximately 30% of the projects by the MHLW were aimed mainly at AI. Other purposes included telemedicine, surveys to understand the current status of AI development and implementation, and human resource development related to AI.

Table 3 shows the numbers and percentages of research projects, among those whose main research purpose was the development and application of AI, with respect to area. More than half of the research projects in total, and more than 80% of those by AMED, addressed the development and application of AI for supporting diagnostic imaging. Conversely, with regard to the specific initiatives identified in the process chart [34], few studies have been conducted on drug discovery and development and support for surgical procedures, whereas research on the application of AI to long-term care and dementia has not yet been conducted.

3. Achievements to date on the application of AI to health and medical care

Prior to the application of AI to the fields of health and medical care, a review of the laws and regulations that AI might affect was initiated. First, in relation to the "Medical Practitioners' Act," a notice was issued on December 19, 2018, stating that even when a physician uses an AI-based program to assist in diagnosis or treatment, the physician is regarded as the main entity that performs the diagnosis and treatment and is therefore responsible for the final decision

Table 2 Numbers and percentages of research projects by main research purpose

	MHLW (51 projects)		AMED (40 projects)		Total (91 projects)	
	No	%	No	%	No	%
Development and application of AI	16	31.4	19	47.5	35	38.5
Preparation of data and infrastructure	23	45.1	16	40.0	39	42.9
Telemedicine	2	3.9	2	5.0	4	4.4
Surveys about AI	3	5.9	1	2.5	4	4.4
Human resource development	2	3.9	1	2.5	3	3.3
Others	5	9.8	1	2.5	6	6.6

Table 3 Numbers and percentages of research projects by area for development and application of AI

	MHLW (16 projects)		AMED (19 projects)		Total (35 projects)	
	No	%	No	%	No	%
Support for diagnostic imaging	2	12.5	16	84.2	18	51.4
Support for diagnosis and treatment	4	25.0	3	15.8	7	20.0
Support for prediction of prognosis	5	31.3	0	0.0	5	14.3
Drug discovery and development	3	18.8	0	0.0	3	8.6
Support for surgical procedures	1	6.3	0	0.0	1	2.9
Evaluation of adverse effects of drugs	1	6.3	0	0.0	1	2.9

[36]. Subsequently, the "Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices" was revised in December 2019, making it possible to flexibly change the approval details based on changes in the performance of the devices after marketing by evaluating the process of improvement of the AI-based medical devices, whose performance can change with learning, when reviewing the approval of such devices [37]. Such a system for the review and approval of medical devices, called IDATEN, has been effective as of September 1, 2020.

With regard to the development of AI infrastructure, databases for diagnostic imaging have been established in collaboration with the Japanese Society of Pathology, Japan Gastroenterological Endoscopy Society, Japan Radiological Society, Japanese Ophthalmological Society, Japanese Dermatological Association, and Japan Society of Ultrasonics in Medicine [38]. Additionally, a program was launched to integrate data held by industry and academia on drug targets, efficacy, and toxicity and to build AI for drug discovery [38]. As of December 2021, 18 firms have participated in this project.

With regard to the implementation of AI, the "AI Hospital System" has been established since the early stages of AI initiatives in Japan [8,24]. Using the results of this program, a consultation assistance system that uses avatars and a database infrastructure that contributes to the development of drugs and vaccines were developed [38]. In April 2021, the Healthcare AI Platform Collaborative Innovation Partnership was developed to promote R&D, contributing to the utilization of AI technology in the healthcare field. Others, such as a platform for smart care prevention, an application for an online day care, a consultation system for long-term care facilities that introduce the use of AI/IoT, and a training program for medical professionals who can develop and utilize AI, have also been developed for the implementation of AI [38].

V. Conclusions

Since the statement by then Prime Minister Abe in 2016, the development and application of AI in Japan has progressed rapidly. First, AI was clearly identified as one of the core technologies needed to promote science, technology, and innovation and to grow the economy of Japan. Consequently, there was a need to develop a specific strategy for accelerating the R&D and implementation of AI. The Artificial Intelligence Technology Strategy, the first comprehensive strategy with regard to AI, was formulated primarily by three ministries (MEXT, MIC, and METI) that had been spearheading efforts to apply AI technologies to their respective fields. An AI Strategy was then developed to co-

ordinate efforts among almost all ministries involved in AI; this strategy is now being promoted accordingly. Although the development of a strategy involving all ministries was considered from the beginning, the differences among the ministries in their efforts toward AI may have prevented the establishment of such a policy. Therefore, it is inferred that through the involvement of the leading ministries in the first phase to set the direction of the strategy, while considering how the other ministries could be involved according to that direction in the next phase, it eventually became possible to develop an AI Strategy that would enable all ministries to work together.

The MHLW recognized the potential of AI even before the statement of Prime Minister Abe and, therefore, was involved in the formulation of the Artificial Intelligence Technology Strategy from the early stages. Additionally, because the fields of health and medical care have been defined from the beginning as priority areas for the application of AI, the MHLW has taken on a leading role and has been promoting its own initiatives in accordance with the strategy on AI. In particular, the process chart formulated by the consortium for accelerating the development of AI in the fields of health and medical care shows the goals and priority areas that can realistically contribute to improving the health and welfare of the population based on an analysis of AI technologies that are currently established and those that are expected to be established in the future.

Discussions about ELSI related to AI were facilitated in parallel with, or even ahead of, the promotion of R&D and implementation of AI. On the basis of these discussions, ministries could have established legislation to promote AI. With regard to the laws and regulations under the jurisdiction of the MHLW, the physician is considered the main entity that performs diagnosis and treatment, as described in the "Medical Practitioners' Act," even if the physician uses an AI-based program. Furthermore, the "Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices" was revised to facilitate the review and approval process for AI-based medical devices. Although laws and regulations often fail to catch up with advances in science and technology in general, it is noteworthy that laws and regulations related to AI are being developed concurrently or ahead of time to avoid discouraging the R&D and implementation of AI.

The challenges to applying AI to health and medical care are being promoted on the basis of specific objectives set forth in various strategies, such as the AI Strategy and the process chart. Although the strategies are consistent with each other, different timelines for accomplishment have been set for each objective, and there are differences in the progression of the various initiatives. Among the various

initiives, the most advanced was diagnostic imaging. In research programs by the MHLW and AMED, the number of research projects conducted in relation to diagnostic imaging was the highest, resulting in the completion of a database through collaboration among related academic societies and the progression of efforts toward the practical application of AI. Significant results have been achieved through this research focused on diagnostic imaging, which is the most advanced technology in Japan. Although AI is expected to have applications in all areas, it is impossible to progress in all areas simultaneously. Therefore, to effectively and efficiently promote the application of AI to health and medical care, it is necessary to promote it through "selection and concentration," as is the case with diagnostic imaging. Through this approach, it is expected that areas that have not yet been fully researched and developed, including drug discovery and development, long-term care and dementia, and support for surgical procedures, will also be developed.

Conflicts of Interest

The author declares no conflicts of interest regarding the publication of this article.

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＜総説＞

日本の保健医療分野における人工知能（AI）の開発と実装の取り組み

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抄録

　本稿では，日本における人工知能（AI）の開発と応用に向けた取り組みを概観するとともに，特に保健医療分野に焦点を当てて，AIの研究開発や社会実装に関するこれまでの成果を振り返り，今後の展望を論述する．

　AIは日本の科学技術・イノベーションの推進と経済成長に不可欠な中核的な技術の一つとして明確に位置づけられている．平成28年度からの第5期科学技術基本計画においてAI は「Society 5.0」を実現するための重要な基本要素であること，また成長戦略においてもAIは日本の経済成長と生産性の向上のための主要な手段であることが明示された．

　平成29年，総務省，文部科学省，経済産業省が設置した人工知能技術戦略会議によって「人工知能技術戦略」が策定され，その中で，生産性，健康，医療・介護，空間の移動，情報セキュリティが重点分野として明示された．また平成31年に策定された「人間中心のAI 社会原則」においてAIを活用する上で考慮すべき倫理面等の問題が提示された．そして同年，これらの戦略や原則を踏まえて，内閣府によって最初の「AI戦略」が策定され，全省庁を含む政府全体でAIを推進する枠組が構築された．この戦略の中で，AIの社会実装を達成すべき優先領域として，健康・医療・介護，農業，国土強靱化（インフラ，防災），交通インフラ・物流，地方創生（スマートシティ），ものづくりが設定された．

　厚生労働省は，保健医療分野が当初からAIを活用すべき分野に位置づけられたため，早い段階から積極的にAIの推進に取り組んできた．令和2年に保健医療分野におけるAI 開発を加速するための工程表が策定され，「ゲノム医療」，「画像診断支援」，「診断・治療支援」，「医薬品開発」，「介護・認知症」，「手術支援」，「予防（PHR）」，「人工知能開発基盤」，「診療報酬支払業務の効率化」を重点領域として様々な取り組みが進められている．特に「画像診断支援」に関しては，関連する多くの研究課題が実施された結果，関係6学会の協働による画像データベースが構築されるなど，著しい進展がみられている．その他，産学の保有する創薬ターゲット，薬効，毒性に関するデータの集約と創薬のためのAIの構築，高度な医療サービスの提供，医療従事者の負担軽減，医療の生産性の向上を目指した「AIホスピタル」などの取り組みが行われている．

　キーワード：人工知能（AI），倫理的・法的・社会的課題（ELSI），Society 5.0，社会実装，画像診断