

**Study Group 'AI governance and its Evaluation'
Report on the Session #4 (Phase III)**

1. Introduction

Japan Deep Learning Association establishes study groups as a forum for deepening knowledge and discussing domestic and international policy trends related to artificial intelligence (hereafter AI) and Deep Learning (hereafter DL). This study group, 'AI Governance and its Evaluation,' defines 'governance' as a system of management and evaluation by various actors and launched a study group in July 2020 to investigate what forms of governance are possible to help build trustworthy AI systems, and the Phase III began in 2022.

In the fourth session of Phase III (December 7, 2022), the theme of "public involvement" for the realization of AI governance was discussed focusing on medical AI. Masaki Okamoto (Harvard Medical School, Massachusetts General Hospital, U.S.A.) presented on issues for the effective diffusion of medical AI and cases of public involvement in its introduction.

2. "Public Involvement approach in the area of Medical AI" by Masaki Okamoto (Harvard Medical School, Massachusetts General Hospital, U.S.A.)

Current Situation of AI in the Medical Field

In recent years, the number AI medical devices approved for use in clinical practice has grown at a fast pace in many countries. In the U.S., products and services that optimize clinical workflow and medical administration, or automate the coding of disease names for insurance claims, are being adopted with the potential directly improve return on investment. On the other hand, the actual adoption of medical image analysis remains small. It is said that more than 90% of medical information is images, and gaining new insights from these images will certainly have a significant clinical impact though, the current situation has yet to motivate decision makers at medical institutions to adopt the system, as the verification of the introduction effects, such as economic benefits, is still insufficient. However, the future expansion of the use of medical AI is already in the works, as evidenced by the ACR (American College of Radiology) and the RSNA (Radiological Society of North America)'s willingness to adopt AI systems as a safety net for physician diagnosis.

The Importance and Challenges of Public Involvement in the area of Medical AI

In Europe and the U.S., a consensus is rapidly emerging on the need for Public Involvement (hereinafter referred to as "PI") in medical AI. Public governance perspectives, such as concerns about the biases inherent in AI models (such as the risk of amplifying existing health disparities if not properly considered and addressed), are one of the major motivators for the introduction of PI.

On the other hand, the subject of medical care itself is highly specialized and involves a variety of complex factors, making it difficult for citizens to learn and deepen their understanding in a short period of time, and the opinions of patients, who are more likely to provide input, do not necessarily represent the ordinary citizens.

Furthermore, AI itself, even if not in the medical field, is complex and fluid, requiring constant updating of the public's understanding for productive discussion, which is another factor that makes it difficult to conduct ongoing PI.

PI Cases in the U.K.

The example of U.K. is instructive when discussing PI in medical AI. First, because it is similar to Japan in that it has achieved universal healthcare through a state-run healthcare system, and second, because it has been digitalizing healthcare to optimize resources from an early stage.

The components of the public governance of medical AI in the U.K., as an extension of the general healthcare PI strategy, are (1) Citizens' Forum, (2) Patient and Public Involvement (hereinafter referred to as "PPI"), and (3) Data Access Committees (hereinafter referred to as "DACs"), each with the following characteristics. By complementing and linking the strengths and weaknesses of each of the three approaches, some believe that a new comprehensive approach to public governance of medical AI could be built.

(1) Citizens' Forums have been experimentally designed since the 1970s, primarily by researchers and think tanks, as an opportunity for citizens to provide their opinions, concerns, and interests on issues of social importance. The advantage is that it is an opportunity for differences of opinion to be democratically mediated and a summarized consensus opinions to be obtained, while ensuring a certain degree of diversity. On the other hand, there are disadvantages, such as the fact that the representative system of participants relies on statistical methods and that it is difficult for individual participants, who are selected at random, to have a commitment to the discussion. Especially in the field of medical research, which requires considerable expertise and abundant resources, researchers almost never routinely adopt a Citizens' Forum as a

governance strategy that is not integrated into existing governance structure. In this respect, they tend to be transitory and pose many challenges from the perspective of a PI strategy, which requires maturing opinions over time.

(2) PPIs differ from Citizens' Forums in that they offer patient experiences and public values, and their participant demographics are not representative of the general public. The integration of PPI into healthcare governance has been a central debate and will continue to be a strong influence in healthcare governance practices. The fact that since 2012, the Healthcare & Social Act has made it a legal obligation to involve citizens in planning, proposing, and deciding on healthcare services has also helped. The advantage is that because PPI members are involved over a long period of time, a stable relationship is established with the organization's decision makers, and the decision makers become aware of the feedback of outcomes to the PPI group. On the other hand, the composition of the members is only representative of a subset of the group, which is insufficient in terms of ensuring universal perspectives and diversity.

(3) DACs are responsible for reviewing and evaluating data use for research at the application stage. In recent years, it has become common in the U.K. for data use for research to go through DACs and involving citizens in this process is considered to reflect their views. DACs have advantage that, due to their nature, participants are often experts with some understanding of the data, leading to more in-depth discussions. On the other hand, it is structurally difficult to include representative citizens in discussions. Although the effectiveness of public involvement in DACs has not been tested at this time, the influence is significant because it can control clinical data access itself, which is the foundation of medical AI, and are likely to be one of the key components for public governance of medical AI in the future.

3. Main comments from the participants

The main discussion topics are as follows.

➤ Stakeholders in Medical AI

- ✓ It is difficult to assess whether the three components of the UK PI case have sufficient stakeholders when taken together, partly because each is spontaneous in nature. At present, approaches are being sought to bring the three components together and ensure that they complement each other.
- ✓ The fact that the scope of stakeholders is so broad and unclear is also an issue in the study of AI standardization. To take a past example, standardization in the telecommunications industry has taken the approach of identifying clear

stakeholders such as regulators, service operators, equipment vendors, and consumer groups (end users), and then inviting representatives from each group.

- ✓ In the case of the UK Citizens' Forum, citizens are not selected completely at random, but rather each element is picked up with some information disclosed (origin, gender, nationality, race, occupation, etc.), so that the composition is as broad as possible in terms of attributes.

➤ **Ensuring literacy of participating citizens**

- ✓ In the case of the Citizens' Forum in the U.K., since participating citizens need to have a certain level of knowledge, measures are being taken to raise the level of knowledge by providing time for lectures and discussions, rather than simply distributing materials in advance.
- ✓ It is difficult to increase knowledge and interest in medical AI, as the citizens are rarely aware of the expansion of medical AI products in their daily lives. In Japan, there have been educational activities by specialized media¹, but it is not easy to improve literacy, partly because it is difficult to put the latest insights into easy-to-understand language. The development of human resources such as science interpreters would be effective.

➤ **Training Data and Privacy Protection**

- ✓ While the quantity and quality of training data are essential for the accuracy of medical AI, citizens have raised concerns about the misuse of images and medical record data. While there are differences among medical institutions in how they handle this issue, a recent example seen in the U.S. is the use of reconstructed images with facial features preserved for AI training as a way to anonymously process facial images. Since the cost of annotating medical data is enormous, some approaches have been developed that allow the public themselves to participate in annotating the data, or others have been developed that do not require annotation at all.
- ✓ In terms of comprehensive consent for the use of personal medical data (adopting agreement at the stage of medical consultation or hospitalization), there is a debate in the U.K. and the U.S. as well as in Japan as to whether algorithms created using patient data containing personal information can be used without limitation in the first place.

➤ **Other Discussions/Issue on Medical AI**

¹ <https://aitimes.media/> (in Japanese)

- ✓ The issue of bias inherent in AI is commonly recognized, and quite a few cases have been identified in the medical AI research community in the U.S. and Europe (e.g., differences in cancer detection rates between Caucasians and non-Caucasians).²
- ✓ In the U.K., discussions are underway involving citizens regarding services other than those related to direct diagnosis by physicians. For example, an application service developed and operated by the National Health Service (NHS) in collaboration with a startup (Babylon Health) that provides an initial diagnosis and suggests where to see a doctor has been the subject of active discussion.
- ✓ In the U.K., there is a move to make it a requirement for grant applications for medical research to include a process of public participation and evaluation of public response at the planning stage (Funding Program by the National Institute for Health and Care Research).
- ✓ There is an impression that the acceptance of medical AI in society is increasing worldwide. How to accept oversights and misdiagnosis will also be a necessary discussion in the future.

The 4th Session (Phase III) of the Study Group

Date/Time: December 7th (Wednesday) 10:00-11:00 (On Zoom)

Contents:

- "Public Involvement approach in the area of Medical AI" by Masaki Okamoto

² Related Reference Article, <https://www.nature.com/articles/s41591-021-01595-0>