

Healthcare Data Policy

PROJECT CASE STUDY

OCTOBER 2020

Project overview

The use of data for public health purposes and public interest purposes is allowed in countries around the world. However, the detailed conditions are standardized and as a result, the use of the data for public health or public interest purposes has not been fully realized. Companies and public authorities who have data tend to use them for their own benefit or overemphasize individual consent to protect individual privacy. As a result, there has been insufficient progress in using data to address dementia and other geriatric diseases that are becoming global challenges.

This project created the concept for Authorized Public Purpose Access (APPA), and presented a framework for enabling data access for authorized public purposes that bypasses explicit consent while protecting individual human rights. Some parts of the content are now reflected in Japanese law. In accordance with this framework, Japan has begun promoting pilot projects for three data use cases:

- In medical institutions and administrative bodies for health promotion and medical care purposes
- In the private sector and academia for research purposes
- In the national government and medical institutions for public health purposes, including measures against infectious diseases

Although legislation and guideline-setting have been considered to be key in the past, it has been shown through pilot projects that laws alone are not effective. The key is to construct rules through a multistakeholder process, securing the rights of individuals and obtaining social consensus after obtaining the consent of data holders. In the future, the project plans to examine applications for various purposes such as disaster countermeasures or the achievement of the UN Sustainable Development Goals (SDGs), and scale them up globally.

Project phases

Assess

Initial multistakeholder community meetings showed that there are challenges with respect to the use of data in the healthcare field, and although there are high expectations for the use of

data to address geriatric disease – such as dementia – they have not yet been met, especially in Japan. However, at this stage, the methods for problem-solving have not been sufficiently narrowed down, including with regard to medical care and disease prevention, or even the promotion of research itself. From the outset, the project involved key stakeholders including Japan's Ministry of Health, Labor and Welfare, Ministry of Economy, Trade and Industry, the Personal Information Protection Commission and other government agencies, members of National Diet, companies and academia.

Design and develop

In cooperation with Japan's national dementia policy and healthcare strategy, especially regarding measures against dementia, C4IR Japan participated in the Future Innovation Working Group organized by the Ministry of Health, Labour and Welfare and the Ministry of Economy, Trade and Industry, and helped formulate national policies. At the private sector level, the Centre in Japan also participated in the Kyoto conference. At the same time, with the aim of achieving a broad solution not only for measures against dementia, both an official and unofficial opinion exchange was held with the Personal Information Protection Commission towards the revision of the Personal Information Protection Law.

In addition, Diet members, academia, medical organizations and companies engaged in discussions towards the enactment of the Medical Information Basic Law. As a result, the APPA concept has been developed and socialized in a way that suited each purpose, as the project team believed that it should be implemented in multiple ways for different purposes with regard to the pilot projects.

Deploy

In accordance with the concept of the APPA, pilot projects have been conducted in Japan. Projects have addressed use in medical institutions and administrative bodies for health promotion and medical purposes, in addition to use in the private sector and academia for research purposes, and use in national institutions and medical institutions for public health purposes.

Niigata Prefecture, Sado City, Iwate Prefecture, Yasu City and Kobe City

C4IR Japan have involved key stakeholders in each region, mainly local governments, and the data held by each local government, medical institution and company are connected to

be used expressly for measures against geriatric diseases, such as dementia and frailty. To this end, the project team has been reviewing current issues and examining whether the introduction of the APPA concept would promote data utilization. Yasu City has already enacted an ordinance for watching over the elderly, including countermeasures against fraud, and thus there is a mechanism for sharing information between the public and private sectors, though medical data remain underutilized. On the other hand, in Sado City, a platform for the use of medical data has been established, but its utilization is insufficient. In addition to sharing information from these local governments, the project has been linked to efforts at the prefectural and national levels to promote the APPA concept.

AMED, NDB-nursing DB

The Next Generation Medical Infrastructure Act was enacted regarding the use of data for research purposes, and the government has been promoting the use of anonymized data. In addition, the AMED research group has been working on promoting the use of research data on dementia in the public and private sectors, and has incorporated the APPA concept with regard to the use of data from the J-MINT study for dementia prevention. Through an amendment of the law in 2019, health/medical data and nursing care data held by the national government are also provided to companies for purposes of considerable public interest. This is another example of the adoption of the APPA concept, and the guidelines are being formulated at a review meeting attended by Project Lead Fujita, with the aim of providing data from September 2020.

Personal Information Protection Commission, Ministry of Health, Labour and Welfare, Tech Team, etc.

Amendment of the Personal Information Protection Law in 2020 allowed the project team to incorporate some parts of APPA concepts (e.g. the use of non-anonymized pseudonymous processed information) in a privacy context. In addition, PPC plans to issue guidelines on the use of data for public interest purposes. With regard to the handling of medical information, including the concept of APPA, C4IR Japan will continue discussions with the government and members of the Diet with the aim of passing the Medical Information Basic Law soon. The APPA concept is also being used in COVID-19 measures. In particular, as one of the members of the national

government's guidelines on privacy and other issues related to the specifications and operation of contact tracing apps, Fujita is aware of the need to ensure that the app has a balance between the government, individuals and data holders, and is involved in other COVID-19 countermeasures.

Monitoring and evaluation

Monitoring and evaluation will be carried out in the future. The evaluation index varies depending on the purpose, but the evaluation is conducted from the viewpoint of how much data usage has increased due to the introduction of the APPA concept, and how much value realization has been achieved as a result.

Key learnings

COVID-19 suggests the importance of the APPA concept for some purposes (e.g. measuring against infectious diseases). There is still a lack of APPA-style balanced data utilization worldwide in addition to many cases in which it was difficult to directly introduce the APPA concept, and cases also relied on consent and anonymization. By organizing these cases, C4IR Japan hopes to enhance the APPA implementation flowchart, including the use of laws and guidelines.

Next steps and scale

In Japan, the Centre will further expand the number of cases in municipalities and increase the number of areas covered, as well as the menu of objectives covered. Furthermore, the team is seeking cooperation with other countries to promote global expansion. With regard to use for medical and administrative purposes, the possibility of cooperation is being explored with Finland, Estonia, Denmark, Thailand, Taiwan and elsewhere, which are promoting use in public institutions. As for the use of genome information for research purposes, C4IR Japan is exchanging opinions with GA4GH.