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# Legal Framework and Challenges in Promoting the Utilization of Medical Data in Japan

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***Abstract***
*This paper examines Japan's legal framework for promoting the utilization of medical data, focusing on the Next-Generation Medical Infrastructure Act and its recent amendments. The Act enables the safe and appropriate use of anonymized and pseudonymized medical data to advance research and development in healthcare. While the framework represents a significant step forward, challenges remain, such as limited participation by small medical institutions and the need for standardized data formats like HL7. Additionally, the current analysis environments require improvements to support advanced research, including container-based customization and high-performance computing resources. Comparisons with the European Health Data Space (EHDS) highlight potential strategies for future revisions of the Act. Addressing these issues is essential to ensure comprehensive data collection and utilization, particularly from small clinics and home care settings, to enhance collaborative care for chronic diseases and other long-term health conditions.*

**Keywords:** The Next-Generation Medical Infrastructure Act, The Personal Information Protection Act (PIPA), Virtual Desktop Infrastructure (VDI), European Health Data Space (EHDS), Certified Anonymous Processed Medical Information Creation Provider.

## Introduction

In Japan, the Act on the Protection of Personal Information was enacted in 2005 to ensure the appropriate use of personal information while safeguarding privacy. Following the 2017 amendment, medical records, including medical history, were classified as 'special care-required personal information,' which prohibits secondary use without explicit patient consent.

To prevent this from hindering medical advancement and the development of healthcare technologies, a special law—the Act on Anonymized Medical Data to Contribute to Research and Development in the Medical Field—was enacted in 2018. This was later revised and enforced in April 2024 as the Act on Anonymized and Pseudonymized Medical Data to Contribute to Research and Development in the Medical Field. In this paper, we refer to it as the Next-Generation Medical Infrastructure Act [1].

The Act establishes a framework for the safe and proper use of anonymized medical data, which is processed so individuals cannot be identified, and pseudonymized medical data, which cannot identify individuals unless combined with other information, to promote research and development in the medical field.

Under this Act, medical institutions may voluntarily provide medical data to certified anonymization and pseudonymization entities (hereafter referred to as "certified processors") designated by the government. While the Act on the Protection of Personal Information requires opt-in consent for third-party provision, the Next-Generation Medical Infrastructure Act allows medical institutions to provide data to certified processors if patients are notified and do not object within 30 days. Once the data is provided, the medical institution is no longer responsible for managing it.

The collected medical data is then linked and consolidated by certified processors based on the approved research purpose, anonymized so individuals cannot be identified, and provided to users after reviewing the public interest and appropriateness of the intended use [2].

Japan's healthcare system allows free access, meaning patients can choose any medical institution. Consequently, most patients visit multiple institutions over their lifetime. Since medical data is stored at each institution, the ability to link and utilize such data under this Act is highly beneficial and groundbreaking.

The EU is also working on a similar framework called the European Health Data Space (EHDS) to manage and promote the use of health data for EU citizens, which shares similarities with Japan's approach [3].

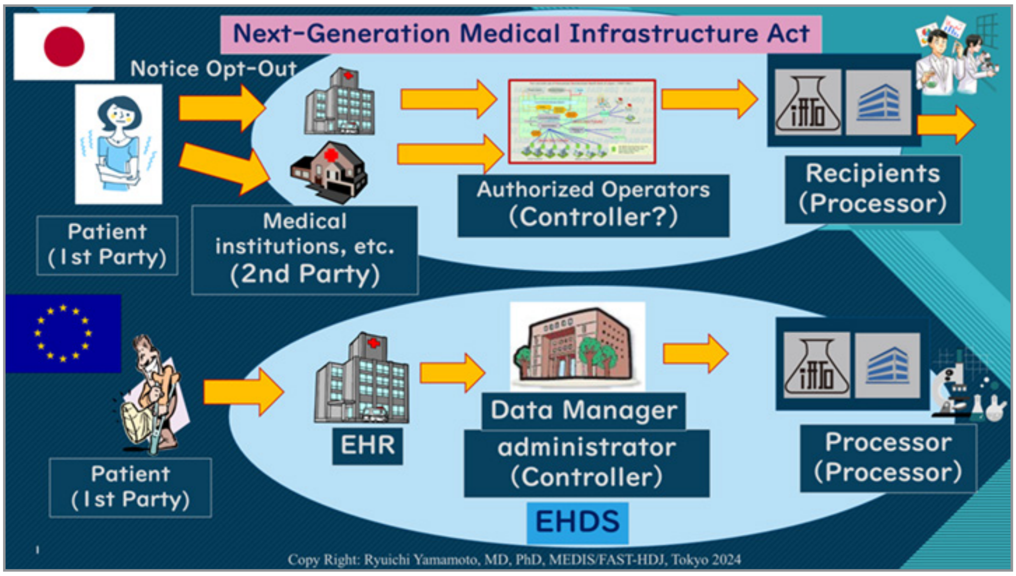

**Figure 1:** Data collection and utilization flow in NGMIA and EHDS

## Methods

To promote the use of medical data in Japan, we identify challenges under the Next-Generation Medical Infrastructure Act. As a countermeasure, we introduce the VDI author environment being developed by our organization, FAST-HDJ, a certified processor, for data users. We also examine overseas cases such as the EHDS framework and the establishment and operation of the Health Data Access Body (HDAB) in the EU, as well as the potential use of mechanisms currently under consideration in Japan for electronic health record (EHR) sharing services.

Furthermore, we considered the integration of Japan's national public databases with certified processors, which became possible following the recent amendment to the NGMIA. Additionally, we examined the potential use of mechanisms under discussion for Japan's electronic health record (EHR) sharing services to enhance data accessibility and interoperability.

Additionally, we considered leveraging mechanisms from the electronic medical record sharing service currently under discussion in Japan. This consideration is based on the recent revision of the Act, which enables the use of medical databases from national public repositories and certified processors.

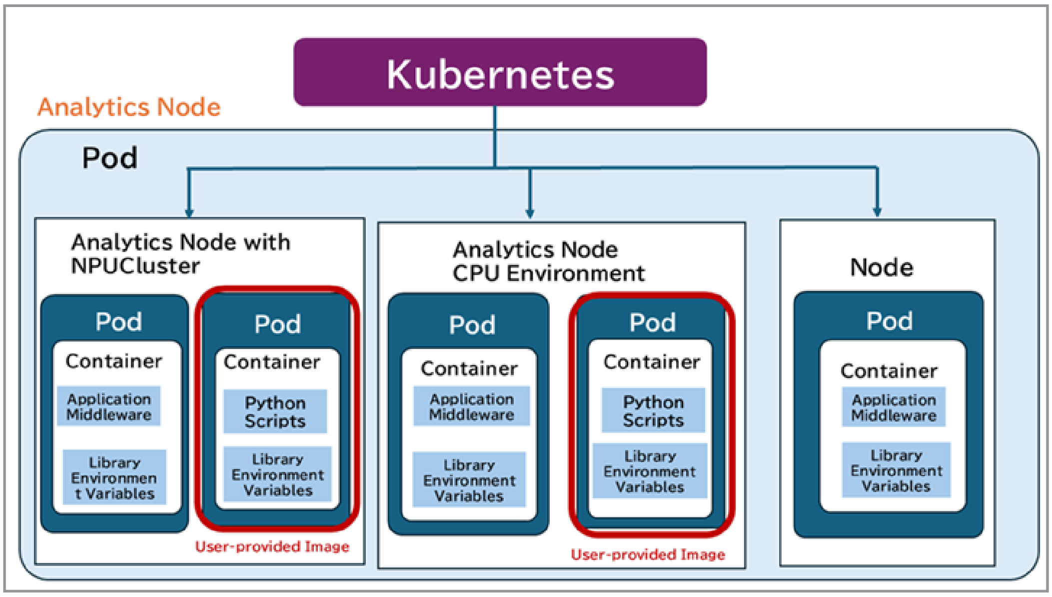

**Figure 2:** Analytics Node with NPU/CPU

## Results

One challenge under the Act is the imbalance in the scale and types of data collected by certified processors. Japan has approximately 180,000 medical institutions, but only about 160 provide data to one of the three certified processors, with almost no participation from small clinics.

Most hospitals handle acute care, so while surgeries and chemotherapy for lifestyle-related diseases and cancers (which affect about half of the Japanese population) are performed in hospitals, subsequent treatments are often handled by clinics specializing in chronic care. However, data from these clinics is not included in certified processors' databases.

This is because data provision by medical institutions is voluntary, and the data collected by certified processors must be in standardized formats such as HL7. For clinics, implementing such systems is burdensome, making participation difficult.

A second challenge is the analysis environment provided to users. Currently, we offer on-site centers and data delivery via physical media, and we plan to launch the VDI author environment this year. This system is similar to the Secure Processing Environment (SPE) under EHDS. In on-site centers, users access anonymized or pseudonymized medical data in a dedicated area and use analysis tools such as Python, STATA, and R provided by us. Data import/export is generally prohibited, and only verified statistical results can be taken out.

The VDI environment allows users to connect via VPN from their own location to a virtual PC gateway, authenticate via finger vein recognition, and then access their schema on the analysis server via SSH. For pseudonymized data, we provide dedicated terminals with restrictions to prevent unauthorized actions such as altering image resolution.

Future needs include enabling advanced data processing for research and development, such as AI technologies, and building infrastructure with GPUs and NPUs. Additionally, users require environments where they can bring their own development environments to the container level.

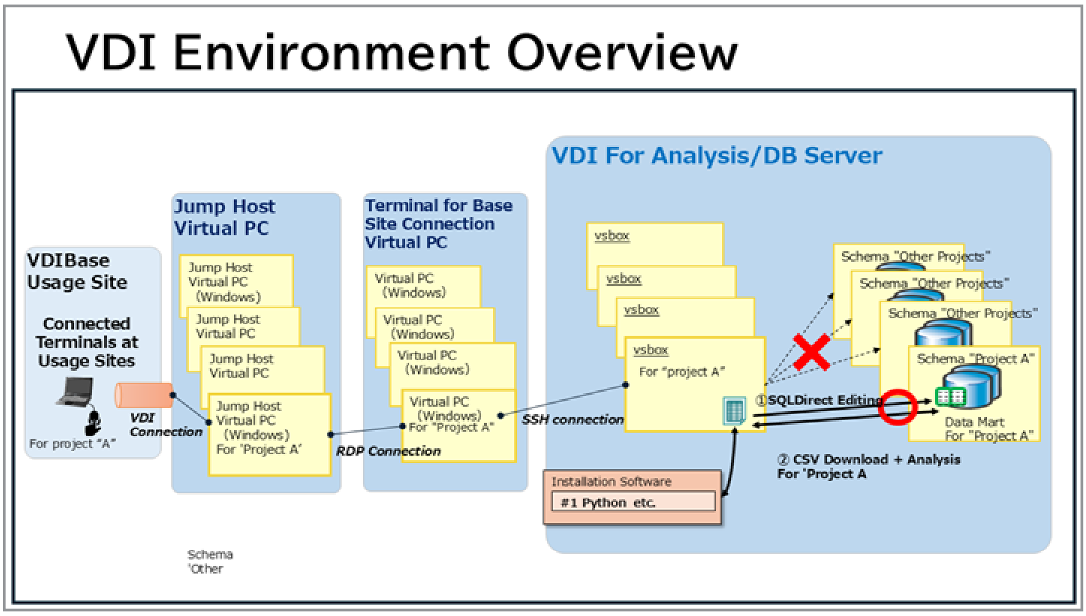

**Figure 3:** VDI Environment Overview

## Discussion

The data provided to certified processors is standardized data in formats such as HL7 ver2 or HL7 FHIR. While many large-scale medical institutions already support these formats, only a small fraction of small-scale medical institutions are capable of doing so. Implementing support involves significant financial burdens. One possible approach is to utilise part of the electronic medical record sharing service mechanism promoted by the government, which collects data in the HL7 FHIR format. Data from small-scale medical institutions such as clinics is largely contained within the National Database (NDB), a government-maintained repository accumulating claims data generated for insurance billing. This database holds input information on most patients' treatments and prescriptions, along with mortality data. Therefore, linking this NDB data is considered effective for accessing information prior to visits to large medical institutions or following hospital discharge [4]. The framework for utilising medical data within the European Health Data Space (EHDS) being advanced by the EU involves uncertainties regarding implementation status and cost-sharing arrangements across participating countries. Furthermore, given the differing healthcare systems and regulatory frameworks compared to Japan, direct comparisons are difficult. Nevertheless, it could serve as a reference point for the next revision of the Next-Generation Medical Infrastructure Act, scheduled in approximately four years.

Regarding challenges in the analysis environment for users, establishing an environment where development environments can be brought in at the container level is required. While the technical challenges are not significant, ensuring the security of Python libraries and scripts brought in by users remains an issue, necessitating continued consideration.

## Conclusion

In both developed and developing nations, chronic conditions such as lifestyle-related diseases and malignant tumors have become central healthcare challenges. Coordinated care across multiple healthcare providers, both sequentially and simultaneously, is crucial, and its evaluation must be appropriately conducted. While Japan has advanced in digitising medical information, collecting data from small-scale healthcare providers and home-based care remains problematic. Under Japan's Next Generation Healthcare Infrastructure Act, the collection and utilization of medical information from large-scale institutions and insurers is advancing, but the collection from small-scale institutions is currently not functioning effectively. Although the Japanese government is developing a standardized electronic health record system for small-scale institutions, it remains unfinished. Within the EHDS framework, the application of EHR requirements is scheduled for 2030, with concrete discussions still ongoing. It is hoped that the collection and utilization of medical information from small-scale institutions will progress.

## Ethics Statement

This study did not involve direct interaction with human subjects. All data used were anonymized and processed in accordance with the Next-Generation Medical Infrastructure Act of Japan.

## Conflict of Interest

The authors declare no conflict of interest.

## Funding

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## References

1. Yamamoto, R., & Nakashima, N. (Eds.). (2022). The Next Generation Medical Infrastructure Law: Epidemiologic research on real-world medical data in Japan. Springer. https://doi.org/10.1007/978-981-19-1622-9_15
2. Japanese Law Translation. (2017). Act on anonymized medical data and pseudonymized medical data that are meant to contribute to research and development in the medical field. Ministry of Justice. https://www.japaneselawtranslation.go.jp/en/laws/view/4845
3. Marcus, J. S., Martens, B., Carugati, C., Bucher, A., & Godlovitch, I. (2022). The European Health Data Space. European Parliament, Policy Department for Economic, Scientific and Quality of Life Policies. https://www.europarl.europa.eu
4. Yasunaga, H. (2024). Updated information on the national database of health insurance claims and specific health checkups of Japan (NDB). Annals of Clinical Epidemiology, 6(3), 73–76. https://www.jstage.jst.go.jp/article/ace/6/3/6_24011/_html/-char/en