

# THE ETHICAL ISSUES ON AI BASED MEDICAL INFORMATION SYSTEM ARCHITECTURE: THE CASE OF TAMBA CITY MODEL

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## ABSTRACT

Utilization of AI in medicine requires the accumulation of integrated personal information. However, there are barriers to accumulate medical and healthcare records. Tamba city of Japan has succeeded in overcoming such adverse conditions with public-private data linkage by adopting a closed and centric structure. Centralized architecture is effective in overcoming the barriers to health information sharing, such as lack of interoperability. At the same time, the asymmetry of information can be increased because the municipal office collects and analyzes personal information, and the results are fed back only to healthcare professionals and service providers. Moreover, there may come to be risk of abuse by service providers. As the variety of information handled increases and more medical institutions are connected to the system, the risk of health professionals abusing personal information increases. In addition, since the data is collected in a specific area and not entire cohort, there is a risk that the analysis results may include a bias, and it is necessary to take countermeasures against such risk. Comprehensiveness of the collected data and respect for the patient's self-determination conflict with each other. Therefore, it is necessary to adopt a balanced architecture and institutional design for social implementation.

**KEYWORDS:** Medical information, architecture, interoperability, public-private data linkage.

## 1. INTRODUCTION

The Internet is a global network with no central server. Each individual participant or organization introduces their own identifiers, data and metadata. This world-wide dissemination enables the Internet to rapidly disperse information and realize scalability. At the same time, such a design generates a huge bottleneck of learning data for AI (Artificial Intelligence). Diverse data specifications, including syntax and vocabulary, make the utilization of fragmented data on the Internet difficult. In contrast, Google, Apple, Facebook and Amazon (GAFA) generate a massive amount of data with unified identifiers and specifications, which is one reason why they have established superiority in AI development.

The unified management of data has advantages in efficient AI-based service development and its applications. However, comprehensive personal information management by a few oligopolistic companies means that they may gain substantial power of control over individuals. Thus, the benefits of the unified management of personal information carry a risk of abuse of power by large IT companies. However, is publicly unified management the best way to balance benefit creation and personal information protection by utilizing big data?

From an ethical standpoint, medical information is a good model for examining such issues because medical and health care services are mostly public services in which governments play an important role. In most institutions, patient medical charts are written by hand; medical charts have been digitized, but progress varies greatly by country and region. Electric Health Records (EHRs) are an aggregation and integration of diagnostic records stored in multiple medical institutions over a wide area. Australia has introduced an EHR nationwide under the name Electronic Health Record (PCEHR) Personally Controlled /MyHR. However, in other countries medical institutions may not be able to actively use information sharing within hospitals, even if they are digitized.

In Japan, medical charts are being digitized, but attempts to share data and operate an EHR have not progressed. Of course, with an aging population there is a need for more efficient medical resources. Thus, the government has been promoting the digitization of medical information. Sustainable universal coverage of health insurance has been made possible by increasing the efficiency of insurance claims through computerization. The Ministry of Health, Labour and Welfare (MHLW) started to establish national standards for medical information in March 2010 and, as of March 2020<sup>1</sup>, 27 standard specifications have been established.

However, there is a barrier to using information accumulated in different medical institutions in a consolidated manner. To avoid the risk of lawsuits, physicians are reluctant to disclose information about their diagnostic processes outside the hospital. Patients are also reluctant to exchange their personal diagnostic records across multiple facilities. On the other hand, there are few cases the medical, and health information sharing is successfully realised, one of them is Tamba city, it is Japanese case as discussed in this study. Tamba city in mountainous area of central Hyogo prefecture, Japan has succeeded in overcoming such adverse conditions and has introduced an Immunisation Determination System of public-private data linkage by adopting a closed and centric structure. The city has now forged ahead with the development of a medical and healthcare information sharing system among clinics, pharmacies, nursing care services and governments to promote a comprehensive care community. The Tamba system has a highly centralized structure in which all systems, including networks and devices installed in medical institutions, are owned and managed by the city hall. The Tamba city model, in which the government manages and analyses health and medical information on a centrally based Basic Resident Register, is an excellent case study an architectural design to improve the public health of local residents through the use of AI.

This study attempts to examine an architecture design for a secure AI based service, analyzing Tamba city model as succeeded case of medical personal data utilisation, based on the case analysis of the previous study (Fukami & Masuda, 2019, 2020). A case study approach was used in the current research because there have indeed been some cases of innovation through standardization. This inductive hypothesis-building study attempted to develop generalizable conclusions from a rare event, which was suitable for research that included 'why' and 'how' questions (Yin, 2014). We conducted interview surveys with responsible person of a city official of the health division and staff of the system integrator company that developed the health and medical information system, conducted field work with medical institutions that introduced the system, and secondary materials analysis on information provided by the municipal office.

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<sup>1</sup> Health information and communication standards organization, List of Japanese national medical information standards, Retrieved from <http://helics.umin.ac.jp/helicsStdList.html> accessed on March 4, 2020.

## 2. RELATED WORKS

### 2.1. Accumulation and utilization of personal medical and health information

Over the 50 years that followed the first implementation of computerized patient medical records in the 1960s, technological advances in computer innovations opened the way for advancements in EHRs and health care (Turk, 2015). The use of data to maintain and improve medical standards has been promoted for a long time. An electronic medical record (EMR) is a real-time patient health record with access to evidence-based decision support tools that can be used to aid clinicians in decision-making (Aceto et al., 2018). The ISO standard defined an electronic health record (EHR) as a repository of information regarding the health status of each treatment in computer processable form (ISO/TR 20514:2005 - Health informatics — Electronic health record — Definition, scope and context, 2005). EHR can include past medical histories and medications, immunisations, laboratory data, radiology reports, vital signs as well as patient demographics (World Health Organization, 2012).

More specifically, an EHR is a longitudinal electronic record of patient health information generated by one or more encounters in any care delivery setting, and the reporting of episodes of care across multiple care delivery organizations within a community, region, or state (Aceto et al., 2018). EHR design is essentially a consolidation of data held by diverse medical institutions, since not everyone is tested and consulted at a single medical institution for a lifetime. Therefore, security for data transaction/sharing and interoperability are exceptionally important. At the same time, healthcare finances are tight, and tend to be designed to ensure security at low cost. There are also obstacles to implementation, such as lack of funding and interoperability of current systems, which decelerate the adoption of EHRs (Devkota & Devkota, 2014).

EHRs are expected to contribute to efficiency in medical services, and its introduction is being promoted by international organizations such as WHO and OECD. At the same time, there are barriers to the introduction of EHRs, as they aggregate important medical and health information. In addition, there is a high risk that the collected data may not be used effectively or may be improperly used. The goal is not to introduce EHRs themselves, but to make data-based medical services more efficient and higher quality.

However, the accumulation of fragmented medical history data does not contribute to the improvement of medical service quality (Blechman et al., 2012). There have been multiple concepts for the digitalization of medical records and to facilitate examination and compose prescriptions, such as computerized physician order entry (CPOE), which improves safety (Eslami et al., 2007). Clinical decision-support systems (CDSS) (El-Sappagh & El-Masri, 2011) are described as 'any computer program designed to help healthcare professionals to make clinical decisions' (Shortliffe, 2011).

### 2.2. Ethical related articles

Riso et al. (2017) identified six core values for the ethical sharing of data using ICT platforms: scientific value, user protection, facilitating user agency, trustworthiness, benefit and sustainability. Global Alliance for Genomics and Health formulated core elements of responsible data sharing; 1) transparency, 2) accountability, 3) engagement, 4) data quality and security, 5) privacy, data protection and confidentiality, 6) risk-benefit analysis, 7) recognition and attribution, 8) sustainability, 9) education and training and 10) accessibility and dissemination (Knoppers, 2014). It is important not only to protect privacy, but also to respect the rights of patients such as data control rights and to operate them with high transparency for sharing medical information.

The accumulated medical and health data is important privacy information, and it needs to utilize it with careful attention. Therefore there have been discussions about ethical codes and guidelines of AI usage for medicine (Luxton, 2014). Vayena et al. pointed that the ethical and regulatory challenges that surround AI in healthcare are particularly privacy, data fairness, accountability, transparency, and liability (Vayena et al., 2018). These are the issues in using medical personal information with AI such as data sharing and privacy, transparency of algorithms, data standardization, and interoperability across multiple platforms, and concern for patient safety (He et al., 2019).

Noteworthy, PCEHR, the national EHR of Australia was developed with emphasis on personal data control rights. However, due to the nation-wide platform on which personal information is shared between medical institutions, the risk of 'secondary use' of personal information by the 900 000 healthcare workers who can access the system has become apparent. Additionally, health records stored in the PCEHR can be created without a person's consent (Masuda et al., 2019).

### 2.3. Usage of AI for medicine

AI usage for medicine has a long history. It has been tried since at least the 1970s and the first paper about AI and ethics in health and medicine was published in 1994 (Tran et al., 2019). The use of AI in the medicine and healthcare can be classified into two types. One is supporting diagnosis and research with big data collected anonymously. According to a meta-survey of the PubMed database, diagnostic imaging is most common, followed by genetic and electrodiagnosis. It is also used for physical monitoring, disability evaluation, mass screening, etc. (Jiang et al., 2017). In particular, many cases have been used for automation of image diagnosis such as diabetic retinopathy (Wong & Neil, 2016), detecting gastric cancer (Hirasawa et al., 2018), cardiac affection (Dilsizian & Siegel, 2014) and so on. Invention of deep learning accelerated usage of AI for diagnostic imaging (Hosny et al., 2018; Wong & Neil, 2016). A widely shared image database The Cancer Imaging Archive is also operated by the National Center for Biotechnology Information (Thrall et al., 2018).

The other is realizing efficient treatment and health maintenance through comprehensive analysis of a variety of data linked to individuals. In the first place, the data generated and accumulated by each medical institution is diverse. Heterogeneity of medical data is a barrier to analysis by AI (Cios & William Moore, 2002). Moreover, there are massive amount of handwritten data such as medical chart. Such data is processed with natural language processing (e.g. Jiang et al., 2017). On the other hand, there are ongoing debates on ethics of AI in health care (e.g. Morley et al., 2019).

## 3. CASE STUDY

### 3.1. Implementation of the Immunisation Determination System

Tamba city in Hyogo prefecture is a small town located in a mountainous area in the north-eastern part of Kobe city. The city launched the implementation of their Immunisation Determination System in April 2017. Tamba city supports the costs of 15 types of vaccines for children between 0 and 15 y of age; for this, subsidies are paid by the city to the clinics.

Statutory immunisation has significantly improved public health, and the number of vaccines eligible for public assistance is increasing. With the development of research related to vaccination, both vaccine type and the rules that must be adhered to, such as the order and interval for vaccinations, have been increased. On the other hand, more than 7000 immunisation accidents occurred in the fiscal

year of 2017 in Japan<sup>2</sup>. Due to an excessive response over adverse reactions in Japan, there are fewer types of vaccination officially required or recommended than in other countries. Such an event is called a 'vaccine gap' (Saitoh & Okabe, 2012). It was needed to promote immunisation of various vaccines while reducing the risk of adverse reactions.

Vaccination is not covered by health insurance because it is not a treatment for an illness. Therefore, most immunisations are subsidised by the public. Most EHRs are designed to utilize data from electronic medical charts and health insurance claim data. However, these data cannot be used in the rationalization of immunisation because most of the people who are vaccinated are healthy individuals, and this medical record is often not placed on an electronic medical chart. Children may not be vaccinated at the same clinic from birth to the age of 15, during which public assistance is used to cover the cost of vaccination. Moreover, an immunisation history is not included in insurance medical records. The history of individual vaccinations is the only vaccination ledger owned and managed by the government, and there is no alternative for improving the efficiency of vaccinations other than using the ledger data.

The statutory vaccination institution has problems in terms of safety and economics. Subsidies for vaccinations are established and operated by each local government. Therefore, if a potential vaccinee relocates out of a city, the subsidies are not paid, and the cost of the vaccine becomes the responsibility of the clinic in the original city. The medical association requested that the city eliminates the need for clinics to bear the inoculation costs of children who were not covered by the government.

The administration of vaccinations could not be managed using distributed data that was closed to individual medical institutions, and therefore had to be based on vaccination ledgers managed by the city. While it is important to use vaccination ledgers (administratively held personal information) it is difficult to directly use this information in private medical facilities from the viewpoint of privacy protection. Clinicians tend to avoid taking responsibility for protecting personal information. However, Tamba City has been using public information held by public institutions in private medical institutions.

Tamba city introduced an Immunisation Determination System. It was successful for two reasons: 1) it did not impose on physicians the role and responsibility of protecting personal information; and 2) it provided physicians with economic benefits (Fukami & Masuda, 2019). Tamba City distribute computer tablets to clinics that are connected to a database synchronized with the vaccination ledger via a closed network. The tablets are owned by the municipal office and the system is owned and operated by the municipal office; therefore, the responsibility for privacy protection rests with the municipal office.

The system was also developed with a closed network for the MVNO in compliance with personal information protection law and is shared through tablets owned by the municipal office. Clinicians working at the core hospitals in the Tamba region access computers for electric medical charts by way of exception. The system is centrally located but is used by diversified stakeholders, such as clinicians. Prescription data and actual medication history are transacted and handled only among clinicians, co-medical staff and care givers. The overview of the closed network immunisation scheme used in Tamba city is shown in Figure 1.

In the past, vouchers were issued to the subjects, and immunisations were conducted based on these vouchers issued by the municipal office. However, if the inoculators relocated out of the city, the subsidies were not paid, and the costs of the vaccines became the responsibility of the clinic. After the immunisation determination system came to work, the system notifies whether or not the subject of subsidy. Therefore, physicians have come to deliver the vaccine after confirming that the vaccinee was

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<sup>2</sup> The Ministry of Health, Labour and Welfare (2019) Report of immunisation accidents, Retrieved from <https://www.mhlw.go.jp/content/10906000/000535721.pdf> on January 13, 2020.

the correct recipient. The Immunisation Determination System has succeeded in decreasing the number of vaccination accidents (Table 1). The system also succeeded in reducing the workload of the municipal office and eliminated mistakes by linking medical and government data.

In this case, a system was developed with a simple and centralized system architecture. The only data resource was the basic resident register ledger generated and managed by the municipal office. The computer tablets that were distributed to clinics were owned by the municipal government, and personal information on the potential vaccinees was processed and managed within the municipal government.

Figure 1. Closed network immunisation scheme used in Tamba city.

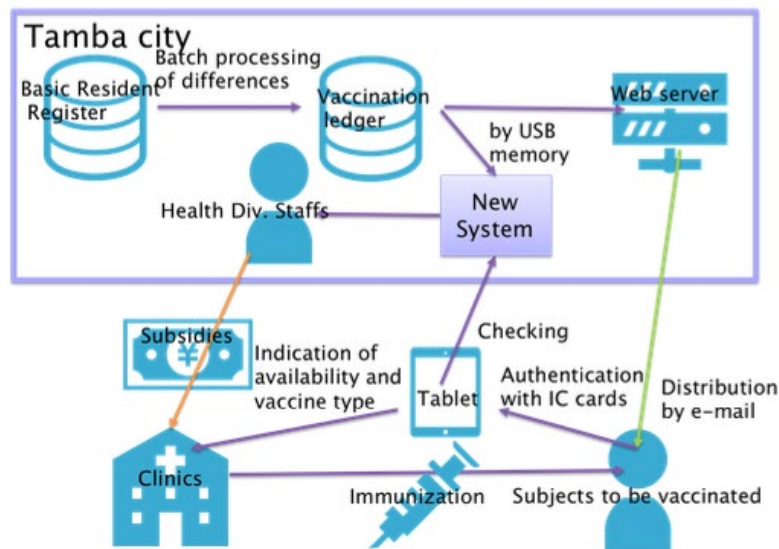


Table 1. Change in the number of vaccination accidents.

Year	Hyogo Pref.	Tamba city
FY2015	280	12
FY2016	309	4
FY2017	427	0
FY2018 (by November)	282	1

### 3.2. Extension to a regional comprehensive care system

Tamba city and the stakeholders in the region have now decided to extend the system to a regional comprehensive care. This means that the system will process various types of data generated by multiple organizations and will exchange information such as prescriptions, caregiver visit records, results of a medical examination and healthcare directives. Expansion to a regional comprehensive care system will be implemented through the distribution of computer tablets to dental clinics, pharmacies and visiting care offices. The data is also sent to the regional core hospital, Hyogo Prefectural Medical Center, in one way with closed network, and displayed on electronic medical charts. The municipal office also plans to add the Municipal Medical Checkup Center established in 2019 to the closed network.

In the immunisation implementation plan, clinicians only access data from the municipal office each time a vaccination is delivered and displayed the examination results. On the other hand, information sharing among medical and nursing staff is implemented in the regional comprehensive care system.

Many functions are to provide information that is referred to ad hoc when consulting or providing services. However, analysis of accumulated data and feedback on measures and medical practices based on it have been initiated.

Due to the universal health insurance system, there has already been structured data for almost all cases of clinician's prescriptions and pharmacy prescription records, respectively. Each prescription has not been matched from the clinic to the pharmacy; therefore, it is difficult to confirm that the medicine was taken as prescribed by the clinician. This regional comprehensive care system provides a function to match between prescriptions issued by doctors and prescription history data of pharmacies conforming to different standard data format specifications. As a result, feedback on the prescription of the drug can be made based on the analysis of the structured data.

Collection of prescription data began in September 2019, ahead of other features. As of January 2020, to reduce medical expenditure in the region, we have calculated the generic drug selection rate of drugs prescribed for patients with lifestyle-related diseases such as diabetes and high blood pressure. The analysis is done only by the municipal officials.

### **3.3. Management form**

The municipal government, the medical association, the dental association, the pharmacists' association, the four hospitals, the social welfare council and the system vendor have established the Tamba Medical Care Collaboration (MCC) promotion organization to develop and operate a regional comprehensive care system. They have planned to allow the evaluation of prescriptions, health records and medical biographies via the MVNO closed network in the same manner as the immunisation records. Therefore, the results of analyses are made available to MCC member companies and organizations.

All data for analysis is collected in a closed network managed by the municipal office, and analysed by staff of the municipal office using computers installed at the city hall with no internet connection. Therefore, the raw data is not disclosed externally and there is no need for anonymous processing or pseudonymization.

The adoption of a configuration complete with a closed network and devices owned only by the city hall produces a robust system from the viewpoint of personal information protection. On the other hand, only municipal staff can handle accumulated data. This means that analysis by external medical and public health specialists is not possible. In the future, it is expected that operational rules will be established in the MCC, including who can access what type of data. This will increase the degree to which outside experts can be involved in analysis and policy making. However, centralized and closed designs that protect the privacy of personal information prevent any correct usage of accumulated data that may offer benefits for the residents.

## **4. ETHICAL ISSUES ON THE SYSTEM ARCHITECTURE**

### **4.1. Merit of centralized and closed structure for AI based solutions**

The medical and health field is an area where there is a great demand for efficiency and labour saving that may be implemented through the use of AI. At the same time, because medical information such

as clinical diagnoses and prescriptions are important personal information, there are still substantial barriers to the realization of EHRs that can be aggregated, stored and utilized. In Japan, where the introduction of electronic medical chart systems is progressing within each individual medical institution, the lack of interoperability between systems has hindered integrated utilization.

Another barrier to efficiency is the lack of cooperation between government departments. For example, data management for health insurance premiums and the subsidy system based on the Basic Resident Register have been developed, respectively, and operated without cooperation. Furthermore, although clinicians record much information on electric medical charts, it does not tend to be shared with other institutions and utilized for analysis.

On the other hand, the system used in Tamba city case has developed integrally with the operation of the subsidy system with a highly centralized structure. The system was also developed with a closed network for the MVNO in compliance with Act on protection of personal information enforced in Japan and is shared through computer tablets owned by the municipal office. Prescription data and actual medication history are transacted and handled only among clinicians, co-medical staff and care givers. Nonetheless, the system is also centralized and used by diversified stakeholders, such as clinicians. Such a centralized and closed design is superior from the point of personal data protection because data transaction is limited to facilities owned by the municipal office, and the risk of data leakage is suppressed.

Moreover, there is no concern about compatibility as the scheme is designed and operated by a single organization. EHRs tend to lack interoperability because of security concerns, even for ones developed by national governments (Masuda et al., 2019), although the accumulation of fragmented medical history data does not contribute to improvement in the quality of medical services (Blechman et al., 2012). However, the system has two ethical issues as follows. One issue involves the asymmetry of expanding information between the government/medical staff and citizens. The second issue is the abuse of service providers.

### **4.2. Information asymmetry**

In the case of Tamba city, people cannot memorize all of their medical activities and their entire treatment history. Because the computer tablets are distributed among medical and nursing service providers, only service providers can access patient records, and citizens cannot access these records. Thus, as more records are accumulated, the information asymmetry between service providers and citizens increases.

In general, medical records are not shared with patients. Even though citizens can accumulate more diversified data with wearable devices and smart phone applications for prescription management, they cannot manage their records because they do not have rights to access the system. While there are reasonable reasons for the limited disclosure and sharing of medical information with patients, their further engagement is needed for decisions on the course of treatment. It is important for patients and citizens to engage in treatment policy decisions, according to patient-centred medicine (Laine & Davidoff, 1996).

Moreover, KPIs (Key Performance Indicators) of regional comprehensive health care must be diversified, and it is beneficial for patients to participate in the selection of metrics for KPIs because the cure rate and survival rate are inappropriate KPIs of long-term care even outside of hospitals. It is also desirable to introduce sensors chosen and owned by patients that enable multifaceted situational understanding according to patients' preferences. Considering such situations, while it is required to reduce the information asymmetry between the citizens (patients) and the medical service provides,



it has been not realised until now. The expansion of information asymmetry may have significant impacts over the autonomy and decisional privacy of the individuals.

### **4.3. Abuse of service providers**

Compared to the immunisation implementation design, much more diversified data is accumulated from citizens in the regional comprehensive care system, and a much greater diversity of engaged persons can access the personal information. Regional comprehensive care information is accessed not only by medical staff but also by government employees, caregivers, and social workers. Services are provided outside of medical facilities, across the region and even in patients' homes for the long term. Therefore, the potential for fraud and blackmail based on medical histories has increased. Even if data are shared among limited professional stakeholders, misuse of the information cannot be prevented.

For example, in Australia where the National EHR (NEHR) was introduced and developed with a decentralized structure, the EHR's privacy chief of national government once refused to take responsibility for the above mentioned security and privacy issues (Grubb, 2018). The incident occurred because the NEHR was developed through linking EHRs of individual medical institutions, and medical staff could view medical records at other medical institutions.

As such, the privacy of EHRs was laid open to abuse by healthcare professionals. On the other hand, in the Tamba city system, as clinicians working at core hospitals in the region rarely access computers for electronic medical charts, municipal staff and not clinicians in medical institutes are able to access data at will. This is because the regional comprehensive care system realizes integrated analysis of administrative resident card data and medical and health data. Even if only a limited amount of action history data is no longer private, if it is accumulated, a detailed profile of an individual can be obtained and converted into important personal information. If the target area is small, it is easy to identify individuals from pseudonymized data

The case of Tamba shows what is possible using integrated analysis of administrative resident card data and medical and health data. Rather than solely supplying medical and nursing resources alone, we can provide effective public services and improve public health standards by providing livelihood protection and other subsidies together. Proactive life interventions can also be performed efficiently and with high accuracy from more multifaceted data. In other word, it implies that social sorting can be generated, utilising huge amount of sensitive personal data and its profiling, and the invisible impacts on the individuals are exerted.

The possession, management and access to data on the system are limited to the municipal office staff in Tamba City although the MCC, a joint operation organization of the system by multi-stakeholders, has been established. However, the data stored in the system includes not only medical/health data, but also administrative information linked to the Basic Resident Register. The city officials can access various types of data, which impacts the provision of a wide range of administrative services. Therefore, if data abuse occurs, the damage to community residents can be severe.

Then, how can we design a system that will deter the usage of shared data for purposes other than the original intent? Is it possible to monitor every activity of all service providers to control the use of data? Such solutions may result in other types of privacy abuse by service providers. Because the system is developed within a closed network in service providers' organisation, it is impossible the governmental bodies or municipalities to monitor how the service providers utilise and analyse the data in complete way.

This tends to make the system closed to protect privacy. However, limiting access to information makes it difficult to regulate abuse by the few parties that do have access. Simply developing a system with a closed network is not sufficient. The range of information to be shared and a means of controlling access need to be defined from patient-centric/citizen-centric perspectives.

### 4.4. Assumed biases and risks arising from them

While just the vaccination history and prescription data were targeted, only factual data was used, so there was little risk of contaminating inappropriate data. Nevertheless, there was a possibility that sampling bias may occur in trend analysis based only on data from the limited number of residents who had agreed to provide information.

In the future, when the input and sharing of natural language data by doctors, nursing staff and care staff will begin, subjective evaluation data regarding the patient's condition will be accumulated. This means that the information arbitrarily created by the service provider is linked to the Basic Resident Register. Depending on the type of disease, the accuracy of a diagnostic result may vary. In addition, there are situations in which the judgment differs depending on the clinician or service provider in charge of the examination. As subjective information is accumulated, even if there is no malice, biased learning data may be generated and remained.

Furthermore, the accumulated data is linked to administrative data and used when providing administrative services. Government services and medical services are provided based on biased data, and decisions may be made on policies based on the results of AI analysis drawn from this data. If AI presents incorrect analyses, it will not only hinder efficient social security implementation but could also cause serious human rights violations.

As the type of available data increases and the range of measures that can be deployed expands, there is a risk that human intervention may take place, leading to violation of human rights. This system was originally constructed based on the vaccination judgment system, and it is therefore assumed that data such as health check results and vaccination histories will have been accumulated while the subject was in a healthy state.

## 5. CONCLUSION

The case of Tamba shows what may be achieved with integrated analysis of administrative resident card data and medical and health data. Rather than solely supplying medical and nursing resources alone, it enables the provision of effective public services and improves public health standards by providing livelihood protection and other subsidies. In addition, proactive life interventions can also be performed efficiently and with high accuracy from more multifaceted data.

If the system is built on the basis of the vaccination register, linked to the basic resident register, the range covered by the system is limited to the administrative area. For this reason, even if the coverage is high, the absolute number of registers is inevitably small. With small amounts of data, the probability of an analytical error increases. If AI presents incorrect analysis results, it will not only hinder the implementation of efficient social security but may also violate human rights. The potential for human rights violations by the regional comprehensive care system is greater than that of EHR, because the data is linked to both medical and health information and the Basic Resident Register.

To protect patients' privacy, a centralized and closed design needs to be adopted. However, such a design is not necessarily advantageous in the protection of human rights. An open and distributed

design is better, even in the context of medical and nursing care, for AI-based decisions according to the concept of patient-centred medicine. This open and distributed design encourages self-determination in medicine and provision of appropriate care. The introduction of AI may change the rational design of systems where tailor-made services are developed with big data including personal information.

It is important that each patient retains control of their own data. However, if authorization is needed to transact data from one institute to others, it is difficult to collect data without omissions. Nevertheless, in the case of Tamba City, where the administration manages data in a unified manner, data can be collected without omission only in the administrative area and integrated analysis can be easily performed. In this regard, it seems that comprehensiveness of the collected data and respect for the patient's self-determination conflict with each other. Therefore, it is necessary to adopt a balanced architecture and institutional design for social implementation.

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