

[Japan]

Health Database in an Information Society^{*1}

Hiroimi ISHIKAWA¹

There is a movement in Japan to take advantage of databases to improve healthcare quality and strengthen research foundations. I would like to introduce health databases that are representative of Japan and report the framework for a privacy protection and national identification number system in the age of Big Data.

The National Database (NDB) was established based on the Act on Assurance of Medical Care for Elderly People to develop optimization plans for national healthcare expenditures. This database includes the health insurance payment claim data and the records from specific health check-ups and health guidance in electronic form. About 6.9 billion cases of health insurance claims and 90 million cases of specific health check-ups are stored. The information is processed for de-identification when collected.

The government review board discussed the framework for the utilization of the National Database, and the trial period for third-party use began in 2011. The database is now available for academic research of significant public interest.

However, it is still underutilized in academic research because exploratory studies are carefully investigated. There are also strict information security requirements for users, and the data are difficult to analyze in terms of specifications.

To understand medical and pharmaceutical product safety information, healthcare information databases have been established in 10 core hospitals. The 5-year project that started in 2011 links databases across the nation to cover 10 million people. The Pharmaceuticals and Medical Devices Agency (PMDA) established a system for the cooperating medical institutions, built an analysis system within PMDA, and is exploring ways to proactively utilize the linked databases.

The test run of the healthcare information database system will be completed in the future.

In order to implement medical and pharmaceutical product safety measures using the data, PMDA will promote the enhancement of data utilization methods with an epidemiological approach and verify the accuracy and reliability of the information extracted from healthcare information databases.

The operation of large-scale healthcare databases has begun already, and it is time to evaluate the framework for privacy protection and the national identification number system.

It has been almost 10 years since the Act on the Protection of Personal Information was legislated in 2005, and it is now inadequate to handle highly sensitive healthcare information. Japan Medical Association (JMA) prepared guidelines for patient privacy protection, but it remains a work in progress for those involved.

This act regulates private businesses that handle more than 5,000 cases of personal information. Its flaw, however, lies in the fact that different hospitals a patient visits may be subject to different laws. Small-scale medical institutions are exempt from this act.

Penalties for violators are minor. Individually, doctors have the duty of confidentiality by the Penal Code, but hospital staff are not legally bound by it.

The exchange of genetic information will become very common in future generations. Breaches of personal information risk affecting family members and may extend to their human rights. However, the current law does not provide sufficient protection.

The national identification number system has been debated as a possible means to link various types of information about an individual. The My Number System was legislated in May 2014. For the time being, its application is limited to taxes, social security, and disaster manage-

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¹ Executive Board Member, Japan Medical Association, Tokyo, Japan (jmaintl@po.med.or.jp).

ment. The healthcare areas subject to this law are limited to insurance benefits provision and insurance premium collection. Healthcare information such as medical records is exempt from the system. This was decided due to sensitive issues such as healthcare information privacy.

Thanks to the development of IT and Big Data technology, we can now collect and analyze a vast amount of information of various kinds. However, the inappropriate use or breach of information has brought serious damages.

This year alone, a railroad company sold 43 million cases of train ticket data purchased by smart cards including boarding records, gender information, and dates, after removing identifiable information such as names and phone numbers. The company provided little explanation or announcement in advance.

A company in the education industry leaked up to 20.7 million cases of customer information, including the names of children and their guardians, addresses, telephone numbers, gender information, and dates of birth. The offender who leaked the information was arrested not under the Act on the Protection of Personal Information but under a different law called the Unfair Competition Prevention Act that controls industrial espionage.

In the age of Big Data, breach of personal information means enormous damage, and there is a risk that even de-identified data can become identifiable. The damage from healthcare information, which is highly sensitive in nature, cannot be undone once it is leaked. The risk will become even higher if it is linked to all-inclusive and unique personal numbers.

The Act on the Protection of Personal Information is currently being revised in order to promote the active utilization of personal data accumulated with Big Data. The government's general principle emphasizes the active utilization of the data, and JMA is requesting the government to generously protect people's privacy and healthcare information.

The analysis of health databases may advance medical research and healthcare policies. Nevertheless, we should consider cases in other countries and discuss separate legislation that aims to protect genetic information in advanced medicine and highly sensitive healthcare information.

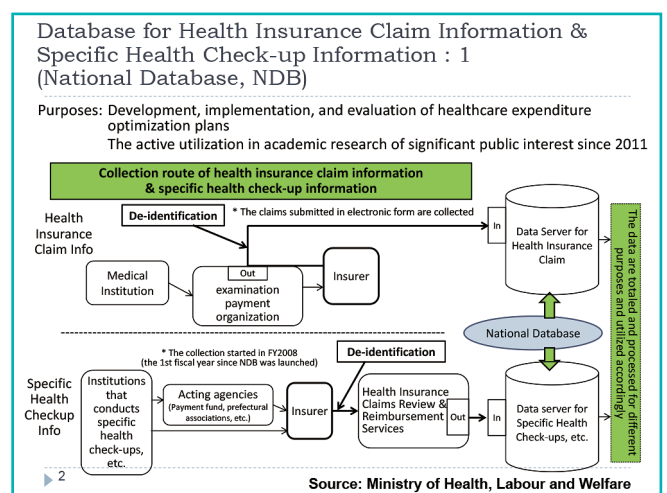
JMA will continue to provide policy recommendations to the government in the interest of the Japanese citizens, while carefully balancing active utilization of healthcare information and privacy protection in the Big Data age.




CMAAO Symposium

The Health Database in an Information Society

Hiromi Ishikawa, MD
Executive Board Member
Japan Medical Association



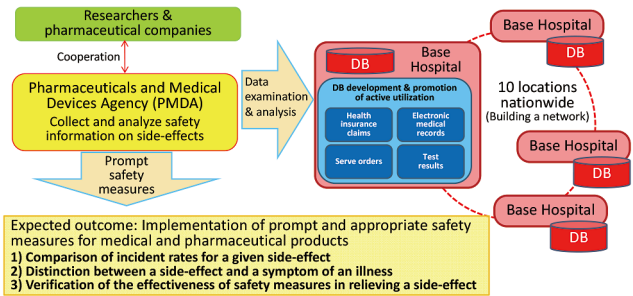
Database for Health Insurance Claim Information & Specific Health Check-up Information : 2
(National Database, NDB)

- ▶ Data included (as of December 2013):
 - **Approx. 6.9 billion cases of health insurance claims** (covers medical examinations performed from Apr 2009 to Sept 2013)
 - * Japan has a universal health insurance system, and more than 95% of health insurance payment claims are digitized. Therefore, almost all citizens' data are accumulated in the NDB.
 - **Approx. 90 million cases of specific health check-ups and health guidance** (covers those performed from FY 2008 to FY2011)
- ▶ The reasons for underutilization in the area of academic research
 - Exploratory research and studies that involve data extraction of an extensive number of categories or high volume are carefully investigated
 - Information security requirements for users are very strict
 - Specification of the data is made difficult for analytic use

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Healthcare Information Database Foundation Preparation Project

Purpose: Promotion of safety measures for medical and pharmaceutical products using a pharmaco-epidemiological approach by utilizing the healthcare information database (DB)



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Source: Ministry of Health, Labour and Welfare

Privacy Protection Laws in Japan

Act on the Protection of Personal Information (Privacy Protection Act, PPA)

- **Approved in May 2003, enforced from April 2005**
- **Problems of the existing act**
 - Insufficient to protect highly sensitive personal medical info. *Medical institutions use guidelines prepared by MHLW or JMA to provide proper privacy protection.*
 - Different privacy protection laws exist for different types of medical institutions
 - Private hospitals = PPA*
 - National hospitals = PPA for Administrative Organs*
 - Municipal hospitals = ordinance for privacy protection*
 - Private hospitals with <5,000 cases of patients are exempt

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Privacy Protection Laws in Japan (cont.)

- **Problems of the existing act (cont.)**
 - The penalty imposed for violations is minor *Medical professionals are legally bound by the duty of confidentiality, but hospital staff are not.*
 - Sharing genetic information not only affect the human rights of the patient but also his/her family members and/or offspring

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Privacy Protection Laws in Japan (cont.)

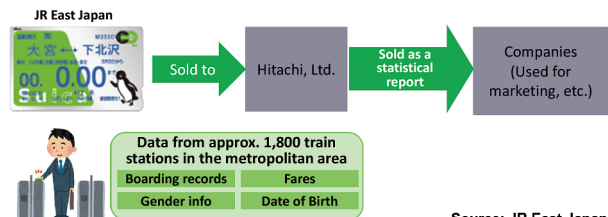
“My Number Law” stipulates the use of identification number in administrative procedures

- **Approved in May 2014, expected to be enforced from January 2016**
- **In what areas will it be used?**
 - Social security (inquiry/provision of pension)
 - Taxes (forms & legal reports)
 - Disaster Management
 - **Healthcare**
Only for “the provision of insurance benefits and collection of insurance premiums”
Healthcare information (incl. medical records) are exempt

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Personal Information Leakage in the Big Data Age: 1

- ▶ Selling of the boarding history data from train tickets purchased by smart cards without notice
- In September 2013, the JR East Japan sold 43 million cases of train ticket data purchased by smart cards to Hitachi, Ltd. The data sold included boarding records, gender, and dates; identifiable information such as names and phone numbers had been removed. The company provided little explanation or announcement in advance.



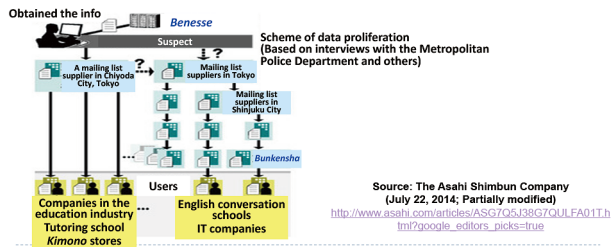
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Source: JR East Japan

Personal Information Leakage in the Big Data Age: 2

▶ Personal information leakage at a company in the education industry

In July 2014, Benesse Holdings, Inc., a company in the education industry, leaked up to 20.7 million cases of customer information, including the names of children and their guardians, addresses, telephone numbers, gender information, and dates of birth. The offender who leaked the information was arrested not under the Act on the Protection of Personal Information, but under a different law called the Unfair Competition Prevention Act, which controls industrial espionage.



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Personal Information Leakage in the Big Data Age: 3

▶ Leakage of personal information means:

1. **The damage is enormous** once leaked.
2. **Even the de-identified data can become identifiable** by cross-referencing with other data.
3. **If highly sensitive healthcare information is leaked, the damage cannot be undone.**

The risk will become even higher if healthcare information is linked to all-inclusive and unique personal numbers.

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Thoughts for the Future

- ▶ The revision of the Act on the Protection of Personal Information is underway in order to promote the active utilization of personal data accumulated in the Big Data.
- ▶ The general principle of the government is to emphasize the active utilization of data.
- ▶ In order to utilize the healthcare database safely, JMA request the government to:
 1. Generously protect the people's privacy and healthcare information.
 2. Carefully discuss the linking of healthcare information to unique and all-inclusive personal numbers, considering the enormous damage brought by the leakage of such information.
 3. Examine cases in other countries and discuss possible solutions, including separate and specific legislation that aims to protect genetic information in advanced medicine, and highly sensitive healthcare information.

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Thank you for your attention.

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