OIST Open Seminar

The Critical Subjects on Personal Data Protection in Medical Research

Shigeto YONEMURA
The Graduate Schools for Law and Politics
The University of Tokyo

1

Profile

- Junior Resident in the Tokyo University Hospital (2000-2001)
- Junior Resident in Showa Hospital in Tokyo (2001-2002)
- Master Course in the Graduate Schools for Law and Politics, the UT (2002-2004)
- Senior Resident/Staff Doctor in the Red Cross Medical Center in Tokyo (2004-2006)
- Associate Prof. in the Graduate School of Law, the Tohoku University (2005-2013)
- Associate Prof. in the Graduate Schools for Law and Politics, the UT (2013-)

2

Contents

3

1. The Japanese Law System in General

4

The History of Japanese Law

- Basic structure of Japanese law was formed around 1900. At the time the legal model was France and Germany.
- The previous Constitution (Meiji Constitution) and Criminal Law derived from Germany.
- The Civil Law derived from France and Germany.

5

The History of Japanese Law

- After the WWII, the new Constitution was enacted, which was affected by the US.
- Then the administrative law and commercial law in Japan was drastically changed to American system.
- But, traditional civil law and criminal law was not so changed.
- The current Japanese law is a mixture of European law and American law.

6

The History of Privacy Rule

- The word and doctrine of “privacy” derives from the US.
- But, in some leading-cases of privacy in Japan, the plaintiffs filed a lawsuit of tort liability.
- The tort law is a typical area of traditional German-like system in Japan.
- So, The Japanese privacy rules has been operated in European system.

7

2. Data Protection Law in Japan

8

Perspective of the Data Protection Regulation in Japan

- Confidentiality of Physician (or other medical experts)
- Data Protection Law
- Others

9

Confidentiality of Physician

- Confidentiality is included in the Criminal Code. (European system)
- It is banned for physicians and pharmaceutical chemists to provide medical data of a patient for another without good reason.
- The meaning of "good reason" is not so clear, but it is argued that most data transfer is allowed in cases of normal use of medical data for general healthcare service or biomedical research.

10

The Statutes on Data Protection

- The Personal Data Protection Act (PDPA): only for private sector
- The Act on Personal Data Protection for Administrative Organs (APDPA)
- The Act on Personal Data Protection for Incorporated Administrative Agencies (APDPI)
- Local Ordinances on Personal Data Protection

2000 Statutes!

11

The Personal Data Protection Act (PDPA)

- The Personal Data Protection Act (PDPA) regulates acquirement and transfer of personal data in general.
- Without consent of a patient, hospitals or other healthcare organizations cannot transfer medical data in principle.
- But, there are three types of exception in PDPA.
  - 1. As long as another statute allows data transfer, the rules on data transfer in PDPA is not applied. (ex. Report of infectious disease)
  - 2. Data transfer without consent is allowed if it is necessary for "public health."
  - 3. Unexpressed or indefinite consent (opt-out) of a patient for data transfer is also valid as consent.

12

APDPA and APDPI

- Those statutes have almost the same rules.
- The original aims were democratic control of data held by public sector. Now it is considered as protection of personal interest.
- Administrative organs and incorporated administrative agencies can use and transfer personal data without consent unless they change the purpose of data use.

13

Guidelines on Medical Research

- In Japan, not statutes but several governmental guidelines have general rules on medical research.
- Around 2000, a governmental committee expressed a policy that regulation on medical research should be settled in guideline in order to refrain from intervening the liberty of research.
- Rules on personal data protection were also written in the research guidelines.

14

Guidelines on Medical Research

- The research guidelines have only single rules on medical research. But, there are 2000 statutes on personal data protection depending on the character of data holder.
- Is it possible to integrate 2000 rules into only one rule?
- According to the governmental policy, the rules of the guidelines cannot be milder than any rules in the statutes. As a result, medical research is now regulated in the strictest way among various activities in Japan.

15

3. The Amendment of PDPA in 2015

16

Amendment of the PDPA

- The Japanese government had planned amendment of the PDPA.
- The main purpose of the amendment was to harmonize the regulation in Japan with that in EU.
- It was fulfilled in September 2015, and came into force in May 30th this year.
- At the same time, guidelines of medical research was also amended.
- Some rules on data protection became stricter than previous rules.

17

Amendment of the PDPA

- Under the amended rules…

(a) some types of information are regarded automatically as personal data ("individual identification code": fingerprint identification data, passport number, etc.),

(b) acquiring and transferring sensitive data are not allowed without definite (opt-in) consent,

(c) some special rules to make data use easier for medical research were denied because of unification of the regulation on personal data.

- The research guidelines was to be amended in accordance with such conclusions.

18

Objection from Researchers

- Through the amendment of PDPA, secondary use of existing medical data for research should have become very difficult.
- Many people concerning biomedical research or healthcare industry feared the situation that the amended PDPA prevents from using and transferring medical data for research or public health.
- So, some of the biomedical researchers expressed objection to the amendment one year after the amendment was performed.
- It was too late, but politically very strong.

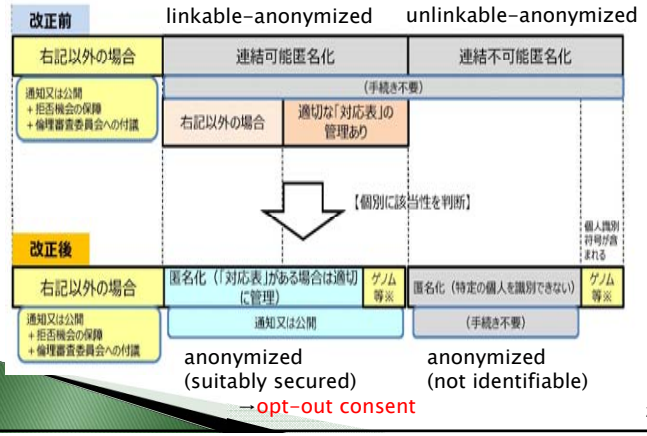
19

The Myth of "Anonymizing"

- In the previous guidelines, biomedical researchers was able to use medical data in any purpose without consent if they "anonymize" the data.
- But such a guideline had been criticized as illegal one by experts of personal data protection law.
- This criticism was right. PDPA defines "personal data" as "person-identifiable data" that includes formally anonymized data. If content of data itself has enough information to identify one person, it should be regarded as personal data.
- Nevertheless, this point became a target of a "counterattack" of biomedical researchers.

20

既存試料・情報の他機関への提供における匿名化の考え方（イメージ）
（改正前後での対比関係）



21

Exclusion from Application

- Why is it possible for researchers to transfer some data with opt-out consent?
- That is because, at the final phase of amendment of guidelines, the personal data protection committee expressed an interpretation that PDPA is not applicable “almost all” research activities.
- But, according to Art. 76 of PDPA, application of PDPA is excluded only for academic activities by private academic organization.

22

Summary of Amendment

- PDPA was amended in 2015, and the research guidelines was also amended.
- The guidelines was to be stricter than before, but there was strong criticism against such amendment of guidelines.
- So, the government (MHWL and MEXT) decided to make the regulation milder. But the amended rules are very complicated and underlying interpretations of PDPA are sometimes doubtful.

23

So, what should we do?

- For the time being, biomedical researchers have no choice but to obey amended PDPA and guidelines.
- But, severe problems in using data might occur under such rules.
- Special statute of specific data use can override the rules of PDPA. So, in order to acquire final resolution, it is necessary to legislate a new statute for research use of medical data.

24

4. New Tendency of Data Use in Medical Research

25

Anonymized Medical Data Utilization Act

- The Japanese government performed a new legislation that enables medical data to be used for various purposes including for research and commercial activities.
- The Bill of Anonymized Medical Data Utilization Act (AMDUA) passed the diet on April 28th this year, and it will come into force in one year.

26

The New Schemes of AMDUA

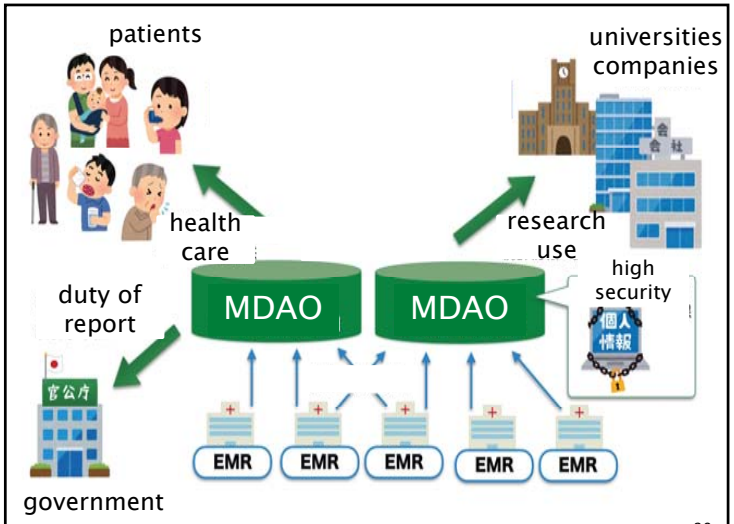
(1) Special organizations (Medical Data Anonymizing Organizations: MDAOs) should be established. The Japanese government should examine aptitude of the MDAOs.

(2) The MDAOs gather medical data from hospitals and other healthcare organizations. Data transfer to an MDAO is possible by unexpressed consent (opt-out) of a patient.

(3) MDAOs must adequately anonymize and store the acquired medical data under strong security.

(4) MDAOs can transfer the anonymized data to other research institutes, drug companies, and so on. The purpose of data use is not restricted, so commercial use is also widely admitted.

27



28

Meaning of the legislation

- Recently, the Japanese government has focused on promoting innovation in the field of drug or medical technology, and expects the system of AMDUA to realize such innovation.
- AMDUA enables data transfer without definite consent by means of "anonymization doctrine."
- The legislation has surely a meaning of a milestone to achieve the goal. But, in my opinion, there are still at least two considerable problems.

29

A Problem of AMDUA-- Efficacy

- Some experts of healthcare industry argue that the scheme of AMDUA is not sufficient because anonymized medical data cannot be so useful to develop new drugs or medical technologies.
- Some types of medical data (ex. genome data) are person- identifiable information in themselves and cannot be anonymized. But, these types of data are often much more important for research.

30

A Problem of AMDUA -- Social Feasibility

- The AMDUA resolves the legal problem on data transfer rule of the PDPA. But, it is uncertain whether it can also resolve the social problem.
- Now many people in Japan are so nervous about use of personal data, so the new system may not work because it is possible for such people to criticize the new system and refuse cooperation to provide their medical data.

31

Conclusion

- Amended PDPA rules and guideline rules have many problems to regulate data use in biomedical research.
- For the final resolution, new legislation that enables suitable data use for biomedical research is necessary.
- Recent enactment of AMDUA is an example of such legislation. Though the efficacy and feasibility is not so clear, it is a milestone to resolve the problems of PDPA rules.

32