How the 8 Principles of OECD Have Affected the Medical Information Systems?

Yoshikazu Nakamura*1

*1Department of Public Health, Jichi Medical University
Correspondence: nakamuyk@jichi.ac.jp

Researchers promoting epidemiologic studies and clinical studies must respect the Use Limitation Principle in the Organization for Economic Co-operation and Development (OECD) Guidelines on the Protection of Privacy and Trans-border Flow of Personal Data in 1980. About the ethical issues on medical research, the national government in Japan has published 4 kinds of guidelines according to the study design; “Guidelines for researches about human genome and gene”, “Guidelines for clinical researches about gene treatment”, “Guidelines for clinical researches”, and “Guidelines for epidemiologic researches”. The “Guidelines for researches about human genome and gene” and “Guidelines for clinical researches about gene treatment” require subjects’ informed consent in all the studies; therefore, there is no violence of the Use Limitation Principle. On the other hand, on the guidelines about clinical researches and epidemiologic ones, researchers using just only the existing data, such as individual clinical records, can use the data without informed consent with some processes, such as the approval of the institutional review board (IRB) and public offering of the information about the research according to the guidelines. These articles are reasonable because in some types of epidemiologic studies, such as studies for disease frequency, it violate the scientific accuracy due to selection bias if the researchers can use only data of those with informed consent. From the view point of the principle of individual participation, it should become better systems if the participants are able to know the fact that their data are used in the study even in the researched in which informed consent is not required according to the guidelines. Because the current rules in Japan are not acts but the guidelines, however, researchers using clinical data secondarily are in an awkward positions, and the situation should be improved.

Key words: Medical informatics, Privacy, Epidemiologic research design, Data collection, Informed consent

1. Epidemiologic Researches and Clinical Researches

Many of epidemiologic and clinical researches need patients’ health data. Of course, although some of such researches do not require patients’ individual data, individual data are the basic materials of epidemiologic researches and clinical, in particular clinico-epidemiologic researches.

One of definitions about epidemiology is that “The study of the occurrence and distribution of health-related states or events in specified populations, including the study of the determinants influencing such states, and the application of this knowledge to control the health problem”1). In former times, it is of “disease frequency,” but nowadays the epidemiology has expanded its fields out of diseases, say “epidemiology of longevity.” Therefore, the definition adopts occur-
ence and distribution of health-related status, not disease frequency. There are three goals of epidemiology; (1) disease prevention, (2) life prolongation, and (3) improvement of the quality of life (QOL). Because researchers usually use participants’ health individual data in many of the epidemiologic studies, which are the most sensitive personal data, the researchers conducting epidemiologic studies must not do it through just only the curiosity, but should do it with at least one of the three goals.

Simply talking, epidemiologic studies reveal the relationship between exposure and disease outcome, as shown in Figure 1. One of the characteristics of epidemiologic studies is that less interest exists in the mechanisms of the disease, which is in the arrow in Figure 1. If an epidemiologic study reveals a relationship between an exposure and a disease outcome, and if one can change the exposure status, then the frequency of the outcome is also changeable. For example, the relationship between smoking and lung cancer has been manifested in many epidemiologic researches, and the frequency of lung cancer has turned to decrease in the United States and other countries because of the efforts of tobacco control.

In this situation, no epidemiologic study has revealed the mechanisms between smoking and lung cancer, but just only relationship between them, say that the frequency of lung cancer is higher in smokers than in non-smokers.

Many study designs has been established in epidemiologic fields as shown in Table 1. Because the subjects of the epidemiologic studies are human being, there is no complete experimental research, like as animal experiment. Some potential target population refuse to participate in a study, or follow-up loss might occur when a participant has moved out from a target field. Or because of the lack of complete experimental research in this field, many types of study designs have been proposed. For example, case-control studies, in which the start point of the observation is disease outcome, not exposure, are non-sense in animal experiments. Except for ecologic studies in Table 2, in which epidemiologists use group data, such as alcohol consumption and mortality rate from myocardial infarction by countries, all the other study designs usually require individual health data. If an epidemiologist wishes to conduct a cohort study to reveal the relationship between smoking and lung cancer, the epidemiologist must collect information about smoking status at baseline, follows all of the participants, and must know whether or not each participant develops the cancer. Of course, there are

### Table 1 Type of Epidemiologic Studies

<table>
<thead>
<tr>
<th>Type</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Observational studies</strong></td>
</tr>
<tr>
<td>- Description</td>
</tr>
<tr>
<td>- Ecologic studies</td>
</tr>
<tr>
<td>- Cross sectional studies</td>
</tr>
<tr>
<td>- Cohort studies</td>
</tr>
<tr>
<td>- Case-control studies</td>
</tr>
<tr>
<td>- Others</td>
</tr>
<tr>
<td><strong>Intervention studies</strong></td>
</tr>
<tr>
<td>- Field intervention</td>
</tr>
<tr>
<td>- Clinical intervention</td>
</tr>
<tr>
<td>- Others</td>
</tr>
</tbody>
</table>

Figure 1 Epidemiologic Research (Exposure and Disease Outcome)
Table 2  Ethical Declaration for Epidemiologic Research by Japan Epidemiological Association (2002)

- All epidemiologic studies must have a purpose to reveal the truth
- All epidemiologic studies must respect subjects’ human rights
- All epidemiologic studies must take the most appropriate method according to the purpose
- All epidemiologic studies must follow the social norms
- All epidemiologic studies must always be opened to the public

epidemiologic studies treating just only exposure, for example smoking rate among a population, and just only disease outcome, for example incidence rate, prevalence, or mortality rate of a disease in a population.

Thus, personal health data are essential for epidemiologic studies including some clinical studies with a small exception.

2. Two Types of the Studies

According to the timing, there are two kinds of epidemiologic studies including some of clinical studies; (1) prospective studies, which start currently and observation should be continued in the future, and (2) retrospective ones, which started in the past and of which the observation should have been conducted as well. All of the interventional studies are prospective, and so are conventional cohort studies. On the other hand, almost all of the conventional case-control studies and the exception of cohort studies, retrospective cohort studies, are, as shown in the name, retrospective.

In a prospective study, researchers can get informed consent, defined as “Voluntary consent given by a subject or a responsible proxy for participation in a study, immunization program, treatment regimen, etc., after being informed of the purpose, methods, procedures, potential benefits and potential harms, and, when relevant, the degree of uncertainty about such outcomes), for the participation in the study from each potential participant. Therefore, it is not too much to say that the informed consent is an obligation of the study.

On the other hand, in many of retrospective studies previously existing data are used. For example, previous medical radiation exposure history data should be collected from medical records in a case-control study of radiation exposure and cancer. Of course, the researcher cannot get informed consent from those who have passed away at the start point of the study. If the researcher would use data of those with informed consent, the results would be suffered from selection bias because all the case patients are still alive and their cancers might not so severe.

Requiring informed consent in all the epidemiologic studies might distort results because of the selection bias.

3. Informed Consent and Privacy

Classically, privacy was defined as a personal right to let be alone, but nowadays it is an authority to decide how to use self information. Therefore, getting informed consent from participants of an epidemiologic study is materialization of the protection of privacy of the participants. Each participant has a right to decide whether he/she allows an epidemiologist use his/her own personal health-related data.

However, as above-mentioned, requiring complete informed consent might introduce incorrect results in some epidemiologic studies. In other words, epidemiologic studies involving only those with consent do not attribute the welfare of human being with distorted results.

4. OECD Guidelines on the Protection of Privacy and Transborder Flows of Personal Data

The Organization for Economic Co-operation
170 How the 8 Principles of OECD Have Affected the Medical Information Systems?

and Development (OECD) issued the “OECD Guidelines on the Protection of Privacy and Transborder Flows of Personal Data” in 1980\(^3\). The 4th principle (Paragraph 10) is the Use Limitation Principle.

*This paragraph deals with uses of different kinds, including disclosure, which involve deviations from specified purposes. For instance, data may be transmitted from one computer to another where they can be used for unauthorised purposes without being inspected and thus disclosed in the proper sense of the word. As a rule the initially or subsequently specified purposes should be decisive for the uses to which data can be put. Paragraph 10 foresees two general exceptions to this principle: the consent of the data subject (or his representative - see Paragraph 52 above) and the authority of law (including, for example, licences granted by supervisory bodies). For instance, it may be provided that data which have been collected for purposes of administrative decision-making may be made available for research, statistics and social planning.*

According to this principle, epidemiologists cannot use individual health data without informed consent of the subjects in retrospective studies.

5. Japanese Situations

In Japan, Individual Data Protection Act was established in 2003. According to this act, persons cannot use personal data beyond the purpose stated to the subjects, and cannot provide the data to third persons. However, the article 50 exempts the obligation for research institutions and researchers in such institutions as well as mass communications and political actions. Instead, the act requires such persons and organizations for self-regulations. Therefore, researchers are able to use individual health data for research outside the regulation of the Act. In addition, health and medical data in medical institutions are regulated by this act. According to the specialties of medical information, specific regulation is needed instead of the regulation by the general act.

It is quite strange that although the Individual Data Protection Act’s requisition is self-regulation, the Japanese government has made four kinds of guidelines for medical research; “Guidelines for researches about human genome and gene” (2001, revised in 2005)\(^4\), “Guidelines for clinical researches about gene treatment” (2002, revised in 2004)\(^5\), “Guidelines for clinical researches” (2003, revised in 2009)\(^6\), and “Guidelines for epidemiologic researches” (2002, revised in 2007)\(^7\). Problems of the national guidelines in this country are discussed later.

The former two guidelines concerning with genetic require informed consent of the subjects in the all situation. Clinical and epidemiologic researches involving genetic analyses are under these two guidelines. Because the study design should be prospective, getting informed consent is not so difficult, and the mandatory requirement of the consent is reasonable. This regulation is comparable with the Use Limitation Principle of the OECD.

On the other hand, informed consent of the study subjects are principle on the “Guidelines for clinical researches”, and “Guidelines for epidemiologic researches”. However, under some conditions, researchers can use individual medical records without agreement of the subjects in clinical and epidemiologic researches. For example, in observational epidemiologic studies, researches can use participants’ health or medical data without informed consent if the researchers open the study to the public through some methods such as the internet, the data is anonymous, and the process is approved by the institutional review board.

These regulations, allowing the usage of medical data without consent, are contradictory to the
Use Limitation Principle of the OECD. However, the regulations are reasonable with some reasons. First, many of medical sciences are empirical ones so that individual health data are essential for the development of the sciences. Second, it is somewhat reasonable to consider that the current patients are blessed with the current medical sciences which have been established using previous data of other patients so that the current data should be served for future patients. Third, no disadvantages except using without consent itself exist on the relevant patients. Fourth, getting informed consent from past patients are tough work, and impossible for patients having passed away. And the final issue is selection bias. If a researcher use individual health data from only those with informed consent, results should be distorted from the true features. The final issue is concerning the scientific issue itself and the most important. Conducting a research the methods of which are incorrect scientifically is unethical itself. Therefore, on the “Ethical Declaration for Epidemiologic Research” by the Japan Epidemiological Association in 2002 lists the scientific property first, before the subjects’ human rights.

For those reasons, using personal health records without consent should be approved with some requirements, despite the violation of the Use Limitation Principle.

6. Problems about the Guidelines

As above-mentioned, there is no specific law about scientific use of medical or health records in Japan. Instead, the Individual Data Protection Act as a general law, and some kinds of guidelines exist. Therefore, the secondary use of individual medical and health records is based on the guidelines.

There are two problems on the base of the guidelines for secondary use. One is a constitutional issue. The Constitution of Japan guarantees the academic freedom. Therefore, the Individual Data Protection Act requires the self-regulation in academic fields instead of legal regulation. It is commonly understood that the self-regulation system is allowed by the low because of the academic freedom warranted by the constitution. However, the Japanese government regulates the academic use of health and medical records with the guidelines issued by its own. Academic organizations also issued guidelines for academic use of individual data. For example, Japan Epidemiological Association has guidelines for epidemiologic research including individual data protection and privacy. However, almost all universities and research institutions, including the author’s university, adopt the national guidelines, and institutional review boards in such institutions are seated based on the national ones.

The other problem is that the guidelines do not protect researchers from legal suits from subjects. Because the national guidelines are administrative guidance, researchers do not have to follow the guidelines. However, if a researcher violate the guidelines, and subjects accuse the researcher’s violation, the researcher might lose the suit case because of the guidelines. On the other hand, if there were a special act for using individual health and medical data, and a researcher followed the act, he/she would win the suit from subjects. However, in fact that the guidelines are just only guidelines, and that they are not lows, the researchers are not protected from the subjects’ protests even if he/she follows the guidelines according to some judgments of the low suits in Japan. Thus, the position of researchers has become the weakest because of the guidelines.

7. Proposal for Solution

As shown above, some epidemiologic studies violating the Use Limitation Principle of the OECD are approved with some conditions. In other words, although the Use Limitation Principle has only two exceptions, consent of the data
subject and the authority of low, there is another exception. The background for the third exception to be approved is not that epidemiologic researches are less sensitive than other medical researches, but that participation of all the potential subjects keeps the scientific property. In this situation, one of the solutions is to make general consensus for using such methods. If researches make dataset anonymous as soon as possible, it might become easy to make the consensus.

The other consensus to be required is that all of the medical institutions including hospitals and clinics conduct researches as well as providing medical services so that visiting a medical institution means not only receiving medical services but also participating in researches. If the society approves these concepts, comprehensive consent for using medical records would be established.

It will take some time before special act for medical records comes to legislation. As shown before, however, it is difficult to regulate the usage of individual medical and health data by the Individual Data Protection Act, which is a general low, and some guidelines.

There are some solutions realistically; First, notifying the scientific use to the data subjects, with guarantees for the subjects to refuse the usage without disadvantages; second, making data anonymous as soon as possible; and finally, approval of the institutional review board.

Also, we have to promote the system in this country referring to the situation in other countries\textsuperscript{10}.

References

3) http://www.oecd.org/document/18/0,3343,en_2649_34255_1815186_1_1_1,00.html (cited on April 14, 2010)