Ethical Issues in Preventive Medicine with Special Emphasis on Epidemiological Research and Practice

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**East and West**

In the countries of Western culture, reliable human relationship in society is exclusively backed with various kinds of contracts, and loyal adherence to them is the basis of ethics. In such a cultural background, informed consent, for example, is an important ethical requirement for the doctor-patient-relationship.

In Eastern countries, on the other hand, the highest moral principle is the maintenance of social harmony supported by consensus of people, and what causes disharmony is condemned as social evil. In such a society it has long been generally accepted as etiquette for a person to be left entirely to a doctor’s care, whenever he or she falls ill.

While Hippocratic oath is constituted of several tangible guidelines, the medical ethics of Confucian teachings in the Eastern countries under Chinese influence such as Japan is prescribed only by a simple axiom saying ‘Medicine is an art of the highest virtue’. It is nothing but an abstract expression of general principle without any substantial indication on physician’s behavior. In this sense physicians are like captains of boats on rough seas without marine charts. In the East, therefore, ethical issues are more difficult to cope with than in the West, because points of dispute are often more obscure and subtle.

On the other hand, physicians under Chinese culture have been classified into three categories: low class physicians who only cure sickness, middle class physicians who heal patients, and high class physicians who care of a nation. In this way the public health doctors were ranked at the top, but in reality the advance of social medicine was much retarded in these Eastern countries, leaving many ethical issues untouched.

**Development of Preventive Medicine in Japan**

As medicine in Japan has remained predominantly herbal under Chinese influence for more than ten centuries, the idea of preventive medicine could not flourish there for long.

In the mid-19th century, however, Japan was obliged to open her window to the West in order to become a member of world society. Because of the sudden social change at that time, various exotic communicable diseases that were then rampant abroad poured into the country in parallel with rapid introduction of Western civilization.

In order to prevent epidemics of unfamiliar acute infectious diseases such as cholera, smallpox or plague, the government had to establish in haste control measures against them, and Peter Frank’s idea of sanitary police was adopted as a principle of public health administration.
The policy proved effective and the threat of the epidemics retreated within a short term. However, in recompense, violation of basic human rights was often behind the scenes, and the patients of such vehement communicable diseases were often sacrificed for the sake of social security to prevent the terrible epidemics, as shown by the example of cholera cases who were unsparingly maltreated and died in poorly accommodated pesthouses.

While the ruthless attitude of government towards such patients has been improved gradually after the Second World War, a new problem was brought about in the field of preventive medicine. That was the environmental pollution incurred by the rapid industrialization policy of the country, highlighted by Minamata disease during 1950’s.

Either caused by pathogenic microorganisms or environmental pollutant, the patients were the victims of a national policy in which the safety or interests of the majority group takes precedence over the human rights of a minority group.

However, with gradual infiltration of the concepts of democracy among the people in Japan, the pendulum started to swing from the side of social security to that of human rights, and the ethical standards in preventive medicine are now changing, depending on the shift of social structure from traditional Eastern enlightenment to modern Western democracy.

Due to the vehemently fluctuating value system of preventive medicine in modern Japan, the attempts of epidemiological research or practice often meet to some extent with frictions provoked by this ethical dilemma.

Motivated by these challenging situations, a study project team on “Ethical Issues in Preventive Medicine” was formed and has worked for past three years in Japan. As at the end of the study it was deemed premature to propose any definite guidelines in such a chaotic ethical situation in preventive medicine, the team scrutinized many ethical issues and put the disputed points in order.

Representing the team, I should like to present to you a part of the results that are relevant to epidemiological research and practice.

**Fundamental Ethical Issues for Epidemiological Research and Practice**

**Tajima’s proposal**

Dr. K. Tajima, a member of the study team, proposed the following 5 items as fundamental ethical requirements for any epidemiological research and practice to be implemented. (i) Social need for the research should be corroborated, (ii) Informed consent of the subjects under investigation should be attained, (iii) Confidence of the study data should be guaranteed, (iv) Physical safety for the subjects under investigation should be secured and (v) Prudence is indispensable in notifying the study subjects about the relevant data and in publishing the results to society.

**Shimizu’s proposal**

Professor H. Shimizu, another member of the team, pointed out similar ethical issues in epidemiological research and practice as follows. (i) Motivation and aim should be clearly defined before it is started, (ii) Full care should be paid to the subjects to be studied, (iii) Deep consideration should be taken in deciding methodology and (iv) Prudence should be taken in case of publication of the study results.

The ideas of both authors are almost the same regarding the points of discussion. Here I should like to present my own idea concerning the issues. It is not far from the ideas of the above two authors.
My proposal

(i) Motivation for epidemiological research

In clinical settings, doctors should respond to the need for medical consultation whenever the patients demand it. On the other hand, in preventive medicine, epidemiologists are not legally responsible to devote themselves to the needs of the people, even if it is urgent. Ethically speaking, however, epidemiologists are expected to be more sensitive than clinicians to hear the silent cry for help of people in need.

(ii) Neutrality of epidemiologists

It is without debate that epidemiologists should come up to the public expectations by their deep insight and caring concern in the complicated value system of health problems.

In reality, however, it is difficult to keep an absolutely neutral stance, for example, in case of environmental problems where the merit of community development and the demerit of environmental pollution are seriously competing. Sometimes epidemiologists are tained and labeled as industry-oriented or resident-oriented. For example, the leaders of movements against the construction of congenitally hazardous installations such as atomic power plants sometimes distrust the epidemiologists and their survey might be refused. At the same time, the same condition might also occur with atomic power plant management.

Therefore, epidemiologists should always be cautious to keep both a strictly ethical attitude and a scientific mind set in order that they be trusted by both confronting sides.

(iii) Informed consent

Because of the bilateral relationship between patient and doctor in clinical settings, the scope of informed consent is limited only to the two persons concerned. In preventive medicine, on the other hand, a multitude of subjects under research are closely relevant to the study outcome, and under such a multilateral relationship informed consent can not be attained in a simple way, because the surrounding situations are often controversial among the people concerned.

For example, professor K. Bai, a member of the team, expressed his idea on specimen collection from the human body based on the standpoint of informed consent. At the moment when a specimen is collected, a part of the patient’s body changes into a mere material. However, it is still a special material, being not only an object of possession of health professionals, but also a non-expiring property belonging to the original personality whose once-expressed consent to the epidemiologist remains valid for a long period of time.

(iv) Safety of method

Any epidemiological research and practice should be innocuous both physically and mentally. It is a matter of course that epidemiologists should be cautious not to harm the bodies of the subjects when they do some research, for example, the evaluation of the effectiveness of some newly exploited drugs or vaccines.

Furthermore they should take precaution as well not to hurt the self-dignity of the subjects under investigation, because the questions on questionnaires directed to their private feelings or subconsciousness are apt to inflict various kinds of damage on their soul.

(v) Confidence of results

In case of bilateral human relationships such as seen in clinical settings, it is rather easy to keep confidence within themselves. However, in the field of preventive medicine where a complicated network of human relationships is at work, confidence is far more difficult to achieve.
As an example in such a situation, professor K. Bai called attention to the ethical issues related to anonymity of subjects in epidemiological research.

Although feedback of some epidemiological data to the original individual among the studied subjects is often beneficial to his or her own health, anonymity is a grave obstacle to achieving it. On the other hand, their privacy would hardly be protected without procedure for anonymity. This is a dilemma in epidemiological research that is difficult to overcome. In such case, epidemiologists should try to reconcile conflicting values by handling the data in more adroit way under the given settings.

(vi) Benefit brought about by research

Generally speaking, medical research is carried out with the aim of bringing benefit to the health of future generations by studying the present one suffering from some disease. In case of epidemiological research, however, it would be desirable that both future and present generations are benefited with better health, because the subjects under study are usually healthy people bestowed with more or less long life expectancies.

Consciousness Survey on Researchers of Preventive Medicine

Professor Y. Inaba et al., members of the team, made a survey on ethical consciousness of about 180 professors at the Departments of Hygiene or Departments of Public Health in medical schools throughout Japan by asking through enquiry sheets their experiences in encountering more or less serious ethical issues in relation to epidemiological research or practice.

About 150 of them (about 80%) responded, and the results were analyzed. Some of the important outcomes are presented in the following tables, where the percentages indicate the frequencies of the named experiences among the professors and not among their epidemiological researches and practices. This means that the figures indicate the proportion of the professors who have ever experienced at least once the named ethical problems during their past career in epidemiological research and practice. In this sense the figures reflect the social consciousness about human rights and the public evaluation of epidemiological study and practice throughout Japanese society.

Forced abandonment of planned epidemiological research or practice

Forty percent of the professors (60/150) have abandoned, against their initial intention, planned epidemiological research or practice before implementation due to various ethical reasons. In most cases they could not attain the consent of the persons who are in charge of administration of the target population or the representative of the community to be studied (Table 1).

Personal protest or complaint raised by the subjects during epidemiological research or practice

Twenty-seven percent of the professors (40/148) have experienced personal protest or complaint raised by some subjects after the epidemiological research or practice was started. In such cases, the professors have to attain individual informed consent anew on the spot in order to continue the research or practice (Table 2).
Table 1  Obliged abandonment of the planned epidemiological research or practice

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<thead>
<tr>
<th>Responses</th>
<th>Number</th>
<th>Percentage</th>
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<tbody>
<tr>
<td>Those who have ever experienced</td>
<td>60</td>
<td>40</td>
</tr>
<tr>
<td>Those who have never experienced</td>
<td>90</td>
<td>60</td>
</tr>
<tr>
<td>Total</td>
<td>150</td>
<td>100</td>
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</tbody>
</table>

Table 2  Personal protest or complaint raised by the subjects during epidemiological research or practice

<table>
<thead>
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<th>Responses</th>
<th>Number</th>
<th>Percentage</th>
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<tbody>
<tr>
<td>Those who have ever experienced</td>
<td>40</td>
<td>27</td>
</tr>
<tr>
<td>Those who have never experienced</td>
<td>108</td>
<td>73</td>
</tr>
<tr>
<td>Total</td>
<td>148</td>
<td>100</td>
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Personal refusal raised by the subjects during epidemiological research or practice

Fifty-nine percent of the professors (68/138) have experienced personal refusal of study or practice at the stage when it was still going on because, although formal informed consent of the study population as a whole was validated beforehand, some members among the target population were not happy with it and refused to commit themselves to the research or practice (Table 3).

Table 3  Personal refusal raised by the subjects during epidemiological research or practice

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<th>Responses</th>
<th>Number</th>
<th>Percentage</th>
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<tbody>
<tr>
<td>Those who have ever experienced</td>
<td>68</td>
<td>49</td>
</tr>
<tr>
<td>Those who have never experienced</td>
<td>70</td>
<td>51</td>
</tr>
<tr>
<td>Total</td>
<td>138</td>
<td>100</td>
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Inaccessibility to epidemiologists of existing public data

A great deal of demographic or health data are being kept in certain public institutions. Epidemiologists formerly made use of them. However, 54% of the professors (67/125), when asking to use this data, have been refused by public officers in charge, because of the contingent breach of privacy of the inhabitants under their jurisdiction (Table 4).

Table 4  Inaccessibility of epidemiologists to the existing public data

<table>
<thead>
<tr>
<th>Responses</th>
<th>Number</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Those who have ever experienced</td>
<td>67</td>
<td>54</td>
</tr>
<tr>
<td>Those who have never experienced</td>
<td>58</td>
<td>46</td>
</tr>
<tr>
<td>Total</td>
<td>125</td>
<td>100</td>
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Conclusion

What I have presented here is the representative ethical issues in preventive medicine in Japan with special emphasis on epidemiological research and practice. Some of them may be common to the whole world and the others specific to this country in the Far East. In any case, I hope that our experiences contribute to the future progress of your epidemiological research and practice.