

**Possibility of Legal Adjustment among
Rights and Duties over Genetic Information
in Japan: Patient's Right to Privacy,
Relatives' Right to Know, and Healthcare
Providers' Duty of Confidentiality**

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Abstract

The remarkable progress of medical genetics has made it possible to diagnose many genetic diseases. While this has led to such benefits as prevention, early detection and treatment, many of them are neither preventable nor curable yet. Ascertaining the genetic mutation that causes disease may bring about discrimination against a person with a genetic disease and blood relatives. Since the Japanese are apt to worry about how they are perceived in public and to think of genetic disease as a disgrace to the family, a person diagnosed with a genetic disease sometimes keeps the result from those around him/her. However, it may be desirable for his/her at-risk relatives to know the result because of the above-mentioned benefits. This situation may confront healthcare providers with the difficult choice between maintaining a patient's confidentiality and disclosing his/her genetic information to his/her relatives. There is a conflict of interest among those persons.

After surveying the current ethical and legal regulations of the World Health Organization and some countries on this matter, I discuss the possibility of legal adjustment in Japan. The patient and blood relatives share some common genetic information. Therefore the genetic information of the patient can be considered as that of relatives' own under specified strict conditions because of their partial genetic identity. Then, access to the patient's information can be legally protected as exercising of the self information control right of relatives.

Keywords:

genetic information, genetic testing, regulation, legislation

Introduction

There has been remarkable progress in medical genetics in recent years. This has made it possible to diagnose many genetic diseases. Nevertheless, many of them are neither preventable nor curable yet. Moreover, there are cases of discrimination against a person with a genetic disease and his/her blood relatives.

Therefore, a patient diagnosed with a genetic disease sometimes intends to keep the test result from not only his/her employer and insurance company, but also his/her family (blood relatives and spouse). However, for the relatives at the same genetic risk, knowing the result may be desirable from the viewpoint of prevention, detection, and treatment at an early stage, when the disease is preventable or curable. Healthcare providers, in spite of their confidentiality regarding the patient's information, may plan to inform the relatives of the genetic risk. If they fail to inform the relatives, they may be charged with inaction by the relatives. In this situation, how should these rights and duties, namely, the patient's right to privacy, his/her blood relatives' right to know, healthcare providers' duty to maintain confidentiality and duty to disclose the patient's information to the relatives, be regulated?

Many genes causing diseases have not been identified yet, genetic testing is not necessarily accurate, and there are concerns about genetic discrimination. Thus genetic testing is being conducted cautiously with restriction so far, especially in Japan. For this reason, conflict among the patient, relatives and healthcare providers may not develop into a major problem in Japanese society. The Japanese traditionally have a strong sense of belonging to their family and they value their family's genealogy being free from genetic disease. Therefore those who have a risk of genetic disease tend to keep it secret. This problem seldom comes to the surface, but is deep-rooted.

First, I overview the rights and duties that may cause conflict in disclosing genetic information to the blood relatives and spouse of the patient. Next, I survey the current stance of the World Health Organization (WHO) and some countries before considering the situation in Japan. Finally, I discuss how the conflict of interest between the patient and relatives should be regulated, and what action healthcare providers should take.

1. Overview of the rights and duties that cause conflict in disclosing genetic information to the blood relatives and spouse of the patient

Below is a functional case including the conflicts between rights and duties.

[case]

A woman in her fifties contracted hereditary cancer. She has a husband and two daughters. One is married with an underage child, and the other is engaged to be married. The prognosis of the disease is unfavorable when missing the opportunity to get treatment at an early stage. But early detection and treatment makes a cure possible. While her doctor thinks that the at-risk relatives should be informed and advised to undergo presymptomatic testing, she is hesitating for fear of discrimination and prejudice against her and her family.

In the case above, conflict may arise between the woman and her doctor, concerning the disclosure of her genetic information. There are four main rights and duties that may cause conflict. In Japan, these rights and duties are discussed as follows.

(a) Patient's right to privacy

The right to privacy had been established as the right to be left alone in

judicial precedent of the court of the U.S. In Japan, there is a district court precedent¹ that defines the right to privacy as a right which ensures that one's private life is not opened to the public without permission and the court held that it is in effect as a private right. Although the right is not provided for in the Constitution of Japan, it is interpreted to be guaranteed by Article 13 of the Constitution, which establishes the right to pursue happiness. As the information society has advanced, the positive aspect of the right to privacy has become emphasized. In other words, it has changed from a negative right, namely the right not to be intruded on by others, into a positive right to control self information (self information control right). Since genetic information should be kept even more strictly confidential than other personal information, one's will to keep it secret must be respected.

(b) Healthcare providers' duty of confidentiality

Healthcare providers in Japan have a duty of confidentiality to their patients under criminal law, and the duty is guaranteed by penalties. They are also obligated to protect the confidentiality of their patients under the Civil Codes. This duty is ethical as well as legal and this concept is reflected in the Hippocratic Oath, the guidelines of the World Medical Association and others. Although the duty has conventionally been considered as absolute, it has become relative with the spread of team practice in medical treatment and the diversification of medical information. In the U.S. the trend has been growing since the Tarasoff Decision.^{2,3}

However, healthcare providers also have an obligation to notify the authorities concerned in order to prevent harm to public health and to promote public welfare. They are not accused of abuse of confidentiality in this case.

(c) Family member's (blood relatives and spouse) right to know

Informing blood relatives of their risk gives them the opportunity to undergo presymptomatic testing. When a genetic defect is ascertained as a result of the testing, prevention or early treatment may be possible. Even if the disease is neither preventable nor curable, some relatives may want to know the result in order to consider the marriage and reproductive prospects. The same goes for the spouse or betrothed. Thus their right to know is claimed, but they are not parties to the medical contract between the patient and healthcare providers. Although they may benefit by being disclosed his/her genetic information, whether the benefit is legally protected or not is another matter.

Contrary to the right to know, the right not to know is also claimed. The reason is that disclosure may bring only fear and despair if the disease is neither preventable nor curable. The right to know or not to know in this context means not the right to know that is claimed as a form of the right to freedom of expression under public law, but the right to private matter such as genetic information. It is included in the above-mentioned self information control right.

(d) Healthcare providers' duty to warn the blood relatives of the same genetic risk as the patient

In Japan, a medical contract is regarded as a quasi-mandate. According to the spirit of Article 645 of the Civil Code, doctors are considered to have a duty to explain their diagnosis, remedy, etc. without special circumstances, if their patient requires.⁴ This is the duty to their patient who is a party to the medical contract, so the duty should be performed towards the patient himself/herself without special circumstances.

The Supreme Court held, in case of terminal cancer, that doctors have a duty to explain to a patient's family, when it is not appropriate to disclose information to a patient.⁵ But this decision does not guarantee the explanation to family by doctor as the inherent right of the family. Doctors ordinarily have no duty to explain to a patient's family who are not parties to the medical contract. Only when it is considered inappropriate to disclose to a patient, for example the terminally ill, the duty to the family is imposed on doctors as the duty incident to the medical contract between the patient and doctor. Therefore doctors have no legal duty to explain to a patient's family in case of genetic disease.

2. Regulation on disclosure of genetic information to a third party without the Patient's consent in WHO and some countries

What requirements should be satisfied in order to disclose a patient's genetic information to his/her family without his/her consent?

Before considering this issue, I survey the regulations on disclosure of genetic information to third parties in WHO and some countries.

(a) WHO

Specialists in genetics discussed ethical issues in medical genetics and services in 1997, and the Proposed International Guidelines on Ethical Issues in Medical Genetics and Services⁶ was published. Section 9, Table 7 states as follows:

9. Disclosure and Confidentiality, Table 7

-If a couple intends to have children, individuals should be encouraged to share genetic information with their partners.

-The provision of genetic information to relatives about the family so as to learn

their own genetic risks should be possible, especially when a serious burden can be avoided.

(b) The United States

Under the Federal Government, the Department of Health and Human Services enacted the Standards for Privacy of Individually Identifiable Health Information (HIPAA Privacy Rule)⁷ in 2001, with the establishment of the Health Insurance Portability and Accountability Act of 1996 (HIPAA)⁸. The rule prescribes protection of personal information including genetic information. It exceptionally permits disclosure of personal information, when disclosure is needed to prevent or reduce a serious and imminent threat to the health or safety of a person or the public. But Offit et al. pointed out that it is questionable whether the uncertain probability of a future genetic disease constitutes an imminent harm or a threat to the public interest.⁹

At the state level, the U.S. has genetic privacy laws. Although the contents of regulations vary by state, several states permit disclosure of genetic information only in a very limited manner.

In addition, the American Society of Human Genetics (ASHG) established ASHG STATEMENT¹⁰ in 1998. The statement refers to this issue in Section I. It states as follows:

I. Points to Consider, B. Exceptional Circumstances That Permit Disclosure

1. Disclosure should be permissible where attempts to encourage disclosure on the part of the patient have failed; where the harm is highly likely to occur and is serious and foreseeable; where the at-risk relative(s) is identifiable; and where either the disease is preventable/treatable or medically accepted standards indicate that early monitoring will reduce the genetic risk.

(c) The United Kingdom

The General Medical Council's ethical guidance, Confidentiality (2009)¹¹, prescribes genetic and other shared information in Paragraph 69. It states as follows:

69. However, a patient might refuse to consent to the disclosure of information that would benefit others, for example, where family relationships have broken down, or if their natural children have been adopted. In these circumstances, disclosure might still be justified in the public interest. If a patient refuses consent to disclosure, you will need to balance your duty to make the care of your patient your first concern against your duty to help protect the other person from serious harm.

(d) Switzerland and Germany

In Switzerland, the Federal Act on Genetic Testing (Bundesgesetz über genetische Untersuchung beim Menschen)¹² was enacted in 2004. Article 19 stipulates disclosure of genetic information.

Article 19

(1) The doctor may disclose genetic test results only to the person concerned or, if he/she is incapable of judgment, to his/her legal representative.

(2) If the person concerned gives his/her express consent, the doctor may disclose the test result to the person's family members, spouse or partner.

(3) If consent is denied, the doctor may apply to the competent cantonal authority as stipulated in Article 321 number 2 of the Swiss Criminal Code to be released from his/her duty of professional secrecy, should the protection of the overriding interests of family members, spouse or partner require that they

receive this information. The authority may request an opinion from the Expert Commission for Human Genetic Testing.

In Germany, Human Genetic Examination Act (Gesetz über genetische Untersuchungen bei Menschen)¹³ was enacted in 2009. Article 11 stipulates disclosure of genetic information.

Article 11

(1) Subject to conditions of subparagraph (2) and (3), the result of any genetic examination may only be disclosed to the subject person and in each instance may only be disclosed by the responsible medical doctor or by the medical doctor who conducted the subject genetic counseling.

(2) Any person or institution authorized according to Article 7 (2) to conduct genetic analyses may only disclose the results of such analyses to the medical person who commissioned the analyses.

As can be seen above, guidelines generally tend to permit disclosure of genetic information to a third party without the patient's consent under strict conditions: severe disease, being possible to avoid an important disadvantage by disclosure, failure to encourage disclosure on the part of the patient and others. On the other hand, legal regulations tend to have no article that permits disclosure explicitly from the outset, or to permit it only in a very limited manner.

3. Ethical regulations on disclosure of genetic information to a third party without the patient's consent in Japan

Ten Genetic-Medicine-Related Societies established the Guidelines for

Genetic Testing¹⁴ in 2003. Section III stipulates disclosure to blood relatives.

Section III. Disclosure of Genetic Test Results

6 Test results may be disclosed to relatives with the examinees' consent. In case of refusal by examinees, disclosure to their relatives may be still possible if all the following conditions are met. (Omitted)

(1) When the results can be utilized as useful information for the prevention and treatment of a clinically serious disorder in relatives,

(2) When judging that disadvantages which relatives may suffer can be prevented by the disclosure,

(3) In cases where, even after repeated explanation to examinees, disclosure consent has not been given,

(4) In cases where requests for disclosure have come from relatives,

(5) When judging that examinees will not suffer discrimination, even if results are disclosed to relatives,

(6) In cases where disclosure can lead to diagnosis, prevention and/or treatment of a particular disease in relatives,

Incidentally, there are no legal regulations specialized for genetic information in Japan. Instead, we have the Act on the Protection of Personal Information¹⁵ as a regulation on general personal information and, in addition, its guidelines specialized for handling medical information, namely the Guidelines for Proper Handling of Personal Information by Healthcare and

4. Legal requirements for provision of personal information to a third party in Japan

Regarding the legal requirements of permitting disclosure of medical information in general to a third party without the person's consent, the Act on the Protection of Personal Information states as follows:

Article 23

(1) A business operator handling personal information shall not, except in the following cases, provide personal data to a third party without obtaining the prior consent of the person:

(i) Cases in which the provision of personal data is based on laws and regulations

(ii) Cases in which the provision of personal data is necessary for the protection of the life, body, or property of an individual and in which it is difficult to obtain the consent of the person

(iii) Cases in which the provision of personal data is specially necessary for improving public health or promoting the sound growth of children and in which it is difficult to obtain the consent of the person

According to the above-mentioned guidelines pertaining to this Act, specific examples of Article 23, paragraph (1), item (i) are notifications of an infectious patient, a drug addict, an abused child and others.

The interests protected by item (i) are public safety, the life and body of a person, etc.; they correspond with the interests protected by item (ii) and (iii).

Therefore, disclosure of genetic information, one of medical information, to a third party can be justified in certain cases that meet the requirements of being necessary to protect important public safety, and the life, body and property of a person.

5. Discussion of requirements

In this section, I discuss whether disclosure of genetic information to a third party without the person's consent can meet the requirements mentioned in the preceding section.

Generally, healthcare providers are considered to be exempted from the duty of confidentiality where important interests of the public or a person can be harmed unless they disclose the patient's information: where he/she has an infectious disease, or is a victim of child abuse, and where serious harm to the identified third party by him/her is anticipated.

Thus, it is a problem whether nondisclosure of genetic information to a third party causes infringement of interests.

Firstly, genetic disease is shared exclusively by blood relatives; it cannot be assumed that nondisclosure harms the public interest. Secondly, it cannot also be assumed that disclosure to a third party prevents harm to the patient

himself/herself, such as the notification of child abuse to the police. Thirdly, even if blood relatives are unable to seek prevention or treatment as a result of nondisclosure, the disadvantage is not brought about by the patient himself/herself. After considering these points, it seems difficult to give priority to the relatives' interests against the patient's will to guard his/her genetic information, even though disclosure is necessary for the protection of their lives or health.

However, as the genetic information of the patient is shared by blood relatives, disclosure can be said to be beneficial to them from the viewpoint of prevention, early detection, and treatment, when the disease is preventable or curable, for example, in case of certain hereditary cancers, and in case of certain familial arrhythmias and familial hypertrophic cardiomyopathy. In the former case, continuous medical examination and preventive surgery, etc. can be effective. In the latter case, preventive treatments, such as implantation of an implantable cardioverter defibrillator (ICD), is considered.

On the other hand, when the disease is neither preventable nor curable, there is no interest of disclosure at least from the viewpoint of prevention and treatment, and furthermore it may drive relatives to despair. Nevertheless, some relatives ought to think that proper understanding of the disease and their genetic risk is necessary for their autonomy in important situations of life: marriage, reproduction and others. From the viewpoints of marriage and reproduction, disclosure can also be significant for the patient's spouse or betrothed.

In this way, disclosure of the genetic information is beneficial to the family. Is it impossible to find grounds which permit disclosure to them without the patient's consent?

Conclusion

Genetic information has outstanding characteristics: it is shared by blood relatives and remains unchanged throughout life. Therefore genetic information about diseases can often cause discrimination against a person with genetic disease and relatives. This makes genetic information a very sensitive issue compared with other medical information and the importance of protection of the patient's privacy is emphasized. On the other hand, since relatives can benefit by knowing his/her genetic information because of their partial genetic identity, relatives' interests conflict with the patient's.

As mentioned above, it is only in quite limited cases (e.g., protection of important public interest, prevention of serious harm to others etc.) that disclosure of personal information to a third party without the person's consent becomes possible. In those cases, the person's interest that will be harmed by disclosure is prudently balanced against others' interests that will be gained by it. In case of genetic disease, the cause of disease is congenitally possessed by each relative with the same genetic mutation. So in balancing the patient's interest against relatives' interests, the former interest must be respected. However, certain protection of relatives is also considered necessary under the following conditions: when disclosure enables them to avoid serious harm in life and health, and there are no other measures to avoid such harm.

While blood relatives have an interest in knowing the patient's genetic information, it cannot be said that their right to know has a legal basis, if we think that his/her information is only his/her own and that it is not his/her relatives'. Nonetheless, I think it is possible to consider the genetic information of the patient as that of blood relatives own because of their partial genetic identity, only under certain strict conditions: where relatives can gain great

interests, which is indispensable to their lives, by disclosure; where there are no other measures; and where the disclosed genetic information is limited to the minimum necessary for relatives' prevention or treatment. When thinking this way, disclosure of the patient's genetic information to relatives by healthcare providers can be considered to be made based on relatives' own right to know (self information control right).

As mentioned in Section 1, healthcare providers' duty to disclose information about the patient must be directed to the patient himself/herself. Therefore we cannot impose a legal duty to disclose his/her information to relatives on healthcare providers. Besides, it is difficult for healthcare providers to disclose the information to relatives at their discretion. It is possible, however, for them to meet the exercise of the above-mentioned relatives' right to know.

The patient's spouse and betrothed also have a stake, but they are not at risk of the genetic disease. Since they have interest only through the patient, disclosure to them should be put into the hands of the patient.

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