Public Policy and Regulation System concerning Genetic Medicine in Japan

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Abstract:
This paper aims to consider the public policy and regulation system of genetic medicine in Japan from the viewpoint of the ethical and social implications of genetic information. This examination is conducted in line with the relation between genetic analysis as a research area and genetic testing and counseling as a clinical area, government and expert groups, and legislation and guidelines. We can find such problems as possible violation of genetic privacy by clinical genetic testing and non-medical business use of genetic information. On the basis of this consideration, we propose that it is necessary to establish a basic and comprehensive law and official guidelines that would regulate all areas of genetic technology including genetic research, clinical practice, and non-medical use of genetic information.

Introduction

In Japan, the research and clinical application of genetic analysis have advanced since around 2000 as a result of public policy. This paper discusses how public policy in genetic analysis has been established and operated, and examines the background, current situation, main features, and problems of the Japanese regulation system of genetic medicine.
In the Japanese system, the government does not restrict the practice of medical experts; however, it shares the responsibility of regulation with expert groups. On the other hand, expert groups restrict the clinical practice area of genetic analysis including genetic testing by their local rules.

There are three main features of the Japanese regulation system of genetic medicine.
* The regulations are based on guidelines, not legislation.
* The Japanese government restricts only the research area of genetic analysis.
* Expert groups regulate the practical area of genetic testing.

The regulation system usually consists of laws and guidelines as manuals for operation of the law. But in Japan, there is no legislation for genetic medicine, which is regulated by the guidelines of government and expert groups; the former restricts the research area and the latter, the clinical practice area. In short, concerning genetic medicine, especially genetic analysis, the Japanese government shares its role of regulation with expert groups. This is the most notable characteristic of the Japanese regulation system of genetic medicine.

In this paper, we examine the background and current situation from the following viewpoints;
* Actor: Who is involved in making public policy?
* Process: What process has been adopted in making public policy?
* Purpose: Why has public policy been made?
* Problems: What problems does the current system face?

I. The Process of Public Policy Making in Japan

1. Japanese Regulatory Circumstances in the Field of Biomedical Technology

(a) Restriction by Legislation

The strongest point of legislation is to add stipulations of criminal penalty, which assures effective performance of the legislation. In addition, compared to guidelines issued by ministries, legislation can restrict a wider range of cases. Those techniques that could cause harm ethically to the public, e.g., cloning techniques, are claimed to be regulated by legislation. However, since legislation requires vast policy loads and costs to be passed in the Diet, each law or act cannot be revised flexibly in response to the changing situation. In the field of biomedical technology, which develops rapidly, both the government and researchers tend to regard legislation as inappropriate.

(b) Restriction by Guidelines

In Japan, there are two types of governmental guideline. One is the operational guideline for specific laws. The other is the guideline just as a ministerial order. An example of the former is the "Guideline for Handling of a Specified Embryo" (2001), which is based on "The Law concerning Regulation relating to Human Cloning Techniques and Other Similar Techniques" (2000). An example of the latter is the "Ethics Guidelines for Human Genome/Gene Analysis Research" (2001), which is backed by no legislation. The latter type is far more popular than the former type in the biomedical field.

But guidelines can restrict only specific groups, namely stakeholders. As a result, a guideline cannot exert a restriction effect on people outside governance. Moreover, neither type of guideline is equipped with penalty codes in itself. Certainly, the former type of guideline can impose criminal penalty indirectly because those who do not abide by the guideline are regarded as violating the legislation, a basis of the guideline.

On the other hand, in the case of the latter type, ministries give stakeholders administrative orders to comply with the guideline, and put a stop to research projects performed by groups that have been found to violate the guideline, or cut research grants on the grounds that they have violated the guideline.

The most notable merit of guidelines is that establishing guidelines requires much less cost for time and procedure than establishing legislation. Moreover, guidelines can be revised much more easily and more flexibly in response to a changing situation. Consequently, in the field of biomedical technology that is progressing rapidly, the governance of guidelines is preferable to that of legislation. "Ethics Guidelines for Human Genome/Gene Analysis Research" is a typical case in point.

(c) The Role and Influence of the Ministry in Japanese Society

Commonly, the regulation system adopts a hierarchical style, that is, specific legislation is first established and the guideline is then issued in order to operate the legislation effectively and restrict more concrete circumstances (more practical circumstances are regulated by the guideline of the expert group).

As noted above, guidelines are usually established independent of specific legislation in Japan. However, it is said that scientists have a compelling reason to comply with guidelines, particularly in the biomedical field. A biomedical research project is implemented under the examination of the ethics committee of the institution or the central government from the viewpoint of scientific and ethical validity. During the review process, observation of the guidelines issued by the ministries is highly required for the research groups.

Whether scientists or research institutions can obtain a governmental grant or not is a life or death matter for them because large non-governmental grants are few and far between. Thus,

they cannot conduct a research project without a governmental grant. As a result, scientists and research institutions have no choice but to comply with guidelines.

(d) Massive Power of Administrative Organizations and Bureaucrats

In Japan, a centralized political system has been maintained since 1885, the Meiji era. The main engine and operator of the system has been administrative organizations and bureaucrats. And the system has survived since the end of World War II because US GHQ utilized the system as a working force to implement its occupation policy effectively.

Why do administrative organizations have such great power and influence over Japanese society? Commonly, the Diet has the power to establish legislation and to decide the national budget. But Japanese administrative organizations have an influence upon the Diet, in that drafts of legislation and budget are also drawn up by bureaucrats of the ministries.

Finally, administrative organizations hold authority over 10,000 approvals and licenses in various fields. The private sector or research institutions in particular cannot continue their business or research activities without that approval and license.

2. The Regulation of Expert Groups

(a) Another Type of Guideline

Up to this point, we have discussed the regulation system at state level. We have pointed out that in Japanese biomedical technology policy, guidelines are more popular than legislation because guidelines include more benefits in terms of costs for establishment and flexibility to change. In addition, another reason is the great power of Japanese administrative organizations and bureaucrats.

There is another type of guideline, which is the guideline issued by expert groups and this is called "a local rule." Examples of expert groups are the Japan Society of Human Genetics (JSHG), the Japan Society of Obstetrics and Gynecology (JSOG), the Japan Medical Association (JMA), and so forth. Guidelines of expert groups have a great influence on their members particularly in the area of medicine including genetic medicine. Thus, it can be said that regulation by the guidelines of expert groups is the "second public policy."

(b) The Restrictive Effect of the Guidelines of Expert Groups

As noted before, the government is sharing roles with expert groups and that is the most notable characteristic of the Japanese regulation system of genetic medicine. The guidelines of expert groups have a great influence on the field of biomedicine, just like government regulation.

Of course, the guidelines of expert groups have less influence than those of the government because expert groups, unlike the ministry, have no official power. But expert groups maintain their influence and compel their members to comply with guidelines, taking advantage of the authority to approve and dismiss membership and warn and admonish those members who do not obey the rules.

For scientists and clinical doctors, it is very important whether or not they hold membership of an expert group. In fact, it is very difficult for a clinical doctor who does not have membership of an expert group to practice new medical technology such as genetic diagnosis. Moreover, for scientists who do not hold membership of an expert group, it is impossible to obtain grants from the government or private foundations and to conduct large research projects.

II. The Guidelines for Genetic Medicine in Japan

1. History and Background of Guidelines in Japan (1995 - 2003)

(a) Major Guidelines

Since 1995, many guidelines and views on genetic medicine have been issued as shown in the following chart. Among them, the main guideline for research is the "Ethics Guidelines for Human Genome/Gene Analysis Research," and the main guideline for clinical practice is "Guidelines for Genetic Testing."

Table: The History of Guidelines for Genetic Medicine (1995-2003)

1994	"Guidelines for Genetic Counseling and Prenatal Diagnosis" (The Japan Society of Human Genetics: JSHG)
1995	"Guidelines for Genetic Testing, using DNA analysis" (JSHG)
1997	"Universal Declaration on the Human Genome and Human Rights" (United Nations Educational, Scientific and Cultural Organization: UNESCO)
1998	"International Guidelines on Ethical Issue in Medical Genetics and Genetic Service" (World Health Organization: WHO)
1998	"Guidelines for Research and Clinical Application of Genetic Diagnosis of Familial Tumors" (The Japanese Society of Familial Tumors)
1998	"The View on Maternal Serum Marker Testing" (JSHG)
1998	"The View on Preimplantation Genetic Diagnosis" (Japan Society of Obstetrics and Gynecology: JSOG)
1998	"The View on Clinical Application Range of IVF and Embryo Transfer" (JSOG)
1999	"The Comment on Maternal Serum Marker Testing" (JSOG)
1999	"Guidelines for Bioethical Problems Associated with Genetic Analysis Research" (Health and Welfare Ministry)
2000	"Fundamental Principles of Research on the Human Genome" (The Bioethics Committee of the Council for Science and Technology)
2001	"Guidelines for Genetic Testing" [Draft] (Eight Genetic Medicine Related Societies)
2001	"Ethics Guidelines for Human Genome/Gene Analysis Research" (Ministry of Education, Culture, Sports, Science and Technology, Ministry of Health, Labor and Welfare, Ministry of Economy, Trade and Industry)
2003	"International Declaration on Human Genetic Data" (UNESCO)
2003	"Guidelines for Genetic Testing" (Ten Genetic Medicine Related Societies)

(b) Sharing Roles: Government Sharing Roles to Regulate with Expert Groups

In the Japanese regulation system of genetic medicine, the research area is regulated by

guidelines of the government, and the clinical area is regulated by those of expert groups; this indicates the sharing of roles by two parties. The role of an expert group guideline is to regulate clinical practice that is not covered by governmental guidelines, and includes not only practical details, but also ethical codes. As a result, the expert's rules restrict the ethical attitude of the members. It is the major feature of the Japanese system that an expert's rules take the partial role of public policy on behalf of the government

(c) The Background of Policy Making

Why does the Japanese government not establish guidelines for clinical genetic medicine? In our opinion, one answer lies in the organizational structure of the Japanese government, especially of the Ministry of Health, Labor and Welfare (MHLW), which has a typical vertical structure in which each section is separated independently.

MHLW has many departments such as pharmaceutical affairs, social insurance, medical affairs, etc. In addition, they are divided into certain sections. When it comes to the medical department, there are sections for each organ such as the liver, heart, etc. Each section is devoted to its own area and therefore no section covers such a comprehensive area as genetic medicine. Furthermore, bureaucrats of the ministry have little interest in those areas that have not caused any problems or require long-term planning for their policy making.

Around 2000, genetic analysis research was promoted on a large scale by the government as one of the science and technology policies called the "Millennium Project." The Japanese government expected that when genetic medical technologies are applied widely for clinical practice such as genetic testing or pharmacogenomics, enormous economical benefit will be produced. As a result, the government established a comprehensive guideline for genetic analysis research in 2001.

2. "Guidelines for Genetic Testing"

(a) The Background to Establishing the "Guidelines for Genetic Testing"

In 1995, two guidelines for genetic testing were issued by JSHG, mainly because the number of genetic diseases that could be identified by genetic testing had increased rapidly. The practice of genetic testing requires special consideration before and after testing, such as practicing genetic counseling and careful handling of human material. Special rules for genetic testing had to be prepared to maintain and develop the quality of genetic testing in Japan.

In 1998 and 1999, some guidelines for the practice of genetic testing that dealt with reproduction, such as maternal serum marker testing, were issued by certain expert groups. The government, however, had little interest in genetic testing because it was regarded as low priority even though it would be used widely for clinical practice in the future.

Therefore, in 2000, eight expert groups (afterward, ten groups) led by JSHG decided to establish a comprehensive guideline for genetic testing because they could not rely on the government. Around 2000, there were some model guidelines in the world, e.g., the "International Guidelines on Ethical Issues in Medical Genetics and Genetic Service" (1998) and "Review of Ethical Issues in Medical Genetics" (2000) by the WHO, which were the basis of the Japanese "Guidelines for Genetic Testing." The contents of the WHO guideline, however, were not drawn upon directly. The working group took into consideration the fact that Japanese society had a characteristic concept of family and genetics when the "Guidelines for Genetic Testing" were

established.[1]

(b) Discussion in the Process of Establishing the Guideline

Were there any conflicts on the perspectives among the members of the working group in the process of establishing the "Guidelines for Genetic Testing"? Even though the concept of genetics varies depending on the society, community, or person, there were almost no conflicts.[2] The members of the working group shared the sense of crisis about the inadequacy of the regulation system for clinical genetic testing at that time.

One point that was discussed, however, intensively as a controversial point is the disclosure of a genetic testing result to the relatives without the client's consent. Few people insisted that no genetic testing result must be disclosed even to the relatives without the client's consent (see "Guidelines for Genetic Testing" III-6 and Note-5).

Incidentally, some disability groups took part in the process of establishing the guideline in order to reflect various opinions in the contents, though they did not participate in the working group. They required JSHG to disclose the draft of the "Guidelines for Genetic Testing," and seemed to accept it after the disclosure.[3]

(c) Current Situation of Genetic Testing and Counseling

Expert groups have established and operated the regulation system in order to develop medical practices in the specialized medical area of genetic medicine. For example, genetic testing must be conducted under the supervision of a clinical geneticist, and genetic counseling is regarded as being practiced by a certified clinical geneticist or genetic counselor. Both licenses are certified by JSHG and the Japanese Society for Genetic Counseling. This is stipulated in the "Guidelines for Genetic Testing," which is just a non-official guideline. However, for hospitals that have no licensed staff, it is actually impossible to practice genetic testing. In particular, large-scale hospitals in which most genetic testing is practiced realize that employing a licensed member of staff is an essential requirement.

From the viewpoint of expert groups, the authority to certify and give the license of medical specialist is the most effective measure to have the members comply with the guideline.

III. The Problems of the Current Japanese Regulation System

1. Restrictions of Expert Groups Facing Limits

As mentioned above, in the field of genetic medicine, the regulation system operated by expert groups has functioned successfully in maintaining and developing the quality of genetic medical practice up to now. But it is also a fact that the effect of the system is facing limits.

Among certain factors, expanding of the application of genetic testing is the biggest factor, which causes the functional failure of the regulation system. Genetic testing has been practiced mostly at large hospitals such as university hospitals. Therefore, expert groups have been able to restrict the practice of the technology more easily because those medical institutions comply with

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[1] From an interview with Prof. Yoshimitsu Fukushima in 17th July 2007, who is the director of the division of clinical and molecular genetics in Shinshu University Hospital and has been the central figure of working group of the guideline.

[2] From an interview with Prof. Fukushima in 17th July 2007.

[3] From an interview with Prof. Mariko Tamai in 17th July 2007, who is the associate professor of Shinshu University School of Health Science and was a member of working group of the guideline.

the related guidelines.

Genetic testing technology has been downsized as well as sophisticated. As a result, small individual hospitals can practice genetic testing, even if they do not employ a certified clinical geneticist. But expert groups do not have the capacity to check that each member complies with the guideline.

In addition, the application of genetic testing is broadening to non-clinical purposes, that is, a non-therapeutic purpose or a commercial purpose. The expansion has driven the management capacity of expert groups to the limit.

2. Expanding of Genetic Testing Practice

We believe that proliferation of the practice of genetic testing provides the main background to the limit of expert groups' governance. More strictly, the technology of genetic testing has become easy to practice even by smaller medical facilities.

But nowadays, genetic testing is practiced for non-clinical purposes. For example, in Japan, we can see some websites established by venture companies. These companies advertise that they can test an applicant's tendency to gain weight by analyzing his/her genetic information. An applicant requests a genetic testing kit from a test company and obtains his/her own tissue from the mouth with the test kit. He/she fills out the questionnaire and sends back the set. After a week, the genetic test result is sent from the test company. Communication between a test company and an applicant is mostly by mail and e-mail. In this situation, the practice of genetic counseling is disregarded; therefore, the clinical usefulness, accuracy, or validity of the test result is not taken into consideration before a test is conducted.

3. The Limit on Protecting Privacy of Individual Genetic Information

The current regulation system for genetic testing faces another significant problem. That is, the current system cannot protect patients or subjects from having their genetic information violated. In 2003, the "Private Information Protection Law" was enacted in order to protect individual privacy information. But the case of using private information for academic research is exempt from the restriction of the law. As a result, there is no rule in cases where private information is used for academic research purposes.

Individual medical information for clinical use that is usually stocked in hospitals is protected by the guideline[4] based on the "Private Information Protection Law." However, medical information is treated just like regular private information such as a telephone number or an address. Therefore, even if the guideline is violated, only a lighter sanction is given. Genetic information, especially that regarding a single gene disorder, requires the highest level of legislative protection among medical information. Although the government's guideline indicates that in handling genetic information, the guidelines issued by related expert groups have to be considered[5], there is no guideline other than the ten genetic medicine-related societies' guidelines to protect the privacy of genetic information, and the guidelines can give no official sanction.

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[4] "Guideline for Appropriate Handling of Private Information in Medical and Nursing Care Related Providers"(2004)

[5] "Guideline for Appropriate Handling of Private Information in Medical and Nursing Care Related Providers" I-10: Appropriate Handling of Genetic Information in The Case of Medical Care

Conclusion

Based on our consideration of public policy and the regulation system concerning genetic medicine, we insist that now it is time for Japanese society to establish basic and comprehensive legislation for genetic testing.

While the research field of genetic analysis is restricted by the government guideline, the clinical practice field such as genetic testing is restricted by the guidelines issued by expert groups. We realize that the government shares a regulatory role with expert groups in the field of genetic medicine, and has not attempted to establish a comprehensive regulation system.

As access to the technology of genetic testing has become easier, non-medical companies increasingly conduct genetic testing for non-clinical purposes as business. However, expert groups have no way of controlling these companies, because the guidelines of expert groups have no regulatory power for outsiders. Since there is no effective regulation to protect private genetic information, individual genetic privacy could be violated.

Then, what is an appropriate regulation system for genetic medicine?

First of all, we should establish a basic and comprehensive law that regulates all areas of genetic technology including genetic research, clinical practice, and non-medical use of genetic information. The fundamental ethical stance of the application of genetic technology for human beings should be presented through the basic law. And it is necessary to impose criminal liability if the law is violated.

Secondly, official guidelines for each area, which are linked firmly with the basic law, should be established. Those official guidelines could be modified as related technologies develop. Not only governmental personnel and academic societies, but also citizens, are required to participate in the process of their making and modification.

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