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## Editorial: Special Thematic Issue on Japanese Bioethics and its Structure

This special double issue of *EJAIB* examines the structure of Japanese bioethics using a three levels structure analysis. This idea is to search for the best solution for ethical problems by reaching the point of equilibrium among three levels, i.e. concrete moral judgments, intermediate principles and basic concepts or principles. The papers come from a research project conducted under the leadership of Prof. Takao Takahashi at Kumamoto University. A variety of topics in bioethics are explored providing a review of the state of bioethics in Japan. Comments are welcome!

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## Three Levels Structure Analysis and its Significance

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### Abstract

Bioethical principles are said to be universal, and this contributes to making bioethics global. Those principles are abstracted from culturally different practices. However, they are intermediate. For example, what underlies the principle of Respect for Autonomy can be Kantian deontology or Mill's utilitarian liberalism, and we apply them to concrete problems. That is to say, those principles exist between the basic level of philosophy and the

practical level of medical practices. The method of reflective equilibrium, which is famous in John Rawls' book *A Theory of Justice*, has two roles. One is to search out the point of equilibrium to find suitable intermediate principles, while the other is to analyze the arguments from the viewpoint of three levels structure analysis.

By three levels structure analysis we can judge the structure of arguments as for example the so-called top down, bottom up or a synthesis of the both. Moreover, three levels structure analysis teaches us that the first level is deeply connected with the third, i.e. the basic philosophical level. According to three levels structure analysis, the characteristic of the structure of the arguments in ethical committees or among medical professionals in Japan is, in general, that the third level are seldom explicitly referred to. Researchers of philosophy refer to the third level, but they tend to neglect cultural differences of medical practices, and rarely look back at Japanese traditional thoughts. Therefore, the arguments of medical professionals and philosophers often don't meet. It also shows the significance of the three levels structure analysis.

### What is three levels structure analysis?

One of the classifications of the structure of arguments, not confined to bioethical arguments, is to define something as a "top down" approach vs. a "bottom up" approach. This classification depends upon the characteristic of the grounds of the arguments. Roughly speaking, a top down approach is based on universal principles or abstract concepts, which are applied to concrete problems, while the bottom up approach tries to solve the problems appealing to customs, current beliefs, in short, practices. But the difference between top down approach and bottom up approach has ambiguity that cannot be ignored, for among the universal principles the top down approach depends upon both an abstract basic principle such as the Kantian categorical imperative "treat humanity always at the same time as an end and never merely as a means to an end" and a concrete principle such as "respect for patient's autonomy" in bioethics. A bottom up approach aims to not only induce concrete principles but apply them to the problems, therefore, its route is, first, from bottom to the principles or norms (bottom up), then from the principles or norms to the problems (top down).

Hence, it will give rise to misunderstandings to grasp the structure of arguments by means of the difference of top down and bottom up approach. Here I propose an alternative framework, i.e. three levels structure analysis, to grasp the structure of bioethical arguments (note 1). The first level contains concrete moral judgments concerning bioethical problems, e.g., "it is not good to produce a human clone", "on certain conditions we can permit 'death with dignity'". In a broader sense, this level contains practices concerning medicine and life sciences. Second level contains concrete principles and norms that judgments of first level depend on or presuppose, e.g., "respect for autonomy", "necessity of informed consent", "do not harm others", or more concretely a

"ban on manipulation on the germ of human life". The third level includes basic concepts and principles that are grounds of the principles or norms of second level, e.g., meaning or definition of the second level principles, and the priority among them, basic concepts of "good", "wrong", "just", "liberty", "equality". This level also contains abstract principles, such as Kant's categorical imperatives. By means of three levels structure analysis we can clarify the level of the principles, concepts and norms, which are referred or presupposed in the arguments concerning bioethics, and we can comprehend the structure of those arguments.

### Three levels structure and the method of Reflective Equilibrium

The idea of three levels structure analysis comes from the method of "Reflective equilibrium", which is well known through J. Rawls' book *A Theory of Justice*. It is the method of finding the best solution for ethical problems by reaching the point of equilibrium among three levels, i.e. concrete moral judgments, intermediate principles and basic concepts or principles. It lays emphasis on coherence among three levels, so at its base there is a coherence theory of truth.

Although three levels structure analysis derives from the method of reflective equilibrium, it is used to analyze the structure of the bioethical arguments in Japan rather than finding the solution for bioethical problems.

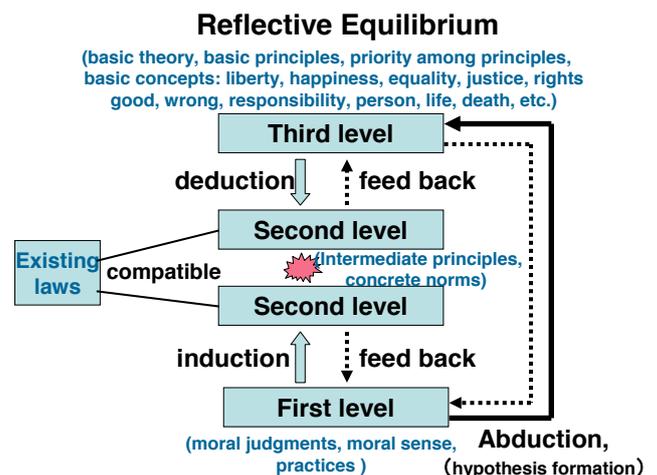


Figure 1: Reflective Equilibrium

J. Rawls used this method in his famous book *A Theory of Justice*, but in the early twentieth century C.S. Peirce had already proposed the outline. However, this figure doesn't show the original version Rawls used in his book. It shows the application of Reflective Equilibrium, strictly speaking, "wide Reflective Equilibrium", to applied ethics; therefore, this figure contains the condition of compatibility with existing laws. Reflective equilibrium is the movement of searching for the principle most suitable for solving the problem. By way of induction we can get an intermediate principle compatible with existing laws, and through abduction (hypothesis formation, interpretation) and deduction, we will acquire another intermediate principle compatible with existing laws. If both principles agree, we have achieved the

equilibrium, but if they disagree, we have to amend the content of each level to reach the equilibrium. Reflective equilibrium has two roles: To find a suitable principle by searching after the point of equilibrium of three levels. This is the main role, i.e., the role of finding a suitable intermediate principle. Second, to analyze the arguments from the viewpoint of three levels analysis. For example, an argument can be classified as having the pattern of setting the principles of three levels as bases. Beauchamp and Childress' bioethical principles can be classified as second level principles.

From the three levels analysis, we can know the position or level of the well-known bioethical principles proposed in *Principles of Biomedical Ethics* by Beauchamp and Childress, i.e., "Respect for autonomy", "Non-maleficence", "Beneficence" and "Justice". They are principles of the second level. They are supposed to be universal which are abstracted from culturally different medical practices; however, they have to be backed up by more abstract concepts or principles of the third level. Therefore, they are in an intermediate level.

**The position of Beauchamp & Childress's Principles of Biomedical Ethics**

Example: Respect for autonomy

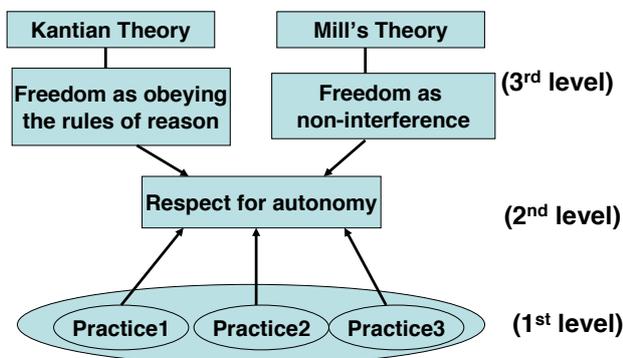


Figure 2: Example of application of three levels analysis to the principle of autonomy

According to Kant, freedom consists in obeying the rules of reason, and freedom of daily practices is as good as freedom of animals. According to Mill's theory, only restriction to the liberty of an individual is "not to harm others". What is stated here applies to other biomedical principles such as non-maleficence, beneficence, justice and human dignity.

We can reach the third level from the first level by way of abduction or interpretation. The reason why the inference from the first level to the third level is possible is that there is a close connection between them. Until now researchers have concentrated their attention on the relationships between first and second level, or second and third level. However, first and third relationships, or equilibrium of first, second and third are worth investigating to clarify the moral practices of first level. When Beauchamp and Childress proposed four principles, they abstracted them from various medical practices. The four principles are regarded as common to diverse practices. At the same time, the basic level, i.e. third

level, is left untouched to be considered in each country. The close connection of the first level with the third level is that the practices of the first level reflect the abstract concepts or principles of third level, or principles of third level function on first level. Analogically, from physical phenomena, by abduction, we make a hypothesis or discover the fundamental principles, because those principles work in physical phenomena.

**The structure of the arguments concerning research of human embryonic stem cells**

As an example of three levels structure analysis, I propose the analysis of the argument at a committee concerning research on human embryonic stem cell (ES cell) in Japan. In order to consider the structure, several main and subordinate principles of bioethics which have been stated or presupposed in the interim report of the Subcommittee of Human Embryo Research released in 2000 will be interpreted. The framework or presupposition of the argument from an interim report is more accessible to consideration, as such arguments do not appear in the final reports. Though the interim report is not the most recent version, it is useful because it represents the typical manner of the arguments in Japanese bioethical committees.

**First level**

Here are concrete moral judgments that members of the committee presuppose, e.g. "Destruction of human embryos is murder and cannot be permissible.", "Human embryos are not yet human beings, so we can justify the research on them.", "It is morally wrong to produce human embryos for research but not so concerning utilizing them."

**Second level**

We can read about intermediate principles in the interim report. This level often consists of plural layers as shown below. (Here I omitted the principle of the necessity of social consensus.)

(A) **Respect for Human Dignity**

- Prohibition against dealing with (e.g. killing, selling, purchasing, etc.) the germ of life of a human being (e.g. embryo, stem cell, etc.) as only a means
- Prohibition against impairing the identity of a species of human beings, e.g. making or producing a hybrid species.

(B) **Safety**

- For the time being, a prohibition on human embryonic stem cell clinical research

(C) **Donor Rights**

- Necessity of Informed Consent in the case of donation of fertilized eggs
- Protection of donor privacy

(D) **Right to Research**

(E) **Usefulness of Research**

(F) **Disclosure of Research Information**

**Third level**

In the interim report the basic principles or concepts are not discussed explicitly. The only thing

we can do as to the third level is to guess what underlies second level, e.g. the meaning of human dignity, moral status of a human embryo, the ground of right or obligation, definition of person, the meaning of liberty and priority among principles. In figure 3 below I suggest third level principles and the concepts that the second level presupposes. For example, what underlies the principle of second level "Prohibition against dealing with (e.g. killing, selling, purchasing,

etc.) the germ of life of a human being (e.g. embryo, stem cell, etc.) as only a means" is the Kantian categorical imperative, "Treat humanity always at the same time as an end and never merely as a means to an end". The priority in the interim report seems to be that self-determination of the donor and the freedom of research are not almighty, but they are restricted by other principles such as the do no harm principle.

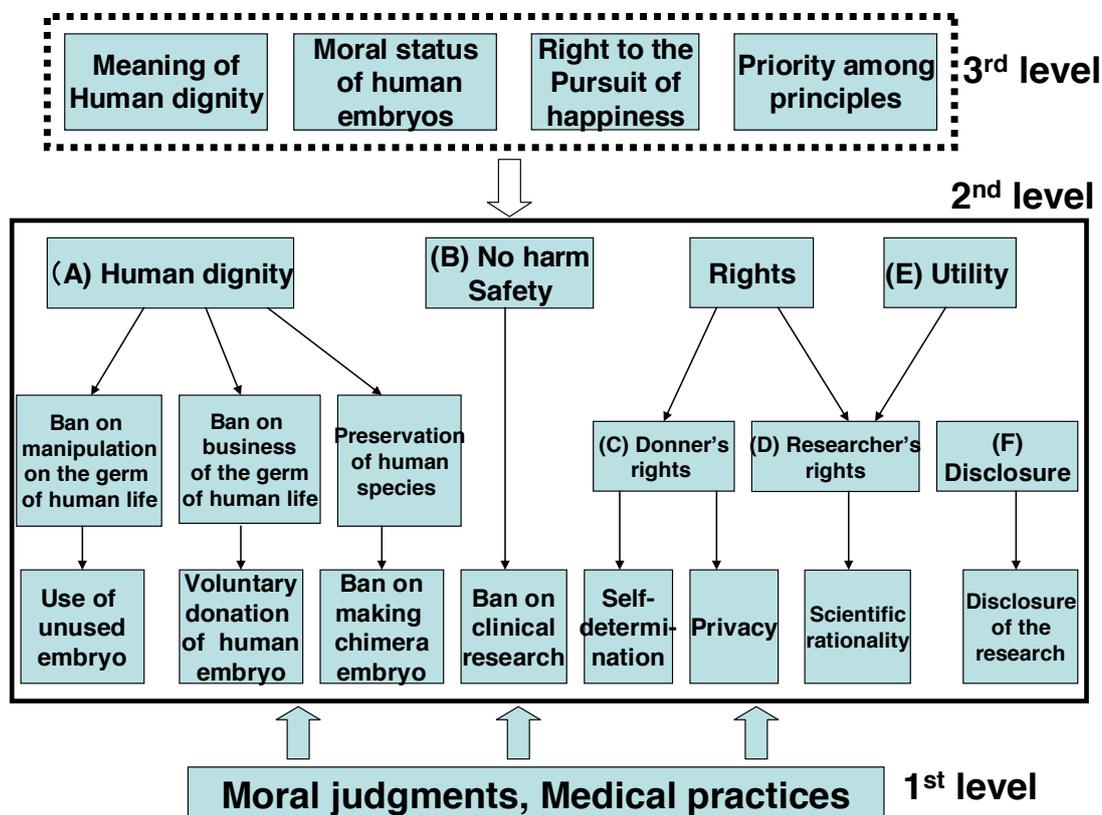


Figure 3: The structure of bioethical arguments in Japan for Research on human embryos

#### The significance of three levels structure analysis

Three levels structure analysis reveals the latent structure of the arguments. The significance of this analysis is as follows: First, it reveals the relationships between second level and third level principles. It may be useful to recognize the difference between second level and third level, because in order to appeal to second level principles to solve bioethical problems we have to interpret those principles usually by referring to the principles or concepts of third level which are very often implicitly or unconsciously presupposed. If we recognize the difference between second and third principles, we will know what lies deep in our mind, and moreover, we can check our way of thinking.

Second, second level principles, especially Beauchamp and Childress's bioethical principles, are standardized, i.e. they are supposed to be universal; however, on first and third level, differences of culture, tradition, custom, religion, in short, differences of practices are remarkable. What's more, first level and third level have a close connection with each other. That is, the third level difference, e.g. priority between Kantian concept of liberty and Mill's concept of liberty, appears on first level as the difference of the use of "autonomy" and this will have a considerable influence on medical practices. In this way, moral judgments of

first level implicitly or unconsciously reflect third level basic concepts.

To find universal bioethical principles is one of the important tasks of bioethics, and to apply those principles to healthcare settings in culturally different countries is another important task. The three levels structure analysis tells us that in order to apply intermediate principles suitably the research on third level concepts as well as first level moral judgments are needed.

Third, as stated above, the characteristic of the structure of the arguments in ethical committees is that in those arguments principles or concepts of third levels are seldom explicitly referred to. The situation is almost the same with regard to the arguments among medical professionals. At the bottom, i.e., first level, there are moral judgments or moral sense rooted in medical practices in Japan. Medical professionals refer to and interpret medical practices, and try to apply intermediate principles to the concrete situations. At that time, they interpret them by unconsciously appealing to third level basic concepts. Without taking third level seriously, ethical committees and medical professionals may solve the individual problems separately, but they cannot grasp the total view of the problems and the solutions are liable to be ad hoc.

Researchers of philosophy or ethics often, in their arguments, refer to third level, e.g., Kantian philosophy, J. Locke's definition of person, Mill's theory of liberty, or H. Jonas's concept of responsibility. They deduce second level principles from third level; however, they often neglect cultural differences of medical practices. Moreover, the third basic level they appeal to is mostly rooted in western philosophy. Generally speaking, Japanese philosophers search after their theoretical background in Western Europe rather than looking back in Japanese traditional thought.

Therefore, medical professionals and philosophers often have no other common ground to talk on than second level principles. It is true that it is desirable to have common concepts and principles, I think this is far from an ideal situation. Second level principles are to be refined or interpreted to be applicable to the problems of healthcare setting. As I indicated, the difference of first level reflects that of third level, therefore the research on the concepts of third level must have much to do with the medical practices of first level. Though consideration on the concepts rooted deep in the culture is required in addition to the concepts of Western philosophy. Otherwise, arguments of medical professionals and philosophers will not meet. Such a problem doesn't seem to be confined to Japan. Here also is the significance of the method of three levels analysis.

#### Note

We use the word "level" instead of "dimension", "layer" etc. This "level" differs from R.M. Hare's "two levels". Hare's first level is the level of intuition and contains the criteria used intuitively in moral judgments. Rights belong to first level. From a utilitarian viewpoint, first level is the level of rule utilitarianism. The second level in Hare's theory deals with the difficult problems which cannot be solved at first level principles. At second level we solve the problem by the calculation of act utilitarianism.

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## Theoretical debates on methodologies in clinical ethics: Top-down, bottom-up, and clinical pragmatism as a third model

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#### Abstract

In order to evaluate the three levels structure analysis, a clinical ethics group conducted a literature review in an effort to clarify the relational structure among them. By following debates on methodologies in clinical ethics, the group focused on a comparison

of the top-down vs bottom-up approaches, which would appear on the surface to be in contrast. A methodology called clinical pragmatism has been proposed to consolidate the two approaches. From the viewpoint of clinical pragmatism, respect for the patient's autonomy, for example, would mean that, while maintaining the central importance of the patient's value judgment, the patient shares the context specific to his or her case with family and medical professionals. The principle is embodied in the process of creating the narrative together in that shared environment.

**Keywords:** top-down vs bottom-up debate, four principles, casuistry, case methods, clinical pragmatism

#### Introduction

One approach to clinical ethics uses the so-called four main principles as the basis for handling moral dilemmas in clinical practice. This theory has been criticized as principlism, implying that it is a top-down theory that fits the four principles to actual clinical settings. A contrasting approach is based on casuistry. Rather than defining clinical ethics as an applied discipline in which principles are fitted to each clinical case, the methodology of casuistry relies on case methods based on knowledge accumulated from clinical cases. Casuistry is thus not a deductive, top-down method based on the four principles of Beauchamp and Childress, but is a bottom-up approach because it begins with an actual case. An archetype of the top-down vs bottom-up debate is provided here.

#### Theory of four principles

The four main principles of medical ethics are often used to handle moral dilemmas in clinical practice. The theoretical standpoint of this method does not adopt a stance based exclusively on either utilitarian or deontological philosophy, but is a compromise between the two. This approach attempts to guide behaviour in individual clinical cases by considering each concrete situation, making adjustments as to which principle to prioritize, and exercising ethical judgment on each moral dilemma.

The four principles are: 1) respect for autonomy, 2) beneficence, 3) non-maleficence, and 4) justice. Philosophic principles such as utilitarianism and deontology do not recognize exceptions; they are considered strong principles specifically because they do not entertain exceptions. T. L. Beauchamp and J. F. Childress together described the four principles, which they consider *prima facie* principles, i.e., tentative principles that are self-evident at first glance (*prima facie*) and have a binding force only to the extent that they do not conflict with other obligations. Therefore, applying the four principles to specific clinical cases requires a balance between the specifications of each particular situation and the four principles<sup>1</sup>.

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<sup>1</sup> Tom Beauchamp and James F. Childress, *Principles of Biomedical Ethics*, 4<sup>th</sup> ed (1994); 28-37.

### Criticism as principlism

As just described, the four principles appear to be tentative principles that depend upon a concrete clinical situation; the four principles are balanced as their relative importance in that situation becomes clear. However, the more one analyzes the pros and cons of each principle, the more obvious the abstractness of these principles becomes, making it difficult to prioritize one principle over the others. The theory of four principles is therefore difficult to use as concrete behavioural guidance.

This theory is occasionally criticized as principlism, a top-down theory in which the four principles are fitted to individual clinical situations. Because this theory was developed primarily at Georgetown University, some people ridicule it by calling it the "Georgetown mantra," as though ethical issues in clinical practice could be solved by simply repeating the four principles like a Buddhist chant.<sup>2</sup>

Beauchamp himself asserted that it is necessary to "specify what each principle intends, in order to match the needs and demands coming from a specific situation, to overcome the lack of contents in the principles, and to face moral conflicts."<sup>3</sup> It is important to understand that these four principles are not a silver bullet that, when applied, immediately resolves moral dilemmas. Rather, these principles are meaningful only if each case is carefully considered.

### Situation ethics

Even before criticism against principlism grew, Joseph Fletcher in 1966 proposed the theory of situation ethics, emphasizing that the moral dilemma of an actual living human being should be treated on an individual basis and in detail, rather than basing action on abstract principles. As symbolized by the slogan "circumstances alter cases," the situation ethics of Fletcher was the historical dawn of the "ethics of cases" as a counterweight to "ethics of principles."

The principles described thus far are too abstract for specific situations, and cannot guide behaviour by themselves. It is no exaggeration to say that no two situations faced by medical professionals are exactly alike. Treating medical ethics issues as complex problems requires one to consider each case within its unique context. Situation ethics is sometimes called contextualism because determining the best action to take while the situation is unfolding depends on the context.

### Situation ethics and ethical relativism

From the perspective of situation ethics, each individual agent should seek the highest good in the current situation and make decisions responsibly, rather than starting from abstract principles. This perspective can be considered a criticism of the legalism hiding in principlism. That is, principlism

emphasizes the importance of principles and rules, thus it can inadvertently create dependence on these rules. In contrast, situation ethics stipulates that individuals should make the best judgment possible in a current situation; however, objective, universal criteria for this best judgment are lacking. Thus, decisions can be significantly influenced by the agent's personal views.

Because situation ethics emphasizes the importance of judgments made by individuals, it tends to overemphasize the specific situation inseparably linked to the case. If the uniqueness of each case is magnified as a result, we cannot deny the possibility that situation ethics may become associated with ethical relativism, which asserts that no objective, universal standard of value exists in ethical judgment.

### Casuistry

In contrast to applied ethics, in which principles are fitted to individual clinical cases, another approach attempts to establish clinical ethics based on casuistry. The methodology of casuistry relies on case method, which involves the accumulation of individual clinical cases. Casuistry originally developed as a rhetorical device during Greek and Roman times. When adapting religious or moral laws to individual behaviour, difficult cases emerged due to contradictions of these laws. When several moral duties conflict with each other, these laws are incapable of determining correct behaviour. Casuistry tried to solve the problem by analogical analyses, comparing the current difficult case with similar cases that were resolved in the past. Thus, casuistry is an attempt to solve current problems based on paradigm cases. Casuistry in modern clinical ethics adapts the same methodology to ethical issues in clinical practice.<sup>4</sup>

### Casuistry and principles

What positions do principles occupy in casuistry? Albert R. Jonsen, one of the authors of "Clinical Ethics" (1982) and a former member of a U.S. National Commission on Bioethics, takes the stance of a moderate particularist, recognizing the action-guiding character of principles. This position differs from that of his colleague, Stephen Toulmin, who is also a casuist and was a consultant and staff member of the same national commission. Toulmin takes the stance of a radical particularist, stressing the importance of individual cases<sup>5</sup>. According to Jonsen et al., however, casuistry is "not a complete substitute for principles, but a necessary supplement for the sake of expansion and progress of principles."

Regardless, casuistry does not employ a deductive top-down method such as the approach based on the four principles of Beauchamp and Childress; rather, it is a bottom-up method that always begins with a

<sup>2</sup> K.Danner Clouser and Bernerd Gert, "A Critique of Principlism," *The Journal of Medicine and Philosophy* 15 (April 1990) 216-36.

<sup>3</sup> Tom L. Beauchamp, "Principlism and Its Alleged Competitors," *Kennedy Institute of Ethics Journal* 5 (1995) 181-89.

<sup>4</sup> Albert R. Jonsen, "Casuistry as Methodology in Clinical Ethics," *Theoretical Medicine* 12 (1991) 297-98; and Albert R. Jonsen, Mark Siegler, and William J. Winslade, *Clinical Ethics*, 5<sup>th</sup> ed. McGraw-Hill 2002, pp.1-12.

<sup>5</sup> Stephen Toulmin, "How Medicine Saved the Life of Ethics," *Perspectives in Biology and Medicine* 25(1982)736-50.

particular case.<sup>6</sup> Their case method approach entails the following steps. (1) Organize issues of the case at hand based on paradigm cases and analogies. (2) Identify moral dilemmas and their characteristics for comparison against general maxims, which are not absolutely inflexible as in principlism. (3) Never seek strict theoretical coherence as in geometric proofs, even if, after comparing against general maxims the problem turns out to be difficult to solve and conflicts arise with these principles. (4) Evaluate not the certainty but the probability of various opinions by taking into account the delicate circumstances of the current situation. (5) Try to accommodate as many arguments as possible and analyze them analogically, to derive a practical resolution as phronesis, not as strict episteme.

Based on this casuistry attempt to gain phronesis, Jonsen et al. propose four topics for case analyses: 1) medical indication, 2) patient preferences, 3) quality of life, and 4) contextual features. These four topics are not principles; rather, they function as a check sheet to organize the many facts involved in a given case to evaluate their importance from various angles.

### Casuistry and the four principles theory

Looking at these four topics of casuistry, however, we can see that they incorporate the four principles of Beauchamp and Childress, but in different forms. Respect for autonomy is included in the second topic, patient preferences. Beneficence and non-maleficence are included in the topic of medical indication as risks and benefits of treatment as well as its futility. Justice is included in contextual features by taking into account the distribution of medical resources and public benefits. In fact, Jonsen himself mentions in *Clinical Ethics*, "Our methods are not to negate the importance of principles or theories. In fact, without them, these methods probably would not work." He also mentions that his book "repeatedly cites important literature such as the *Principles of Biomedical Ethics* by Beauchamp and Childress." However, even though the four principles are certainly important, Jonsen's method is more closely linked to clinical cases than to abstract principles and theories. For example, on the subject of respect for autonomy, he argues that because this is a broad and general expression, it is still too abstract for casuistry as applied to clinical ethics. His point is that the principle should be embodied at the level of maxims, such as "respect a patient's intention that has undergone careful consideration" or "respect a patient's value judgment."

### Top-down vs bottom-up—beyond its conflict

We have so far observed that the four-principle theory of Beauchamp and Childress was criticized as principlism by Bernard Gert and Danner Clouser, and that casuists also criticized its deductive top-down method. In response, Beauchamp and Childress offered the following counter-argument, which could

be considered a step toward compromise with casuistry, "We think that both casuists and principlists should agree to the following before considering cases and policies. That is, (1) There are virtually no principles that were formed without referring to concrete experiences of cases. (2) There are virtually no cases that became paradigm cases without any relationship to general rules."

For a basic theory of clinical ethics, which should be the starting point, top (basic concepts and principles) or bottom (concrete cases and situations)? It is probably a mistake to ask this question. Although casuistry and the four-principle theory differ as to whether we should use maxims as guidance or principles, they are not entirely different in the following sense. Both approaches employ a method that establishes rules and propositions with some universality, and using these as a guiding thread, they attempt to clarify the thought process by organizing complex matters.

### Clinical pragmatism

A methodology called clinical pragmatism has been proposed to consolidate the two approaches.<sup>7</sup> Pragmatism is derived from the Greek word *pragma* (plural, *pragmata*) meaning things that are already done and behaviour. It is based on the criticism of formalism and the idealism of mainly Kantianism origin. In pragmatism, moral goodness is not something transcendental (roughly equal to ideological or abstract a priori). Although the approach acknowledges several shortcomings of utilitarianism, it regards utilitarianism highly for seeking goodness in human desires and preferences, as well as in the concreteness of social lives, that is, it only exists in daily life. In other words, moral goodness is not an abstract or formalistic (and sometimes annoyingly intrusive) concept that is applicable to everyone. Rather, it is always something concrete and unique; therefore, justice and kindness cannot be sought or obtained in a generic form. This is because we are not generic humans. Each of us is a unique human being struggling with concrete matters; thus, it is impossible that one's happiness is identical to the happiness of other people.

Therefore, even from the standpoint of pragmatism, those surrounding a patient such as family members and medical professionals should not impose their values on the patient. It is important to support patients as they clarify their own life philosophies and values and share in that process by adopting an attitude of active waiting. Accordingly, people surrounding a patient should wait until the patient spontaneously brings up his/her philosophy and values. This does not mean that we should leave patients alone (passively wait), but that we should

<sup>6</sup> Albert R. Jonsen, "Casuistry: An Alternative or Complement to Principles?" *Journal of the Kennedy Institute of Ethics Journal* 5 (1995), pp.246-47.

<sup>7</sup> J.J.Fins, M.D.Bacchetta, and F.G.Miller, "Clinical Pragmatism: A Method of Moral Problem Solving," *Kennedy Institute of Ethics Journal* 7 (1997); 129-45. and J.Fins, M.Bacchetta, F.Miller, Clinical Pragmatism: A Method of Moral Problem Solving, in *Pragmatic Bioethics*, MIT Press, 2003.

offer support as we wait patiently until they introduce the subject (weaving stories).

### Methodology of clinical pragmatism

Philosophically anchoring a process to be shared with other people, such as families and medical professionals, around the value judgment of a patient involves an important thought process called doubt-inquiry in pragmatism<sup>8</sup>. This can be broadly formulated as follows.

1. Antecedent conditions for inquiry—uncertain situation that creates doubt.

A confusing situation occurs in which a matter that had been progressing smoothly suddenly becomes stuck, leaving the person uncertain as to what action to take.

2. Setting up the problem

The problem is recognized as a problem, and the inquiry begins.

3. Modeling of problem-solving—formation of a hypothesis concept

Acknowledge that a hypothesis formed by inference is fallible (i.e., capable of being wrong). Be aware that there is always room for modification. This awareness, called provisional warranted assertability, helps prevent self-righteousness and dogma.

From the viewpoint of clinical pragmatism, respect for the patient's autonomy, for example, would mean that, while maintaining the central importance of the patient's value judgment, the patient shares the context specific to his or her case with family and medical professionals. The principle is embodied in the process of creating the narrative together in that shared environment. The methodological pillar in clinical pragmatism is the doubt-inquiry process. We can safely say that critical theoretical points of clinical pragmatism encompass the following.

1. Fallibilism: acknowledge and be constantly aware that each person has a unique experience, thus our understanding of facts and value judgments may contain errors (e.g., preconceived notions, prejudices, and fallacies).

2. Pluralism: even if our value judgment differs from that of others, do not confute the other's judgment from the point of objective truth; rather, try to achieve mutual recognition without coercion through dialogue from the perspective of tolerance as opposed to indifference.

3. Inquirism: value a continuous process by which we can approach the ideal limit as in a mathematical asymptotic line, without being trapped by the idea that no value exists or by science.

## Bioethical Concerns of Medical Genetics: Global Standards and Japanese Consideration of Culture and Value

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### Abstract

To comprehend bioethics of genetic medicine two viewpoints are crucial; the first is based on global insight, such as the UNESCO Declaration. In the second, bioethics depends to a great degree on the culture and the values of the people living in each country. Japanese is known to have a rather unique culture and civilization according to the words of Watsuji, Nakamura and Huntington. The unique features reflected in Japan are heteronomy rather than autonomy, seeking for harmony rather than conflict, and a scrupulous or conscientious need to maintain a good relationship. The features can be traced to the influence of Japanese history and the geographical limit of an island country. Another factor to be considered is the paucity of the experience of major genetic diseases, such as cystic fibrosis and haemoglobinopathy in Japan. Such a characteristic and situation may have an influence on decision making related to the medical genetics, which, to a degree, are different from those of other countries.

**Keywords:** genetics, culture of Japan, reprogenetics, newborn screening, genetic information

### Introduction

"Geneticisation" coined by Abby Lippman [1] is a heuristic tool that can help to refocus the moral debate on implications of new genetic knowledge towards interpretational relations, the power of medicine, the cultural context and social constraints, rather than emphasizing issues as personal autonomy and individual rights [2]. Genetic diseases provide diverse reactions depending on the culture the people belong to. Felix Konotey-Ahulu said: "I was born in the Krobo tribe with extra digits at birth in Ghana. Had I been born a few miles southeast across the Volta River, there would have been great rejoicing because local tribesmen had it that I was destined to be rich. If my mother had given birth to me a few miles northwest beyond the hills, I would not have been here to write to you—I would have been drowned soon after birth. Fortunately the Krobo was neutral about extra digits." [3] Thus, it is necessary to consider a relationship between genetic disease itself and the public reaction to it.

A more important influencing factor to public perception is education of genetics and the incidence of the genetic diseases in the country they live in. In Japan, major genetic diseases, such as sickle cell diseases, beta-thalassaemia, cystic fibrosis, and haemochromatosis seen throughout the world, are

<sup>8</sup> F.G.Miller, J.J.Fins, and M.D.Bacchetta, "Clinical Pragmatism: John Dewey and Clinical Ethics," *Journal of Contemporary Health Law and Policy*, 3 (1996) 27-51; F.Miller, J.Fletcher, J.Fins, Clinical Pragmatism: A Case Method of Moral Problem Solving, in *Introduction to Clinical Ethics*, UPG, 1997.

really uncommon. This fact, accompanied with insufficient programs of education about human genetics at schools possibly resulted in a confusion or diverse reactions among persons, when the decision-making is called for the issues dealing with genetic situation.

In Japan, there was an active discussion in relation to the statement of "prevention is not eugenics" which had been introduced by the WHO guidelines in 1995. Dorothy Wertz and her associate prepared the guideline in which they introduced the effort of dramatic reductions of the incidence of beta-thalassaemia in Cyprus and Sardinia resulting from individual/couple choice [4]. Otherwise, health care costs of these countries will be highly elevated and cause a most serious condition. Individual / couple choices include avoiding conceptions, using donor gametes or using prenatal diagnosis followed by genetic abortion to avoid birth in case of an affected child. If most couples were to make the same choice, an overall outcome could be a reduced population frequency of disorder, but it does not justify a "eugenics" label. However, people involved with the disability movement and even some geneticists in Japan were against the above statement, insisting that "prevention in genetics is eugenic". To most people, eugenics means a social program imposed by the state. Such a program should not be accepted, since it denies human freedom, devalues some human beings, and falsely elevates the reproductive status [4].

The modern dilemma in the genome era must be discussed most carefully to seek general agreement approving genetic privacy according to each national sentiment. The purpose of this essay is to discuss the current guidelines in Japan and the attitudes of Japanese about medical genetics, as well as how the Japanese traditional culture influences the concept.<sup>1</sup> "Time and place" as the key words to comprehend bioethics Tetsuro Watsuji, a Japanese philosopher, argued in his book that the principle of ethics depends on the mutual relationship between people and the society they belong to. However, the moral principle (natural law), such as respect for human rights and dignity, prohibition to expose people to danger, to avoid risk and to maximize the benefit will be accepted as a universally applicable rule. The concept of ethics must change depending on the era and the culture (civilization) in the situation, when (time) or where(place) the individuals lived [5].

When the concept is adapted to a health care system, "time and place" could be the key words to grasp or to realize the biomedical ethics (ethical, legal and social implication; ELSI). The idea of "time" as a key word is well illustrated in the Helsinki Declaration where the statements had been revised regularly every few years until now (since 1964). For example, the guidelines for using a placebo in the clinical trial for new drug development, which was not included in the Declaration of the first edition, is described in detail in the most recently revised guidelines [6]. The meaning of "place" as a key word for comprehending ELSI which can be explained by the fact, for example,

that the legal situation for repro-genetics such as the fetus's condition (when the fetus has a severe genetic abnormality) for the reason of selective abortion, pre-implantation diagnosis for severe genetic diseases and using surrogate mothers for infertility are different even in the European countries of which the basic religious faith is Christianity. Selective abortion because of an abnormal fetus's condition is approved in England, France and the USA, but not in Germany where the fetus's condition, which had been previously approved, was prohibited since 1995. Pre-implantation diagnosis is approved in England, France Spain, the Netherlands, Norway and Sweden, but not in Germany, Switzerland, Canada, Australia, and Ireland. A surrogate mother used for infertility is approved in many states in the USA, but not in France and Germany. In France, surrogate mothers were once accepted and even at times recommended prior to 1984.

Especially in the area of genetic technology, such as pre-implantation diagnosis, even within the limit of western values, there is a distinction between the debates in Germany and the USA suggesting that in Germany the focus is on whether certain things should be done and in USA on how they should be done. [7] In Japan selective abortion because of fetus's condition and surrogate mother are not approved. In the case of pre-implantation diagnosis, it is necessary to approve minutely every case by the Ethical Committee of the Japan Society of Gynecology and Obstetrics. (Note 1).

However, it is important to note the basic distinction between legal norms and ethical norms. Michel B Vallotton and his associate expressed: "*While the former (legal) are founded on the latter (ethical), there is no necessary one to one correspondence between each legal and ethical norm. A law may be regarded as unethical by some people (e.g. a law prescribing the death penalty for certain crimes) and likewise, an ethical norm may be regarded as unlawful in a country (e.g., one involving female genital mutilation). Thus it cannot be expected that ethical guidelines which translate ethical principles into the form of recommendations (rather than of strict norms), will always coincide with legal prescriptions*" [8].

### Traditional thought and value in Japan

It is said that basic thought of modern bioethics is rooted in the European philosophy found in the 18th to 19th century, like deontology by Immanuel Kant, utilitarianism by John Stuart Mill, and communitarianism by George Wilhelm Friedrich Hegel. The basis of all philosophies, however, is Christian faith [9]. Then, the most important question for Japanese, at present, is what the cultural basis or traditional value adopting on ELSI will be in Japan. Even though the traditional value in Japan seemed to be influenced by Americanized ways of thought in recent times, the very profound area of our own thinking pathway or traditional value will be unchanged over the coming 5 decades. If so, we will need to develop, as shown in our history, "cycles of importation of external cultures" and "indigenization"

of cultures through replication and refinement, inevitable turmoil resulting from exhausting the important and creative impulse, and eventual reopening to the outside world [10].

Historically, Japan was the first Asian country to adopt Western technology on a large-scale basis. Dorothy Wertz and her collaborator summarized Eastern Ethics, as follows: *“Although Western Ethics is based on rights and principles and Asian ethics is based on caring and relationships, often the practical outcomes of the two approaches are similar. Experienced Western genetic counselors know that they cannot base their practice entirely on individual rights and autonomy. In fact, in the U S, the National Society of Genetic Counselors (1993) has a Code of Ethics based entirely on relationships rather than on principles. Conversely, Western principles of non-maleficence, beneficence, and justice are implicit in the Confucian ideal of humanness. The difference between Asian and Western ethics lies principally in the amount of credence given to the autonomy, privacy, and rights of atomized individuals”* [11]. On the other hand, Samuel Huntington expressed another view as follows, which is more acceptable for me. *“Some scholars combine Japanese and Chinese culture under the heading of a single Far Eastern civilization. Most, however, do not and instead recognize Japan as a distinct civilization which was the offspring of Chinese civilization, emerging during the period between A.D.100 and 400”*. He classified Japanese civilization (including culture) as being very unique and one of the nine civilizations in the present world [12].

Yasushi Haga had a similar view for the Asian civilization and culture, which will be classified into two types named as “concavity culture” and “convexity culture” according to his idea. And Japanese culture belongs to the former culture, and China and Korea located in the Eurasia continent fit in the latter culture [13]. By the interpretation I have made the character trait of our concavity culture as being ambiguous heteronomy rather than autonomy, disciplined, loving harmony rather than conflict, trying indirect or suggestive expression rather than a direct expression avoiding to injure a partner, and scrupulous or conscientious to keep a good relationship, whereas that of convexity culture is autonomy, assertive, insisting on one’s own idea, self-governing and self-assertiveness. The difference is possibly dependent on the geographical location, the climate and the history we have had so far.

In the book named “A history of the development of Japanese thought”, Hajime Nakamura discussed the Japanese philosophical thought under three categories, such as 1) esteem for human nature, 2) the spirit of harmony or concord (j. wa 和), and 3) concept of law.[14] The basic or main discussion among these three categories was rooted in the Constitution of Prince Shōtoku (574-622), which was believed to be prepared by Prince Shōtoku himself based on his unique thought including the comprehensive concept of Buddhism, Confucianism and traditional Japanese thought [5, 15]. When the Constitution is carefully studied, “wa” (j. 和)idea may

include various elements, such as sympathy, empathy, agreement, collaboration, solidarity in addition to harmony and concord [16]. Actually, “wa” is a part of the letter of “Hei-wa”(j. 平和), that means “peace” when translated to English. The principle of Buddhism summarized as humanitarianism (love of others), moral self-reflection and tolerance had much influence upon the Japanese way of thinking, although a part of the original form of Buddhism had been arranged into a different style somehow after Buddhism had been brought over to Japan from China in ancient times.

The love of others in its purest form is called “benevolence” (Sanskrit: *matrim karuma*), which is the fundamental idea of Buddhism, and this was also the basic thought with the Constitution of Prince Shōtoku [5]. He emphasized “harmony” or “concord” in human relations, as written within the first article of Constitution: “Above all else esteem concord (wa); make it your first duty to avoid discord.” This sentence is very similar to “wa” idea in Confucianism where it was said, “Of the things brought about by rites, harmony (wa) is the most valuable.” [17] In another section of Confucianism, it was said that :*“For where there is even distribution there is no such things as poverty, where there is harmony (wa) there is no such things as under-resourcing and where there is stability there is no such things as overturning.”* [18], indicating mutual support or corporation, which might be a prototype of “solidarity” (Note 2). The Constitution of Prince Shōtoku denounced the absolute rule and stressed the necessity of discussing things with others, as stated in Article X: “Discussion on important matters should in general not be made by one person alone. They should be discussed with many others”.

Nakamura speculated as follows: *“Actually Japanese society developed from small localized farming communities under a temperate cultural climate. The Japanese did away with nomadic life early on, and settled down to cultivate rice fields. People living on rice must inevitably settle permanently in one place. In such a society families continued on, from generation to generation and individuals were closely bound to each other, forming an exclusive human community. Thus an individual who asserts himself will hurt the feelings of others and then do harm to himself. The Japanese learned to adjust themselves to this type of familial society, and created forms of expression suitable for life in this situation”*. [14] Possibly, the fact that Japan is an insular state and no invasion has occurred as well as no despoliation by foreign countries has been experienced since the beginning of the country, is another factor to keep such a “closed community”. Whereas, people in the countries located in the Eurasia continent like China and Korea had great migrations and where one race conquered another, only to be conquered by still another. In such society, struggles for existence were based not on a mutual trust but relied on rational plan and a stratagem in their history. Nakamura said that even today there is a strong tendency within the Japanese social structure to settle closely around such tutelary gods and local deities. This tendency is deeply rooted in the people and has led to their attitudes, such as 1) acceptance

of actuality (acceptance of natural human qualities, spirit of tolerance, cultural stratification, weakness of the spirit of direct criticism), 2) tendency to emphasize a particular social nexus (emphasis on human relations, human relationships of greater importance than the individual, closed character of sects and cliques) and 3) non-rational tendencies (non-logical tendencies, weakness in ability to think in terms of logical consequences, intuitional and emotional tendencies, lack of ability to form complex representations) [14]. This conclusion corresponds to Haga's description of "concavity culture", as described above [13].

### Development of Genethics in Japan

#### *Ethical guidelines of medical (genetic) research and testing*

The first step of development of biomedical ethics in Japan was "importation" of the American concept of bioethics (ELSI) to our health care systems. Some of them, such as obtaining informed consent and searching for a second opinion in the clinical practice situation seemed to be successfully accepted, although sometimes people in Japan feel a sense of confusion and a sense of discomfort in several situations, such as brain death for organ transplantation, telling the truth (such as about malignancy) to the patient directly, abortion because of an affected fetus, decision making only by himself/herself (autonomy) especially in case of the minor (such as pregnancy or drug addiction) [19], passive euthanasia, issues of the treatment for severely impaired newborn and so on.

For Japanese who have a tradition to consult relatives to make decisions, autonomy, though it is understandable as a principle itself, seems to present a wide array of impediments for implementation. Nevertheless, many guidelines, including the Ethical Guidelines for Human Genome Research (2001, 2004, 2005, and 2008), the Ethical Guidelines for Epidemiological Research (2002, 2005 and 2007), the Ethical Guidelines for Gene therapy (2002, 2004), the Ethical Guidelines for Clinical Research (2003, 2004) have been established on the basis of international or global ethical norms by the Ministry of Education Culture, Sports, Science and Technology (MEXT), the Health, Labour and Welfare Ministry (HLWM) or the Ministry of Economy, Trade and Industry (METI). All guidelines were revised in the years above, as shown in brackets. In the first Ethical Guidelines for Human Genome Research in 2001, the use of an anonymous sample was the basic idea and the use of an anonymous but coded sample was an exception if anything, whereas in the revised Guidelines in 2004, this relation was reversed in every aspect of the guidelines and also the realistic meaning, since the Personal Information Protection Law became effective in 2004. Minor revisions were implemented in 2005 and 2008.

The international ethical guidelines from UNESCO [20], CIOMS [21], Development for Economic Cooperation and Development (OECD) [22] and WHO [23] should play an important role in the clinical and

experimental research involving human subjects even within our country, since the Japanese government or Science Council of Japan is tightly linked with these international bodies. Otherwise, the international collaboration study, such as International Conference of Harmonization for new drug development, could not be performed. Fundamentally there are no differences among all of these guidelines. However, attention is required in connection with "genetic exceptionalism", which was coined by Thomas Murray in 1997.

Genetic exceptionalism is the belief that the particular nature of genetic information gives rise to greater risk or particular risks that are different from another health related risk [24]. This idea brings about discussion of the nature of genetic information and genetic privacy. At present, "Ethical, legal and social aspects of genetic testing: research, development and clinical application" (2004) from European Union [25], "Pharmacogenetics – Towards improving treatment with medicines" (2005) from CIOMS [26] and "Pharmacogenetics" (2005) from Nuffield Council on Bioethics [27] expressed a negative opinion, saying "genetic exceptionalism" to be inappropriate. UNESCO, however, mentioned nothing about the issue directly in "International Declaration on Human Genetic Data" (2003), rather supported the concept of genetic information being special in comparison to ordinary clinical information, saying 1) they can be predictive of genetic predispositions concerning individuals; 2) they may have a significant impact on the family, including offspring, extending over generations, and in some instances on the whole group to which the person concerned belongs, 3) they may contain information, the significance of which is not necessarily known at the time of the collection of the biological samples, 4) they may have cultural significance for a person or group [20]. Recently, OECD (2006) said that concerning the nature of genetic information, participants of the OECD workshop did not reach a consensus on the discussion of genetic exceptionalism [28].

In Japan no conclusion or comment was agreed upon, as to whether genetic exceptionalism became acceptable or not. Support of the idea regarding genetic information is similar to UNESCO's declaration.

### Several perspectives of genetics in Japan

#### Genethics for newborn screening

In 1977, newborn screening (NBS) was started in Japan, nationwide. A guideline for NBS was prepared in 1998 in Japan, according to the classical principle of Wilson-Jungner proposed in 1968 from WHO [29]. In Japanese guidelines it was said that: 1) informed consent should be required from the parents participated in the screening, 2) residual blood spots should be used only for the purpose contributing to the scientific progress and under an anonymous condition [30]. This was proposed according to the statement of "there should be an agreed policy on whom to treat as patients" in the classical guideline [29]. However, in the US, NBS have been performed on a mandatory basis without an informed consent, except in only

three states.[31] There were several reasons to have the test performed without informed consent, such as, not being convenient to require informed consent or informed refusal from the participating parents, and NBS should be acceptable for parents since NBS is no doubt suitable for bioethical principles; maximizing benefit and minimizing risk for newborn infants [31,32]. Such reasons seemed to be acceptable only when NBS was limited to PKU and congenital hypothyroidism since these diseases are completely treatable resulting in an improved condition and give us a highest cost/effectiveness and cost/benefit, as were reported [31]. However, things have changed since MS/MS was introduced in the way of NBS, where 54 diseases (core: 29, secondary: 25) including 6 classical diseases like PKU were targeted for the screening [33]. At this moment, Thomas H Murray and Virginia A Moyer expressed major concerns, because natural history of the newly added diseases are poorly understood and cost / effectiveness and cost/ benefit of these diseases are not yet clear, and despite these situations, NBS was performed in all these diseases without informed consent and thus with a mandatory basis [34,35].

In 2008, the Bioethics Committee of the President expressed the views in the White Paper for those issues [36], where they proposed 1) NBS should proceed according to the classical principle proposed by Wilson-Jungner [29], and 2) the other diseases after MS/MS had been introduced should be proceeded only after obtaining informed consent (not mandatory) and should be intended as a pilot study. In Japan several institutes have performed screening with MS/MS in addition to the 6 classical diseases at this time, as a pilot study and by obtaining informed consent from the participating parents. Fukushi reported that 98.7% of the parents (total number 64,835) agreed to participate in the MS/MS pilot study from 2005 to 2009 in Sapporo.[37] Contents of the informed consent included agreement for performing the screening test and keeping the residual blood specimens to reuse for other studies, such as creating a DNA bank.

Our NBS system has been strictly controlled by regulating guidelines, especially after MS/MS had been introduced. Another issue should be discussed is for those diseases which are untreatable even if found by NBS. In 1975, National Research Council Committee for Inborn Error of Metabolism insisted that NBS be considered when the effective therapy is available and NBS will then bring about substantial public benefit. In the latter option the Council Committee proposed three conditions: 1) to the infant (to provide management and support even when direct treatment is unavailable), 2) to the family (to inform subsequent reproductive decisions), and 3) to society (to provide knowledge of the true range and incidence of the condition) [38]. This means, in some cases such as DMD or fragile X syndrome, NBS will be performed not for the early treatment of the screened infant itself, but only for the information to be used for the next round of reproduction decision making. This condition will be unacceptable from the viewpoint of original principle of NBS [23,29] and also by overall Japanese sentiment. Nevertheless, it is said

that DMD will be the most interesting future target of NBS by the Center of Disease Control and Prevention in US [39].

### **Japanese attitudes to repro-genetics**

In 1988 the maternal multiple-marker tests measuring alpha-fetoprotein, estriol and chorionic gonadotropin in maternal serum during early gestation (by amniocentesis) had been established for screening the fetus for Down syndrome, 18 trisomy and neural tube defects in the UK [40]. The test has been recommended for pregnant women under 34 years of age by the American Academy of Pediatrics and American College of Obstetrics and Gynecology in 1997 (pregnant women over 35 years of age are recommended to have amniocentesis) [41], and actually 60% of the pregnant women received an explanation of the test at the survey conducted in 1990 within US (Baltimore) [42]. In 2007, the UK National Committee recommended screening for Down syndrome, as a Policy Recommendation [43].

No such recommendation has been proposed by any Academic Society in Japan, although the multiple-marker tests are available in Japan produced by several commercial clinical examination laboratories since 1992 [44]. In 1999, the Executive Committee for Triple-Marker Testing set up by HLWM recommended that 1) very careful correspondence is required for offering such a test, since at that time even doctors did not understand clearly that the test is a risk assessment and not a diagnostic test and 2) the test should not be available as "a screening program for chromosomal abnormalities for the fetus", in the same manner as NBS [45], since termination of pregnancy is clearly not "therapy" in the usual sense of the word. Another point is, as described above, the fact that a selective abortion because of an abnormal fetus's condition is not officially approved in Japan. Already a very similar recommendation was proposed from the Japanese Society of Human Genetics in 1998.

In Germany, similar to Japan, the screening program in prenatal care on a population basis is not actively promoted and is not to be found on the policy agendas of professional and scientific association [46]. In our survey only 4% of pregnant women above the age of 35 underwent amniocentesis in the survey which covered more than 80% of all women in Japan in 1997 ~ 1998 [47]. In France, more than 60% received the same test in 1984 already [48]. In order to know what people think about repro-genetics, we did a small survey, in which it became clear that most Japanese are reluctant to give a definite answer in the decision making process. For example, 38.1% of Japanese, 0.5% of Chinese, and 3.7% of Panamanian choose the answer of "neither agree nor disagree" for the statement "A pregnant woman should have prenatal diagnosis, if medically indicated by factors of her age and family history". (Note 3) This will be a typical attitude of "concavity culture", as previously discussed, showing ambiguous behaviour, heteronomy rather than autonomy. Even in the Guideline for Genetic Testing in Japan (2000), it is said that "prenatal diagnosis should be performed only upon request from the couple who have understood the implications of the test", indicating that the test

must be performed after a couple's agreement, but not by the pregnant woman's decision alone [49].

Fundamentally, repro-genetic decision making is a very private matter. It will depend on the case in which the mother (family) is concerned, and the decision will change from case to case, even in the same family. General discussion such as "prenatal diagnosis is acceptable or not" will not give us a significant conclusion. Receiving a prenatal diagnosis and the acceptance of selective abortion must be discussed independently, although these are correlated with each other.

According to Richard K Zimmerman, even if 79% and 58% of the people said they accept prenatal diagnosis for genetic diseases, only 22% and 20% agreed to have a selective abortion when the fetus is affected, in African Americans 13 and in Caucasian Americans, respectively [50].

Kirstin Finn Schwant said that: "the ability to know prenatally whether or not a child will have a birth defect may raise difficult questions for some Christians. If a baby is born with a chromosomal abnormality, most people feel obligated to love and take care of the child. Should that belief change when a fetus is prenatally diagnosed with a chromosomal abnormality? Perhaps the parents feel that preventing the birth of the child is the most loving decision. On the other hand, the couple may decide to continue the pregnancy, believing that God will provide the strength required to take care of such a child. What they believe about God can shed light on such a choice" [51].

Another factor for receiving the abortion will be the severity of the affected babies. Japanese clinical geneticists agreed to perform selective abortion in cases of anencephaly (90.0%), Trisomy13 (77.6%), severe spina bifida (69.0%), achondroplasia (53.6%), Trisomy 21 (42.9%), Huntington disease (42.1%), XXY (30.1%), cleft lip and palate (5.8%), and those figures are slightly less than the results surveyed in the USA and in Germany [52]. In the case of male patients with ornithine transcarbamylase deficiency (sex linked inherited disease), the mutations of Ser192Arg and Arg126Gly resulted in an early onset of the disease with a severe prognosis, while the mutations of Arg40His and Arg129 His had a late onset type with a favourable prognosis when found and treated in the early age [53]. In the two male cases with the former mutations (one with Ser192Arg, one with Arg126Gly), the pregnancy was terminated by the parent's decision. On the other hand, in three male cases with the latter mutation (two with Arg40His, one with Arg129His) the pregnancy was continued after giving a positive result of the prenatal diagnosis, and medical treatment immediately after birth resulted in normal development. The children are over 10 years old right now and under dietary control. [54]

### Protecting genetic information

HLWM stated "Guidelines for Protecting Personal Information with Healthcare Provider" based on "The Personal Information Protection Law" in 2004. In those

guidelines they said that "UNESCO's Declaration on Human Genetic Data" and "Guideline for Genetic Testing" prepared by the Japanese Genetics Related Societies in 2003 [49] should be followed for protecting private genetic information, since the information is very sensitive and when disclosed, the person involved and his or her relatives will have possible risks and discrimination [54]. The Japanese Association of Medical Science (JAMS) decided to take the same position. Both HLWM and JAMS were not originally intending to establish their own set of guidelines concerning the genetic information. The basic idea of the Guidelines of Genetics-related Societies of Japan was rooted in UNESCO's Declaration on Human Genetic Data stating that genetic data (information) possessed several natures such as 1) unchangeable for life long, 2) being inherited by the posterity, 3) containing predictive information for genetic disease, 4) sharing the information with relatives, and 5) having risk factors with an insurance contract, employment or stigmatization [49]. There is another possibility which brings up the unexpected fact, such as a different parent-child relationship could be realized accidentally by gene analysis within the family (the element of surprise).

Actually, based on these characteristics, George Annas expressed the genetic information is especially sensitive and personalized, as "future daily" as he coined. He and his associate had proposed a model "Genetic Privacy Act" for protecting genetic information, when "Genome Project" was funded jointly by the Department of Energy and NIH, with many other government agencies world wide, and private biotechnology companies [55]. Every state in the USA has its own regulation or legislation in terms of protecting genetic information, although the definition of genetic information is different from state to state; Some states target only DNA data and other states include family history for genetic information [56]. Murray asked: "What, if anything, makes genetic information different from other health-related information? Can it, in concept and in practice, be singled out? Regardless of whether it really is different from medical information, are there characteristics of genetic information or for society into which it will flow that should lead us to act as if it were different?" [57]. He criticized Annas's idea as a "genetic exceptionalism", since, "genetic information is neither unique nor distinctive in its ability to offer probabilistic peeks into our future health", according to his words [56]. After a long discussion, he concluded that he supported a weaker form of genetic exceptionalism, since: "genetic information is sufficiently distinctive from other forms of information that it ought to receive greater privacy protection". Another assertion by Murray is that genetic exceptionalism promotes genetic determinism or genetic reductionism, which is most unacceptable since this thinking is complicit in genetic discrimination [24]. Recently, a definition of "genetic information" has become more confused in legal theory [56], even in scientific meaning, since the information of monogenic disease, such as a

Huntington disease gene is evidently different from that of polygenic common disease, such as coronary disease and allergic disease, in terms of a penetrance and predictive ability of the involved gene (Note 4). Generally, incidence of monogenic diseases is very small, while the type of the diseases is more than 10,000, carrying the possibility of severe symptoms. Although the number is limited, some of them are treatable, such as PKU. The genetic information, therefore, should be classified into several different groups and the more important is our attitude to genetic knowledge rather than the knowledge itself. Another aspect is how a lay person will react to such different sort of genetic information. If the people speculate that genetic testing is useful for their clinical management, such as pharmacogenomics or pharmacogenetic testing, they will be delighted to accept it, whereas they may feel danger in the possibility that the results will be misused for genetic discrimination (Note 5). They will, therefore, not accept the testing. In conclusion, there is considerable difficulty in discussing various genetic factors. Regardless of whether genetic exceptionalism is acceptable or not, we should maintain a code of confidentiality so as to protect the individual genetic information as closely as possible.

#### **Genetic privacy - Right to know and right not to know - Privacy and autonomy in medical genetics**

Words corresponding to “rights”, “personality”, and “privacy” expressing the basic idea of humanity in Japanese language were actually created in Japanese as new loanwords or used as “phonogram” without translation during the Meiji period or after World War. The word “privacy (leave me alone)”, “puraibashi (j. プライバシー)” in Japanese is one example [52]. The idea of privacy has said to be developed possibly after the room first became locked. The structure of the room in a traditional building in Japan was made simply of a sliding paper door; “fusuma” (j. 襖) and “shouji” (j. 障子) and no key were used. Eiichiro Ishida coined the word “kagi-no- bunnkakenn” (j. 鍵の文化圏), meaning “the cultural sphere represented by key society”, in which, he said, countries in the Eurasian continent such as China and Korea, but not Japan are included [57]. Such thought is very similar to the idea of “concavity culture” and “convexity culture”, as discussed previously by Haga. [13] Anyway, only after World War, when a locked room became popular inside a building for the general population, the idea of privacy became to be realized in Japan. Actually, privacy itself was developed as a right of autonomy or right to be alone while making a decision. The elements of “genetic privacy”, in this context, is composed of protecting personal genetic information by confidentiality, autonomous decision making about genetic issues and the right to know/not to know in terms of the genetic information. In 2004, the Personal Information Protection Law was enforced in Japan. Genetic (personal) information is now protected by this law, on the basis of the Constitution, the 13th article “All people shall be respected as individuals. Their right to life and the pursuit of happiness shall, to the extent that it does not interfere

with the public welfare, be the supreme consideration in legislation and in other governmental affairs.” In the USA, a right of privacy has been imported by interpretation into the Constitution itself [58]. It has been stated in the 4th Amendment: “protects Americans in their belief, their thoughts, their emotions and their sensations. They [the framers] conferred as against the Government, the right to be let alone—the most comprehensive of rights and the right most valued by civilized men” (1928, p. 478-479).

After further information protection laws, including the Health Insurance Portability and Accountability Act (HIPAA), has come into force, the Senate and the Lower House of congress approved the Genetic Information Non-discrimination Act (GINA) (Note 6) enacted in 2008 to prohibit discrimination on the basis of genetic information (clinical record is not included) with respect to health insurance and employment [59]. They said, “Although genes are facially neutral markers, many genetic conditions and disorders are associated with particular racial and ethnic groups and gender. Because some genetic traits are most prevalent in particular groups, members of a particular group may be stigmatized or discriminated against as a result of that genetic information.” [59] Sharing the genetic information with relatives Ruth Chadwick said that there are at least four central concepts in the right to know/not to know debate: autonomy, confidentiality, privacy, and solidarity [60], and Ann Sommerville and Veronica English add communitarianism as another concept [61]. Concerning the right to know especially in genetics will have two situations, in which the first is to know one’s own genetic information, and the second is to know the genetic information not of himself/herself, but about the relatives. Both are closely related. Concerning the first situation, Rosamond Rhodes argues: “if I have an obligation to learn what I can when genetic information is likely to make a significant difference in my decisions and when the information is obtainable with a reasonable effort, I do not have the right to remain ignorant. From the recognition of my own autonomy, I have a duty to be informed for decision-making.” [62] As the result, autonomy, in the case of genetic knowledge, means that people have a moral duty to know about their genetic disorders in order to be free and autonomous [62,63]. However, this argument seems to be too strong to insist, as it is, since people also have the right not to know as the moral philosophy [60]. Although there is an assumption among health care professionals and lay people that it is generally better to know than not to know one’s own genetic information, the low uptake rate of pre-symptomatic testing for Huntington’s disease, estimated at only 10-20%, can be seen as a challenge for this assumption [61]. The information of Huntington’s disease has a specific situation, since the disease is unpreventable and untreatable, even so, these data indicate that a considerable number of the population at risk does not wish to know of their own genetic status. The UNESCO Declaration of Human Genome and Human Rights Article talks about the individual deciding whether or not to be informed of the results of a genetic examination [19]. In the second indication, when A has a right to know about

his/her own genetic information, and another person B, who knows A's genetic information, the question is whether or not B should have the responsibility to tell the information to A. Thus, in view of the relevance of the information to others, the question arises as to whether they are morally entitled to make this decision.

In many situations, we can only tell the information which could help to prevent serious harm to the health of the individual, and this will be possible only within a family or relatives, or through a health professional, since genetic information should be confidential. Human genetics is concerned with direct biological relationships and the transmission of certain traits or susceptibilities within families. The family is at the core of communitarian concepts or solidarity of mutuality, responsibility for others and inter-dependence. We should carefully consider that individuals recognize the risks and harms for others close to them when they have certain information. Confidentiality is one of the cornerstones in medical genetics, but this is not an absolute duty. Stephan Eriksson said that where there is a moral demand to inform biological relatives, telling the information to them is neither a paternalistic line of action, nor does it undermine the autonomy of the relatives [62]. As one of the bioethical principles we have a duty of warning the third party. The General Medical Council of UK said; "disclosure may be a necessary in the public interest where a failure to disclose information may expose the patient, or others, to the risk of death or serious harms" [64]. Based on this concept, in the Guideline for Prenatal Diagnosis and Genetic Testing in Japan in 1995 [65], we said as follows. "If the sharing of information with another specific person (family member at present or future) will avoid serious injury to that person, if necessary to seek the consent of the subject to reveal that information, and even if agreement cannot be obtained, if it is judged necessary the obligation of confidentiality can be broken. Such an exception must be made following the judgment of the responsible ethics committee, not by the counselor. Therefore, in our opinion, in such cases, the committee, not a single counselor, will decide if disclosure of the information to the relatives should be made." In 2003, we provided further details of this issue and described them below [49];

#### "Disclosure of Genetic Test Results

1. The rights of examinees to know or not to know the test results should be equally respected.
2. When disclosing genetic test results, the wishes of examinees to have results disclosed or to refuse them to be known should be respected. Individual genetic information gained from testing must be subject to confidentiality, and therefore fundamentally should never be disclosed to relatives or any third party without obtaining permission from examinees themselves. Even when the examinees agree to open individual genetic test results, these results should be protected from access by employers, health insurers and schools." ...

"6 The tests must be disclosed to relatives with the examinees' consent. In case of refusal by examinees,

disclosure to their relatives may still be possible if all the following conditions are met. However, decisions for disclosure in such cases should not be made on the sole judgment of the directing physician, but should be made within the jurisdiction of an institutional review board, whose decision should be final. (1) When the results can be utilized as useful information for the prevention and treatment clinically, (2) When judging that disadvantages which relatives may suffer can be preventable 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 diseases in relatives."

We have had much discussion concerning the above item (4), since in the previous Guidelines made in 1995 this specific item was not included. A point was that even if the information is very useful for preventing a "disadvantage for relatives", there is a possibility that the informed relative may insist the right not to know and brings a legal claim, because of the broken confidentiality of the patient. Maria Bottis was one such case which made the case against disclosure of the genetic information to the relatives without their request, introducing a special case. (Note 7)[66]. ASHG introduced another case, where the court asserted that duty for warning the family in case of genetic carcinoma is limited to the patient only, and not the physician in charge (Note 8) [67].

Another issue which must be discussed is how to define "disadvantage to the relatives". This might depend on the values of the people involved. Dorothy Wertz and her associate proposed another case; "there could be a temptation on the part of geneticists to include a wide variety of disorders under the heading of "treatable", even if treatments are not especially effective, leading to the danger of unwarranted breaches of confidentiality. There are also disorders that are not treatable but could be prevented in future generations if prospective parents become aware in time." [68] However, an expectation for prospective parents to have the "best" alternative available, a healthy child is said to be considered as a contestable presumption. "First, it takes for granted that a disabled child is always the worse scenario. Secondly, it assumes that families with disabled children will always be more burdened (emotionally and economically) than other families. Thirdly, it presumes that the world would benefit more than the birth of a non-disabled individuals in some cases." [69] Therefore, it remains unclear as to whether or not we have a duty to tell the information without the consent of the patient and without the request from the genetic relatives in such a case (actually untreatable, only useful for repro-genetics decision making), although it is agreeable that the patient has a moral duty to share the genetic information between the relatives. There is still a possibility that genetic relatives will refuse to be informed, depending on their values.

In contrast to the WHO guidelines [68] we decided to make case decisions within the ethical committee, not an individual genetic counselor. The Committee should decide whether the patient's genetic information will be disclosed to the genetic relatives without the consent from the examinee. Wertz and her associates support our idea in some cases, saying that "using an ethics committee as an intermediary decision body may be an effective solution, especially if the geneticist is facing a problem where he or she would search out a second opinion. This may also be provided through a system of ethical consultation." [68]. Our idea depends on the "wa" idea, as discussed above; "Discussion on important matters should be generally not made by one person alone. They should be discussed with many others" [14]. The actual reaction must be discussed. In the survey asking geneticists in Japan; "Patients should tell their relatives the results of their own genetic tests if they are relevant to the relatives' health or reproduction", 38% of the respondents agreed, 20% disagreed, and 42% neither agreed nor disagreed [51]. This result suggests that almost half of geneticists had a typical attitude of "concavity culture", as discussed above [13], showing ambiguous behaviour, heteronomy rather than autonomy. This is probably due to non-rational tendencies (non-logical tendencies, weakness in ability to think in terms of logical consequences) of Japanese as discussed previously by Nakamura [14], or they understand the moral duty of sharing the genetic information with genetic relatives is most desirable, but they hesitate to decide by his or her own idea.

Another comment will be that the ethical committee adopts Western bioethics, at least, in formal approaches and a professional statement, while some geneticist may have another consideration. As to the legal countermeasure, only Australia approved such in a Private Legislation Amendment 2006, saying "permits use of disclosure of genetic information about an individual to a genetic relative in circumstance where the genetic information may reveal serious threats to a relatives' life, health or safety, but not necessary an imminent threat." And "This amendment will ensure a medical practitioner is able to disclose genetic information to genetic relatives where there is a serious risk to the health of genetic relatives." [70] However, no guidelines are available to proceed with the law at present.

### Attitudes to Medical Genetics in Japan in the Future

It was claimed that people in Japan have a desire to hide rather than to open the fact of having a genetic disease within their family, because the genetic disease is rare and negatively thought of in a "closed society", where people are conscious of eyes of a stranger. They are possibly afraid of genetic discrimination, when the genetic information becomes public [71, 72]. The survey using the multiple choice format was administrated to health care providers, lay persons, and family members of the patients with genetic disease (mostly Duchenne muscle dystrophy). [73] The question was: "what is your impression about

"genetic disease"?", and the answers obtained are shown in Table 1.

Table 1 Reaction to the question "What is your impression about "genetic disease"?".

	Health care providers (n=712)	Lay persons (n=637)	Family members (n=140)
1) Prefer not to disclose, if I have patient(s) of genetic disease in my family	9.3 (%)	8.3 (%)	12.5 (%)
2) I have a concern, if the family of my partner has some genetic disease	37.0 (%)	34.9 (%)	39.0 (%)
3) Afraid to give birth to a baby with genetic disease	63.8 (%)	55.4 (%)	51.5 (%)
4) Would like to live without worry about genetic disease	39.2 (%)	40.4 (%)	43.4 (%)

Among the three groups, statistically no difference was observed.

In contrast to the previous statements, a small number of the participants "prefer to hide, if I have the patient(s) with genetic disease in my family", and almost half of the family members "would like to live without worry about the disease". This result may be related to the activity of the patients and their supporting organizations, which have developed into more than 50 organizations in Japan up to now. Possibly the "wa" (j. 和) idea being the soul of solidarity became evident in this field. A relevant education for those involved with medical genetics including ELSI is insisted by many authors so far [74] and this will open the doorway to a community without genetic discrimination and prejudice, not completely but to a sufficient degree. Challenge to public engagement in genetic science and technology is also essential to solve the issues we faced in genetics [75].

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### Notes

1. In Japan the Eugenic Protection Act, under which those with mental disabilities were possibly sterilized by force, was repealed in 1995. Instead, new Maternal Protection Act was passed in 1996 where abortion is legal, if continuation or delivery possibly may cause considerable harm to maternal health for either physical or economic reasons. The Ethical Committee of the Japan Society of Gynecology and Obstetrics approved 143 cases of preimplantation diagnosis, in which Duchenne muscle dystrophy, habitual abortion due to balanced translocation (the most cases), adrenoleukodystrophy and OTC deficiency were included.
2. Solidarity has three essential features, according to Gefenas; the first, solidarity as a group concept presupposes sufficient emotional bonds among the members of the group. Secondary, it is also essential that the group be united by common goals and/or ideals. Thirdly in order to reach the same goal, members of the group are committed to sacrifice some of their own welfare (or even their life in extreme circumstances), which in itself is a sign of emotional involvement. (Gefenas E: Social Justice and

Solidarity. In *Bioethics in a European Perspective*. Edited by ten Have H and Gordijn, B. Kluwer Academic Publisher. Dordrecht. 2001.p 2069).

3. Unpublished data. To understand the public opinion concerning the issues related to genetic health care the survey was conducted in Japan (n=280), China (n=202) and Panama (n=202) in 2008 to 2009.

4. The person carrying Huntington disease gene develops the symptoms without exception in the future, while the person carrying BRCA1 gene will suffer from breast cancer at the rate of 4 times higher than that of the non-carrying person. Note 3. Unpublished data. The numbers of people who participated in the survey are 280 in Japan, 202 in China, and 218 in Panama (performed in 2008~2009) No difference was found among healthcare givers and lay persons in every country.

5. Genetic discrimination is defined as; discrimination against an individual or against members of that individual's family solely because of a real or perceived difference from the normal genome of that individual. Genetic discrimination is distinguished from discrimination based on disabilities caused by altered genes.

6. In GINA, genetic information includes information about: a person's genetic tests, genetic tests of a person's family members up to and including fourth-degree relatives, any manifestation of a diseases or disorder in a family member, and participation of a person or family member in research that includes genetic testing, counseling, or education.

7. Sophie has a genetic form of breast cancer linked to the BRCA1 gene. Cure is possible and a mastectomy is the most effective measure to be taken. Sophie has two sisters, Katie and Sally. Katie is phobic about needles and hates hospitals. Sally is depressive and has recently discovered that she is pregnant. Sophie does not want to tell her sisters about her disease, but should Sophie's doctor inform the sisters, even though the knowledge might have an adverse implication for their lives?

8. The American Society of Human Genetics (ASHG) Social Subcommittee for Family Disclosure introduced the case of a daughter of the mother suffering from medullary thyroid carcinoma. "She sued her mother's attending physician because 1) her mother's diagnosis is one that is hereditary carcinoma, 2) this situation reflects a duty to warn 24 the mother that her children might be at risk and that they should be tested,3) had she been tested, she would have taken preventive measures, and 4) her condition would have been preventable. The court ruled, on the basis of state law protecting the confidentiality and pursuant to prevailing standard care, the physician had a duty to warn the mother –but not the daughter. The court noted that "to require the physician to seek out and warn various members of the patient's family would often be difficult or impractical and would place too heavy a burden upon the physician".

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## Three levels of discourse on human reproductive cloning in Japan

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### Abstract

This paper reviews three levels of discourse on human reproductive cloning (HRC) in Japan: everyday life, fundamental theory, and public policy. In addition to articles with headlines on HRC in the *Asahi Shimbun* newspaper, 224 publications were found on HRC and categorized by publication year, author specialties, and contents. Contents of 100 publications were assigned to the following categories: cultural differences, acceptance of HRC, aversions to HRC, arguments against HRC (human dignity, safety, diversity of the gene pool, discrimination, children's feelings, and religion), rebuttals and utilitarian arguments, arguments concerning regulation, and ethical principles, including the right to healthcare and children's rights and welfare. An opinion poll and public policy were also reviewed. Bioethics on HRC in Japan is primarily based on Western ethics and is communitarianistic, but some arguments are traditionally anti-anthropocentric and vitalistic. Public policy does not seem to reflect bioethical principles, but instead reflects practical needs.

**Key words:** human reproductive cloning; Japan; ethics; three levels.

## Introduction

The issue of human reproductive cloning (HRC) emerged when the birth of a cloned sheep, Dolly, was published in 1997 (Wilmut et al. 1997). However, discussions on human cloning seemed to be focused on the development of human induced pluripotent stem cells (iPSCs) in 2007 (Takahashi et al. 2007), although fertilization with gametes derived from iPSCs will likely be an issue in the future. Reflection on this seemingly settled issue as an example of bioethics in Japan might reveal its features and position in the society, and suggest ways to manage both ongoing and new issues. Such a reflection has been made by Hayashi (2002) and Horres et al. (2006). Hayashi (2002) dealt with the process of "solving" problems such as organ transplants from brain-dead donors, assisted reproductive technologies, and human cloning technologies from the perspective of the history of social construction of life science and technology. He analyzed discussions on human cloning technologies by the Bioethics Committee of Japan, and argued that it presupposed a ban on HRC with little discussion of the reasons, primarily examined a method for the ban, and separated HRC from research cloning and justified the latter. He concluded that bioethical principles were rarely discussed and consequently, bioethics has not played a major role in the ethical assessment of life science and technology in Japan.

Horres et al. (2006) analyzed public opinion, governmental decision making, and bioethical reasoning on human cloning in Japan. They pointed out that public opinion is generally favourable, that bioethicists with a background in humanities are the strongest opponents to human embryo research, but, as Hayashi (2002) pointed out, their arguments have been virtually ignored by the public, the government, and scientists. They also remarked that arguments in favour of a comprehensive criminalization of all forms of human cloning are virtually absent in Japan, and that the complete irrelevance of religious arguments is a specifically Japanese trait.

These reflections are full of suggestions, but they do not broadly review HRC discourse in Japan. Collecting literature that reflects HRC discourse as a whole would allow analysis of three different levels of the discussion: everyday life, fundamental theory, and public policy. This paper reviews literature on HRC in Japan and analyzes these three structural levels of discourse. I found that discussions seemed communitarianistic and included not only humanistic, but also some anti-anthropocentric ideas. More public discussion on the fundamental question of the relationship between human beings, science and technology, and nature may be necessary.

## Methods

A list of literature on HRC in Japan was generated by accessing databases: Kikuzo II Visual for Libraries for the Asahi Shimbun newspaper, and NDL-OPAC for magazine and journal articles and books. Keywords for the search were "clone ningen" (cloned human), "fukusei ningen" (duplicate human), "hito clone"

(human clone), in headlines and titles. This list was supplemented with other references that were found in the literature. I excluded translations and literature that seemed to focus solely on embryo research. Serial publications were counted as one publication. The first authors were divided into four categories: (1) journalists, writers, and critics; (2) scientists and medical doctors; (3) humanities researchers and social scientists; and (4) others. The first specialty of each author was used for categorization. Contents of a half of the publications, mainly journal articles and books on the list were analyzed.

## Results

### 1. Number and distribution of publications on HRC

In the *Asahi Shimbun* newspaper database, I found a total of 109 headlines, which excluded 26 headlines with the phrase "hito clone hai" (human cloned embryos), from 1993 to 2009 (as of June 7, 2010) (Table 1). Most of them (91/109) were with the phrase "cloned human". Approximately 10 headlines with this phrase appeared each year for the years 1997, 1998, 2000, and 2003, while 2001 and 2002 each had about 20. Three-fourths (32/43) of articles with the phrases "cloned human", "duplicate human", or "human clone" in their headlines from 1997 to 2000 were about the regulation of HRC. Three-fourths (40/55) of articles from 2001 to 2003 were about plans for HRC. In addition, 12 headlines that had the phrase "human cloned embryos" appeared in 2004. These trends reflect the enactment of the Act on Regulation of Human Cloning Techniques at the end of 2000, the announcement of several plans for HRC in 1998 and from 2000 to 2004, and the Expert Panel on Bioethics of Japan's allowance of research on human cloned (somatic cell nuclear transfer, SCNT) embryos in 2004.

In NDL-OPAC database, I found 179 articles and 34 books from 1978 to 2009 (as of May 11, 2010). Among them, 135 articles, 19 books, and 7 articles and a script in 7 books were on HRC. In the end, I found a total of 224 publications on HRC from 1962 to 2009, in addition to those newspaper articles. One hundred seventy-five (78%) were articles and 19 were books. Among 187 media, some of which included multiple authors, there were 61 magazines, 54 journals and 58 books. 191 (86%) of the publications were from 1997 to 2003, with about 40 publications in each of the years 1997, 2001, and 2003. There were 177 groups of authors. Approximately 70 were journalists, writers, or critics, and about 30 were scientists or medical doctors. Among 70 researchers in the humanities and social sciences, there were 30 jurists, 15 ethicists, and 10 religion scholars. Nineteen of the authors were journalists in 1997, 17 in 2001, and 14 in 2003. About 10 scientists and medical doctors appeared in each of the years 1997 and 2003, and humanities researchers and social scientists numbered about 10 each year from 1999 to 2004.

### Contents of HRC publications

Contents of approximately half (92/244) of the publications, except the newspaper articles, were

analyzed and grouped into the following categories. (The 92/244 publications break down into 63/175 articles, 13/19 books, and 16/29 other publications in 18/54 journals, 38/53 books, 6/61 magazines, and 8/14 other media.)

### **Before the publication of Dolly**

Before the birth of Dolly, there were familiar old stories, such as Eve in the Old Testament and Sun Wu-K'ung in Hsi-yu chi. After the development of embryology and genetics in the 20th century, Fukumoto (1979) addressed a confusion caused by Rorvik (1978), who wrote a claimed "nonfiction" book on HRC in the United States. She warned that life science technology had become life manipulation. A novel (Abe 1962) and manga (Tezuka 1980, Shimizu 1993-2005) that addressed HRC were also published. Although Abe described self-cloning as absurd, manga writers were sympathetic toward cloned humans. Levin's novel "The Boys from Brazil" was translated in 1982. Cloning issues were addressed on the screen in "Blade Runner" (1982) and "Jurassic Park" (1993).

### **Arguments concerning HRC beginning in 1997**

#### *Cultural differences*

After the publication of Dolly, Japan was slow to respond to the possibility of HRC compared to the extreme reaction seen in Western countries (Yahagi 1997, Yonemoto 1997a, Yamazaki 1997, Kumagai 1997). European countries could regulate HRC by modifying existing laws on reproductive technologies, which had been developed in the Christian tradition and to guard against Nazism. In contrast, the debate over abortion between Christianity and liberalism in the United States made the regulation of reproductive technologies impossible. In Japan, there had been little discussion on the beginning of life and reproductive technology. There is no metaphysical basis for banning HRC in Japan (Yonemoto 1997b), and religions in Japan do not express clear opinions on HRC (Kumagai 1997). Therefore, a firm basis in common sense is required for banning HRC in Japan (Yonemoto 1997b).

### **Acceptance of HRC**

Some authors argued that HRC cannot be stopped and a cloned human will eventually be born (Yahagi 1997, Yumemakura 1997, Fuse 1997, Murobushi 1997). Human cloning is only utilizing the mechanisms of nature (Yumemakura 1997, Fuse 1997), and HRC is the current of event (Yahagi 1997, Fuse 1997). Murobushi argued that HRC is realistically one of our desires (Murobushi 1997), and Kumagai argued that it might be our fate (Kumagai 1997). The view that HRC should not be resisted, but accepted, might be because the Japanese do not believe in the Creator (Yumemakura 1997, Takagi 1997, Suzuki 1997, Takeda 1997, Kumagai 1997). Buddhism teaches that all are destined and to be accepted (Kumagai 1997).

### **Aversions**

In addition to those arguing for acceptance of HRC, some argued that ignorance and an illogical aversion to HRC uniformly prevailed (Yamazaki 1997, Takeda

1997, Murobushi 1997). I identified several arguments that I classified as aversion to HRC. Yahagi expressed the opinion that human beings should follow nature and live their given lives (Yahagi 1997). Goto argued that the Japanese have fostered a sense of unity with nature (Goto 1997a, b, c), and that a baby is a unique "gift" of nature (Goto 1997a, c). Many Japanese attach importance to preserving harmony, and sometimes do not have their own opinion, but are conservative and just cater to the majority (Murobushi 1997). As their gods are not the Creator, the Japanese may not be enterprising, whereas people who believe in God model themselves on Him (Takagi 1997, Machida 2007).

### **Arguments against HRC**

These arguments focus on human dignity, safety, preserving the diversity of the gene pool, preventing discrimination, cloned children's feelings, and religion. Cloned children would be treated as a means rather than an end. This would disrespect a cloned human and violate his/her dignity (Goto 2007 a, b, c). HRC is not yet safe (Kato 1997a, b; 1999b), and might reduce the diversity of the gene pool (Takagi 1997, Kato 1997a, 1999b; Kumagai 1997). Several authors focused on potential negative consequences to cloned children: they would be discriminated against (Yumemakura 1997), they could not have genetic parents and would feel terribly lonely (Goto 1997a, b, c; Kitahara-Frisch 1998), and they would feel distressed (Kitahara-Frisch 1998, Murakami 2000, Sakurai 2004, Aono 2007). There are both good and bad aspects to everything, and duality in nature favours sexual reproduction (Deguchi 2001). Animism is against the manipulation of life. As gods were born and die and are continuously changing in Japanese myth, we should be aware of recurring change and just accept it (Kamata 2007). Individuals should be wise enough to give up unnatural desires (Yamaguchi 2002, Machida 2007).

### **Rebuttals**

This content includes rebuttals of arguments against HRC and utilitarian opinions. Genetic determinism is incorrect (Yonemoto 1997a, b; Yahagi 1997, Kato 1997a, b; 1999a, b; Takagi 1997, Suzuki 1997, Takeda 1997, Fuse 1997, Kumagai 1997) and HRC would not violate the dignity of a person (Kato 1997a, b; 1999a). Sexual reproduction as well as asexual reproduction is intentional; we should be more responsible for reproduction and personality development (Takeda 1997). Naturalness and artificiality are not appropriate criteria for determining right and wrong (Kato 1998, 1999a, Okamoto 2002). A limited number of cloned people would not affect the diversity of the human gene pool (Kato 1997a, Takagi 1997). Society is responsible for the equal treatment of all people (Kato 1997a, 1999a, Goto 1997b). Cloned children would be treated not only as a means, but also as an end. Having children for various purposes is not blameworthy in itself (Kato 1999a). Cloning technologies would greatly contribute to medicine (Kushida 1997) and useful for infertility treatment (Iwasaki 1997, Imai 1997, Murobushi 1997). Feminists might welcome asexual reproduction

(Suzuki 1997, Okonogi 1997, Kumagai 1997). Realistically speaking, a eugenic society will come (Murobushi 1997). The Japanese are realistic and view things in a practical way (Kumagai 1997, Murobushi 1997). New religions in Japan tend to promise benefits in this world (Kumagai 1997).

### **Arguments concerning the regulation of HRC**

Some proposed that the government should set up an Office of Technology Assessment and a National Bioethics Committee to introduce policies and regulations (Yonemoto 1997a, b, Yamazaki 1997, Kumagai 1997). The Bioethics Committee was established in the Council for Science and Technology Policy of the Prime Minister's Office in September 1997 and renamed the Expert Panel on Bioethics in 2001. How much to promote human cloning technology is not to be decided by God, but by human discussions (Yonemoto 1997b, Kushida 1997, Okonogi 1997). Ethical standards and regulations have to be universally applicable to the world (Kato 1997a, Imai 1997). Japan, however, should not just follow regulations set by the United States and Europe (Takagi 1997, Yamazaki 1997, Yonemoto 1997b). Japan should flexibly promote the development of human cloning technology (Kumagai 1997). Science communication in society is also inevitable (Kushida 1997, Iwasaki 1997, Kumagai 1997).

### **Ethical Principles**

Ethical and legal discussions progressively deepened. The main principles were the right to healthcare and children's rights.

### **Right to healthcare**

HRC would not violate the dignity of a person and a complete ban on HRC for reasons of possible harmful effects (e.g., discrimination, instrumentalization, and eugenics) would be wrong (Kato 1997a, 1999a). Kato emphasized the liberalist principle that freedom is to be restricted only when it harms others (the harm principle). Safety is then the only reason that HRC can be banned. HRC for the purpose of infertility treatment would be permissible based on the right of access to healthcare. However, the use of healthcare for purposes such as enhancement and arbitrary selective birth could be restricted. While part of the right to pursue happiness, these are not included in the right to healthcare. Access to healthcare benefits the public and is a matter of social justice. In Japan, there is a communitarian interpretation of liberty in which social approval confines the limits of self-determination. The individualistic libertarian interpretation of the right to pursue happiness, in which all actions are permissible as long as they do not harm others, has not been established in Japan.

Humanism and utilitarianism aim to reduce pain and increase happiness, and therefore support HRC with the condition that children are treated as ends. In a pluralistic and liberal country, HRC would be permissible for the purpose of infertility treatment (Uemura 1999, 2003).

Human dignity includes both individual dignity and public dignity. Public dignity includes maintaining public order and the human species, and restricting individual freedoms and rights. Whereas the United States is an individualistic society, Europe is more community-based. A balance between these two kinds of dignity is at issue (Nudejima 2001).

### **Children's rights and welfare**

Some bioethicists argued that children's rights and welfare would limit reproductive freedom. Referring to a report by the French Ethics Consultation Committee and the writings of Habermas, which establish a master-slave analogy for the relationship between cloner and clone, these authors contended that determining the biological features of children would violate their freedom and rights (Kitahara-Frisch 1998, Kinjo 1998, Kimura 2001) and prevent them from being autonomous to take responsibility (Asami 1999). HRC as an intentional copy would go beyond reproductive freedom (Kurata 2000, Shimoda 2001). Referring to Feinberg, some authors argued that children have the right and freedom to an open future (Nakazawa 2001, Kimura 2001). Since HRC for treating infertility is not motivated by copying the original, it does not invade children's rights (Nakazawa 2001). The issue of children's rights and welfare is also applicable to other reproductive technologies (Kitahara-Frisch 1998). While the risk of HRC might be against the best interest of children (Wada 2003), their interest cannot be compared with non-existence. Unfortunately, emphasizing safety issues might discriminate against disabled people (Nanba 2003).

### **Policy Making**

This section briefly reviews the opinion poll and HRC public policy in Japan.

### **Opinion poll**

The Prime Minister's Office conducted an opinion poll on the bioethical problems of cloning in 1998 when the Bioethics Committee discussed the regulation of cloning. Respondents were 2,700 experts representing several fields. The response rate was 78.2%, with 92.3% answering that they had an interest in cloning and 93.5% answering that HRC was unacceptable. While 67.3% were against HRC for the purpose of infertility treatment, 22.0% thought it acceptable under specific regulations, with 71.2% advocating legal regulation of HRC. Although 60.2% expected a balanced regulation on HRC with other reproductive technologies, 66.9% favoured a fast implementation of regulations; 59.4% supported an unlimited ban on HRC, but 36.9% preferred a revision within 5 years.

### **A policy by the Bioethics Committee and the Act**

The Bioethics Committee completed a report, *The Basic Policy on Human Reproductive Cloning*, in 1999 that provided the basis for the law on human cloning. The ethical principles in the report can be summarized as follows: human dignity and safety should restrict academic freedom, which is however supported by

utility. The report addressed the violation of human dignity, stating that HRC would be human breeding, instrumentalization, a violation of human rights, disrespectful to individuals, and that it would have harmful effects on society because it is far removed from a basic understanding of human reproduction. Based on the principles of human dignity and safety, the report proposed a legal ban on HRC as well as the reproduction of human chimeric or hybrid individuals. Because of utility, however, it suggested continuous consideration for research on human SCNT, chimeric, and hybrid embryos. The Committee left the ethical examination of human embryonic stem cell research and of human embryos in general as forthcoming considerations.

**Reflection on the policymaking process**

Reflecting on the policymaking process, some authors commented that the act of regulating HRC was in fact promoting embryo research (Ogoshi 2001, Nudejima 2001), and that the reasons for prohibiting HRC had not been considered carefully in relation to other reproductive technologies (Hayashi 2002). Discussion continued after the law was enacted as to whether HRC would always violate human dignity and whether or not the law was appropriate (Machino 2001, Aoyagi 2002, Ishizuka 2002). The handling of human embryos in general remained at issue.

**Discussion**

The discourse on HRC cannot be characterized by comparison with discourse on other bioethical issues here. Journalists, writers, scientists, and medical doctors quickly responded to the issue of HRC, while it took more than two years for most researchers in the humanities and social sciences to join the discussion and publish their opinions. Discussions increased even after the law was enacted. In the case of HRC, examinations of ethical, legal, and social issues (ELSI) fell behind rapid scientific research and technological development. The systems of the Bioethics Committee and ELSI research need to be improved. HRC discourse can be analyzed on three structural levels: everyday life, fundamental theory, and public policy.

**Everyday life**

On the level of everyday life, HRC seemed to find both acceptance and aversion. Attitudes regarding HRC seem to be influenced by general attitudes toward science and technology, and sympathy toward infertile couples and cloned children, regardless of the level of knowledge about HRC.

**Fundamental theory**

Attitudes toward HRC can also be explained by differences in basic ideas about the relationship between gods, nature, and human beings. In Japan, the human activities of science and technology seem acceptable when they are understood as a part of nature, but they seem unacceptable when understood as artificial and apart from nature. In animism and Buddhism, human beings are to be one with nature and gods. In contrast, Westerners set God against nature. When they understand themselves as creatures in nature, HRC is unacceptable because it is perceived as playing God. However, when they understand themselves as creative beings in the image of God, HRC could become acceptable. These differences in Japanese and Western perceptions of themselves in relation to nature and God/gods might be reflected in their approval and disapproval of scientific and technological activities.

The fundamental theories involved in HRC discourse in Japan are summarized in Figure 1. While most discussions are based on theories and principles of Western ethics, some authors argued from animistic and Buddhist viewpoints that people should be aware of their desires that go against the transitory nature of life and death, quit manipulating life, and accept everything as is. Such arguments are anti-anthropocentric and vitalistic; however, these arguments are weak now. People are secularly modernized and are quicker to accept technological developments. Anthropocentric and humanistic discussions based on Western ethics in Japan are closer to communitarianism in Europe than individualistic liberalism in the United States.

Table 1: Headlines on HRC in the Asahi Shimbun newspaper (1993-2009)

	93	97	98	99	00	01	02	03	04	05	06	07	08	09	Total	(97-03)
"clone ningen" (cloned human)	1	10	13	3	7	21	19	9	4	3			1		91	82
"fukusei ningen" (duplicate human)		1						1								2
"nito clone" (human clone)			3	2	4		1	4		1	1					16
"hito clone hai" (human cloned embryos)						6	1	12		2		1	2	2		26
Total	1	11	16	5	11	27	21	14	16	6	1	2	2	2	135	

**Public policy**

On the level of public policy, the law on human cloning is communitarian in the sense that it aims to maintain public order. It does not, however, reflect difficult questions on ethical principles such as the right to access infertility treatment and children's rights. Instead, it reflects the needs on the practical level of everyday life, i.e., the opinion of the general public, international conformity with Western countries, and the promotion of human embryo research. Should we be more thorough in our consideration of

fundamental theories and principles? Should we be more modernized or traditional? Some argued that to resign unnatural desires of HRC and other life-manipulative technologies is the ethics of self-restriction on individual judgment, which is beyond laws and regulations affirmed by individualistic liberalism (Yamaguchi 2002, Machida 2007). At the same time, communitarian bioethics on HRC and embryo research are accepted not only in Europe and Japan, but also in the United States (Komatsu 2005). This is reminiscent of the common morality principles

by Beauchamp and Childress (2009). Communitarian rules will be common among different people and countries with different cultures. But when the public participates in regulating the development of science and technology, the basic ideas of human beings, nature, science and technology, and happiness might require reconsideration of their personal values and the common good. Humanities, in cooperation with social sciences, may have a role in clarifying these ideas in the development of natural science and technology.

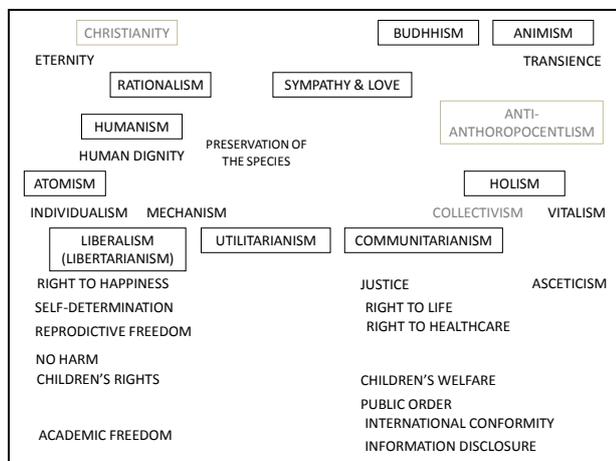


Figure 1: Basic and mid-level principles of human reproduction in Japan

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## Analysis of Legal and Ethical Problems Related to Preimplantation Genetic Diagnosis in Japan and Policy for Clinical Settings

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### Abstract

The reality is that the assisted reproductive medical community in Japan is trapped between a rock and a hard place on the question of whether to expand the indications for PGD as a therapeutic method. In light of this situation, in this article we engage in a two-stage discussion. We start by (1) setting out the standpoint of current legislation concerning the beginning of human life. We subsequently (2) offer a dissertation on the selection of fertilized eggs prior to implantation (the legal and ethical validity of PGD). In concrete terms, we set out five points from the arguments of those who oppose or counsel caution on the clinical use of PGD and describe the arguments in favour, before adding our own discussion of the arguments against this method. Finally, we mention policy for clinical settings.

**Keywords:** bioethics, law, Japan, PGD

### Introduction

Louise Joy Brown, the world's first child to be born as a result of the *in vitro* fertilization and embryo transfer (IVF-ET) technique developed by physiologist Robert Edwards, obstetrician Patrick Steptoe,<sup>1</sup> and their colleagues, was born in 1978 in Oldham General Hospital, England. Since then, about 30 types of assisted reproductive technology (ART) have been developed, and these are widely used in the diagnosis and treatment of infertile patients. Although ART has proved the salvation of many infertile patients, it cannot be denied that it has raised social, legal, and ethical questions. Naturally, preimplantation genetic diagnosis (PGD), one application of ART, is not excluded from such social, legal, and ethical issues.

Professor Yuji Taketani of the University of Tokyo, former chairperson of the Japan Society of Obstetrics and Gynecology (JSOG), which recommends and provides guidelines on assisted reproductive medicine in Japan, revealed his honest opinion that "reproductive ethics are the subject that most troubles this Society" in a message on assuming the chairpersonship of the JSOG (published on the JSOG website in April 2005).

The reality is that the assisted reproductive medical community in Japan is trapped between a rock and a hard place on the question of whether to expand the indications for PGD as a therapeutic method: it is caught between patients who want to use this treatment and their supporters, who are trying to

respond to these patients' wishes, and those who argue for caution out of concern that PGD could be overused (commercially developed), as well as powerful opposing groups that claim the selection of fertilized eggs based on PGD results amounts to discrimination against disabled people.

The JSOG is caught in this position and troubled by the bioethical issues surrounding assisted reproductive medicine. Nonetheless, it approved a change of policy to extend the indications of eligibility for PGD, which until then had been limited to "severe genetic disorders," to also include "recurrent miscarriage caused by reciprocal translocation" at its Annual General Meeting in April 2006. In line with this, the JSOG also added chromosomal translocation to its existing list of "severe genetic disorders" as an approved clinical indication of eligibility for PGD, in addition to severe single-gene disorders (such as Duchenne muscular dystrophy [DMD], myotonic dystrophy, and adrenoleukodystrophy [ALD]) and Leigh encephalopathy.

With these revised criteria, the JSOG had by May 2010 given approval for 147 cases of PGD. There have been 171 applications for clinical or research uses of PGD to date (147 approved, 4 refused, 15 ineligible for review, 1 withdrawn, 4 under review) (Minutes of the 1th Meeting of the Board of Directors for FY2010).

In light of this situation, in this article we engage in a two-stage discussion. We start by (1) setting out the standpoint of current legislation concerning the beginning of human life. We subsequently (2) offer a dissertation on the selection of fertilized eggs prior to implantation (the legal and ethical validity of PGD). In concrete terms, we set out five points from the arguments of those who oppose or counsel caution on the clinical use of PGD and describe the arguments in favour, before adding our own discussion of the arguments against this method. Finally, we mention policy for clinical settings.

## 1. The Current Legal Standpoint on the Start of Human Life

When does human life begin? At the moment of fertilization, at the point at which the human form starts to take shape (two weeks after fertilization), at the point of viability outside the mother's body (in Japan this is defined as from 22 weeks), or at the moment of birth?

We set out below the legal standpoint of current legislation in Japan on the beginning of human life.

### (a) Human life

In current legislation, human life is handled according to two categories: after birth and before birth. Life after birth is that of a human being, while life before birth is that of a fetus. Any infringement of this life is punished in the former case as homicide (Articles 199–203 of the Criminal Code) and in the latter case as criminal abortion (Articles 212–216 of the Criminal Code). Accordingly, it is clear that the scope of legal protection on the basis of the Criminal

Code is that of a human being after birth and that of a fetus before birth.

When do the states of "human being" and "fetus" begin according to current legislation?

### (b) The beginning of a human being

The Civil Code, which lays down that "The enjoyment of private rights shall commence at birth" (Part 1, Article 3), treats the birth of a human being as one who holds private rights as "the point at which a fetus has been completely born from the mother's body" (complete exteriorization theory) In contrast, the Criminal Code, which protects the lives and bodies of human beings, recognizes a "human being" at the point at which a part of the fetus is outside the mother's body (partial exteriorization theory).

### (c) The beginning of a fetus

Neither the Civil Code nor the Criminal Code contains any stipulation on the beginning of a fetus. According to the Act on Regulation of Human Cloning Techniques, a "fetus" means a conceptus following the start of implantation of a fertilized egg into the uterus from the beginning of the formation of the placenta until birth (Article 2 [vii]).

### (d) Legal protection of the fetus

In light of the situation outlined above, how far does legal protection extend to the fetus?

From the standpoint of obstetrics, in which an individual is called a "fetus" from the time the main organs are complete at 8–9 weeks, not only should a fetus older than 22 weeks be the subject of protection by the Criminal Code, but this protection should also extend to fetuses older than 8–9 weeks.

The termination of a fetus younger than 22 weeks without the consent of the mother, even as the result of carelessness, would be regarded as an illegal abortion, that is, the crime of criminal abortion. This is irrespective of any flexibility in the actual implementation of justifiable induced abortion for medical (health) reasons, social (economic) reasons, or ethical reasons (e.g., rape) on the basis of the Maternal Protection Act (Article 14, revised from the Eugenic Protection Act in 1996), which permits the use of artificial termination of pregnancy as an exception to criminal abortion.

Conversely, if we adhere to the definition of a "fetus" according to the Act on Regulation of Human Cloning Techniques, the protection of the Criminal Code should extend to the embryo (under 8–9 weeks) and the conceptus after the start of implantation into the uterus (the preembryo aged at least one week but less than two weeks), raising the question of debate on the establishment of an embryo protection act.

In either case, according to current legislation, even if the definition of a "fetus" is broadly interpreted, the conceptus prior to the start of implantation, that is, the preembryo aged less than 1 week old, which is the origin of human life, is not recognized as a form of human life (see figure below).

## 2. Legal and Ethical Validity of PGD

From the foregoing steps, we can derive the following conclusion.

The individual prior to the start of implantation—i.e., the preembryo aged less than 1 week old—is not recognized as human life and is not protected under current legislation.

What, then, of the ethical validity of PGD?

(a) Arguments against PGD

The arguments made by those who oppose PGD and those who counsel caution on its use (Network Against Eugenics<sup>1</sup>, 2004) can be summarized in the following five points:

- (1) Preimplantation genetic diagnosis constitutes discrimination against disabled people.
- (2) Preimplantation genetic diagnosis constitutes oppression against women.
- (3) Preimplantation genetic diagnosis objectifies the increasing manipulation of life and fertilized eggs.
- (4) The technique is in its experimental research stage, and its safety has not been established.
- (5) Commercialized applications need to be restricted.

(b) Arguments in favour of PGD

The original reasons for the utility of PGD can be summarized as follows (website<sup>1</sup> of the Otani Women's Clinic):

- Prevention of recurrent miscarriage
- Improved pregnancy rate following IVF
- Reduced miscarriage rate following IVF
- Potential of pregnancy for sufferers of repeated IVF failure
- Reduced multiple gestation rate following IVF
- Diagnosis of trisomy
- Diagnosis of genetic disorders

The following points<sup>1</sup> can also be identified as further advantages of PGD:

- Reduction of the mental and physical burden on genetic high-risk patients and achievement of a healthy child using the polymerase chain reaction (PCR) method to diagnose single-gene disorders (or using sex selection by sex diagnosis as a highly accurate diagnostic method for supplementing the diagnosis of genes for somatic disorders).
- Diagnosis and prevention of delayed (late-onset) disorders with genetic predisposition.
- Diagnosis and prevention of multifactorial disorders (disorders with genetic predisposition with a high rate of occurrence among adults).
- Human leukocyte antigen (HLA) typing of fertilized embryos enabling the selection (immunogenetic selection) of HLA-matched (tissue-typed) embryos to act as future stem cell donors for saving the lives of brothers and sisters suffering from congenital or acquired spinal cord disorders, leukemia, or genetic hematologic disorders.
- Avoidance of abortions associated with antenatal diagnosis (fetal diagnosis) in clinical settings.

Below are some arguments against PGD:

(1) Discussion of the claim that "Preimplantation genetic diagnosis constitutes discrimination against disabled people"

In the medical setting, we receive requests from patients who want to use PGD, and we want to respond to these patients' wishes. This provides us with an important starting point for debate; first, we must consider whether it is really true that PGD, which is so strongly desired by patients with critical genetic diseases, not only leads directly to discrimination against disabled people but is also a form of eugenics resulting in the selection of certain forms of life over others.

If it is forbidden for a patient or doctor to artificially select between fertilized eggs, even for diagnostic or therapeutic purposes, and all the functions of life are to be left completely up to nature, then the treatment of disease must also be a sacrilegious act that goes against nature. If this is true, all medical advances could be impermissible.

Some have made compelling claims, pleading that "I want my next child to be healthy" or "We want our disabled child to have brothers and sisters who can support him or her after we're gone." However, the Network Against Eugenics asserts that "What is actually required is the provision of social systems for disabled children and adults, as well as people with genetic diseases, the development of support systems, and the elimination of discrimination and prejudice."

Nonetheless, to insist that the achievement of a welfare state without discrimination must take precedence, that research on sophisticated, advanced assisted reproductive medicine should be cancelled, and that such techniques should not be used, is to shut one's ears to the voices of patients who are crying out for help. To delay diagnosis and treatment until the day a fully functional welfare state is achieved—a date that is entirely unpredictable—is to rob desperate patients who have no time to spare of their right to choose a treatment, which violates the people's right to the pursuit of happiness (Article 13 of the Japanese Constitution).

As readers will be aware, patients who have made the decision to request PGD have reached this conclusion after a great deal of thought. The parental feelings of patients who ask that the next child to whom they give birth be healthy in mind and body are natural human emotions that no one can condemn. If this parental desire for the birth of a mentally and physically healthy child is condemned as eugenics leading to discrimination against disabled people, virtually the whole of the world's population must be regarded as eugenicists. Accordingly, the standpoint of patients who have made their own choice to undergo PGD after serious consideration must be respected in exactly the same way as the perspective of other parents who have made the decision to bring up their baby even if it is disabled, just as they would a healthy child.

In this sense, PGD performed for medical reasons should be offered as one of the choices available to worried patients.

Even if a patient should decide to screen out fertilized eggs that carry a disability, this in no way negates the existence of disabled people alive today. To choose between fertilized eggs is a personal

decision that should not involve the state or government.

We must be careful to learn the lessons of history dispassionately. For example, before PGD was developed, antenatal diagnosis also came under fire as a sophisticated, advanced assisted reproductive technique that enabled selection of human life (fetus), and was denounced as negating the existence of disabled people. Has discrimination against disabled people markedly intensified during the half-century since antenatal diagnosis came into use in the 1960s as a result? If this cannot be proved to be fact, it is reasonable for those of us who live according to the Constitution of Japan to respect the diversity of each other's individual decisions.

2) *Discussion of the claim that "Preimplantation genetic diagnosis constitutes oppression against women"*

IVF-ET is a technique that is indispensable for PGD. One of the complications of IVF-ET is ovarian hyperstimulation syndrome (OHSS), a side effect of ovulation-inducing drugs. PGD involves this risk in oocyte retrieval. This is fully explained in advance to patients who wish to use PGD at the genetic counseling stage, and their informed consent is obtained before continuing with the procedure. Accordingly, as patients themselves are ultimately the ones who decide to use PGD, it is far from a form of oppression against women. If even acts of self-determination concerning reproduction by adult patients are to be obstinately labeled "oppression against women," then all medical actions permitted only to doctors on the basis of the patient's consent—the illegality of medical invasion is only removed after the patient has given consent—are without exception forms of "oppression against human beings." After all, medicine is an invasive act against the body or mind and is not always 100% safe. People who persist in this extreme argument negate the concept of Western medicine in its entirety, including surgical treatment.

3) *Discussion of the claim that "Preimplantation genetic diagnosis objectifies the increasing manipulation of life and fertilized eggs"*

Opponents of PGD and those who counsel caution on its use make the following claims:

(3-1) The selection of human fertilized eggs by PGD constitutes the selection of human life.

(3-2) Because the selection of human fertilized eggs constitutes the selection of human life, PGD cannot be approved.

The reality in Japan is that every year, over 300,000 fetuses are aborted at the mother's request under the broad interpretation of the Maternal Protection Act. With this in mind, if claim (3-1) were to be accepted—that is, if the selection of fertilized eggs constitutes the selection of life—then abortion is nothing but the glaring destruction of human life, and we should not ignore this. To overlook the destruction of over 300,000 human lives while advocating respect for human fertilized eggs prior to implantation is hypocritical. Further, calls for a declaration of the

human rights of embryos or the formulation of an embryo protection law represent a backwards set of priorities—indeed, it would be ridiculous if the preimplantation genetic diagnosis of fertilized eggs were to be more strictly regulated than antenatal diagnosis resulting in termination, and if fertilized eggs were thus better protected than fetuses. How do opponents of PGD and those who counsel caution on its use reconcile their words and actions with respect to this inverted situation?

If claim (3-2) were to be accepted, infertile patients and sufferers of congenital genetic disorders who are pinning their hopes on PGD would be abandoned in a single stroke. PGD is capable of distinguishing among fertilized eggs with greater analytical precision than can the naked-eye appraisal of the morphology of fertilized eggs used in regular IVF. In light of this, should doctors continue to be unable to use PGD, patients suffering from recurrent miscarriage due to chromosomal abnormalities (both structural and numerical) will undergo further mental and physical distress either by continuing to attempt natural pregnancies until one of their few normal fertilized eggs implants by chance (pregnancy = conception), or by giving up the idea of having their own child entirely.

At the same time, sufferers of congenital genetic disorders must prepare themselves either to give birth to a disabled child, to undergo antenatal diagnosis during pregnancy, or to give up the idea of having their own child.

To begin with, almost all fertilized eggs with chromosomal abnormalities are culled naturally<sup>1</sup> in the womb. The clinical application of PGD to prevent recurrent miscarriage is a way of selecting and saving the few fertilized eggs that possess the inherent potential to survive. If the utility of PGD in ameliorating the burden on the mother's body is also taken into account, the clinical application of PGD to prevent recurrent miscarriage should be used in a flexible manner.

The clinical application of PGD to avoid critical congenital genetic diseases is a useful measure for avoiding the tragic circumstance of everyday abortion based on antenatal diagnosis, and this should also be handled flexibly.

4) *Discussion of the point that "The technique is in its experimental research stage, and its safety has not been established"*

In terms of the safety of PGD, there is a major divergence of opinion between the standpoints of the JSOG and of Dr. Tetsuo Otani. Owing to a divergence in their awareness of the facts concerning the status of implementation and regulation of PGD in other countries, whereas the JSOG recognizes PGD as being in the "clinical research phase," Dr. Otani regards it as an established assisted reproductive technology capable of "clinical implementation." In fact, if we rely on the survey of the results achieved over ten years at the world's three largest PGD centers<sup>1</sup> carried out in FY2004 by Professor Munné and colleagues,<sup>1</sup> 4748 people have undergone the procedure, with 754 live births resulting. There are

207 continuing pregnancies. Five cases of false diagnosis in the implementation of PGD have been reported (three false diagnoses of trisomy 21, one of cystic fibrosis, and one of fragile X syndrome).

The safety of embryo biopsy during PGD, in which one or two cells are aspirated from the 4-8 cell stage embryo, is underlined by the fact that there have been no reports of damage among the more than 1000 PGD live births that have already taken place worldwide. Incidentally, it was reported in 1994 that the safety of embryo biopsy had been established in mouse embryos.<sup>1</sup>

As PGD involves a diagnosis being made from a single cell, false diagnoses are difficult to avoid (limits of diagnostic accuracy) but the correct diagnosis rate for a single fertilized egg is over 90%,<sup>1</sup> and even if embryo transfer of a fertilized egg carrying a chromosomal abnormality were to occur as a result of a false negative diagnosis, there are few instances in which the pregnancy would continue to term. Of course, informed consent is obtained from patients to this effect.

In addition, it is normal for 1-2 cells to be lost from the conceptus when frozen fertilized eggs are defrosted,<sup>1</sup> but this has no particular effect on the fetus, and pregnancy can be achieved even if half of the blastomeres die. Injury to the embryo may occur as a result of the procedure, but at a frequency no different to that of injury to the embryo from intracytoplasmic sperm injection (ICSI) (PGD has "an equivalent level of safety to that of the implementation of IVF-ET"<sup>1</sup>), meaning that injury to the embryo does not directly imply injury to the fetus.

As reported by Professor Munné and colleagues in the same paper, over 1000 live births have now resulted from PGD, with a rate of congenital disability among these children of 5-6%. If this rate is compared with the rate of congenital disability from natural pregnancy, there is no significant difference.<sup>1</sup> "This number validates that there is no ostensible evidence of any incurred adverse effect."<sup>1</sup>

After Handyside pioneered the clinical use of PGD in the UK, by 2004 the technique had already been used in over 6000 cases in countries other than Japan.<sup>1</sup> According to Professor Munné in the United States, the leading expert in the clinical performance of PGD, over 5000 cycles of the technique had been carried out in his institution alone by 2005, increasing to over 7000 cycles by March 2006. Accordingly, Munné estimates that a total of 7000 cycles of PGD (2000 cycles in his own institution, 5000 elsewhere) are performed in the United States every year. Reports such as the European Society of Human Reproduction and Embryology (ESHRE) PGD Consortium Data Collections III-IX and the multicenter report from the world's three main PGD centers<sup>1</sup> demonstrate that PGD techniques are no longer in the research stage and their safety has been established.

##### 5) Discussion of the argument for "Commercialized applications need to be restricted"

The commercial development of PGD could involve intentional gender selection of babies for non-medical reasons, paving the way for "designer babies." In other words, "commercialized development" would

comprise the intentional selection of births on the basis of medical reasons (such as avoidance of single-gene disorders or screening for chromosomal aneuploidy during infertility treatment) and sex selection for non-medical reasons.

If there is genuine concern over the "overuse" of assisted reproductive technology (ART), that is, its "commercialized development," then what should be considered first is the "overuse" of prenatal diagnosis (PND) occurring alongside the introduction of unregulated IVF-ET for reasons other than those approved under the Maternal Protection Act (revised in 1996 from the Eugenic Protection Act), which comprise medical (health) reasons, social (economic) reasons, or ethical reasons (e.g., rape). Specifically, the JSOG, which is the leading organization for doctors associated with providing assisted reproductive technology in Japan, should give priority to dealing effectively with "*the reality that the reasons for abortion are not limited to so-called severe cases but also encompass a variety of disorders, Down syndrome, and even sex selection.*" To ignore the more than 300,000 artificial terminations of pregnancy that take place annually while strictly regulating PGD, which screens fertilized eggs, rather than PND, which leads to abortion, is to put the cart before the horse by protecting fertilized eggs more carefully than fetuses.

The viewpoints of particular disabled people's organizations that completely oppose the clinical application of PGD, and the JSOG's policy of the restriction of PGD to "critical genetic disorders" due to excessive concern about its use for gender selection, are based on the "slippery slope theory" of firmly cutting off the possibility of "designer babies" at its source. The judgments of these individuals, however, abandon patients suffering for medical reasons (such as avoiding single-gene disorders and screening for chromosomal abnormalities as part of infertility treatment), which risks infringing upon the right to the pursuit of happiness protected under Article 13 of the Japanese Constitution. So long as citizens neither (1) infringe others' rights, nor make decisions that are (2) self-destructive or (3) offensive to public order and morals, those who wish to impose limits at any cost on other people's right to the pursuit of happiness, as enshrined equally for the people by the Constitution, must properly present an appropriate constitutional interpretation. Furthermore, patients have the right to decide for themselves on the disposal of their own bodies (the right to choose treatment and the right to refuse it). Doctors, who bear the responsibility for patients' lives, have the obligation to concentrate on treatment. Doctors who do not offer a full explanation to patients about the utility of PGD as the latest medical treatment can not only be accused of violating their duty of accountability to patients under the Medical Care Act (Article 1, Paragraph 4), but are in default (Article 415 of the Civil Code) with respect to arbitrary medical actions without the consent of a client who is unable to choose one option. Such doctors may accordingly be engaged in an illegal act (Article 709 of the Civil Code), potentially rendering them responsible for damages.

Table 1: The standpoint of current legislation on human life

Preembryo implantation starts	Early embryo = preembryo	Origin of life (government view of life: germination of life)	Non-implantation	Government: Research use of human embryos (human fertilized eggs, cloned human embryos) conditionally permitted	
1 week		Start of implantation (pregnancy) (start of placenta formation)			
Preembryo implantation complete		Origin of life (government view of life: germination of life)	Early miscarriage		Criminal abortion
2 weeks		Implantation complete, formation of primitive streak			
Post-implantation embryo	Embryo	Germination of life	Early miscarriage	Expulsion of a fetus older than 12 weeks is treated as delivery, and a notification of stillbirth is required (in line with regulations on notification of stillbirths (Ministry of Health, Labour and Welfare ordinance). Conversely, expulsion of a fetus under 12 weeks old is not treated as delivery under the Maternal Protection Act, and the fetus is disposed of as medical waste under the Medical Waste Treatment Law.	Criminal abortion
8-9 weeks		Organ germs complete (human appearance on external observation)			
Fetus		Germination of life	Early miscarriage		
12 weeks		Major organs complete (external reproductive organs complete)		A dead fetus over 4 months old is subject to the laws governing cemeteries and funerals (notification of death and permission for funeral)	
Fetus		Germination of life	Late miscarriage		
22 weeks		Viability (capable of survival outside mother's body)			
Fetus		Life	Premature birth/stillbirth	As above	Criminal abortion
37-40 weeks		Birth			
Human being		Life	Death	As above	Homicide

### Conclusion

As summarized in section (1), the human life of the conceptus prior to implantation (the preembryo less than 1 week old) is not legally recognized, and preembryos are thus not subject to protection under current legislation. This means that PGD, which involves preembryos less than 1 week old (preimplantation embryos), is not illegal.

Nevertheless, although the handling of conceptuses prior to implantation (preembryos less than 1 week old) is not illegal under current legislation, the objectification of fertilized eggs is open to discussion from an ethical viewpoint. In Japan, social norms and public sentiment are taken into account in order to resolve this ethical issue. This contrasts with the United States, a Christian nation in which many people believe that an almighty God reigns who created humanity in his own image. In Japan, which lacks a background of philosophical thought from which human dignity can be ethically derived in the context of the relationship between God and humanity, it is impossible to argue for the conclusion of original human dignity by singling out humanity alone from among all the diverse forms of life on

Earth. The concept of the "infringement upon human dignity" must accordingly be argued from the standpoint of prevalent social norms and public sentiment.

Thus, from the standpoint of social norms and public sentiment, is a human fertilized egg a "human being" that possesses dignity? To start with, a human fertilized egg does not exist as a "personage" in the same class as a human being subject to legal protection. In Japan, everyone knows that although the spirits of aborted babies are placated as "personages," those of fertilized eggs are not. If a declaration of the human rights of the embryo or the formulation of an embryo protection law were to be achieved in Japan and the personages they assert did really exist, those who argue for the "dignity of the human fertilized egg" would be urgently faced with the prior task of saving the over 300,000 fetuses aborted by their parents every year.

Human fertilized eggs are not "human beings" according to current legislation, nor are they the same as "humans" who possess dignity from an ethical viewpoint (from the standpoint of social norms and public sentiment), but form the "germination of human

life," as recognized by the government (Council for Science and Technology Policy Expert Committee on Bioethics, Cabinet Office). In other words, they are, strictly speaking, "the origin of human life." This means that the selection of human fertilized eggs does not constitute the selection of human life, but rather, as it were, the selection of the origin of human life. As stated in the Commentary to the JSOG report "Opinions on Research Dealing with Human Sperm, Eggs, and Fertilized Embryos" (March 1985), the time within two weeks after fertilization is a period before the potential for development as a human individual is established, and a preembryo less than 2 weeks old is not the same as a fetus or embryo. Even among preembryos less than 2 weeks old, during the period when individuality has not been established and blastula cells possess multipotentiality, PGD selects preembryos that are less than 1 week old and constitute "the origin of life." Its clinical application should be permitted for specialized medical reasons (such as avoiding single-gene disorders and screening for chromosomal abnormalities as part of infertility treatment) while paying the greatest possible concern to ethical issues.

## Analysis of Issues Related to *in Vitro* Fertilization and Embryo Transfer Using Egg Cells from Voluntary Donors in Japan and a Proposal to the Diet

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### Abstract

The outline of the final report by the ART Section of the Health and Welfare Scientific Council is as follows:

- Use of sperm and egg cells from non-spouses is allowed, embryo donation is not prohibited.
- Surrogate conception, including both gestational surrogacy and genetic surrogacy, is prohibited.
- Donation is voluntary. Exchange of a corresponding sum to cover actual costs is allowed.
- Donors shall remain anonymous. Blood relations, including siblings, may not act as donors.
- Donors shall be compensated for counseling sessions.
- Legal regulations involving penalties concerning ART by sperm cell, egg cell and embryo donation shall be implemented.
- The woman who gives birth to the child shall be the legal mother, and the mother's husband, with his consent, shall be the legal father.

• The child is entitled to personal information (identifying information) about the donor.

• A public institution shall be established for the administration and management of sperm, egg, and embryo donation.

**Keywords:** bioethics, Japan, IVF-ET, Egg Cells

### 1. Current Regulations concerning *in Vitro* Fertilization and Embryo Transfer (IVF-ET) Using Egg Cells from Voluntary Donors in Japan and Analysis of Bioethical Issues

In 1996, obstetrician and gynecologist Yahiro Netsu at Suwa Maternity Clinic successfully achieved the pregnancy of a married woman suffering from infertility (Turner syndrome<sup>1</sup>) via IVF-ET using egg cells from a blood-related donor.

After Netsu published his results in June 1998, he was temporarily expelled from the Japanese Society for Obstetrics and Gynecology (JSOG) for violating the society's *Opinions on IVF-ET Techniques* (October 1983), which had forbidden the use of blood-related donors in fertility treatment. The fact that Netsu raised the issue, risking his career, has become the motivation behind appeals to both JSOG and the Japanese government for the revision of the current restrictions on IVF-ET, which forbid the use of blood-related donors and paradoxically preserve both the anonymity of the gamete (sperm/egg cell) donor and the child's right to know his or her origin.

In February 2001 and April 2003, the JSOG Ethics Council presented to the JSOG Ethics Committee, its parent committee, two reports—*On the Performance of Non-spousal In Vitro Fertilization and Embryo Transfer by Egg Cell Donation* (February 2001) and *On the Subject of Making Sperm Cell and Egg Cell Donors Anonymous Third Parties* (April 2003)—that conditionally approved the use of the IVF-ET technique using egg cells from anonymous non-blood-related donors (non-spousal IVF-ET).

Following the establishment in October 1998 of the Specialist Committee for Assisted Reproductive Technology (ART) under The Cutting Edge Medical Technology Evaluation Section of the Health and Welfare Scientific Council, and the acceptance in December 2000 of a report from the same specialist committee (*Report on ART by Sperm Cell, Egg Cell and Embryo Donation*) by the Japanese government (more specifically, the former Ministry of Health and Welfare), the ART Section of the Health and Welfare Scientific Council began operation in June 2001, targeting the development of a system revision based on the December 2000 report. Confirming to a large extent the conclusions of the specialist committee, the ART section produced a final report that conditionally approved non-spousal IVF-ET (*Report on the Adjustment of the System for ART by Sperm Cell, Egg Cell and Embryo Donation*, April 2003).

The specialist committee and the ART section agreed on the following six items:

1. The welfare of the child shall be given priority.
2. Human beings shall not be used merely as reproductive resources.
3. Safety shall be given sufficient consideration.
4. Eugenics shall be avoided.

5. Commercialism shall be avoided.
6. Human dignity shall be protected.

JSOG president Professor Yasunori Yoshimura of Keio Gijuku University briefly summarizes the outline of the final report by the ART Section of the Health and Welfare Scientific Council as follows (conclusions that differ from those of the specialist committee report are underlined):

1. Use of sperm and egg cells from non-spouses is allowed, embryo donation is not prohibited.
2. Surrogate conception, including both gestational surrogacy and genetic surrogacy, is prohibited.
3. Donation is voluntary. Exchange of a corresponding sum to cover actual costs is allowed.
4. Donors shall remain anonymous. Blood relations, including siblings, may not act as donors.
5. Donors shall be compensated for counseling sessions.
6. Legal regulations involving penalties concerning ART by sperm cell, egg cell and embryo donation shall be implemented.
7. The woman who gives birth to the child shall be the legal mother, and the mother's husband, with his consent, shall be the legal father.
8. The child is entitled to personal information (identifying information) about the donor.
9. A public institution shall be established for the administration and management of sperm, egg, and embryo donation.

Given the above-mentioned developments, the Japanese government (Ministry of Health, Labour and Welfare, Family Bureau, Maternal and Child Health Division) immediately began preparations for the legalization of non-spousal IVF-ET. However, the bill was not presented during the normal 2004 Diet session due to the resistance of Seiko Noda—a former infertility patient and member of the LDP Diet and the House of Representatives who received surrogate conception treatment—towards the final report, which sought to prohibit and criminally penalize surrogate conception treatment and the mediation for such treatment (III-7). The ART bill in question has thus not yet been enacted.

Although IVF-ET using egg cells from anonymous third-party donors (not including friends and sisters) has been universally approved in Japan since April 2003, the application preceding approval has in no way been submitted to JSOG. As countless infertility patients may have passed the reproductive period without knowing that non-spousal IVF-ET had been approved, this situation is clearly unacceptable.

## 2. Affirmative Remarks on IVF-ET Using Egg Cells Donated by Friends and Sisters (Not Anonymous Third-party Donors)

(a) *Voluntary egg cell donation by friends and sisters (not anonymous third-party donors) and the correlation between such donation and the Japanese*

*government's final report or indications from involved scientific associations (JSOG Ethical Council report)*

Following the first successful pregnancy via non-spousal IVF-ET using egg cells from a blood-related donor (without application to the JSOG) in 1996, Hiroshima HART Clinic Director Katsuhiko Takahashi, along with a group of uncompensated volunteer egg donors, filed the first application for the approval of the IVF-ET technique with the Japanese Institution for Standardizing Assisted Reproductive Technology (JISART) in 2006. In 2008, two patients who had applied for the IVF-ET technique gave birth.

The treatment in these cases consisted of egg cell donation by friends and sisters rather than anonymous third-party donors. As a result, these cases were in violation of the provisions for application of IVF-ET using donated egg cells approved by the Japanese government (Ministry of Health, Labour and Welfare, Family Bureau, Maternal and Child Health Division). Specifically, the treatment in these cases violated Section III-3-(2)-1 of the provisions: preservation of anonymity in sperm cell, egg cell, and embryo donation. Voluntary egg cell donation by friends and sisters rather than anonymous donors also violates the conditions outlined by JSOG in the 2001 report *On the Performance of Non-spousal In Vitro Fertilization and Embryo Transfer by Egg Cell Donation*, which states that egg donation "must be limited to an anonymous third party" (2-(1)).

The Japanese government's report, while declaring that "anonymity in sperm cell, egg cell and embryo donation will be protected", simultaneously emphasizes the "child's right to know the origin of donated egg and sperm cells" (III-3-(3)). While the JSOG Ethical Council's report states that "at this time, the sperm cell/egg cell donor will be an anonymous third party" (conclusion), the Council also predicts that "if, hereafter, new results arise from a reproductive poll among the Japanese people, and favourable public opinion towards the child's right to know its origin becomes more widespread, relaxation of the requirement for anonymity can conceivably also become social consensus."

The law's emphasis on the preservation of anonymity in sperm cell, egg cell, and embryo donation while simultaneously establishing the "child's right to know" has been noted as a troubling contradiction in reports by both the Japanese government and the JSOG council. Indeed, it is nearly impossible to find a voluntary anonymous egg cell donor willing to donate without financial gain while at the same time maintaining the "right to know" of the child that will be born as a result of the treatment.

This is also true because, in contrast to sperm donation, which can be achieved relatively quickly and easily, the process of egg cell donation is extremely time-consuming and physically demanding. In addition, volunteer egg donors are required to go to the hospital and receive medical treatment during a certain period in order to give egg cells, and the possibility exists that donors might develop ovarian hyperstimulation syndrome (OHSS) as a side effect of fertility drugs.

Today, along with rapid developments in the field of ART, the perceptions of Japanese people towards ART are rapidly changing, and it is only natural that the reports by the Japanese government (April 2003) and the JSOG council (February 2001, April 2003), both prepared more than 7 years ago, no longer satisfy the Japanese people's needs. These reports, now remote from the actual realities of infertility treatment, must be revised.

*(b) Safety and effectiveness of third-party egg cell donation (including friends and sisters)*

Non-spousal IVF-ET has been considered an effective infertility treatment for more than 27 years, since Alan Trounson<sup>1</sup> of Monash University (Melbourne, Australia) first reported successful results in 1983. According to Viveca Söderström-Anttila,<sup>1</sup> the number of non-spousal IVF-ET egg cell donation cycles in 2002 was 13,183, with a high birth rate (number of birth cycles/number of embryo transfer cycles) of 50%. Therefore, it is undeniable<sup>1</sup> that IVF-ET using third-party egg cell donation (including friends and sisters) is an effective infertility treatment that can improve fertility in patients lacking egg cells.

Nevertheless, the following two points concerning the safety of the recipient and the donor should be carefully considered:

1) The high rate of multiple pregnancies (45% as compared to the natural multiple pregnancy rate of approximately 3%), caused by multiple transfers of high-quality embryos in accordance with patients' wishes, is associated with complications at birth.<sup>1</sup>

2) Egg donation involves a number of physical risks.

In order to avoid multiple pregnancies, it is necessary to decrease the number of embryos transferred during treatment. This means that, as a rule, a single embryo should be transferred per treatment. However, transfer of two embryos is allowed for women over the age of 35, as well as for those who have been unsuccessful in achieving pregnancy more than twice in succession. Married couples receiving treatment must be informed about the availability of freezing conservation technology for untransferred embryos so that they can be used in later treatment cycles.<sup>1</sup> Using preimplantation genetic screening (PGS)<sup>1</sup>, which is highly accurate in identifying high-quality embryos as compared to the common IVF technique, in which the embryo's form is judged visually, it is possible to decrease the number of embryos transferred to the mother's body and thereby reduce the physical risks associated with multiple pregnancies.

Next, regarding the physical difficulties faced by egg donors, obstetricians and gynecologists must remember that, although the risk of serious complications (such as OHSS) during egg cell extraction is lower than that during bone marrow extraction, the physical risks for the donor during egg cell extraction are not zero. Doctors must consider the well-being of the third-party donor as well as the infertile couple during treatment.

*(c) Incidence of hereditary handicaps in children conceived via ART (IVF, intracytoplasmic sperm injection [ICSI])*

The Committee for the Investigation of Actual Conditions of the Japan Society of Fertilization and Implantation (chaired by Takahide Mori) has reported the results of an investigation into the incidence of hereditary physical and psychological developmental abnormalities in 5-year-old children conceived using ART in 1997. Hereditary abnormalities were discovered in 25 (3.09%) of the 809 children that could be traced. In general, the incidence of handicaps after birth increases with age, and it is presumed that, during the first year after birth, the rate increases two to three times as compared to the period immediately after birth. Using this observation, the incidence of hereditary abnormalities in the period immediately after birth in the 809 children conceived using ART can be estimated as between 1.03% and 1.55%.

According to the homepage of the Statistical Investigation Report on Visible Handicaps edited by the Yokohama Municipal University International Hereditary Handicap Monitoring Center of the Japan Association of Obstetricians & Gynecologists, the frequency of visible handicaps in naturally conceived children born between 1999 and 2002 (total number of handicapped children/total number of children born) ranged from 1.42% to 1.77%.

The incidence of hereditary handicaps among children conceived using ART is thus not significantly different than that among naturally conceived children. "However thoroughly the preventive measures, such as testing for infectious diseases like HIV and checking sperm cells, egg cells and embryos for genetic diseases at extraction,"<sup>1</sup> are performed, it is possible that children conceived using ART may inherit single-gene disorders or chromosomal abnormalities, resulting in hereditary handicaps or genetic diseases. Naturally, in such cases, we must also acknowledge that there will be situations in which parents refuse to accept the child that ART has helped them to conceive.

In order to properly deal with these issues, it will be necessary for clinics to preliminarily provide sufficient informed consent and counseling to their patients.

*(d) Legal position and welfare of children conceived using egg cells from third-party donors (including friends and sisters)*

1) Delays in putting together the JSOG report and the final report of the Japanese government, together with the lack of continued deliberation and the postponement of deliberation by the ART Examining Committee of the Science Council of Japan (hereinafter the Examining Committee)

The JSOG first acknowledged artificial insemination by sperm cell donation (AID) officially in its report *Opinions on Non-spousal Artificial Insemination and Sperm Cell Donation* (May 1997). However, AID was performed in Japan for the first time decades earlier, in 1948. Between 1948 and 1997, though technically against the regulations of the JSOG, the technique was performed as a public

secret, with Professor Ando from Keio Gijuku University as its greatest proponent. However, the official report by JSOG was released nearly half a century after the first child in Japan to be conceived using non-spousal AID was born in 1949. It seems that the appearance of a sperm trading website in 1996 finally forced the JSOG to act on the issue, and the JSOG officially approved AID in 1997.

Given that the JSOG has tacitly approved of AID (using sperm from non-spousal, unrelated donors) to give male infertility patients the chance to have children since 1948, taken together with the fact that the Japanese constitution offers equal rights for men and women, it is within reason to argue that non-spousal IVF-ET using egg cell donation for female patients with Turner syndrome who wish to have children should also be approved. Given the clear medical, legal, and ethical validity of non-spousal IVF-ET, then, the delay in the presentation of the JSOG reports *On the Performance of Non-spousal In Vitro Fertilization and Embryo Transfer by Egg Cell Donation* (February 2001) and *On the Subject of Making Sperm Cell and Egg Cell Donors Anonymous Third Parties* (April 2003) and the subsequent delay in approving, albeit conditionally, non-spousal IVF-ET are inexcusable. The Japanese government's final report, *Report on the Adjustment of the System for ART by Sperm Cell, Egg Cell and Embryo Donation* (April 2003), which has similarly arrived at the conclusion to conditionally approve non-spousal IVF-ET, has also come too late.

Furthermore, the JSOG's failure to conduct review deliberations based on a consciousness survey of the Japanese people amounts to an outright dereliction of duty.

The Examining Committee (active from December 2006 until April 2008) postponed deliberation on third-party (including friends and sisters) egg cell donation for IVF-ET; at the same time (2007), applications were sent from JISART (which has approved applications for donation by friends and sisters from Dr. Takahashi, Director of the Hiroshima HART Clinic) to the JSOG, the Science Council of Japan, and the Ministry of Health, Labour and Welfare.

## 2) Legal position of children conceived using egg cells from third-party donors (including friends and sisters)

Under the current law, the succession rights of a child conceived using AID with consent of the husband are acknowledged (Civil Law, article 776); however, because the right of the husband to deny the legitimacy of the child is protected in the event of delivery of child via AID by the wife without the husband's consent (Civil Law, article 774), the husband is allowed to file a lawsuit for denial of legitimacy within a period of one year (Civil Law, article 777). Also, as a condition of ART, the sperm donor will not receive requests for acknowledgement from the child, and the sperm donor himself is also not able to claim parental rights (i.e., request for acknowledgement of a parent-child relationship based on blood relation). This aspect requires clear legal treatment.

Based on these legal conditions, it follows that under the Japanese constitution, which declares equal rights for men and women, children conceived using non-spousal IVF-ET by a third-party egg cell donor (including friends and sisters) with the consent of the wife will win recognition of their succession rights. Again, as a condition of ART, women who have donated egg cells will not receive requests for acknowledgement from the child, and the donor herself will not be able to claim parental rights over the child. Legal resolution of this issue is currently an extremely important subject in Japan.

## 3) Welfare of children conceived using egg cells from third-party donors (including friends and sisters)

The welfare of the child is most important—this is the greatest concern of the JSOG and the Japanese government in their conditional approval of non-spousal IVF-ET using egg cells from anonymous third-party donors. This concern brought about the simultaneous approval of conditional non-spousal IVF-ET, which limits donation of sperm and egg cells and fertilized eggs to non-blood-related third parties, as well as the compilation of a report designating surrogate conception, including gestational surrogacy and genetic surrogacy, as a punishable criminal offense (*Report on the Adjustment of the System for ART by Sperm Cell, Egg Cell and Embryo Donation*).

This comes in sharp contrast to the current situation in South Korea, where, in addition to non-spousal AID (*shineri*) and genetic surrogacy (*shibaji*), non-spousal IVF-ET using egg cells donated by friends and sisters is also commonly performed.

According to Professor Lee Limsoon of Soonchunhyang University in South Korea and Hong Hyunsu, anthropologist and former researcher at the Civilization Institute of Science and Technology (disbanded in March 2007), non-spousal IVF-ET using egg cells from sisters and family members rather than unrelated donors is normal in South Korea, where egg cell trading was prohibited by the Bioethics and Biosafety Act (legislated on December 29, 2003, issued as a proclamation on January 29, 2004, enacted on January 1, 2005, revised in part on March 24, 2005). It is said that children conceived using gametes from third-party donors (including friends and sisters) are unlikely to grow up unhappy in South Korea due to the tight relationships between brothers and sisters and the strong involvement of household and family members in egg cell donation.

Japan, in contrast, has approved non-spousal IVF-ET only in the case of sperm cell, egg cell, and fertilized egg cell donation by non-blood-related third-party donors, insisting that conception using egg or sperm from a blood-related donor is not in the best interests of the child. In light of the situation in South Korea, however, the Japanese government needs to change its current notions regarding the welfare of children conceived using gametes from third-party donors (including friends and sisters). In order to accomplish this, we must first pay close attention to the voices of patients who have already undergone

IVF-ET treatment using egg cells from a blood-related family member at Suwa Maternity Clinic.

Stories of patients from South Korea, as well as those who have undergone the technique in Japan<sup>1</sup> (at Suwa Maternity Clinic) and outside of Japan, are invaluable. This is precisely the material that is needed to force the Japanese government to reshape its groundless assumptions that the donation of egg cells by blood relations will complicate relations between household members, become an adverse factor for the welfare of the child, and pressure blood relations to donate egg cells to infertile family members.

### Conclusion

In consideration of the above, the author judges that, in addition to IVF-ET using egg cells from voluntary anonymous third-party donors, the Japanese government and the JSOG should also approve IVF-ET using egg cells from friends and sisters.

Should this happen, a short outline of important reference points is as follows:

- 1) From the beginning, the safety of egg cell donor and recipient alike must be viewed from the perspective of the welfare of the child. As such, clarification of the legal parent-child relationship according to Civil Law must be at the heart of the legal revision.
- 2) In the event of the legalization of IVF-ET using egg cells from voluntary friends and sisters, treatment facilities must ensure that, at the time of treatment, informed consent, counseling by a specialized ART psychological consultant, and a personal information administration system are readily available to both patient and donor.
- 3) In the future, the Japanese government should expect existing assisted reproduction facilities to shut down following the death or retirement of facility directors. To avoid problems associated with the closing of these facilities, the Japanese government should establish an official management and administration institution for the handling of information related to IVF-ET.

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## Analysis of Bioethical Problems Regarding Surrogate Conception in Japan

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### Abstract

In the Examining Committee's external report proposing the basic prohibition of surrogate conception, *Issues in assisted reproductive*

*technology with a focus on surrogate conception—Moving toward a social consensus* (April 8, 2008), the Committee indicated the following problems with surrogate conception: Surrogate conception should be prohibited by law. The practice, solicitation, or mediation of surrogate conception for the purpose of profit, including that done in other countries, should be a punishable act for the parties involved, with the exception of the surrogate mother. After the conditions and procedures for implementation have been legally determined, conducting surrogate conception trials (clinical trials) may be considered. In cases when surrogate conception is conducted, the woman who gives birth shall be the mother. Formation of a parent-child relationship by adoption or a special adoptive relation may be recognized.

**Key words:** Bioethics, Japan, Surrogate conception

On 30 November 2006, in response to the repeated expression of concerns by obstetrician and gynecologist Yahiro Netsu at Suwa Maternity Clinic, the Japanese government (Ministries of Justice and Health, Labour and Welfare) asked the Science Council of Japan (Ichiro Kanazawa, President) to examine Japan's stance on the issue of assisted reproductive technology (hereafter, ART), focusing in particular on surrogate conception (popularly called surrogacy). The Council held repeated deliberations through the ART Examining Committee of the Science Council of Japan (hereafter, the Examining Committee) (committee term: December 21, 2006-April 30, 2008) for a broad discussion of ART overall, centered on the pros and cons of surrogate conception. The Examining Committee issued a final report on March 7, 2008, the essential features of which are fundamentally the same as the preliminary report adopted on January 30, 2008, at the 15th meeting of the Examining Committee. The key points of the Examining Committee's final report were:

- Surrogate conception should be prohibited by law.
- The practice, solicitation, or mediation of surrogate conception for the purpose of profit, including that done in other countries, should be a punishable act for the parties involved, with the exception of the surrogate mother.
- After the conditions and procedures for implementation have been legally determined, conducting surrogate conception trials (clinical trials) may be considered.

In cases when surrogate conception is conducted, the woman who gives birth shall be the mother. Formation of a parent-child relationship by adoption or a special adoptive relation may be recognized.

Strong objections were voiced both inside and outside the committee in response to this preliminary report. For example, at a public lecture sponsored by the Science Council of Japan (January 31, 2008, Science Council of Japan Lecture Hall), committee member Hisatake Kato argued that the preliminary report did not reflect the diversity of the committee's opinions (although no one argued that surrogate conception should be permitted without regulations, half of the committee members felt that it should be accepted with restrictions, one quarter felt that it should be prohibited without punishment, and one

quarter felt that it should be prohibited with punishment), and that the report was biased with respect to its discussion of prohibition with punishment of surrogate conception. In addition, there was an outpouring of opposition and critical writings from a patients' association (Nirinso-no-kai) and their lawyers (facilitating attorney Naoya Endo, *Criticism of Science Council Report*) calling for the legalization of surrogate conception.

Despite the strong opposition to the preliminary report from inside and outside, the Examining Committee, after obtaining approval of the board (including that of the president, vice presidents, and other members of the Science Council of Japan) for the report dated March 7, 2008, which advocated a "basic prohibition of surrogate conception," released an external report entitled *Issues in assisted reproductive technology with a focus on surrogate conception—Moving toward a social consensus* on April 8, 2008.

The Japanese government (Ministries of Justice and Health, Labour and Welfare) received the Examining Committee's report on April 16, 2008 and requested deliberation in the legislature for the introduction of a law provisionally entitled the "Assisted Reproductive Technology Law."

The present article analyzes the bioethical problems surrounding surrogate conception in Japan up to the release of the 8 April 2008 external report that elicited strong opposition from both inside and outside the Examining Committee.

### **Current Regulations on Surrogate Conception in Japan—Analysis of Bioethical Problems**

Reasoning of the government (the ART Section of the Health and Welfare Scientific Council (hereafter, the ART Section)) for prohibiting surrogate conception (genetic surrogacy / traditional surrogacy / intrauterine insemination (IUI) surrogacy and gestational surrogacy / *in vitro* fertilization (IVF) surrogacy) with criminal penalties. The fundamental principles of the ART Section regarding ART are summarized in the following 6 points:

- The welfare of the child shall be given priority.
- Human beings shall not be used merely as reproductive resources.
- Safety shall be given sufficient consideration.
- Eugenics shall be avoided.
- Commercialism shall be avoided.
- Human dignity shall be protected.

In particular, the government (ART Section) concluded that surrogate conception (genetic surrogacy and gestational surrogacy) should be prohibited with criminal penalties because it violates numbers 1 through 3 of the fundamental principles regarding ART (as outlined in the final report conditionally approving non-spousal IVF-ET (*Report on the Adjustment of the System for ART by Sperm Cell, Egg Cell and Embryo Donation*, April 2003)).

### **Critical opinion of the Japanese Society for Obstetrics and Gynecology (JSOG) on surrogate**

### **conception (genetic surrogacy and gestational surrogacy)**

JSOG formulated its position in *Position on surrogate conception* (April 2003), with conclusions similar to the government (ART Section). The reasons given by JSOG to prohibit surrogate conception are summarized in the following four points:

- The welfare of the child should be given priority (corresponds to 1 in the fundamental principles of the ART Section).
- Surrogate conception is associated with considerable physical risk and mental burden (corresponds to 3 in the fundamental principles of the ART Section).
- Surrogate conception complicates family relations.
- Society as a whole does not accept surrogate conception contracts as ethical. In other words, surrogate conception associated with an exchange of monetary compensation is seen as reducing the human body to a simple machine or reproductive resource (corresponds to 2, 5, and 6 in the fundamental principles of the ART Section).

In addition, the JSOG, expanding on the principles outlined by the government (ART Section), concluded that surrogate conception (genetic surrogacy and gestational surrogacy) should be prohibited with criminal penalties because it violates numbers 1 through 3 of the fundamental principles regarding ART.

### **Critical opinion of the Japan Federation of Bar Associations (JFBA) on surrogate conception (genetic surrogacy and gestational surrogacy)**

On 7 February 2007, the JFBA submitted a proposal to the Ministry of Health, Labour and Welfare (MHLW) requesting the enactment of a reproductive medicine law including prohibition of surrogate conception (genetic surrogacy and gestational surrogacy) and the development of relevant systems. The 2007 Proposal of the JFBA (*Supplement to the 'Proposal on legal restrictions to the use of reproductive technologies'—Posthumous conception and surrogate conception*, January 19, 2007), which supplemented the 2000 Proposal submitted to the MHLW in March 2000, stated that "the right of couples to pursue happiness and their right to self-determination are not unrestricted," and concluded that "surrogate conception should be prohibited." The reasons given by the JFBA that surrogate conception should be prohibited by law are summarized as follows:

#### *Fundamental problems*

The first problem is the problem of the welfare of the child (corresponds to 1 in the fundamental principles of the ART Section). Second is the concern for the damage to human dignity. Surrogate conception is associated with considerable physical and mental burden, and contracting a woman for pregnancy and birth only, regardless of whether compensation is provided, is seen as reducing the female body to the status of a "reproductive machine," which infringes upon human dignity (corresponds to 2,

3, 5, and 6 in the fundamental principles of the ART Section).

The third is the risk of economic discrimination that may result from differences in social standing between the person making the request and the potential surrogate mother (i.e., the person making the request, who is theoretically in an economically advantageous position, may use the surrogate mother, who is theoretically in an economically disadvantaged position, as a birthing device; this corresponds to 2, 5, and 6 in the fundamental principles of the ART Section).

The fourth is the risk of deterioration in family relationships that may occur when a surrogate mother is sought as a volunteer, eschewing commercialism. Without payment, it is very likely that, in practice, nearly all cases of surrogate conception in Japan would involve close relatives. In that case, the facts of gestation and birth will probably not be unknown to the husband and children of the surrogate mother. There is thus a high probability that these facts will also be recognized by other people close to the surrogate mother, forfeiting all chance for anonymity and altering family relationships. This may also represent a disruptive influence in the lives of children born through surrogate conception (corresponds to reason 3) given by the JSOG for the prohibition of surrogate conception).

The fifth is the problem of guaranteeing self-determination for women.

### **Critical opinion of the ART Examining Committee of the Science Council of Japan on surrogate conception (genetic surrogacy and gestational surrogacy)**

In the Examining Committee's external report proposing the basic prohibition of surrogate conception, *Issues in assisted reproductive technology with a focus on surrogate conception—Moving toward a social consensus* (April 8, 2008), the Committee indicated the following problems with surrogate conception from medical, ethical and social perspectives:

#### *Medical perspectives*

Medical problems of surrogate conception

Risk and burden taken on by the woman carrying the fetus (corresponds to 3 in the fundamental principles of the ART Section)

Effects on the fetus/child (corresponds to 1 and 3 in the fundamental principles of the ART Section)

Medical grounds for surrogate conception

Medical grounds for the woman making the request

Age limitation of the woman carrying the fetus

#### *Ethical and social perspectives*

Rights and benefits of the child, the person making the request, and the woman carrying the fetus.

Self-determination of the person making the request and the woman carrying the fetus, and the limitations of this self-determination (corresponds to A-5 of the critical opinion of the JFBA).

Welfare of the child (corresponds to 1 in the fundamental principles of the ART Section).

Problem of biological order (corresponds to 1, 2, 3, and 6 in the fundamental principles of the ART Section),

Confusion in bioethical and medical settings (corresponds to 1, 4, and 6 in the fundamental principles of the ART Section).

Based on the above medical and ethical/social issues, the Examining Committee (Science Council of Japan President Ichiro Kanazawa) submitted the following *Recommendations for problems related to assisted reproductive technology* to Justice Minister Hatoyama and Health, Labour and Welfare Minister Masuzoe on April 16, 2008, and at the same time proposed enactment of the provisionally titled "Assisted Reproductive Technology Law" to the government (Ministries of Justice and Health, Labour and Welfare).

### **Recommendations for Problems Related to Assisted Reproductive Technology**

A. Pros and cons of regulations on surrogate conception. Surrogate conception needs to be regulated by law (for example, "Assisted Reproductive Technology Law" (Provisional title)), and a basic prohibition based on that law is desired. Surrogate conception for the purpose of profit should be punishable by law. Those subject to punishment shall be the performing doctor, mediator, and the person making the request. With respect given to protection of the mother's body and the rights and welfare of the child, and in view of the need to understand the related medical, ethical, legal, and social problems, trials of strictly controlled surrogate conception (clinical trials) may be considered in certain cases, restricted to women who are congenitally missing a uterus (Rokitansky-Küster Hauser-syndrome) or those who have undergone hysterectomy as a result of necessary medical treatment.

In conducting clinical trials, a publicly operated institution with staff specialists in areas such as medicine, welfare, law, and counseling should be established. If, after a fixed period, the medical safety and social and ethical propriety of surrogate conception are examined and found to be free of problems, the law shall be revised and surrogate conception shall be permitted under certain guidelines. Trials in which many negative effects are observed shall be discontinued.

B. Parent-child relationships between child and surrogate mother and couple who requested surrogate conception.

In regard to the parent-child relationship, the surrogate mother shall be the mother.

The couple that requested the surrogate conception may establish a parent-child relationship with the child through adoption or a special adoptive relation.

C. Right of child to know his or her origin, problems of egg donation, and other matters.

C-1. The right of a child to know his or her origin should be given the utmost respect from the perspective of the child's welfare. This is an important issue for future investigation and should be judged for cases of surrogate conception after first investigating the practice of artificial insemination (AID) using

sperm other than that of the mother's partner, which has been performed in Japan for many years.

C-2. There are issues on which debate continues, such as egg donation and conception using frozen sperm after the sperm donor's death, and new problems may emerge in the future. As a result, it is necessary to continue deliberations related to ART.

C-3. In view of the importance of the various bioethical problems, it is hoped that together with the founding of public research institutions, a new permanent public committee will be established to continue addressing these problems, including policy planning.

C-4. In debate on surrogate conception and other ART, priority should be placed on the welfare of the child.

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## A Question in End-of-life Medicine in Japan: Three Levels Structure Analysis of the Ethics of Provision of Permanent and Active Artificial Nutrition and Hydration for Elderly who Cannot Eat

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### Abstract

This article will focus on issues concerning the provision of artificial nutrition and hydration (ANH) to patients who are extremely old, completely bedridden, and totally dependent on others. These patients have no advance directives, no malignancy, suffer from persistent but unstable disturbance of consciousness as well as severe cognitive impairment, and cannot eat sufficient amounts of food to maintain their lives. Should ANH be provided? Some would agree while others would maintain otherwise. The underlying values and normative theory behind each argument are quite different. In this paper, I will present opinions, comments, and arguments concerning the provision of PANH to such patients and examine each using the Takahashi's three levels structure analysis. Utilitarianism is a fitting ethical theory for the third level in arguments against the provision of PANH to patients in question, and the non-religious sanctity of life doctrine covers the opposite position.

**Keywords:** Japan, artificial nutrition and hydration, utilitarianism, sanctity of life, Three Levels Structure Analysis

### The Patient

Mr. A, a 95-year-old patient, was bedridden and unable to set foot on the floor for several years. He spent almost the entire day in a drowsy state. He could do nothing without the help of healthcare professionals. Eating required careful and skillful nursing. He was incoherent and unable to communicate, even with family members or attending nurses. His oral intake had been recently decreasing. He tended to be somnolent and his level of consciousness seemed unstable. More often than ever, he missed meals because of his untimely sleep. Difficulty in swallowing was apparent and he quite often choked on his food. Despite the fact that there was no underlying disease or comorbidity causing anorexia, swallowing disorder, or consciousness disturbance, his medical condition deteriorated. No advance directives existed. He would soon be unable to take food or water orally. What course of action should be taken for the patient?

### Background

Hundreds of thousands of patients whose medical conditions are similar to those of Mr. A are thought to currently exist in Japan. I believe that the course of action to be taken in caring for such patients would perplex almost everyone. There are six possible alternatives: percutaneous endoscopic gastrostomy (PEG), use of a naso-gastric (NG) tube, total parenteral nutrition through central veins (TPN), intravenous drip, continuing active efforts to provide food through the patient's mouth, and letting nature take its course (no food or water would be given unless the patient explicitly expressed his desire to eat). Euthanasia without the patient's request is another possible alternative. However, this paper will not discuss the ethicality of euthanasia because such an act is unrealistic in the current clinical setting, and it is beyond the scope of my argument.

In this article, I will focus on issues concerning the provision of artificial nutrition and hydration (ANH) to patients like Mr. A. These patients are extremely old, completely bedridden, and totally dependent on others. These patients have no advance directives, no malignancy, suffer from persistent but unstable disturbance of consciousness as well as severe cognitive impairment, and cannot eat sufficient amounts of food to maintain their lives (hereafter, I describe such patients simply as "patients like Mr. A"). What course of action should we take for such patients? Specifically, should ANH be provided? Current Japanese law specifies nothing to this end. An acceptable social norm that dictates the boundary of a physician's obligation during such treatment remains obscure. It is reported that provision of ANH remains the social norm and PEG is most commonly used for bedridden, incapacitated patients over 75 years of age with cerebrovascular disease or dementia. My experience as a clinician is also compatible with a previous report (i.e., ANH through NG tube or PEG is the treatment of choice for patients like Mr. A). The two types of tubes are similar in that both are intended to give adequate nutrition and hydration to patients

who can not to eat, in order to actively sustain their lives for as long as possible. Even though there is no overwhelming evidence, I think that permanent and active ANH (PANH) is utilized to maintain the lives of patients in Japan, except in extremely special circumstances.

Should we provide PANH to older patients with severe cognitive impairment who cannot eat? Some would agree while others would maintain otherwise. The underlying values and normative theory behind each argument are quite different, and each holds true to the views on life and death that are the foundation for every decision. For the rest of this paper, I will present opinions, comments, and arguments concerning the provision of PANH to patients like Mr. A. I will examine each using the three levels structure analysis framework proposed by Takao Takahashi.

The three levels structure analysis consists of the following three tiers: the first level is a concrete normative statement or position such as "We ought to provide the patient with PANH," or "We should withhold or discontinue PANH for patients like Mr. A." The second level consists of principles, concepts, or values that form the basis of normative judgment of the first level; this includes autonomy, human dignity, rights or human rights, right to life, right to death, liberty, safety, efficacy, utility, interests, transparency, consensus, social norms (socially accepted ideas), justice or fairness, no harm, truthfulness, empathy, obedience to law, caring, naturalness, natural death, humanity, honesty, quality of life (QOL), sanctity of life, pleasure, suffering, futility, and so on. The third level is the most basic level of our normative statement that includes content, evidence, definition, explanation, meaning, standard, and considerations of right or wrong; these form the basis of the principles and values of the second level. It should be noted that the second and third levels are often not clearly distinguishable.

### Implications

I believe that the ethicality of PANH provision to patients like Mr. A is probably the hardest question in end-of-life medicine in Japan, aside from issues related to euthanasia and physician-assisted suicide. Once we have a convincing answer to the question, it is reasonable to think that many other end-of-life issues in Japan could be resolved. This is possible because our question (i.e., whether or not we should provide PANH to patients like Mr. A) lacks the supporting factors for termination of life-sustaining treatments in other circumstances. I believe that the following statements are generally true to both healthcare professionals and the families of patients.

It is ethically, socially, psychologically, and probably legally easier to accept the refusal of life-sustaining treatment by patients who are capable of making decisions, compared to those who are not.

It is ethically, socially, psychologically, and probably legally easier to accept the refusal of life-sustaining treatment by patients with advance directives, compared to those without advance directives.

It is ethically, socially, psychologically, and probably legally easier to accept the refusal of life-sustaining treatment by patients with malignant illnesses,

compared to those who do not have such illnesses.

It is ethically, socially, psychologically, and probably legally easier to accept the refusal of life-sustaining treatments that are aggressive, burdensome, and intrusive, compared to those that are not.

It is ethically, socially, psychologically, and probably legally easier to accept the termination of life-support for patients in permanent comas, compared to those who are conscious but not self-aware.

It is ethically, socially, psychologically, and probably legally easier to accept the refusal of life-sustaining treatment by patients who are suffering gravely, compared to those who are not.

It is ethically, socially, psychologically, and probably legally easier to accept the refusal of life-sustaining treatment by patients whose prognoses are definitive, compared to those whose prognoses are uncertain.

It is ethically, socially, psychologically, and probably legally easier to terminate medical treatment than to discontinue "care."

It is ethically, socially, psychologically, and probably legally easier to accept the termination of life-support for patients when a legal precedent exists, compared to when it does not.

It is ethically, socially, psychologically, and probably legally easier to accept the termination of life-support for patients who act in accordance with social customs, compared to those who do not.

It is ethically, socially, psychologically, and probably legally easier to accept the termination of life-support for patients when treatments are easy to start and maintain, compared to those that are not.

The decision for PANH provision to patients like Mr. A falls under the latter category in all eleven situations, and lacks the reason for withholding PANH. This lack of support makes the decision more difficult. I believe that it is extremely important to carefully consider the reasons for discontinuing treatment to patients, since care-providers never do so without a good motive. One fundamental objective of medical care is to provide treatment to patients who came or were brought to the medical facility, and to keep them healthy for as long as possible. As such, the "default" reaction of care-providers is to provide continuous treatment. Mr. A is no exception. Treatment is not withheld from patients unless there is a good reason to do so (2).

### Arguments against the provision of PANH to elderly patients with severe cognitive impairment who cannot eat

In this section, I quote several passages from publications written by those who support withholding PANH from patients like Mr. A. The quotes represent the first level in Takahashi's three levels structure analysis. First, Yo Kusakabe expresses his opinion on the appropriateness of PANH in his book on healthcare for the elderly. The following are quotes from his book, followed by my own analysis which represents the second level. *"In the old days, people died naturally and quietly once they could not eat by themselves. Nowadays, healthcare professionals give them all the nutrition they need through NG tubes or PEG. People can no longer die naturally. Rapid progress in various life-prolonging technologies has*

been made due to the uncritical approval of a desire to live longer. Medicine has neglected the fact that what matters most is the quality of people's life rather than its length." (p. 60). Kusakabe addresses the importance of accepting a peaceful natural death. "Dying naturally" is perceived as favourable but difficult to achieve. He is critical of uniform life-prolongation without careful consideration of quality of life and the interests of patients like Mr. A. "At present, risk of longevity increases while the danger of premature death decreases. Once ANH via PEG or a respirator is initiated, it is extremely difficult for anyone to stop it because discontinuation results in death. No one dares attempt it." (p. 61). Longevity and the healthcare supporting it are not necessarily perceived as positive. Kusakabe considers QOL to be more important than the sanctity of life, and he determines that longevity is not desirable in some cases.

By saying, "Medicine prolongs human lives by means such as intravenous drips, tube feeding, respirators, and various drugs. The lives sustained in such ways are not good existences." (p. 184). Kusakabe frankly claims that a medically prolonged life is not good. He makes judgments on the quality of human life.

Second, Hajime Hashimoto refers to medical indications of ANH in his comprehensive book on ethical issues concerning elderly care (4). "The provision of nutrition through tubes or intravenous drips should be limited to patients who are expected to recover from the condition that leads to difficulties in oral intake. It would be meaningless to provide ANH to patients with disturbed-consciousness who are bedridden if they cannot recover from using nutritional support. Provision of ANH is a medical therapy. If it is categorized as medical treatment, then its benefits must outweigh its burden and physicians should initiate treatment based on its medical indication." (p. 117). Hashimoto argues that it is meaningless to perform medical interventions for patients with incurable disturbed-consciousness or those who are bedridden. He believes that there is no medical indication when the therapy is expected to fail to provide positive effects for the patient. According to his claims, we should not take for granted the provision of PANH to patients like Mr. A. Its unconditional use is inappropriate and it should be carefully chosen based on medical indication, after weighing the risks and benefits.

"We should set a definite goal at the beginning of ANH provision, and once it is judged that there is no chance of recovery, ANH should be discontinued." (p. 278). Again, he addresses the significance of setting a goal and suggests that some conditions do not deserve to be pursued. Merely living is not considered a worthy goal.

Finally, Jiro Shibata's comments are worth mentioning (5). "Once a patient's condition stabilizes and he or she neither improves nor worsens, it is common for the patient's family to become tired of having to care for the patient. If the patient falls into a coma, some say that the situation is similar to dry-nursing a big pet. Even beneficent families become

exhausted and begin to question how much meaning there is in such care. A bedridden elderly person is, though the wording may be wrong, just a living object." (p. 38). He points out that care or nursing for patients in certain conditions are questionable. His positions appear to be based on "Philosophical Personhood Arguments", as suggested by his use of the phrase "just a living object."

### **Arguments for the provision of PANH to elderly patients with severe cognitive impairment who cannot eat**

In this section, I quote several passages from publications written by those who support the provision of PANH to patients like Mr. A. The quotes represent the first level in Takahashi's three levels structure analysis.

First, Yoshihiko Saito strongly argues against the termination of life prolongation for patients like Mr. A and maintains that PANH for patients like Mr. A is absolutely indispensable (6). "Withdrawal of ANH from a patient who cannot eat by him or herself is not just a discriminatory act, but undoubtedly constitutes murder. Those who declare that certain medical states of living are miserable or inhumane, who claim legitimacy to discontinue the provision of ANH which leads to death, and who state that it is preferable to restart oral intake for patients on ANH without considering risks of aspiration and aspiration pneumonia, are all companions in crime and no better than the Nazis who killed a large number of disabled individuals who were judged worthless to live." (p. 229). Saito takes a strong stance on this issue arguing that no one is allowed to discriminate against the elderly and that their human rights must be protected. He concludes that termination of ANH is indisputably murder and should never be permitted. He states that regardless of the condition of an individual's life, he or she has the right to live. We must not make value judgments on the individual's life, because it forces another's value system onto the patient.

"A patient in a vegetative state would die within a few days to a month once ANH is discontinued. The death of a patient from the termination of ANH is an intentional human act, and not a natural death... Use of terms such as 'death with dignity' or 'natural death' hides the true nature of these acts, which is killing of the patient. The use of such terms is misleading." (p. 232). He states the importance of honesty and truthfulness. He points out that the concept of dignity is subjective and use of the terms 'dignified death' or 'natural death' is deceptive, when withdrawing life-sustaining treatments from the patient. Discontinuation of medical treatment based on the intention of others is murder and therefore never permissible.

"We must not stop a treatment which, through its discontinuation, can lead to a patient's death, such as ANH, intravenous drip, hemodialysis, antibiotics, and so on. These are all general and basic treatments. Starvation is immoral... To intentionally stop the provision of general treatment is nothing more than 'murder.'" (p. 234). Again, he states that termination of treatment is murder and inhumane.

"When we talk about life-prolongation of the elderly, I think that we tend to forget the *warmth* that we can feel by touching the person. Despite the patient's *miserable* appearance, we can feel his or her warmth by shaking hands or rubbing his or her body. This warmth is a reminder for us to think of life and death of the elderly in a humane way. To forget the patient's *warmth* during a discussion of life-prolongation can lead to inhumane arguments and dangerous logic such as "*we can discontinue life prolongation for the patient because he does not deserve to live.*" (p. 238-239). The author addresses the importance of human warmth and states that any logic that ignores this is dangerous. He appears to suggest that we should not make any value judgments on the life of patients like Mr. A, whose bodies are warm.

Second, Shoko Mukai states that a choice to not provide PANH to patients like Mr. A is problematic and questionable (7). "*Why on earth is it time to die a natural death if we can no longer eat on our own?*" (p. 196). She denies the idea that it is natural to die when we cannot eat any longer due to old age. "*Older people's happiness or unhappiness tends to be determined by those around them. An aspect of getting old is the arbitrary judgment that the happiness or unhappiness of the elderly is determined by other people. People often say 'He would rather die than lead such a life', but the truth is that they expect him to die sooner because they are annoyed by his very existence.*" (p. 198). The author points out the problematic arbitrariness of judgments made by others on the benefits of treatment and vulnerability of the elderly. She is also doubtful that a person would really "rather die", regardless of the person's state of living. She also mentions that expectations of death have a serious impact on the evaluation of "interests of patients" like Mr. A.

Finally, Hiroshi Shiono argues against placing a high value on personhood (8). "*There is an idea that a patient who has lost his or her personhood does not deserve medical treatment. Support of this argument leads to discrimination based on "quality of life."* It is invalid to withhold or withdraw treatment when loss of consciousness is irreversible... The problem of patients in a vegetative state is not solved by shortening their life; rather, they are solved with a nationalistic perspective in understanding how to help the patients and their families." (p. 94-95). He states that judgments based on personhood lead to infringement of the patient's human rights. He also argues that human dignity must not be determined by the presence or absence of a person's autonomy or personhood.

The principles, concepts, and values involved in arguments against the provision of PANH to patients like Mr. A includes at minimum: the significance of being natural, acceptance of the natural span of life, importance of considering the patient's QOL and interests, utility of medical interventions, criticism of mere life-prolongation, and necessity of personhood and self-awareness. It is also claimed that it is meaningless to provide medical treatments to a bedridden unconscious patient who cannot recover because such treatments cannot bring about positive

utility. The authors maintain that it is not necessarily always good to have advancement of medical technology and a longer life span. We can interpret "unwanted prolonged life" in various ways, but it might mean a life that is undignified, deprived of liberty, enforced, futile, harmful, low in QOL, and unnatural. We may call it an "inhumane state of life."

Conversely, the principles, concepts, and values involved in arguments for the provision of PANH to patients like Mr. A can include at minimum: vulnerability of the elderly, absolute prohibition of discrimination, categorical prohibition of discontinuing ANH, discontinuation of ANH being equivalent to murder, human rights such as the right to live, and unconditional prohibition of value judgments on human lives. Others must not impose their arbitrary perceptions on the value of life, such as the perception of low QOL and meaninglessness or futility of living for patients like Mr. A. Such acts are dangerous. The term "natural death" is deceptive and the truth is that it is murder. Value judgments of human lives based on the presence or absence of a patient's personhood and consciousness constitute infringement of fundamental human rights. Finally, the warmth of a patient must be consciously affirmed. The life of a patient must be endlessly and aggressively sustained as long as he or she remains warm.

During my research, I encountered many divergent views concerning the ethicality of PANH provision to patients like Mr. A. Each group uses completely different principles, concepts, and values to support their position in the second level of Takahashi's three levels structure analysis. What exists in the third level?

As previously mentioned, the third level of Takahashi's three levels structure analysis is the most basic level of our normative position that includes content, evidence, definition, explanation, meaning, standard, and considerations of right or wrong; these underlie the principles and values of the second level. What is the underlying basis of the two opposing groups? It seems that the differences can be simplified to those who support QOL and those who support sanctity of life (SOL). In other words, this is a confrontation between those who approve the evaluation of QOL for patients like Mr. A and those who forbid it.

It is my opinion that utilitarianism is a fitting ethical theory for the third level in arguments against the provision of PANH to patients like Mr. A. QOL, subjective happiness, personhood, sentience, interests, and utility are key concepts and values in utilitarian arguments. In contrast, the non-religious SOL doctrine covers the principles, concepts, and values used in arguments for the provision of PANH to patients like Mr. A. Supporters of the non-religious SOL doctrine would highly value the warmth of patients and their existence. I cannot answer why some people believe in either utilitarianism or the SOL doctrine. As Hume states, we eventually reach a point where we cannot answer why we hold a particular point of view (9). We cannot logically explain why pleasure is better than pain. We may seek pleasure over pain, but as to why, the reason is unclear. Seeking pleasure is a preference that is beyond

reason. Similarly, the premise that we use for ethical inferences cannot be ultimately explained by reason. It is what theorists believe to be desirable (10). Similarly, we cannot explain why a sentient patients' utility is by far the most valued attribute among believers of utilitarianism. We also cannot explain why the warmth of a patient's body is by far the most valued attribute among believers of the SOL doctrine.

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## Organ Transplantation and Brain Death

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**Key words:** brain dead body, living body, medical care of the patient from brain death to cardiac death and mortuary practice<sup>9</sup>, recognize brain death as legal death,<sup>10</sup> death of the third person,<sup>11</sup> brain dead person, relationship, relationship-focused approach,<sup>12</sup> the dying process,<sup>13</sup> intercorporéité,<sup>14</sup> presentation,<sup>15</sup> death of the second person.<sup>16</sup>

## Introduction

Here we introduce some discussions about organ transplantation and brain death in Japan. This chapter is divided into two sections. In the first section, I review the history of organ transplantation in Japan. Then I present a structural analysis based on three viewpoints about brain death in Japan.

## History of Organ Transplantation in Japan

Table 1: Timeline

1958...	The Cornea Transplantation Law
1968...	The first heart transplantation case at Sapporo Medical College
1979...	The Cornea and Renal transplantation Law
1985...	The Takeuchi's Criteria
1990-92...	Provisional commission for study on brain death and organ transplantation
1997...	The Organ Transplantation Law
1999...	The official first case of organ transplant from a brain-dead person at Kochi Red Cross Hospital
2006...	Amendment A and B
2007...	Amendment C
2008...	Istanbul Declaration
2009...	Amendment D. A revision to the Organ Transplantation Law (based on amendment A) was adopted
2010...	A revision to the Organ Transplantation Law becomes effective

The Cornea Transplantation Law, the first official law about transplantation in Japan was enacted in 1958. The Cornea and Renal Transplantation law was established in 1979. Since then, cornea and renal transplantation using organs obtained from the cardiac death bodies (so called cadaveric donors), have been considered as established treatments. Living-donor transplantation (liver, renal, skin transplantation) has also become a commonly used treatments beyond legal regulation.

In contrast, the rule-making process of transplantation from brain dead donors took a lot of time. In 1968, the first heart transplantation in Japan was performed in Sapporo Medical College. In its case, ambiguities of both 'the brain death diagnosis' and 'the indication of recipient for transplantation' had invited public suspicions. Surgeon Wada was charged with murder. This case generated a feeling of distrust among Japanese people with regards to brain death and organ transplantation.

In 1997, around three decades after the first heart transplantation, the Organ Transplantation Law was established and became effective. This law laid down a set of rules about organ transplantation using organs obtained from dead bodies including brain dead individuals, thus legally allowing organ transplantation from those that are determined brain dead. Policy makers chose the opt-in system in this law. Japanese people were allowed to choose beforehand whether to donate their organs at the time of a legally diagnosed brain death. A person had to have decided to donate beforehand and a medical

<sup>9</sup> Morioka (2000) chapter 2.

<sup>10</sup> The position of the new organ transplantation law.

<sup>11</sup> These type of terms are originally introduced by Vladimir Jankélévitch.

<sup>12</sup> Morioka (2000)

<sup>13</sup> Morioka (2001) p.26

<sup>14</sup> Ibid. p.73

<sup>15</sup> Ibid. p.78

<sup>16</sup> Yanagida (1986)

team had to determine brain death. However, family members of a brain dead person could indicate rejection even if the patient had wished to make a donation.

In this law, brain death was considered the cause of death only in the case of a brain dead transplant. In other cases, cardiac death was regarded as the cause of death. Under this law, the Takeuchi's Criteria in 1985 was adopted as criteria for diagnosis of brain death. (See table 2). In fact, brain death was death of the person if and only if he/she wanted to donate beforehand and when the medical team could attempt transplantation. In other situations, cardiac death was deemed the cause of death. This double standardization of death may be a characteristic of Japan.

Table 2: Takeuchi's Criteria

Brain Death: Irreversible failure of all-brain systems (including interbrain)
Two experienced determination doctors having no relationship to transplantation are desired. Legal Brain Death requires the following six conditions:
1. Deep coma
2. Papillary dilatation and fixation
3. Loss of brain stem reflex
4. Flat brain waves
5. Cessation of natural breathing
After 6 hours, check 1-5 again, and that could be considered the time of death
Prerequisite: organic brain disorder, certainty of diagnosis and irreversible disorder
(Exceptions include: children under six years of age, drug addicts, hypothermia (below thirty-two degrees centigrade) and metabolism or endocrine disorder)

Since the Organ transplantation Law came into effect, the number of brain dead donors has not been sufficient to meet demand. Between October 1997 and December 2009, Japanese organ providers as brain dead donors numbered just 83. In addition, this law prohibited organ donation by children under 15. Some recipients, including children, had moved overseas to undergo transplantation. Though following the Istanbul declaration in 2008,<sup>17</sup> Japanese

<sup>17</sup> This declaration was adopted at Istanbul Summit on Organ Trafficking and Transplant Tourism April 30 to May 2, 2008/ Istanbul, Turkey. (excerpt)...each country should strive both to ensure that programs to prevent organ failure are implemented and to provide organs to meet the transplant needs of its residents from donors within its own population or through regional cooperation ...Organs for transplantation should be equitably allocated within countries or jurisdictions to suitable recipients without regard to gender, ethnicity, religion, or social or financial status. (Principle .) ...Jurisdictions, countries and regions should strive to achieve self-sufficiency in organ donation by providing a sufficient number of organs for residents in need from within the country or through regional cooperation. (Principle 5)...Organ trafficking and transplant tourism violate the principles of equity, justice and respect for human dignity and should be prohibited. Because transplant commercialism targets impoverished and otherwise vulnerable donors, it leads inexorably to inequity and injustice and should be prohibited. (Principle 6)...

organ recipients have not been able to go overseas to have surgery done. Under the current transplantation law, children who require organ transplants cannot survive. Therefore, in order to save the lives of recipients, including children, Japanese transplantation law required an urgent change.

In 2009, a revision to the Organ Transplantation Law was adopted. Key changes to the law are as shown below; acceptance of supplying organs to family members, requirements of harvesting organs and brain-death diagnosis were switched from Opt-in to Opt-out, and approval of organ donation from children under 15. (See also Table 3).

Table 3: Changes to the Organ Transplantation law

<i>Giving increased priority to family members as recipient</i>
Old law...postpones decision.
New law...accepts (From January 2010).
<i>Requirements of harvesting organs and brain death diagnosis:</i>
Old law...Opt in, and agreement of family members.
New law...Opt in or Opt out, and agreement of family members. (From July 2010).
<i>Treatment of child donors:</i>
Old law...People aged 15 and over have to indicate a willingness to donate.
New law...for all ages, agreement of family member. (From July 2010).
<i>Action on abused children:</i>
Old law...not stated.
New law...deals appropriately with the issues to prevent harvest from abused children. (From July 2010).

This new transplantation law came into effect from July 2010. We need to focus on future trends.

### The Three-Level Viewpoint Analysis of Brain Death in Japan

In this section, we try to analyze discussions about brain death in Japan. A large part of this analysis relies on Masahiro Morioka's approach.<sup>18</sup> I want to take this opportunity to pay respect to Professor Morioka.

People in Japan have had a great interest in brain death since the mid-1980's, influenced by some good books written by ardent journalists. The concept of 'brain death' expanded from the ICU, and was opened to the public as an object of discussion. Japanese people's views on brain death are divided into the following three viewpoints (Each viewpoint listed was adopted for reasons of expediency; there may be some people who hold different views) The viewpoint of families, close friends...paying attention to relationship, process. Impressions and depictions of the Brain Dead body: "I can't actually feel that he/she is dead", "he/she is just in a coma",<sup>19</sup> "he/she is warm", "he/she is still living", "he/she may become conscious",<sup>20</sup> "the invisible death", "the warm death",

<sup>18</sup> Morioka (2001) Introduction, Chapter 1.

<sup>19</sup> Ibid. p.13

<sup>20</sup> Ibid. pp.15-16

“the wistful death”,<sup>21</sup> “the communication that is felt through warmth”.<sup>22</sup> The viewpoint of care workers, medical care professions...paying attention to body, medical treatment and care. Impressions and depictions of the Brain Dead body: “he/she is warm”, “he/she also has ability to metabolize”, “he/she looks like a deep sleeper”, “he/she has blood flow and lives”, “he/she has voluntary movement of limbs”, “the living body (except for the brain)”.<sup>23</sup> The viewpoint of medical scientists, natural scientists...paying attention to reason (brain), law, utility. Impressions and depictions of the Brain Dead body: “Differ from traditional death”, “Cessation of natural breathing, just breathing assisted by a respirator”,<sup>24</sup> “The brain death is the irreversible end of all brain activity. Later, it is also leads to cardiac arrest, respiratory arrest and dilated pupils”,<sup>25</sup> “non-filling”,<sup>26</sup> “flat brain waves”,<sup>27</sup> “we can see just spinal reflexes on the brain-dead body (ex. Lazarus sign)”.<sup>28</sup>

Each Japanese individual would choose a suitable attitude for themselves from these three viewpoints, and provisionally embrace it as their own view. These viewpoints are located on the second level of Takao Takahashi’s Three Levels Structure Analysis method. The viewpoint of families and close friends may be associated with Identity Theory based on Japanese culture (e.g. Shinto religion, Japanese Buddhism, Communitarianism and so on. Some of Japanese Buddhist’s perspective on brain death and organ transplantation are discussed in detail by the paper in this issue, “Patterns of reasoning in religious positions on organ donation in Japan and Germany”.) People who take on this viewpoint sometimes interpret that there will still be a spirit of the dead person in this lower world, not only in the case of brain death, but also in the case of cardiac death. They may think that death is not a point but a process. From this viewpoint, the dead person is still living unless he/she completely loses his/her spirit or relationship with others. The viewpoint of care workers and medical care professions has a link with Holistic Theory, and some of the social-cultural environment of Japan. They regard human death as an organic death that is brought about by the loss of all local autonomic functions<sup>29</sup> of each organ and tissue independent from function of the cerebrum. They treat the brain dead body as a living body. They care for and talk to the brain dead person as a patient. The viewpoint of medical scientists and natural scientists are associated with Mechanistic Theory. This attitude was seen in the report of the Provisional Commission Study on Brain Death and Organ Transplantation.<sup>30</sup>

Proponents of this viewpoint usually see the human body as under the control of the cerebrum. They claim that all synthesis of the body will be lost when brain activity is stopped.

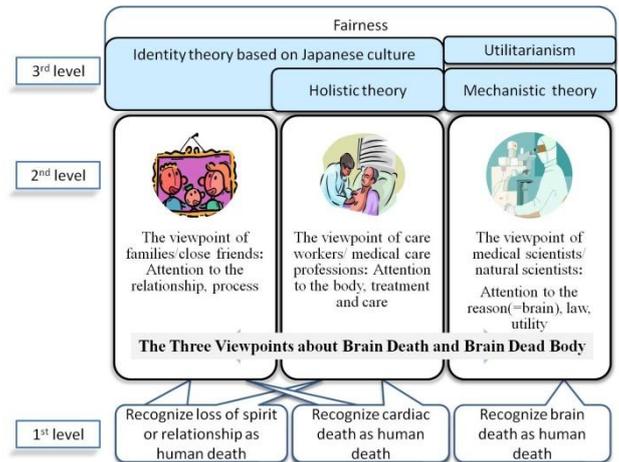


Figure 1 : Three Levels Structure Analysis of Brain Death (or death)

Needless to say, these types of discussions are likely very common throughout the world. It is worth noting that both the general public and non-medical professionals have joined in the discussions of brain death and organ transplants from brain dead donors for nearly thirty years in Japan.

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<sup>21</sup> Nakashima (1985) pp.9-12  
<sup>22</sup> Morioka (2001) p.67  
<sup>23</sup> Ibid. pp.71-72  
<sup>24</sup> Yamaura et al (2005) p.133  
<sup>25</sup> Morioka (2001) p.30, Yamaura et al(2005) p.133  
<sup>26</sup> Yamaura et al(2005) p.136  
<sup>27</sup> Kanda (2008) p.515  
<sup>28</sup> Morioka (2001) pp.33-35  
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## Analyzing the Trilaminar Structure of Judicial Precedent

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### What is judicial precedent?

Originally, judicial precedent was not a legal term, but today it is used in various legislation, including Articles 405 and 410-2 of the Code of Criminal Procedure, and Articles 318-1 and 337-2 of the Code of Civil Procedure.

Ordinarily, judicial precedent as legal terminology refers to 'the judgment of a court on a specific case' or 'a legal judgment indicated in the given reasons for judgment. This can be applied to the judgments of any court (district, high or Supreme), but there are clear differences in the strength of the judicial precedent according to its origin. As such, judicial precedent as referred to in this article indicates solely those set by the Supreme Court.

### The significance of judicial precedent

Social rules are prescribed through the law (positive law). In that case, why is judicial precedent so important? The law is not, in fact, as easily applied to the reality of our daily social lives as one might think. For example, Article 204 of the Penal Code holds that a person who "causes another to suffer injury" shall be "punished by imprisonment with work for no more than 15 years or a fine of not more than 500,000 yen". The latter half of the Article, the punishment, has changed (become tougher) along with the times, while the former half (Tatbestand, elements of the offense) remains unaltered since 1907.

Over that period, however, the question of what constitutes "injury" – whether it includes the cutting off of hair, transmitting infection, neurasthenia brought on by crank calls, anxiety and depression brought on by aggressive bullying, and so on – has come to be widely debated. It is judicial precedent, however, that has determined how far the scope of this concept of "injury" should be allowed to extend.

In this way, the scope to which concepts referred to in statutes (such as 'injury', 'to kill a person', 'abortion',

'negligence') are to extend has inevitably been unclear from the very outset. Indeed, in societies, a vast number of events occur, and most of these occur in borderline areas, where it is undecided whether or not they are incorporated into this concept.

For this reason, judicial precedent is extremely important, particularly that set by the Supreme Court, which has significant influence over the lower courts. In other words, "for young legal apprentices, who have successfully passed the bar and find themselves working in the Legal Research and Training Institute, discovering how to become real practitioners of law, there is one thing that is truly surprising. And that is the strength of judicial precedent, which is incomparably more authoritative than any theory. Whatever the legal question in hand might be, the issue of what relevant judicial precedents exist will – must – be considered. If there is judicial precedent, then most of the time it will be followed. What the apprentices learn from this is that, whether they like it or not, the simple fact is that the practical world of law is ruled by judicial precedent. All the theory their professors might have taught them in school fades into the background when compared to judicial precedent"<sup>31</sup>. Put simply, it is no exaggeration to say that, in practice, the law is dominated by judicial precedent.

### The theory of judicial precedent thus far

Until now, judicial precedent has principally been approached and analyzed by law scholars in terms of the basis of its influence as judicial precedent (binding precedent) upon the courts, and the scope of that influence. Japan's statutes contain no provisions to directly or expressly confirm any such binding effect, and a judgment against precedent would not necessarily make that judgment illegal per se. Detailed discussion of the basis and the scope of judicial precedent, then, is of relevance to the issues taken up by this article. Take, for example, the distinction between a conclusive proposition and a reasoning proposition; of the latter a distinction should be made between an abstraction of a conclusive proposition (a general legal proposition) and a further generalized legal proposition (a general legal proposition for the purpose of reasoning).

### An analysis of new structure and bio/medical ethics

Thus far, however, theory on judicial precedent has concentrated on analysis from the horizontal axis; looking at a certain judicial precedent and questioning what theoretical structures are in place in order to produce a conclusive proposition – analysis on the vertical axis – is what is being examined here. Traditionally, it is the so-called "hard cases" (cases where the application of existing statutory law is problematic, or cases in which there is an absence of (a gap in) relevant law but judgments are made based on legal jurisdiction and review) where theoretical structure is contested in this way. Bioethical issues are almost always such "hard cases".

<sup>31</sup> *Judicial Precedents and their Interpretation*, p10.

**Judicial precedents for specific analysis**

No	Alias	Main points of case	Judgment record
1	Frozen sperm case	Consideration of whether paternity can or should be established between a child conceived and born to a woman through artificial insemination using the frozen sperm of a man who had died subsequent to the sperm being stored and the deceased man from whom the sperm was taken.	Supreme Court Second Petty Bench September 4 2006 Notes on Civil Cases of the Supreme Court, Vol. 60, No. 7, p2563
2	Surrogate conception case	The question of who should be legally recognized as the mother of a child conceived and born to a woman through assisted reproduction techniques using the ovum of a woman other than herself.	Supreme Court Second Petty Bench March 23 2007 Notes on Civil Cases of the Supreme Court, Vol. 61, No. 2, p619
3	Statute of limitations: immunization	The right of victims left in a permanent state of insanity as a result of an act of tort to claim compensation for damages and the commencement of the statute of limitations as stipulated in the latter part of Article 724 of the Civil Code.	Supreme Court Second Petty Bench June 12 1998 Notes on Civil Cases of the Supreme Court, Vol. 52, No. 4, p1087
4	Statute of limitations: pneumoconiosis	The commencement of the statute of limitations as stipulated in the latter part of Article 724 of the Civil Code where the damages caused do not manifest themselves until a considerable period of time after the act causing damage was completed.	Supreme Court Second Petty Bench April 27 2004 Notes on Civil Cases of the Supreme Court, Vol. 58, No. 4, p.1032

**Judicial precedent 1: Logical structure**

Recognition of presumptive facts

The legislation on the relationship between child and parent as prescribed in the Civil Code is based in principle on the parent and child in question being related by blood (biological parent-child relationship). For a legitimate child, a legal parent-child relationship is formed with the parents when that child is born, and in the case of the legal relationship between the father and an illegitimate child, only when the child is recognized by the father after birth; thus the parent and child are legally recognized as forming a parent-child relationship as stipulated in the Civil Code, and having a legal relationship as relatives as stipulated in other relevant law. At present, artificial insemination, which is carried out using assisted reproduction technology, goes beyond the mere substitution of one or several elements of the natural process of reproduction and makes possible conception that would be otherwise have been impossible naturally. Posthumously conceived children fall into this category of children conceived as a result of artificial reproductive techniques that surpass the scope of natural reproduction, and as such the current legislation contains no assumptions as to the legal relationship between the posthumously conceived child and the deceased father.

Substantial evidence

Current legislation as outlined above does not contain any stipulation that would recognize the formation of a basic legal relationship between a posthumously conceived child and a deceased father. As such, the issue of the formation of a legal parent-child relationship between those two parties must be considered from multiple perspectives, taking into account the bioethical issues related to the use of the frozen sperm of a deceased man for artificial insemination, the welfare of the posthumously conceived child, the awareness of the parties concerned in terms of the formation of legal parent-child relationships and relationship with natural relatives, as well as general social perception. Only after such issues have been duly considered can it be determined whether or not a legal parent-child relationship should be recognized, and, if it is recognized, what requirements and effects should be stipulated in law to resolve the issue.

Conclusion

As long as no such legislation exists, it is not possible to recognize the formation of a legal parent-child relationship between a posthumously conceived child and a deceased father.

**Judicial precedent 2: Logical structure**

Recognition of presumptive facts

The Civil Code contains no stipulations which appear to suggest that a woman who has neither conceived nor given birth to a child can or should be recognized as that same child's legal mother. Current legislation therefore contains no stipulations concerning the resolution of the legal status of this type of relationship.

Substantial evidence

The biological parent-child relationship is strongly linked to the public interest and to the welfare of the child; this matter therefore should be determined uniformly according to unambiguous, clear standards.

Conclusion

The current interpretation of the Civil Code holds that the woman who conceived and gave birth to a child must be considered the legal mother of that child. Even in those cases whereby another woman provided the woman who conceived and gave birth to the child with an ovum from which the child was conceived, it is not possible to

recognize a legal mother-child relationship between the child born and the woman who did not give birth to said child.

### Judicial precedent 3: Logical structure

#### Recognition of presumptive facts

The purpose of the latter part of Article 724 of the Civil Code is as interpreted above; therefore, if the stipulation in said Article is interpreted to the letter, then if the victim of the tortious act, being in a permanent state of insanity and with no appointed statutory agent, is not able to issue a claim for compensation during the period of six months preceding the expiration of the period of prescription, namely the twenty year period starting from the moment when the tortious act was committed, then he or she will lose his or her said right to claim compensation for damages.

#### Substantial evidence

However, according to the above interpretation, even if the permanent state of insanity of the victim is consequent to the tortious act to which the contested statute of limitations applies, the victim, in his or her inability to execute his or her right to claim compensation for damages, loses any such right simply because the twenty year period of prescription has passed, while the perpetrator, again simply because the twenty year period of prescription has passed, escapes his or her duty of compensation; this is clearly a strong violation of basic concepts of justice and fairness. That there is a need, therefore, at least in the circumstances described above, to protect the victim remains the same as any other case of statute of limitations, and that it is therefore perfectly reasonable for the period of prescription for the statute of limitations as stipulated in the latter half of Article 724 of the Civil Code to be regulated as necessary.

#### Conclusion

Therefore, in special circumstances, such as where the victim of a tortious act has not placed a claim for compensation for damages during the period of six months preceding the expiration of the twenty year period of prescription beginning from the tortious act itself, and where said victim is in a state of permanent insanity and has no statutory agent who can make such a claim on his or her behalf, and furthermore where said victim has subsequently been granted an interdiction, and a person appointed as his or her statutory agent makes a claim for compensation within six months of that interdiction being granted, the statute of limitations as stipulated in the latter part of Article 724 of the Civil Code shall be interpreted as not applicable, in consideration of the spirit of the law as outlined in Article 158 of the Civil Code.

### Judicial precedent 4: Logical structure

#### Recognition of presumptive facts

The commencement of the period of the statute of limitations as stipulated in the latter half of Article 724 of the Civil Code is "the time of the tortious act", and when the offending act results in damages being caused as the tortious act is being carried out, then the offending act itself is indeed the commencement of the prescribed period of the statute of limitations.

#### Substantial evidence

By recognizing that the period of prescription for the statute of limitations begins to elapse from the time of the tortious act, rather than from the time when the damages occur, is particularly ruthless on the victim. It also means that the perpetrator should expect to receive a claim for compensation from a victim who re-emerges after a significant period of time has elapsed, according to the nature of the damages inflicted through his or her offending actions.

#### Conclusion

In the case of certain kinds of damages, such as those from substances which cause damage to health through accumulation in the body, and those which only present symptoms after a certain period of incubation, where the damages only become clear after a significant period of time has elapsed as a result of the inherent nature or properties of said damages caused by the tortious act, then the commencement of the period of prescription for the statute of limitations should be interpreted as beginning when all or part of the damages manifest themselves.

In other words, as an example of the difficulty in application of current statutory law, we can consider the withholding or turning off of an artificial ventilator for end-of-life patients. The Penal Code indicates only such abstract stipulations as "a person who kills another" (Article 199), or "a person who causes another to suffer injury" (Article 204), and the application of Tatbestand, or the elements of the offence, has been left to the interpretation of the prosecutor's office and that of the court. That is to say it is unclear whether the withholding or turning off of an artificial ventilator constitutes an act of murder, or under which conditions it would come (or not come) to constitute such<sup>32</sup>.

Moreover, we can assume the following, when considering the position of court judges. Namely, that, the courts of today constantly face circumstances which have not been anticipated by the law. In such cases, the meaning, requirements, and range of the law as a set of rules will be violently contested by all related parties. This is the reason why legal hermeneutics, which considers the nature of the application of law, is so necessary. For judges, one model for the interpretation of law is that they, as judges, should not interpret the law at all, but rather apply it mechanically. Another model is that the judges, "faced with a dispute, intuitively find the most reasonable solution, and the reasoning subsequently indicated through the letter of the law is little more than argument added subsequent to the initial instinctive judgment. Whatever the solution might be,

<sup>32</sup> Akabayashi, A. et al., *An Introduction to Medical Ethics II*, p153 ; Inaba, "The Space between Law and Ethics".

then, if the law is interpreted flexibly then a justification can be provided".

In fact, however, the formation of determination among court judges and of the judgments they pass is not carried out according to one model or the other, but rather results from a combination of both models. This can be considered an indication of prudence. In other words, it is rare for the process through which a judgment is formed to be carried out based solely on a logical sequence that follows legal syllogism; rather, it is carried out through the evaluation of evidence, through fact finding and, through the selection, interpretation and application of legal norms, these multiple elements all feeding back into the judgment-formation process. Interpretations thus gleaned are then filtered through the determination and conference of judges, along with trial-and-error-type reflection (reflective equilibrium).

In this kind of case, an experienced judge will, in order to ensure that his or her interpretation of the law is not simply ad hoc, give due consideration to the following specific points: consideration and confirmation of consistency with well established legal principles is a professional responsibility of judges working in the hierarchical court system (where errors can be rectified in higher courts) where a discourse of interpretation is declared, since it is to be an official interpretation, it must be reasonably applicable to other similar cases; and 3) it must not go against justice nor a sense of equilibrium (substantial justice)<sup>33</sup>.

As such, we can reconfirm the following as having been established thus far: If we are to accept judicial precedent, in particular those set by the Supreme Court, as the highest form of public judgment, then analysis of the logic underpinning such judicial precedent is vital. Second, such examination must comprise the analysis of the structure of judicial precedent, rather than the basis and scope of the binding effect of judicial precedent. Third, while courts and judges are subject to positivistic restraints ("all judges shall be independent in the exercise of their conscience and shall be bound only by this Constitution and the laws" Article 76-3, The Constitution of Japan), in reality many elements are taken into consideration.

Amongst these elements are (explicit and implicit) values and ethical principles that go beyond substantive law. This is particularly true for so-called "hard cases" (where the scope of the law is being contested, or where the absence of relevant law leads to a contest of differing opinion). Fourth, as a result, the analysis of the logical structure of judicial precedent facilitates the crucial analysis of intermediary and practical principles as well as basic concepts and principles (as read from the law) upon which the practical field of application is based. In the field of bioethics, in particular, legal systems can face challenges arising from new scientific knowledge and new interests brought about by such scientific

discovery (most of these are "hard cases"), and it is vital to be aware of this logical structure (or, rather, it is vital to be able to trace back to the fundamental reasoning behind the structure).

### Conclusion

Having analyzed the above judicial precedents, we can identify several point keys to the formation of precedent. First, that bioethical issues are related to the use of the frozen sperm of a deceased person for artificial insemination, the welfare of the posthumously born child, the awareness of the persons concerned in terms of the formation of legal parent-child relationships and relationship with natural relatives, as well as general social perception. Second, biological parent-child relationship is strongly linked to the public interest and to the welfare of the child. Third, the victim, in his or her inability to execute his or her right to compensation, loses any such right simply because the twenty year period of prescription has passed, while the perpetrator, again simply because the twenty year period of prescription has passed, escapes his or her duty of compensation. Fourth, this is clearly a strong violation of basic concepts of justice and fairness. Perfectly reasonable is particularly ruthless on the victim.

In this way, at least for the four cases examined, it is possible to extract, as intermediary and practical principles and basic concepts and principles, concepts of justice and fairness contained within the judgments, as well as reason, the welfare of the child, and general social perception and public opinion.

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## Bioethics and the Law on Informed Consent: Three-level Structure Analysis of Jurisprudence Research Papers, Guidelines and Declarations, and Culture

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### Introduction

The three-level structure analysis of bioethics to which this research refers comprises the following: the first level comprises issues and judgments in medical settings and bioscience research front. The second level comprises laws, guidelines and the specific and intermediary principles that inform these laws and guidelines, which function to resolve issues and make judgments more assured. The third level is composed of the basic concepts that are the foundation of the

<sup>33</sup> Akabayashi et al., *An Introduction to Medical Ethics II*, p194 onwards; Inaba, "Law and Justice".

specific and intermediary principles comprising the super ordinate concepts of the second layer.

The fields covered by bioethics are expanding without limit. This article, however, examines informed consent, one of the most important bioethical principles to be considered in the field of bioethics and the law in Japan. It therefore considers patient self-determination, and its relationship with this three-level structure.

This article will first examine the principles of informed consent, the patient's right of self-determination which forms the core of such consent, and the way in which these have developed over time. It will then examine relevant jurisprudence literature, guidelines, and ethical codes.

### The development of bioethics

The field of bioethics has been formed in conjunction with the development of medicine and medical technology, acknowledging and seeking to resolve many emerging issues and problems that affect patients in medical settings. It is possible, therefore, to state with confidence that "there has been a marked increase in general public interest in the nature how bioethics should be involved with the law"<sup>34</sup>. Bioethics has formed as a type of professional ethics, encompassing both medical ethics and biomedical ethics. Biomedical ethics received much attention in the 1970s, particularly in the United States, where there was an active patient rights movement at that time; this prompted widespread debate about biomedical issues. Through litigation, patients fought for their right to self-determination in medical care, and the doctrine of informed consent evolved. For the development of bioethics, informed consent has been, and continues to be, the oldest and most fundamental of all legal means. It is also the outcome of a long battle with medical paternalism, and distrust of medical care.

The doctrine of informed consent was developed outside of Japan, and only began to be introduced to and studied in Japan at the beginning of the 1970s. For example, Kohichi Bai, a scholar of civil law and medical jurisprudence, introduced German medical care and law to Japan<sup>35 36</sup>, while Ikufumi Niimi, a scholar of civil law, conducted detailed research on judicial precedents set in the United States relating to the doctrine of informed consent<sup>37 38 39</sup>.

<sup>34</sup> Tanaka, S. (2005). Seimei-rinri heno houteki kan-yo no arikata nit suite: jiko kettei to goui keisei wo meguru joronteki kousatsu [Law in bioethics: a preliminary discussion on self-determination and consensus making] In S. Tanaka (ed.) Gendai hou no tenbou: jiko kettei no shosou [Perspectives of Modern Law: Aspects of Self-determination], Yuuhikaku, pp. 131-175.

<sup>35</sup> Bai, K. (1970). Chiryō kou ni okeru kanja no shoudaku to ishi no setsumei [Patients' agreement and doctors' explanation in medical settings] In Ijhougaku heno ayumi [Steps to medical law]

<sup>36</sup> Bai, K. (1974). Kagaku to hou to seimei to [Science, law, and life] in Seimei Kagaku Nooto, Tokyo University Press.

<sup>37</sup> Niimi, I. (1975). Ishi to kanja no kankei: setsumei to doui no houtewki sokumen (1) [Doctor-patient relationship: The problem of informed consent (1)], Hosen Ronsyu (Journal of Law and Political Science), 64, 67-106.

It is impossible to ignore the presence of the Christian faith at the roots of bioethics as developed in Europe and the United States, and it is therefore important to be aware of the fact that Western bioethics has been established through a process of conflict and compromise between Christianity, and philosophy, thought, and science. By contrast, in Japan, it can be argued that "the vast majority of Japan's intellectuals, including members of the legal profession and legal scholars, conduct themselves as 'men of good conscience' with no belief in any higher power. Lack of any such faith makes such men utilitarian, and profession to being 'men of good conscience' essentially means they are adopting the view of life and concepts of goodness found in Christianity, without expressing upon what moral code those views and concepts are founded"<sup>40</sup>. It cannot be said, therefore, that the nature in which the foundation of Japan's own bioethics has been constructed has been properly debated. What must be said, however, is that bioethical issues are universal issues, and that Japan has learned and considered bioethics based on the bioethics debate outside of Japan.

### In medical settings: the first level

Japan has mostly learned about bioethics from bioethical debate conducted outside of Japan. That is not to say, however, that there have been no grounds upon which a bioethical foundation could have been built in Japan. Japanese patients, like those outside of Japan, were also aware of the need for information from physicians, and the importance of patient self-determination. Issues in medical settings, which form the first level of the three-level structure which we are examining, manifest themselves within the framework of 'bioethics and the law' most notably in the shape of litigation.

Two cases may illustrate this point. A physician charged with the care of a patient suffering from an aggressive form of tongue cancer, without informing the patient of the name of the disease, instead informed the family, reaching an agreement on the excision of the tongue. The patient, however, who had not been informed of the name of the disease, did not agree to the excision of the tongue even after the necessity of such excision was explained to him, and refused the operation. The physician, in response, explained that he was suffering from an ulcer, and that the operation would involve burning that part of the tongue off, thereby succeeding in making the patient agree to the operation. In reality, however, the physician removed one third of the patient's tongue. The patient then claimed for solatium on the basis that he had not agreed to the excision of any part of his

<sup>38</sup> Niimi, I. (1975). Ishi to kanja no kankei: setsumei to doui no houtewki sokumen (2) [Doctor-patient relationship: The problem of informed consent (2)], Hosen Ronsyu (Journal of Law and Political Science), 65, 182-224.

<sup>39</sup> Niimi, I. (1976). Ishi to kanja no kankei: setsumei to doui no houtewki sokumen (3) [Doctor-patient relationship: The problem of informed consent (3)], Hosen Ronsyu (Journal of Law and Political Science), 66, 149-177.

<sup>40</sup> Nagao, R. (1985). Seimei kagaku to houtetsugaku tonō taiwa [dialogue between life science and legal philosophy]. Houritsu Jihou, 57, 71.

tongue. In 1973, the Ohmagari Branch of the Akita District Court held the physician's actions as illegal, placing great weight on the fact that the patient had clearly refused to consent to any operation to remove any part of his tongue<sup>41</sup>.

Another case also concerns an operation carried out on the consent of the patient's partner, despite clear refusal by the patient. In 1978, the Sapporo District Court heard the case of a lobotomy carried out on a patient who was suffering from mental disability at the time, ruling that, even if the patient is mentally disabled, "if the patient has enough capacity to be aware of the situation that he or she is in, of the meaning and nature of the medical care being proposed, and of the dangers inherent in that medical care", then the consent of the patient concerned was necessary. The court further held that despite "it being clear that the patient held a will to refuse the carrying out of the operation concerned", the decision to carry out the operation based on a decision that consent could be assumed from the patient's admittance to hospital was illegal<sup>42</sup>.

### Judicial research papers: the second level

With such issues arising in medical settings, then, informed consent, and the right of the patient to self-determination, naturally comes to be debated in the realm of jurisprudence. Kohji Satoh, one of the first and foremost scholars of constitutional law in Japan, assumed the right to the pursuit of happiness to include "the right to personal autonomy (the right of self-determination)". He also held that personal autonomy (the right of self-determination) comprised "the right according to which the individual is entitled to decide for him/herself regarding certain important personal affairs, without any intervention from public power". Moreover he defines these 'important personal affairs' as being "vital for personal existence"<sup>43</sup>. Affairs protected by the right to self-determination include 'affairs related to the end and disposal of one's own life and body', and Satoh argues that "they are concerned with the most basic form of autonomy, the autonomy over human life and death, and informed consent, as well as issues such as the refusal of treatment and death with dignity, are ultimately related to this same autonomy"<sup>44</sup>. As superordinate concepts upon which to lay the foundations for the personal autonomy (self-determination) which comprises the second layer of the three-level structure of informed consent, Satoh employs the principle behind Yukichi Fukuzawa's notion of "national independence through individual independence", Natsume Sohseki's individualism, and

John Stuart Mill's concept of liberty<sup>45</sup>. The individual that Satoh imagines as the self-determining agent is mature, the same image of the individual assumed by Western ethical thinking.

Norio Higuchi, a scholar of British and American law and medical law, in his consideration of patient self-determination, proposes the 'Fiduciary Model' as a way to approach the physician-patient relationship. This model holds that "the patient is able to entrust decisions to his or her physician, and is also able to withdraw that entrustment subsequently. The patient is able to decide to make decisions on his or her own, but is also able to make decisions having been given information and advice by his or her physician, which is likely the most usual case"<sup>46</sup>. Here, Higuchi is assuming an individual who is able to make decisions alone, and also free to not make decisions.

In formulating the assumptions upon which this physician-patient model is based, Higuchi examined judicial precedents and academic theories in the United States, as well as judicial precedents in Japan.

### Guidelines and declarations: the second level

The Japan Medical Association (1990) Report on the Round-Table Conference on Bioethics. An increasing number of judicial precedents have been passed in Japan, since the 1970s, on cases contesting issues related to patient consent and the duty of physicians to provide appropriate information. In response to this, in 1988 the Japan Medical Association held a Round-Table Conference, taking as its theme "explanation and consent", and the results of the conference were published as a report in 1990. This indicates that the issue of consent given after explanation, which had first emerged in the United States, had by that time "come to be a pronounced topic"<sup>47</sup> in Japan also. In the words of the report, "traditionally, Japanese society has held a quite different approach to the nature of the individual and interpersonal relations than the United States and Western European countries", and it takes as prerequisite the need to distinguish the nature of the individual in Japan as distinct from that assumed by Western individualism. The report points out that in Japan "until recently there has been a tendency among patients to 'leave it all to the doctor'", along with a similarly strongly rooted belief among doctors that "all the patient needs to do is let me get on with things". The report affirms those circumstances, stating that "this tendency to 'leave things to the doctor' is a firm indication that patients have encountered capable physicians worthy of trust", and

<sup>41</sup> Akita District Court Ohmagari Division 27 March, Showa 48 [Hanrei Jihou, 718, pp. 98]

<sup>42</sup> Sapporo District Court 29 September, Showa 53 [Hanrei Times, 368, pp. 132]

<sup>43</sup> Satoh, K. (1984). In Y. Higuchi, et al. (eds.) Chushaku Nihonkoku Kempou Vol. 1. pp. 302-305.

<sup>44</sup> Satoh, K. (1995). Kenpou [Constitutional Law], (3<sup>rd</sup> ed.), Seirin Shoin. (P. 460)

<sup>45</sup> Satoh, K. (2007). 'Jinkakuteki jiritsuken' ni kansuru horon [A note on the right to personal autonomy] In Abe Teruya Sensei Kiju Kinen Ronbunshuu, pp. 3-30, Seibundo.

<sup>46</sup> Higuchi, N. (1993). Kanja no jikoketteiken [Patients' right to self-determination] In Iwanami Kouza: Gendai no hou [Modern Law] Vol. 14: Jikoketteiken to hou [Right to self-determination and law], pp/ 63-99, Iwanami Shoten.

<sup>47</sup> Japan Medical Association Round-Table Conference on Bioethics (1990). Report on the Round-Table Conference on 'Explanation and Consent'. Nihon Ishgikai Zasshi [Journal of the Japan Medical Association], 4, 515-535.

taking the stance that “physicians and patients are not of equal standing; the physician has specialist knowledge and experience which place him in a leadership role”. The report went on to suggest that a prerequisite for informing the patient or his or her family members was, even in the case of a cancer diagnosis, the ability to accept diagnosis”, and that “although in principle the patient him or herself should be informed, in certain cases it will be appropriate not to inform the patient directly, but instead inform his or her family members”.

In drawing up these guidelines, the Japan Medical Association referred to the Nuremberg Code of Ethics in Medical Research, the World Medical Association’s Declaration of Helsinki, the American Hospital Association’s Statement on A Patient’s Bill of Rights, the World Medical Association’s Declaration on the Rights of the Patient, and the U.S. President’s Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioural Research.

In 1992, the Japan Federation of Bar Associations (JFBA) took “Declaration on to the Establishment of Patient Rights” as the theme of its annual Convention on the Protection of Human Rights<sup>48</sup>. The declaration held that medical care in Japan at that time “overall, could not be said to be respecting the independent will of the patient”, and that “the right of the patient to have his or her independent will respected with regard to medical care originates in basic human rights, a fact recognized by international human rights law. It further stated that the very core of this right was “the basic principle of informed consent, whereby a patient, having been provided with reliable and accurate information on the nature of his or her illness, the objective of the medical practice being proposed, its methods, the risks it poses, and any alternative methods of treatment, is able to autonomously choose, give consent, or refuse, as he or she so determines. As such, this right is, along with the right to receive appropriate medical treatment, a vital element of medical care itself”.

In drawing up the declaration, the JFBA referred to such material as the Nuremberg Doctor’s Trial, the World Medical Association’s Declaration of Helsinki, the American Hospital Association’s Statement of A Patient’s Bill of Rights, patient’s rights acts as passed in various American states and foreign countries, and the Principles for the Protection of Persons with Mental Illness and the Improvement of Mental Health Care (UN Principles). It contains some reference to medical paternalism. It appears that the JFBA, while describing this declaration, assumed that patients were independent and autonomous.

In 1996, Japan’s Ministry of Health, Labour and Welfare (MHLW) published a report on informed consent drawn up by a committee chaired by Kunio Yanagida, entitled “MHLW: On the Nature of Informed Consent – Towards a policy of informed consent that will benefit the patient”<sup>49</sup>. This report took as the basis

of “informed consent as appropriate to Japan” the notions that “it is vital that medical care professionals provide sympathetic and careful explanations designed to promote understanding” and that simultaneously “the will of the patient should be respected as greatly as possible”. It goes on to expound that “the relationship between the patient and medical care professional should not be construed in terms of hierarchy or confrontation. It is important that each party seeks to understand the position of the other, and deepen mutual understanding.

All parties need to consider how high quality medical care that will secure and improve the quality of life of the patient can ultimately be achieved”, thereby defining medical care as a collaborative activity between the patient and the medical care professional. With regard to the question of informing patients of the specific name and nature of their illness, the report acknowledges that increasing numbers of patients wished to be informed (particularly in the case of cancer), while also noting that “it is not the case that all patients should be uniformly informed; consideration must also be given to those patients not wishing to know the details”. When explaining the details of an illness to the patient, the report also places importance on the need to give “due consideration of the family and social background” of the patient, and emphasizes the significance of family. Moreover, it talks about the need for patients, families and nationals to be themselves aware that the choices that they make about medical care will ultimately be based on the wishes and will of the individual patient.

In 2001, the Tokyo Metropolitan Hospitals Ethics Committee published a report entitled “Patient’s Bill of Rights in Metropolitan Hospitals”<sup>50</sup>. As reason for drawing up the Bill of Rights, the Committee noted that “the level of public trust amongst the metropolitan community towards the medical care being provided has been severely shaken as a result of frequent medical accidents and failure to provide patients with adequate information”, adding that “at present, it cannot be stated with any confidence that due and proper consideration has been given to the provision of medical care services that focus on the perspective of the patient”, thus indicating the need for further discussion on the matter in hand. The preamble shows mindfulness of the importance of patient-oriented medical care, of cooperation between patients and medical care providers, and of the need for the proactive participation of the patient in his or her medical care. It also states that medical professionals working in metropolitan hospitals are to provide support for the proactive participation of patients. Within this Bill of Rights, patient rights include the equal right to quality medical care, the right to receive medical care in the context of a mutually cooperative relationship with the medical care providers whereby one’s character and values

<sup>48</sup> Japan Federation of Bar Associations (1992). *Kanja no kenri no kakuritsu ni kansuru sengen* [Declaration on patients’ rights]. Author.

<sup>49</sup> Ministry of Health, Labour and welfare and Yanagida, K. (eds.) (1996). *Informed consent no arikata ni kansuru*

*kentoukai houkokusho: genkino deru informed consent wo mezashite* [Report on Informed Consent Committee: Towards User-friendly Informed Consent]. Chuuou Houki.

<sup>50</sup> Tokyo Metropolitan Hospitals Ethics Committee (2001). *Patient’s Bill of Rights in Metropolitan Hospitals*. Author.

are respected on an individual basis, the right to receive adequate explanation and information in a way that is easy to understand and until such time as the patient feels able to make an informed decision, and the right to refuse treatment; these rights are declared specifically and in detail.

What is unique about this Bill of Rights is that it also sets out the responsibilities of the patients. The responsibilities of the patient include a duty to provide to the medical care provider, with as much accuracy as possible, information on his or her own health, a duty to ask questions of the medical care provider until he or she fully understands the explanation being given, and a duty not to hinder the treatment of other patients or medical care being provided by staff at metropolitan hospitals. In formulation of these practical principles, the Committee referred principally to the World Medical Association's Declaration of Helsinki and its Declaration on the Rights of the Patient. Today, large-scale medical facilities and individually-run clinics alike are establishing charters setting out medical care guidelines and patient rights, and publicizing these to patients.

### Self-concept and self-determination

Brief review of court cases, judicial papers, and ethical declarations suggests that the concept of the third level is relayed to the concept of self --- the agent that is given information and that determines what to do in medical settings. We think that how Japanese see self differ from profession to profession and from time to time. A certain salient feature becomes clear. It is not the case that physicians are determining medical acts without any sort of disclosure in the medical care setting. In most cases, even in the case that the physician had not given any adequate explanation to the patient, the physician clearly outlined the nature of the illness and the treatment to be taken to the patient's family members, and had sought and received the consent of them. By the second half of the 20<sup>th</sup> century, however, some patients began to state their objection to such an approach through litigation. These include the cases noted in this article, and these cases epitomize how bioethical issues have developed over time. So why might it be that physicians have disclosed information and sought consent from the family members rather than the patient? On the one hand, we have seen academic discourses, declarations, and bills of rights that place great value on the decision-making capability of the patient as an individual. So why, on the other hand, is there such reference to the family in what should be a two party relationship between the physician and the patient? It may well be that, in Japan, there exist two super ordinate concepts, and the conflict and collusion between them has resulted in dispute and litigation on the medical care setting.

Considering self-determination in medical care in the context of Japanese culture and value system first requires that thought be given to the nature of self-concept in Japan. How have people interpreted

themselves as individuals within and throughout Japanese culture? Self is an equivocal concept<sup>51</sup>.

Firstly, there is the self as agent, which acts autonomously. Secondly, there is the self as viewed by the agent-self, in other words the self as object. Furthermore, there is the "cultural self", as per Kitayama et al., where the self is envisaged as an image and model shared culturally and created historically within a certain region or group. Individuals who are born, raised and live in a specific culture defined their selves as being objects under the influence of the cultural self-construal which that same specific culture provides. In other words, self construal is not formed in isolation from the cultural construal of self. It influences the way in which information is processed intrapsychically<sup>52</sup>. Self-concept also affects the emotions and motivations of individuals<sup>53</sup>.

In their review of the differences in self construal that exist between the United States and Japan, Markus and Kitayama propose that while self construal in the United States can be described as "independent self construal", Japanese self construal is better interpreted as "interdependent self construal"<sup>54</sup>. Independent self construal is defined as the self construed as separate from its social context, whereas interdependent self construal defines the self as intertwined with its social context. The former type of self concept is singular and stable, while the latter is flexible and variable. In terms of their significant characteristics, independent self construal emphasizes internal and individual attributes, such as ability, thought and feeling, while interdependent self construal accentuates the external and the public, such as status, role and relationships. The role of self-concept also differs: for independent self construal it is to promote the individual as unique, to express the self, to realize internal attributes, and to fulfill personal goals; for interdependent self-construal it is to belong and conform to society, to behave appropriately, and to fulfill goals given to you by another person. As such, independent self construal demands that direct action of the self, that one speaks one's mind, while interdependent self construal demands indirect action of the self, that one reads the thoughts of the surrounding people. Within the former, the role of others is to act as reference models for self evaluation, whereas for the interdependent self-concept, interaction with others in a defined social context is what defines the self. The root of self-esteem lies, for independent self construal, in the expression of the self, and in the attachment of value

<sup>51</sup> Kitayama, S., & Karasawa, M. (1995). Jiko: Bunkashinrigakuteki shiza [Self: A cultural psychological perspective]. Jikken Shakai Shinrigaku Kenkyuu [Experimental Social Psychology], 35, 133-163.

<sup>52</sup> Markus, H. R. (1977). Self-schemata and processing information about the self. *Journal of Personality and Social Psychology*, 35, 63-78.

<sup>53</sup> Markus, H., & Wurf, E. (1987). The dynamic self-concept: A social psychological perspective. *Annual Review of Psychology*, 38, 299-337.

<sup>54</sup> Markus, H. R., & Kitayama, S. (1991). Culture and the self: Implications for cognition, emotion, and motivation. *Psychological Review*, 98, 224-253.

to internal attributes. For interdependent self construal, this same self-esteem is achieved by conforming to the wider social context, and maintaining harmony within it.

These differences in self construal are also reflected in differences in the defining features of respective moral codes. Moral values are ambiguous, and have been noted to be closely linked to moral emotions. From a psychological perspective, Haidt et al. have suggested that there are five moral foundations<sup>55</sup>. The first of these is 'harm and care'. This holds that is a particular ability of primates to be sensitive to signs of the pain of others as if it were our own pain. This sees cruelty and aggressiveness as vices, and kindness and compassion as virtues. The second is 'fairness and reciprocity'. This assumes a long history among humans of cooperation with non-kin individuals, and further that such cooperation has fostered mutually beneficial altruism. From this, concepts of fairness and justice have emerged.

The third moral foundation is 'ingroup and loyalty'. This is related to the formation of groups based on kinship, and to the ability of man to recognize members of ingroups, to trust them, and to achieve cooperativeness with those members. At the same time, it accounts for feelings of cautiousness and distrust towards members of outgroups. Since value is found in the ingroup, those who sacrifice themselves for the ingroup are respected, while those who betray it are held in contempt. Loyalty, patriotism, and heroic acts become moral norms.

The fourth is 'authority and respect'. Hierarchy is established within the ingroup, and those at the top serve as the protectors of those at the bottom, while those at the bottom have high regard for those at the top while showing humility in themselves. Respect for authority, awe, and admiration is demanded, and the virtues of the leader are held to be magnanimity, fatherliness, and wisdom.

The fifth foundation is 'purity and sanctity'. Humans became carnivores, thus eating the carcasses of animals; from this emerged the feeling of disgust. Disgust was derived from the feeling experienced instinctively towards those things capable of causing disease, such as excrement, vomit, and rotting meat. This feeling of disgust eventually developed into similarly uncomfortable feelings towards certain physical appearances (disease) and vocation (jobs involving the handling of rotting meat). At the same time, the notion was developed that there was virtue in keeping the body, where the soul resides, as pure as possible. We can suggest that independent self construal places great emphasis on 'harm and care' as well as 'fairness and reciprocity', while interdependent self construal will take as its primary moral norms concepts of 'ingroup and loyalty' as well as 'authority and respect'.

The agent of self-determination is the self. If we re-evaluate this self from this cultural and psychological perspective, it seems that the self has value in its social relevance, having only a comparatively weak

value as the only agent of that which is to be determined. In his discussion of the ethics of self-determination, Koyanagi notes that the self-determinative ideal type of "I will determine what happens to me" transforms into other patterns: "we will determine what happens to us" and "I will determine what happens to us"<sup>56</sup>. If this is the case, then the pattern of "We will determine what happens to me" can be presumed to be the superordinate concept of the reality in medical care where "the family members determines what happens to the patient". In a culture of interdependent self construal, respect for the authority of medical care providers has strong moral value, and moreover trust in the loyalty of the family as ingroup and respect of its decision seems to have allowed self realization and psychological adjustment on the part of the patient. However, independent self construal was historically predominant in the latter half of the twentieth century, a situation which led eventually to the emergence of people decrying paternalistic decision-making conducted by persons other than the individual, believing rather that moral value lies in the autonomous express of self. Independent self construal, then, has been the superordinate concept in medical ethics for the latter half of the twentieth century.

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## Issues regarding Doctors' Professionalism in Japan

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### Introduction

The purpose of this paper is to review, in brief, the issues pertaining to doctors' professionalism in Japan. This paper consists of three sections. Section 1 describes the outline of the status of doctors in Japan. Section 2 contains the analysis of the professional code of ethics. Section 3 examines the problems of doctors' professionalism through a recent medical accident case.

### Status of doctors in Japan

In Japan, the modern medical system began with the promulgation of the *Isei* (medical system law) in 1874. The *Isei* comprised 76 articles on topics like public health administration, medical educational system, and the separation of dispensing and prescribing functions (Shinmura 2006, p.227). However, at this stage, there were no unified qualifications in the medical practice. At that time, the population of Chinese medicine doctors was four times as large as that of Occidental medical doctors (ibid. p.237). In 1883, the *Ishimenkyo-kisoku* (Medical

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<sup>55</sup> Haidt, J., & Graham, J. (2007). When morality opposes justice: Conservatives have moral intuitions that liberals may not recognize. *Social Justice Research*, 20, 98-116.

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<sup>56</sup> Koyanagi, M. (2009). Jikokettei no rinri to 'watashitachi no jiyuu [Ethics of self determination and our freedom]. Nakanishiya.

License Act) was established by the government, which controlled the qualification for medical treatment.

In 1906, the *Ishi-hou* (Medical Practitioners Act) was constituted, which made the medical license not only a license for practice but also an indicator of the individual's professional and social status. This law demands that doctors establish medical associations voluntarily (later obligatorily) (*ibid.* p.254 ff.). We can see these processes as an act to induce professionalism among the doctor community. The *Nihon-ishi-kai* (Japan Medical Association) was established as a nationwide association for doctors in 1923. The first president of this association was Shibasaburo Kitazato (1853–1931)<sup>57</sup>.

In the war-time year of 1942, the *Ishi-hou* (Medical Practitioners Act) was changed to the *Kokumin Iryou-hou* (National Medical Law). This change was basically aimed at national correspondence with WWII. In other words, such a reform at war-time had the totalitarian ideology that the government should directly control the national medical service. The *Nihon-ishi-kai* (Japan Medical Association) was also disincorporated in 1943.

In 1947, after WWII, the new *Nihon-ishi-kai* was re-founded, which doctors affiliated themselves with arbitrarily. In 1948, the *Ishi-hou* (Medical Practitioners Act) was also constructed, which is still under the law. In 2007, the *Nihon-ishi-kai* had about 165,000 members (*Nihon-ishi-kai*, 2008, p.4), which constitutes about 60% of all the doctors in Japan.

Article 1 of the *Ishi-hou* (Medical Practitioners Act) of 1948 mentions doctors' social roles and responsibilities as follows: "Doctors contribute to the improvement and advancement of public health by administering medicine and health guidance, by which they assure the healthy life of the nation." It is stipulated in Article 7 that the Minister of Health, Labour and Welfare takes disciplinary actions against some crimes or inappropriate actions that question a doctor's reputation as a professional. In Article 18, this law prescribes a non-doctor to not use the title of a doctor or a confusing name. In Article 19, it is stipulated that a doctor engaged in diagnosis and treatment, if asked to treat a person, must not refuse without a reasonable motive.

Medical education in Japan is offered in the form of a six-year curriculum at the Department of Medicine in universities or Medical Colleges. Qualifications for candidacy for the national examination are obtained by completing these curriculums. The license of a doctor is a national qualification that is delivered by the Minister of Health, Labour and Welfare. Any individual who passes the national examination registers his/her name with the ministry. The Medical Practitioners Law (Article 16-2 of the *Ishi-hou*) has made it mandatory for newly qualified doctors to take clinical training for two years. The hospital specified for clinical training is examined and recognized by the Ministry of Health, Labour and Welfare.

There is no system to update one's medical license. The "Idou-shingikai (Medical Ethics Council)" of the Ministry of Health, Labour and Welfare can deprive the individual of the qualification. As a rule, doctors can diagnose all illnesses. They can choose to give a free consultation or health insurance treatment; since all persons are assured medical insurance, many doctors prefer the latter option. The doctor does not have a retirement age. There is a specialist system that a professional society authorizes.

In Japan, many doctors had a private practice under the free-practice system until the last half of the 1970s, when group practice in hospitals was communized. After around 1990, on the one hand, doctors with private practices decreased, while those in hospitals increased (Fujisaki 1995, pp.36–43). The ratio of doctors with private practices to those in hospitals was about 1:1.76 from 2002 to 2006 (Ehara, 2008).

### Professional Code of Ethics

In this section, I will analyze the *I-no-rinri-kouryou* (Medical Code of Ethics) of 2000 to view the ethical problems faced by the doctors. The *I-no-rinri-kouryou* is the medical code of ethics established by *Nihon-ishi-kai* (The Japan Medical Association).

The *I-no-rinri-kouryou* (Medical Code of Ethics) of 2000 was originally established as *Ishi-no-Rinri*, which was laid down by *Nihon-ishi-kai* (Japan Medical Association) in 1951. Later, in 2004, *Ishi no sokugyou-rinri-shishin* (the doctor's guideline of professional ethics) was established as the more concrete guideline of doctors' actions. In 2008, this *shishin* (doctor's guideline) was revised and the *I-no-rinri-kouryou* (Medical Code of Ethics) was added at the beginning of it. As we can see from the composition of the revised edition of 2008, the *I-no-rinri-kouryou* (Medical Code of Ethics) and *Ishi no sokugyou-rinri-shishin* (the doctor's guideline of professional ethics) correspond to each other in their forms and contents. Here, I will try to analyze the *I-no-rinri-kouryou* (Medical Code of Ethics) of 2000, the preamble of which is described as follows: "*Medicine and Medical services are supposed to not only treat patients but also keep or promote public health. Doctors must recognize such important responsibilities and render to everybody their services based on love for humanity.*" The last half of this preamble defines the professional duties and responsibilities of doctors. It is believed that medicine and medical service cover humanity at large, and their professional duty is to "*render to everybody their services based on love for humanity.*" "Love for humanity" means love for humanity at large, which is apprehended as love for every human being regardless of nationality, thought, and creed. In this respect, "service for everybody" means the same thing. It implies that doctors must not render their services to specific people but must serve every human being. This professional obligation is derived from the public welfare aspect of the doctors' profession. Such an idea is also defined in *Ishi-hou* as *Oushou-gimu* (obligation of treatment). In Japan, this

<sup>57</sup> Shibasaburo Kitazato is a doctor and bacteriologist who studied under Robert Koch (1843–1910)

obligation is supported by the universal healthcare system in the institutional respect.

Article 1 of the *I-no-rinri-kouryou* (Medical Code of Ethics) mentions the lifelong learning obligation of doctors as follows: Doctors must inculcate in themselves a lifelong learning spirit and make an effort to acquire knowledge of medicine and technique of diagnoses and treatments, by which they work toward their advancement and development.

Article 2 describes that doctors have dignity and responsibility as professionals; therefore, they must make reasonable efforts as follows: Doctors must exert efforts to be consciously aware of the dignity and responsibility of the medical practice, to cultivate them, and to develop their personality.

Article 3 mentions respect for the patient's personality, explanation for the patients, and their confidence as follows: Doctors must respect the patient's personality and treat them with a gentle heart. Doctors must endeavor to explain the content of the treatment and must gain the trust of the patients.

Article 4 prescribes that "*Doctors must respect each other and contribute to medical care while simultaneously cooperating with healthcare practitioners.*" This article mentions the doctors' mutual esteem and combined effort with other healthcare practitioners.

Article 5 describes the publicness of the medical service and compliance. "*Doctors must respect the publicness of the medical service, by which they contribute to the development of society and observe the laws and regulations and make efforts to form the legal order.*"

Article 6 requires nonprofitability on the part of doctors. "*Doctors must not treat patients from the viewpoint of profit making.*"

The key ideas extracted from these articles again are "*lifelong learning obligation of doctors, dignity and responsibility of doctors, respect for the patient's personality, explanations to patients, gaining confidence of the patients, doctors' mutual respect, cooperation with other healthcare practitioners, awareness of the publicness of the medical service, and compliance and nonprofitability of medicine.*" They are based on those in the preamble, which promote public health as the aim of medicine and medical service and the love for humanity. All these are second-level concepts, and they are supported by the third-level concept, which is more fundamental in nature. The third-level concept here is "the professionalism of doctors." In the *I-no-rinri-kouryou* (Medical Code of Ethics) of 2000, there is no description of "the profession" or "the professionals." In addition, there are only two short references (in the preamble and chapter 4) in the *Ishi no sokugyou-rinri-shishin* (the doctors' guideline of professional ethics) of 2008 as well.

### Problems in the Professionalism of Doctors

#### Fukushima prefectural Ohno hospital medical accident case<sup>58</sup>

In December 2004, a 29-year-old woman underwent a Caesarean section and was pronounced dead about

4.5 hours after the operation. In March 2005, the medical accident investigation committee, which was voluntarily established by this hospital, reported that the death was caused by the failure of the synechiotomy of the placenta accreta and insufficient preparation of the blood transfusion. The surgeon was arrested on suspicion of professional negligence resulting in death and for violating the Medical Practitioners Act in February 2006 and was charged in March. Article 21 of the Medical Practitioners Act requires doctors to report to the police, within 24 hours, when the cause of a patient's death seems to be abnormal.

In March 2006, *Nihon-ishi-kai* (Japan Medical Association) pointed out three problems as follows: (1) It was quite regretful that the obstetrician-gynecologist was placed in custody, (2) There seems no reason for the obstetrician-gynecologist to be personally charged in this case, (3) The concept of "abnormal death" in the context of the medical treatment is still controversial as a legal interpretation.

This case elicits many reactions from physicians across Japan. This is especially because they believe that too much responsibility was placed on the obstetrician-gynecologist as a professional. The problem of a criminal trial is that the medical standards are estimated by the police and the judge, who are not always experts of the medicine or medical treatments. It is a serious problem for doctors if the result of the medical treatment is a charge of professional negligence resulting in death. They probably think that they might be next. However, in October 2008, the obstetrician-gynecologist was judged as not guilty.

In October 2000, guidelines were established by the committee to make a risk management standard manual (in the Ministry of Health and Welfare). It determined medical accident and medical malpractice as follows<sup>59</sup>: In the place related to the medical treatment, the *Iryou-jiko* (medical accident) implies all accidents resulting in injury or death generated in all processes of medical treatment, regardless of the presence of healthcare professionals' mistakes and faults. The *Iryou-kago* (medical malpractice) is one pattern of a medical accident, which is the act that causes damage to the patient against medical standards. Generally speaking, the *Iryou-kago* (medical malpractice) is treated as a civil trial case on the one hand. The *Iryou-jiko* (medical accident) is treated as a civil and criminal trial case on the other hand, which is incriminated typically as a "professional negligence causing injury" or "professional negligence resulting in death."

According to the proclamation of the *Nihon-ishi-kai* (Japan Medical Association) in March 2006, the Fukushima Prefectural Ohno hospital case does not correspond to the *Iryou-kago* (medical malpractice) but corresponds to the *Iryou-jiko* (medical accident). In other words, the practice of the doctor in this case was well adopted according to medical standards, and the doctor was not at fault in that operation.

The problem here lies in the following points. On the one hand, the accident investigation committee in that prefectural hospital submitted a report declaring

<sup>58</sup> *Asahi Shinbun*, a morning edition, p.15, April 12, 2006

<sup>59</sup> [http://www1.mhlw.go.jp/topics/sisin/tp1102-1\\_12.html](http://www1.mhlw.go.jp/topics/sisin/tp1102-1_12.html)

that it was the doctor's "fault." On the other hand, the *Nihon-ishi-kai* (Japan Medical Association) and several doctors considered that this obstetrician-gynecologist was not at fault for which he must take on legal responsibility as a professional. The "fault" that they speak about must be specified. Their concept of "fault" does not always seem to be flexible.

### Conclusion

What we can see from the case is the fluctuation in doctors' professionalism. From the layman's point of view, it is natural for one to wonder why the inconsistency of opinions occurred among doctors, or at least they should explain why such an inconsistency occurred. As professionals, they should reach a common consensus regarding this important issue. As I mentioned in the first section of this paper, the *Nihon-ishi-kai* (Japan Medical Association) is the largest nationwide association of doctors, to which about 60% of doctors belong. However, we can also say that the opinions of the *Nihon-ishi-kai* (Japan Medical Association) constitute the opinions of only about 60% of the doctors. I think that this is one reason the ethical code or guideline of the *Nihon-ishi-kai* has a few descriptions of the "professionalism of the doctors."

We know that every doctor works very hard<sup>60</sup> according to his/her "professionalism." It is true that their daily dedications bring Japanese medical services into existence. However, at the same time, we need a more unified image of doctors as "professionals." Thus, professionalism must be unified by the professional group in order to identify who is a professional. Nonprofessionals trust a professional not only as a person but also as an authorized member of a professional group.

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<sup>60</sup> Recently, it has often been argued that there is a shortage of doctors, which makes doctors' work overtime. The Committee of doctors practicing in the hospital of the *Nihon-ishi-kai* (Japan Medical Association) pointed out that the shortage of doctors is directly caused by the policy, which reduces medical costs and decreases the enrollment limitation of the medical school. Indirectly, it is caused by (1) The specialization and segmentalization of medicine, (2) The insufficient wage standards and poor working environment, which fail to match their hard work, (3) Increment of the medical malpractice or accident suits and rise of the patients' demands (expectation). (Nihon-ishi-kai, 2010)

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## Bioethics in Nursing – Specialty in Nursing

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The practical guidelines of bioethics in nursing in our country stem from "The Ethical Platform of Nurses" which is based on "The Ethical Platform of Nurses" (ICN-International Council of Nursing). "The Ethical Platform of Nurses" declares that "in practical nursing, the individual right to life, the right for individual dignity, right to receive respectful and equal nursing should be strictly ensured". They are more specifically classified into four basic categories, i.e., "nurses and people", "nurses and practice", "nurses and nursing professionals", and "nursing and assistants". This classification embodies the internationally established ethical platforms of nurses.

However, while these ethical principles serve as the guidelines for action and judgment, we respect, in the evaluation for one's action or judgment, each sense of value by which each individual seeks for cooperation and harmony on the basis of the paternalism that has been nurtured and maintained within organizational/cultural atmosphere specific for Japanese. In this article, the three-leveled structure of the bioethics of nursing in Japan will be discussed from the standpoint of specialty in nursing.

On the "feeling: sensuous thinking" step of the first level, nurses realize the current status and problems found in the sharpened sensitivity, exhibiting concreteness of judgment. Throughout the experience of the first level, nurses advance to the second level. Key words of the second (middle) level, i.e. "mind: figuratively thought" are "human dignity," "human rights," and respect for "self-determination," The third level is "thinking: fundamental thought" with the highest degree of abstraction. This represents abstraction, ubiquity, essentiality, theory, intelligence and principles, and corresponds to the third step of the three-level structure. Namely, they are "dignity," "protection of right," "safety," "comfort," and "credibility," all of which are the concepts respected by the Japanese nurses when they practice nursing.

Finally, refer to the evaluation for one's action or judgment, each sense of value by which each individual seeks for "harmony" on the basis of the paternalism that has been nurtured and maintained within organizational/cultural atmosphere specific for Japanese.

### Introduction

The practical guidelines of bioethics in nursing in our country stems from "The Ethical Platform of Nurses" (Japanese Society of Nursing, 1988; revised 2003) which is based on "The Ethical Platform of Nurses" (ICN-International Council of Nursing, 1953; revised 2005). The nurses that are herein referred to represent certified professional nurses, i.e., registered nurses, practical nurses, public health nurses, and midwife nurses. The preamble to "The Ethical Platform of Nurses" declares that "in practical nursing, the people's right to live, the right for individual dignity, right to receive respectful and equal nursing should be strictly ensured,"<sup>1</sup> thereby clearly demonstrating the extent of responsibility in the practices of professional nursing.

"The Ethical Platform of Nurses" is comprised of the preamble followed by 15 provisions which are classified into three groups: Provisions 1 – 6 state the virtues and obligations in offering nursing; Provisions 7 – 11 state the efforts for fulfilling the responsibility; Provisions 12 - 15 defines individual characteristics and organizational approaches as the foundation of nursing. They are more specifically classified into four basic categories, i.e., "nurses and people" (Provisions 1, 2, 5, and 14), "nurses and practice" (Provisions 3, 4, 6 – 8, 12, and 13), "nurses and nursing professionals" (Provisions 10, 11, and 15), and "nursing and collaborators" (Provision 9). This classification embodies the internationally established ethical platforms of nurses.<sup>2</sup>

On the other hand, the bioethics of nursing in our country is characterized by another aspect according to which the practical activities are determined by the principle-based ethics as ethical behaviours or grounds for judgment. The ethical principles are respect for autonomy, non-maleficence, beneficence and justice, as demonstrated by Beauchamp and Childress,<sup>3</sup> The grounds for ethical activities are classified more specifically as beneficence (liability for good deeds), non-maleficence (obligation for evading harms, justice (pertinence and impartiality), autonomy (freedom of determining one's activity according to the plan set up individually and respect for those with determined mind), honesty (telling the truth, not lying, not deceiving others), fidelity (responsibility for being honest to commitments, obligation for trust inherent in between patients and physicians and confidentiality of information), all of which are important ethical principles for practical nursing of Fry.<sup>4</sup>

However, while these ethical principles serve as the guidelines for action and judgment, we respect, in the evaluation for one's action or judgment, each sense of value by which each individual seeks for cooperation and harmony on the basis of the paternalism that has been nurtured and maintained within organizational/cultural atmosphere specific for Japanese. In this article, the three-layered structure of the bioethics of nursing in Japan will be discussed from the stand point of the specialty of nursing.

### Growing responsibility and sensibility of nurses

When one surveys a historical outline of ethics in Japanese nursing, it seems clear that nurses were expected to be assistants to physicians from the Edo era through Meiji and Taisho to early Showa eras and

they emphasized their values on their obedience, purity, reticence and subordination, and these characteristics had been considered as virtues. We Japanese are earnest and tolerant by nature and when one becomes a patient one would subject oneself to medical doctors in the form of "submissive treatment" and leave any judgment to doctors. In medical practice up until the 1970s doctors had tried their best to fulfill the patients' expectations, while nurses followed the doctors' advices for the sake of doctors and patients. These efforts had contributed to provide good results for the three parties, i.e., patients, nurses, and doctors. Thanks to the benefit of medical treatment, patients' illnesses have been cured and doctors receive increasing respect and nurses have brought happiness to patients by facing the patients' anguish along with doctors. Though diligence, kindness, and cleanliness are still regarded as virtues of nurses even in medical practices today and following doctors' advices obediently is regarded as important as ever before.

However, as medical practices have more advanced, improved, and become more sophisticated, medical practitioners have begun to ask whether or not continuing life-sustaining treatment serves for the patients' benefit, how the quality of life is going to be after the lesion is excised by operation, whether the patient will suffer from the adverse effect of chemotherapy, whether or not the genetic diagnosis or genetic therapy is a virtue for the patients, whether prolonging patients' life for one minute or one second longer is an absolute virtue, whether the consideration of patients' quality of life more than anything is worthwhile for their benefit. Nurses have witnessed physical and mental misery of patients who have blindly subjugated themselves to doctors or the misery by choosing or not choosing the therapeutic options. On these occasions even though nurses have realized that these arose by neglecting patients by medical staffs, the nurses did not have courage to protect patients' rights and are left with the ethical dilemma for not taking proper actions. During the Convention of the Japan Academy of Nursing Science in 1992, Anne J. Davis gave a plenary lecture entitled "Ethical aspect of human caring,"<sup>5</sup> which reflects the nursing ethics being problematic in Japan. According to Anne J. Davis, different societies are characterized by different cultures and ethics and therefore the ethical completeness beyond different cultures should be taken into account, though one should tolerate and respect values and ethical sentiment of others.<sup>6</sup> The exploratory committee of nursing ethics of Japan Academy of Nursing Science announced in 1993 that, as the "ethical issues facing Japanese nurses and their responses,"<sup>7</sup> (1) offering medical information, (2) participation in medical practice, (3) determination of life and death, (4) comfortable atmosphere of medical facilities, and (5) unreasonable physical and emotional impairment of patients are ethical themes. While patients may not always be respect as individual human being, nurses become distressed by their inability to protect the patients' rights.<sup>8</sup> In order to endorse patients' comfort nurses should not restrict themselves within the frameworks of the strong and the weak or upper and lower in social hierarchy or

male and female but they should attempt to create the environment where they can cooperate and collaborate to cure and overcome the illness. Creating such environment is the most important challenge for the Japanese medication<sup>9</sup>.

With these issues in the background, The Japanese Nurses Society (JNS) presented six ethical assignments for nurses in 1999 to cope with the dilemma on the part of nurses, i.e., participation of patients in medicine, confidentiality in medicine, responsibility and role of nurses, patient-nurse-doctor interrelationship, organ transplantation, and clinical examination and research.<sup>10</sup> In 2003 JNS adopted "Nursing Ethics" as the main theme for the "White Paper of Nursing" as the token of strong awareness of the need for nursing ethics as well as their effort for its dissemination<sup>11</sup>.

Furthermore, natural and medical sciences have experienced revolutionary advances lately, resulting in the possibility of manipulating human life on the genetic level. This not only leads nurses to be aware of ethical problems but also entails ethical judgment by nurses. They are required to hold the ability to think and judge critically. Since the illness structure has recently shifted from acute phase to chronic phase, patients are required to coexist with illness and impediment. This in turn results in the necessity of declaring their views of life and death in terms of life they prefer and doctors and nurses and other medical staffs have naturally come to protect the patients' dignity and respect the their wills and try to promote comfortable medical treatment. They have also recognized that the patients' wills have become influential in determining the therapeutic strategy and it is quite natural for the nurses to realize their necessity to respect the patients' wills as the defender of the patients' right, as patients' different senses of value have helped them to become more aware of their sense of right. The fourth provision of "The Ethical Platform of Nurses" declares that "the people's right to know and to determine should be respected and their rights should be endorsed."<sup>12</sup> Nurses should try to offer safer and more comfortable treatment and create mutual trust with patients on the basis of human dignity in order to keep the patients' life in order and help them to maintain their independence. JNS defined "*The Guidelines for Nursing Research*"<sup>13</sup> in 2004 and "*The Fundamental Guidelines for Treatment of Nursing Record and Clinical Information*"<sup>14</sup> in 2005 and urged nurses to take appropriate care toward the ethical aspects of medical research and information.

The law for organ transplantation (commonly called organ transplant law) was enacted in 1997 and new form after the amendment in 2001 presents its basic standpoint that "the living will of the brain-dead donor and the consent of the donor's family should be respected as the fundamental premise." The organ transplant law was revised in 2010 and the following requirement has been added: "Even when the willingness to donate one's organ(s) is unclear, the bereaved family can endorse it by a written statement." Accordingly, though all the brain death

cases should not be considered as the definition for being dead, nurses are expected to care and attend brain-dead patients wishing for their survival and care the family with the agony of becoming bereaved. The nurses are also required to attend those patients waiting for organ transplantation. These actions tend to drive the nurses to complex psychological stresses. Nurses are also forced to face such difficult question as to whose rights should be defended for what reasons and their ethical judgments are sometimes strongly urged.

The medical treatment fees in Japan were revised in 2006 and safe and sophisticated medical treatment and nursing as well as "hospitals as nurses houses" are being pursued.<sup>16</sup> The international nursing day in 2006 declared its main theme as "safe staffing saves lives" and positive roles and potentiality of nurses are being highly expected.

Under these circumstances generalist nurses with expertise in every field as well as specialist nurses with expertise in particular fields have been institutionalized and "certified nurse specialists" and "certified nurses" were established in 1996 and 1997, respectively with an aim to improve nursing quality. At the time of February, 2010, certified nurse specialists are promoting (1) state-of-the-art nursing practices, (2) consultation, (3) coordination, (4) ethical adjustment, (5) pedagogic roles, and (6) research activities in ten different fields, e.g., "nursing cancer patients", "nursing psychopathic patients", "community-based nursing", etc. Certified nurses are trying to raise their expertise in 21 different fields, e.g., "emergency nursing," "excretory and dermatologic caring," and "palliative caring," engaging in (1) practice, (2) training, and (3) consulting. These attempts include handling ethical problems faced during their practice. Improving their ethical sensitivity to cope with the growing responsibility is challenging issue for nurses.

### Search for the three-layer structure in bioethics of nursing

Time has come for us professional nurses to be aware of the importance of each expertise and to improve individual ethics and to improve each ability. The underlined terms that are presented above in "bioethics of nursing – specialty of nursing" of Section II, i.e., "dignity," "protection of right," "safety," "comfort," and "trust" represent five principles of nursing ethics embraced by Japanese nurses<sup>17</sup> and ranked in the third layer of the highest degree of abstraction within the three-layer structure. Nurses always examine the quality of their nursing in their practice in the individual cases, since the problems for improvement becomes clear by highlighting the progress and insufficiency. By this examination each nurse reaffirms the significance of his/her nursing performance, leading to greater improvement of the actual performance and greater value for nursing. During the examination nurses understand the situation under which they perform nursing, using the general concept as the basis of thinking process. In practical nursing, they practice taking the combination of cases with under different condition into

consideration. Questioning "what is actual nursing?" leads to conceptualization of practical nursing and objectivization of actual performance. The very objectivization of the actual practice should lead to realization to communicate in words what they do, think and judge. In order to understand the broad framework of the practical nursing, nurses sense certain things in the situation the patients are thrown into when they face patients. For instance, feeling pain, agony, misery, anger, anxious, happiness is not initiated by "feeling" but "feeling" initiates these senses. When the emotion of "feeling" begins itself, this stage is located in the first step with the greatest degree of concreteness in the three-level structure if "feeling: sensuous thinking" is utilized as the first step. Practical nursing is pushed by the "feeling: sensuous thinking" toward the side of the actual patients and speaks to the patients, comforts them, encourages them, their hands, massages their legs, and warms them. While making much of the relation between nurses and patients, nurses take these actions sitting intimately close to them. At this stage nurses approach each patient taking the patient's specificity, condition, situation, and experience into account. These activities are themselves sensitivity of feeling emotions. For these reasons nurses are required to obtain "high sensitivity" or to "brush up sensitivity" as their basic ability. In the first layer, nurses realize the current status and problems found in the sharpened sensitivity, exhibiting concreteness of judgment.

Through the action on the "feeling: sensuous thinking" step of the first level, we will go on to the next emblematic level of "thinking: metaphoric reasoning." In this stage we will think by employing and abstracting to some degree individuals, reality, and images. As the concrete actions of the status, problems, and judgment surrounding the nursing ethics of the first level, nurses speak to the patients, comfort and encourage them, grab their hands, massage their legs because these actions actually are the actual announcement of "human dignity," creation of "confidential relationships," securement of "protection and safety," "fulfilling operational responsibility," and actual performance of action in accordance with "desirable standard." These actions also represent respect for "human rights," offering "equal nursing," and collaboration with "medical care staffs." In addition they are respect for "the right to know," respect for "self-determination," protection of "right," "confidentiality of information," protection of "private information," "continuation of study," and creation and development of "knowledge and technology of specialty" and they all will "contribute to the involvement of nursing science. The concept of the terms presented above, i.e., "human dignity," "human right," "offering equal nursing," "confidential relationship," "respect for the right to know," "respect for self-determination," "protection of right," "confidentiality of information," "securement of protection and safety," "fulfilling operational responsibility," "continuation of study," "collaboration with medical care staffs," "desirable standard," and "creation and development of knowledge and technology of specialty," represent the second or the middle level. In the second (middle) level, recognition

of status and issues surrounding the nursing ethics and concreteness of different judgments seem to possess adjusting properties and pedagogic function. Furthermore, they also possess a publicity function that appeal to propagandist thinking and consciousness and draw on actions. The very consciousness of the middle level persuades them of the explanation as to why nursing is actually performed and fulfills their accountability.

In addition, practical nursing will reach the third layer of "thinking: fundamental thought" with the highest degree of abstraction. This represents abstraction, ubiquity, essentiality, theory, intelligence and principle and correspond to the third level of the three-level structure. Namely, they are "dignity," "protection of right," "safety," "comfort," and "credibility," all of which are the concepts respected by the Japanese nurses when they practice nursing. As far as the "protection of right" attached to the third level is concerned, the concrete action and performance will be realized when it becomes clear as to what should be protected. To "protect human rights" or to "protect rights of man" or to "protect legal rights" or to "protect the right to know," which emphasizes the self-determination of patients, or to "protect the rights for self-determination" or to "protect the private information" or to "protect securement of protection and safety" or to "protect human dignity" important for human existence or to "protect confidentiality of information" should all be attached to the second or middle layer.

Though these three levels show timing and stage at certain point, thinking processes always descend in a bottom-down fashion, illustrating, individualizing, materializing and specializing descending pattern of improvement. At the same time, improving in bottom-up fashion will lead to legitimization, generalization, abstraction, universalization and substantiation. These are brain activities and epistemological activities and lead to credibility for action and judging grounds. As different nurses have different standards of value, there are nurses with confidence in sensitivity, intuition, and experience of the first level, while other nurses are good at metaphors and allegories of the second or middle level and still other nurses base themselves on the theories and logics of the third level. Whichever the case may be, they will be endowed with rich thinking and judging ability by making each concrete experience more objective and by telling their actual experiences.

For instance, in speaking of practical nursing, they become convinced, as the "agreement of all," over the considerations for the importance of human dignity, for becoming protectors of rights, for the protecting safety as absolute principle, for offering comfortable care as important missions, for creating confidentiality between nurses and patients as of absolute value. However, when they witness patients with agony, it is important for them to talk to them, hear them and offer suitable care after sound judgment. In considering over the ethics of nursing, nurses should always ask for what purposes they do those things, how they actually carry them out, and whether they realize their confidence as professionals. Japanese nurses are good at offering kindness and compassion to patients

and emphasize the importance of behavioural aspect as symbolized by the word "smile." Contact with patients begins with behavioural attitudes towards them.

The very continuation from the first to the second and to the third level brings meanings and values to nursing activities. Emphasis on the harmony maintains the integrity of organizations. If the importance of harmony is recognized, there exists risks where members of the organization suppress their own views and agree with others against their wills when they are surrounded by different views of doctors and other nurses after they realize the importance of harmony even though they recognize ethical problems in the actual situation of the first layer. If too much emphasis is burdened on the organizational harmony, chaos will be avoided without friction with the surrounding, even in the presence of problems, and the members in question are left with anxiety, asking themselves "was I correct in taking those behaviours?" This will not lead to the resolution of ethical problems, even if one is aware of the problem from the ethical sensitivity.

Additionally, the relationship between "the individuals" and "the family" is often synchronized within the value of "harmony." Even in the case where individual view should be respected as that of a patient, the "individuality" as a patient is synchronized within the organization of "family" and the patient as an "individual" holds a standpoint that respects the view of the entire family more than the view of the individual patient. The relationship of an "individual" within the "family" is specifically characteristic of Japanese culture and this very relationship tightens the judgmental toughness as to whose standpoint should be respected over the others in solving the. Furthermore, the father's intention and those of male members are better regarded, as symbolized in paternalism, and adopted in determination of the family view. This is reflected in the ethical judgment being in danger and adoption of paternalism in cases otherwise.

As these circumstances demonstrate, we have tried to emancipate ourselves from paternalism while maintaining the family in harmony and we have such cultural tendency of bringing about the positive consideration toward certain things from generous and sympathetic thinking. Generous and sympathetic thinking alone does not lead to ethical judgment based on scientific grounds and evidence.

Nevertheless, there are instances where actual phenomena in the practical nursing do not reach the principles of the third level ever after the phenomena in question bottomed up toward the second (middle) level. Although an inductive look at the actual and ethical circumstances will usually lead to fundamental principles, half of the ethical problems experienced have been left unsolved and people involved in the problem tend to avoid them out of specifically Japanese way of thought by following Japanese aphorisms, "capping the pot containing bad smells" or "do not wake a sleeping baby." It has become urgent to identify the discrepancy between the actuality and

the theoretical outcome that should be derived through correcting problem-avoidance, through inductively reasonable principles suitable for solving individual ethical cases. Facing the discrepancy of the ethical problems straight and confronting the reality directly are important assignments of practical nursing in Japan. Meanwhile, the problems concerning specific matters are also problems of ethical sensitivity of individual nurses and how the organization deals with them will become the sensitivity problems of the organization itself and problems concerning the sensitivity of Japanese of nursing ethics also exist within the nursing organizations. The practical nursing actions cannot be treated as smoothly as "actual facts", "intermediary principles", "principles", "actions," as often found in clerical works or operations. There lies conflict based on emotion and merit as well as on diversity of subjectivity and objectivity and they will not lead to timely resolution. For this reason, how to support patients will become a fundamental question. What can be achieved by bottom-up actions will support such conflicts as mentioned above and if organizations protect nurses and their work venues, the quality of individual ethical sensitivities and ethical viewpoints will be greatly improved. These are problems of sensitivity of individual nurses and ethical sensitivity of organizations, and the two parties, i.e., nurses and organizations, are highly expected to brush their sensitivity and play deterministic roles in ethical determinations.

### Epilogue

We often confront dilemmas in Japan when we encounter ethical problems. They will lead to the following difficulties as those in nursing: the relationship with doctors, which stems from the different directions of the doctors in treatment and in facing patients from those of nurses); offering information to patients (there are incidents where information cannot be offered to patients even when nurses realize the dilemma of how much information can be offered, confronting the patients' desire to obtain information), patients' thoughts and those of the families (when nurses respect patients' thoughts, they often differ from those of the families and the nurses face difficulty in determining how to act as nurses, feel dilemmas by being pulled by the views of the families); abilities of patients themselves and difficulty in performing nursing (nurses realize that they cannot offer proper cares for the patients by their insufficient ability in addition to excessive obligations as nurses they also realize their inability coming from their immaturity as professionals<sup>18)</sup>). In these instances the autonomy of nurses as a profession will be said to become problematic. Now is the time for the nurses to establish their independence, to try their best for the patients, to look ahead for the ethical principles as to what are good deeds, what are innoxious, what are fair, what are righteous, what are honest, and what are loyal. Now is also the time to watch closely the reality and specific status of the first level, watch intentionally the principles (of the second or middle level) of human dignity, respect for rights, offering

equal nursing, fulfilling responsibility of performing nursing, confirm the principles (of the third level) of securing dignity, right protection, safety, comfort, confidentiality in a bottom-up manner. Also nurses are not accustomed to moving from the third to the first level in a bottom-down manner. The ability to recognize the ethical problem that are initiated by the categories given above and brushing up of the sensitivity as sensation as well as search for the principles and fundamental rules are found as future themes.

We would like to correct the current innocence of the ethical problems and to correct performance of practical nursing without realizing the ethical problems. Patients and nurses alike have diverse value, judgment, and way of living. Precisely for these reasons it is of fundamental importance to look closely (watch, observe, diagnose, care, and view), hear closely (listen and ask), speak intensively (conversation), touch closely. By sitting or standing close to the patients and supporting them for suitable life processes as living persons, there exists significance in applying theoretical intelligence and practical intelligence in dealing with ethical problems of patients.

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## Patterns of reasoning in religious positions on organ donation in Japan and Germany

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The Japanese debate on medical ethics, especially on the problem of brain death and organ donation, continues to attract considerable interest of Western scholarship and has frequently been the subject of in-depth studies in Western languages.<sup>1</sup> Likewise, Buddhist approaches to contemporary biomedical issues have been introduced to Western readers through extensive studies, for example by the works of Damien Keown.<sup>1</sup> However, systematic analysis of Japanese Buddhism's contributions to the debate on medical ethics has not been undertaken yet, which in view of (a) the necessity to differentiate between the various forms of Buddhism, and (b) the significance of Buddhism in the Japanese context as one of its major religious traditions, is still a desideratum.

Focusing on the problem of postmortem organ donation, the purpose of this paper is therefore to offer an exemplary descriptive analysis of perspectives and arguments of Japanese Buddhism on this particular problem of medical ethics. Accordingly, this paper is intended as an investigation of the question: What positions on organ donation are derived by Japanese Buddhism from its traditional doctrine, its dogmata and canonical scripture, and what kind of patterns of argumentation are made use of in order to support its positions? Based on the assumption that religious factors play a crucial role in contemporary debates on the various dilemmas in the field of medical ethics, this paper aims at deepening the understanding of not only structure and patterns of reasoning in Buddhism's contributions to the Japanese discussion on medical ethics, but thereby also of the specifics of Japanese medical ethics in general.

To extract the characteristics of the Buddhist discourse on medical ethics in Japan, the position on organ donation held by the main German Christian churches will be used as a comparative foil, in front of which the specifics of Buddhist positions and the characteristics of the patterns of Buddhist argumentation are expected to emerge in an articulate way. In its analysis, this paper focuses on religious voices in their institutionalized form, i.e. official memoranda and communiqués on the problem of brain death and organ transplantation released by Buddhist denominations in Japan, as well as the respective views held by the Christian churches in Germany. Positions and opinions of individual

Buddhist thinkers or Christian theologians will not be considered in this paper.

For its method and framework of analysis, this paper turns to the “three-level-model”<sup>1</sup> proposed by Takao Takahashi (2009) for the analysis of structures of argumentation in the field of applied ethics. This paper thereby constitutes the attempt to apply this model on the analysis of patterns of *religious* reasoning on a problem of medical ethics. Interpreted in the light of the “three-level-model”, the “concrete decision or statement” (Takahashi, 2009, p. x) of a religious denomination in favour for or against organ donation, constitutes the first level of argumentation. “Intermediate principles which the first level takes as its premises” (ibid, p. x) represent the second level – in the religious context i.e. virtues, precepts, dogmata etc., from which the decision on the first level is deduced. The third level finally offers “examination concerning content, grounding, definition, explanation, meaning, point of reference, relation and order of priority, good and evil, right and wrong etc. of the intermediate principles” (ibid, p. x). In religious reasoning, the third level corresponds to the fundamental anthropological and ethical beliefs as well as to the worldview of the relevant religious tradition, from which the intermediate principles of the second level originate and have their foundation in respectively. Such concepts of the third level may be horizontally interconnected with other third-level concepts, but are not further based on deeper-lying principles. Since it is to be expected, that in the attempt to legitimate their positions, Christian as well as Buddhist statements refer to their particular canonical texts, the question arises as to how such references to authoritative scripture should be located in the three-level-model. To answer this question, both the grade of authority assigned to a certain text, as well as the argumentative function of the reference has to be considered.<sup>1</sup>

At first, this paper examines the perspective of the Christian churches in Germany on the problem of organ donation, whereby special emphasis is placed on the analysis of their theological-ethical assessment of the problem as well as the patterns of argumentation and reasoning applied (Section II). The next step is to identify the positions and patterns of Japanese Buddhist reasoning on organ donation, drawing on an exemplary selection of statements brought forward by Buddhist denominations in the 1990s (Section III). Finally, the results of the analysis of Buddhist approaches and patterns of reasoning are contrasted against its Christian counterparts. In conclusion, it is suggested that differences in the patterns of reasoning are one of the reasons for the different degrees of public and political influence that Christian and Buddhist positions achieve to exert. Further, methodological problems of the Buddhist patterns of argumentation as revealed by the analysis of the denominational statements of Japanese Buddhism are addressed, and a recent attempt to resolve these by offering an alternative approach to the topic, is discussed (Section IV).

The position of Christian churches in Germany on

organ donation – theological-ethical assessment and patterns of argumentation. It is not only the large body of theological contributions to the debate on biomedical problems and the strong institutional basis of academic theology within universities, enjoying relative independence from the churches, which is considered as one of the characteristics of German bio- and medical ethics (Schoene-Seifert et al. 2004, p. 1627). In comparison to the situation in Japan, the high degree of impact on media and public opinion achieved by statements and communiqués of the Christian churches on dilemmas in medical ethics, stands out as a striking feature of German medical ethics.<sup>1</sup> Also, a profound influence of Christian medical ethics on relevant political decisions and legislation can be observed (Pinter, 2003). This influence is exerted for example through the election not only of representatives of academic theology, but also of leading members of the two large Christian churches in Germany (Protestant Church and Roman-Catholic Church) into the German Ethics Council (Deutscher Ethikrat).<sup>1</sup> Although also dissenting – and at times quite influential – positions are voiced by (especially protestant) academic theology and individual Christian thinkers, it can be further observed that the two large Christian churches strive to demonstrate an ecumenical consensus in their “official” statements on the various issues of medical ethics.<sup>1</sup>

Concerning the problem of brain death and organ transplantation, such an ecumenical consensus on the institutional level has been demonstrated long before the passage of the German Transplant Law in 1997, and has been expressed in two statements issued conjointly by the Protestant Church in Germany (Evangelische Kirche in Deutschland EKD) and the Roman-Catholic Church (represented by the German Bishops’ Conference (Deutsche Bischofskonferenz DBK)) in the late 1980s and in the beginning of the 1990s respectively.<sup>1</sup> The ecumenical statement *God is a friend of life: Challenges and tasks in regard to the protection of life* (Kirchenamt der Evangelischen Kirche in Deutschland, and Sekretariat der Deutschen Bischofskonferenz [EKD and DBK], 1989) is considered to constitute the fundamental consensus of the German Christian churches on bioethics, moreover since it is subscribed to by another 13 German Christian churches. While this statement does not confine itself to the discussion of brain death and organ transplantation, and offers an examination of a broad spectrum of bioethical problems as well as theological, ethical and biblical foundations of Christian bioethics, the statement *Organ transplantations* (Sekretariat der Deutschen Bischofskonferenz, and Kirchenamt der Evangelischen Kirche in Deutschland [DBK and EKD], 1990) offers a more in-depth treatment of the Christian position on brain death and organ transplantation. Although the release of both statements dates back even before the passage of the Transplant Law in 1997 and yet two decades have passed, these two statements still have to be considered to represent the current fundamental position of the major Christian churches on the problem of brain death and organ donation. Until present, both statements have not

been revised or replaced by announcements or statements of comparable weight.

In their evaluation of transplantation medicine, the Christian churches arrive in both statements at a positive assessment by accepting in principle the concept of brain death and acknowledging the authority of the medical field to establish the concrete criteria for brain death diagnosis. The decision for organ donation is valued as an expression of charity, of "love of neighbour" (*Nächstenliebe*) and "solidarity" (*Solidarisierung*) with diseased fellow human beings. A potential recipient's desire to save or prolong his endangered life by means of a donated organ, is accepted in principle, although admonishments are made as to adopt a humble attitude towards the possibilities modern medicine offers, and to accept God as the master of life and death. Further, the churches declare their intention to support organ transplantation, in particular by their efforts to increase peoples' willingness to donate organs, but also through offering religious rituals accompanying organ transplantations as well as care and counseling for the persons concerned and their relatives.<sup>1</sup>

Turning now to the patterns of theological-ethical reasoning underlying both statements, the way in which the Christian churches justify their positive evaluation of postmortem organ donation shall be analyzed by means of the abovementioned three-level-model. Firstly, on the level of concrete judgment and decision (level 1) not only the explicit acknowledgement of the legitimacy of organ donation in general, but also a clearly positive appreciation of an individual's personal decision to donate their organs can be noted. This attitude also corresponds to the efforts of the churches, to actively "arouse and strengthen" (EKD and DBK, 1989, p. 103) the willingness of the people to donate their organs, however without going so far as to declare organ donation a "Christian duty".<sup>1</sup>

As for the intermediate level of argumentation (level 2), both texts draw explicitly on "love of neighbour" as an important concept of Christian ethics, as the argumentative basis on which they advocate organ donation. Thus, the statement *God is a friend of life* states: "In principle, the intention to help suffering fellow human beings or those whose life is even threatened, by means of organ donation and organ transplantation, is to be approved of. Therefore, the churches' statements have hitherto encouraged organ donation upon one's own passing away. The churches want to continue to arouse and strengthen the willingness to donate organs. Organ donation can constitute an act of love of neighbour beyond one's death" (EKD and DBK, 1989, p. 103). In addition to "love of neighbour", the statement *Organ transplantations* further refers to the principle of "solidarity": "From the Christian perspective, the willingness to donate one's organs upon death is a sign of love of neighbour and solidarity with the sick and handicapped" (DBK and EKD, 1990, p. 26). However, beyond this postulate of the possibility and legitimacy to interpret organ donation in view of the Christian teachings as an act of love of neighbour, the analyzed texts offer no further explanation to clarify or support this proposed argumentative relation between the positive assessment of organ donation (level 1) and "love of neighbour" and "solidarity" as principles of Christian ethics (level 2). Only the statement *Organ*

*transplantations* refers to John 15:13,<sup>1</sup> which can be interpreted as an attempt to strengthen the argumentative relation between levels one and two by identifying the willingness to donate organs upon brain death (level 1) as the ultimate manifestation of the Christian love of neighbour (level 2) and legitimating it through scriptural evidence: "At the same time, organ donation may reveal some of the 'greater love' (John 15:13) which Jesus demands of his disciples" (DBK and EKD, 1990, p. 23).

In regard to further grounding of the intermediate concepts "love of neighbour" and "solidarity" (level 2) in fundamental principles of the Christian worldview, anthropology and ethics (level 3), no explicit explanations are presented. One reason that the third level of reasoning is not addressed might be related to the character of both statements, which are not intended as academic-theological treatises but rather aim at providing the general public – both Christians and Non-Christians alike – with an appealing and at the same time concise explanation of the churches' point of view.<sup>1</sup> It can admittedly only be assumed here, that the level-two-concepts the statements draw upon – the social principle "solidarity" certainly to a far higher degree, but also "love of neighbour" – were regarded by the authors of the statements as basic and widely accepted concepts of German society. The assumption can further be made that the authors therefore considered the validity of these concepts to be intuitively comprehensible also to Non-Christians (even though probably not shared in all of its implications), so that the lack of explanation of the third level would not be perceived as a deficit by the readers.

Despite this lack of an explicit foundation of the level-two-concepts in fundamental principles of the third level, some of such potential principles can be deduced from the statement *God is a friend of life*, especially from its discussion of the Christian concept of human dignity (EKD and DBK, 1989, pp. 39-53). Among the fundamental theological, anthropological and biblical principles of Christian bioethics discussed in a statement, for example "image of God" or the "unconditional dignity of the human person" can be seen as such principles potentially serving as the argumentative foundation (level 3) of organ donation as an act of "love of neighbour" and "solidarity", although this is not explicitly expounded on in the statements.<sup>1</sup>

### **Buddhist denominations on organ donation in Japan – positions and patterns of reasoning**

In contrast to the ecumenical consensus amongst the Christian churches of Germany on the problem of brain death and organ transplantation in general and in their positive assessment of organ donation in particular, statements and communiqués issued by the various Buddhist denominations of Japan show a rather broad spectrum of differing points of view. Both in their assessment of transplantation medicine as a whole, and in their evaluation of its individual aspects such as the concept of brain death, organ donation, and reception of an organ, the denominations of Japanese Buddhism develop a wide range of different patterns of argumentation.

In the following, several of these voices of Japanese Buddhism in its institutionalized form – i.e. official<sup>1</sup> statements and communiqués issued by

Buddhist denominations – shall be analyzed in their respective patterns of argumentation by means of the three-level-model. The four texts selected for exemplarily analysis represent the statements of Buddhist denominations made public in the 1990s, previous to or shortly after the passage of the Japanese Transplantation Law of 1997.<sup>1</sup> Although the revision of the Transplant Law in 2009<sup>1</sup> – especially with its equation of brain death = human death (Asahi Shinbun, 2009c) – certainly constitutes a further challenge to fundamental ethical and anthropological doctrines of Japan's Buddhist denomination, up until now this revision has not yet led to the announcement of renewed official statements of comparable weight.<sup>1</sup> Therefore, the four statements treated in the following must be esteemed as still expressing the denominations' valid and current positions on the problem.

As in the analysis of the Christian positions, the voices of individual Buddhist thinkers or other participants in the debate who make use of "Buddhist" arguments cannot be examined here, although such voices may very well exceed the statements made by the Buddhist denominations in terms of public impact and media attention. Likewise, as for the illustration of the context from which these Buddhist statements emerge, the debate on brain death and organ transplantation in Japan, "the most contentious ethical debate of the last thirty years" (Lock, 2002, p.3), this paper has to confine itself to refer to the treatment of this problem given in the papers in this volume by Taka Fuji (2011) and Shuhei Taguchi (2011), and to the relevant literature (e.g. Lock, 2002, pp. 130-146, pp. 167-190 as the standard reference on this topic).

### The Nichiren-school<sup>1</sup>

In 1994, the Nichiren-school released a brief statement commenting on the final report of the Japanese government's "Provisional Commission for the Study on Brain Death and Organ Transplantation", which was published two years before and provided the basis for the legislative process (Lock, 2002, pp. 167-170). Although the Nichiren-school expresses in its statement criticism towards the notion of brain death, it nevertheless arrives at a positive evaluation of organ donation and transplantation (level 1) "From the viewpoint of the Lotus-Sutra and the dogmatics of the Nichiren-school, we determine that the view is appropriate that, (1) to decide human death by means of the brain death criterion, still many problems remain unsolved and this momentous shift in the concept of death cannot be entrusted to medicine alone. However, concerning (2) organ donation, we arrived at the conclusion to recognize organ donation as an act consistent with the Buddhist spirit of compassion (j. *jihishin* 慈悲心) and to not oppose to open the way for transplantation medicine based on brain death" (Nichirensū Shinbun, 1994).

Thus, on the intermediate level of argumentation (level 2), the statement of the Nichiren-school refers to the virtue of compassion (skt. *karuṇā*), a basic principle of Buddhist ethics, especially valued in the tradition of Mahāyāna-Buddhism, which Japanese Buddhism is generally categorized in. Yet, no further efforts to substantiate this interpretation of organ donation as an act of compassion to diminish suffering

of a fellow human being are presented here. Due to the brevity of this statement (the quotation given above constitutes about half of the statement's text), naturally no detailed third-level-arguments can be expected here.

### The Tendai-school

In its communiqué made public in 1996 (Tendaishū 'Nōshi oyobi zōki ishoku' ni kansuru tokubetsu iinkai, 1996), the Tendai-school arrives at an affirmative stance on organ transplantation in a similar way as the Nichiren-school. While rejecting the notion of brain death, the Tendai-school formulates a positive assessment of organ donation by mainly drawing on paradigms of the Lotus-Sutra, the prime authoritative scripture of Tendai-Buddhism. The basic idea is the assumption, that willingness to donate one's organs upon being declared brain dead can be interpreted as the deliberate renouncement of one's own life in favour of a fellow human being. Under certain terms, organ donation could thus be made plausible as a soteriological meaningful act of self-immolation, originating from the insight into the Buddhist teachings, an act of "generosity" (skr. *dāna*, j. *fuse* 布施).

At first, for a possible legitimization of self-immolation from the viewpoint of Tendai-Buddhism, the statement refers to the ideal of "indifference regarding one's life" (j. *fushaku shinmyō* 不惜身命) taught in the Lotus-Sutra.<sup>1</sup> According to the Tendai-school's interpretation of this ideal, one should not hesitate to sacrifice one's worldly body and life in order to "gain eternal life, true life" (ibid, p. 11). On the one hand, this soteriological rationale for organ donation links the self-sacrifice of one's body to a positive effect on reaching enlightenment, but on the other hand, precisely this donor's insight into the true reality of all things (in the statement referred to as "eternal life, true life") is at the same time considered to be the premise on which a – in the Buddhist sense – genuine act of self-immolation and generosity could take place. This required insight of the organ donor is further identified with the "revelation and recognition of the Buddha-nature" (j. *bussō no kaiken* 仏性の開顯), meaning "to become aware of the dignity of man, the dignity of all life" (ibid, p. 11). As for the question, how such an insight as the prerequisite for an organ donation acceptable from the Buddhist viewpoint can be attained, the statement of the Tendai-school refers to the Buddha's vow to guide all beings to enlightenment as described in the Lotus-Sutra as well as the "fivefold meditation" (j. *gokan* 五觀) also taught in the Lotus-Sutra: "Through the understanding, that all things in the universe transform moment by moment and possess no constancy, and through giving up the attachment to them (j. *shinkan* 真觀), they can be perceived in their beauty as they are in their forms of appearance in the world of reality (j. *shōjōkan* 清淨觀). Thereby, it can be understood, that our own existence is part of all things of nature mutually harmonizing and constantly changing, and – at the same time – represents them in their entirety (j. *kōdaichiekan* 廣大智慧觀). Then, suffering of others can be felt as our own suffering (j. *hikan* 悲觀), and our own joy can be shared with others (j. *jikan* 慈觀)" (ibid, p.11). According to the Tendai-school, on

grounds of such kind of insight on the part of the organ donor, his self-sacrifice upon brain death has to be acknowledged as a Buddhist act of generosity.

Summarizing the perspective of this statement, it can be stated that the Tendai-school – in a similar way as the Nichiren-school – explicitly recognizes and highly values the willingness to postmortem organ donation under certain conditions (level 1), whilst clearly opposing the notion of brain death (ibid, pp. 10, 12). In its attempt to relate organ donation to its doctrinal system, the Tendai-school also employs a core concept of Buddhist virtue on the second level of argumentation, the virtue of generosity. In order to support the argumentative link between the first two levels, the Tendai-school – in the same manner as the statement of the Christian churches in Germany – refers to its authoritative scripture, the Lotus-Sutra, while further extending the validity of the second-level-principle generosity as far as to also comprising the sacrifice of one's body and organs. However, the Tendai-school takes a step further by also including principles of the third level in its reasoning, i.e. references to the doctrinal background of "generosity", specifically to the "Buddha nature" (j. *bussō*) innate to all sentient beings and the contemplation of five essential aspects of the Buddhist worldview (j. *gokan*). It is these fundamental Buddhist beliefs, a potential organ donor has to be conscious of in his decision, for that his donation can be interpreted in the light of the Buddhist teachings as an acknowledgeable act of generosity. However on the other hand, this insight in the third-level foundation is at the same time considered to be the fruit of an act of generosity in the form of organ donation.

### The Ōtani-branch of the Jōdo-shin-school

The Ōtani-branch of the Jōdo-shin-school published its perspective on brain death and organ transplantation in two brief statements. The first statement was released in 1997, on the occasion of the passage of a first bill of the Transplantation Law in the House of Representatives (Shinshū Ōtaniha, 1997), the second commenting on the first organ transplantation carried out on the basis of the Transplantation Law two years later (Shinshū Ōtaniha, 1999).<sup>1</sup> Both statements express a fundamental rejection of both the notion of brain death and the practice of transplantation medicine rendered possible by the legal provisions. In contrast to the two Buddhist positions analyzed previously, the Ōtani-branch does not combine the rejection of brain death with a positive acknowledgement of individual willingness to donate one's organs. On the contrary – the statement of 1999 in principle denies the individual to decide matters of life and death as one pleases, to "appropriate" the life one was bestowed with, as it is expressed in the following section:

*"There are amazing advancements in modern medicine, and many of us receive its blessings in our lives. And yet, life and death are also realities of human existence. Death cannot be overcome by efforts to keep away death and to extend only life. Rather, we are being lived by 'the working of a life beyond the idea of self' (the immeasurable life, j. *muryōju* 無量壽).<sup>1</sup> At the time, when we become aware of ourselves and thereby repent our tendency to 'appropriate life' and accept both life and death as something bestowed on us, we can awake to the*

*meaning of 'life' in the precious here and now"* (Shinshū Ōtaniha, 1999, p. 94). These rather vague formulations, which seem to primarily intend to assess the reception of an organ donation or organ transplantation in general, are interpreted by some authors as including also a rejection of organ donation. This interpretation is for example proposed by the Jōdo-shin-school-Buddhist Mitsunori Kitazuka in his analysis of the section quoted above (2001, pp. 16-31).<sup>1</sup> With the intention to trace the Buddhist foundations underlying the above-quoted section of the statement, Kitazuka identifies the fundamental Buddhist concept of "dependent origination" (j. *engi* 縁起, skt. *pratītya-samutpāda*) as the background on which the rejection of organ donation as the "appropriation" of the "bestowed" life is assumingly based on. According to Kitazuka, it is this concept of dependent origination, the statement of 1999 implicitly uses in order to oppose the idea of placing the human body at one's disposal and thereby also rejecting the donation of one's organs. In regard to this assumed deduction of the prohibition of donating one's body from the concept of dependent origination, Kitazuka – who actually criticizes and refutes the reasoning of the statement – further quotes the former president of Ōtani University, Ichijō Ogawa, who is considered a spokesman of the Ōtani-branch (Ikoma, 2002, p. 88) *"This is based on the fundamentals of Buddhism, namely that our life is not our property, but rather non-self, non-ego. Our existence is 'dependent origination' (j. *engi* 縁起). We are beings of 'contingent karma' (j. *gūen* 遇縁), constituted in relation with others. For that reason something called 'self' does not exist. Through relation with others the self becomes the self. It is not 'the self is living' but 'the self is being lived'. This is the foundation of Buddhism. (...) I do not think that ideas emerge from Buddhism, which asserts humans could choose euthanasia by themselves, or choose an easy death, or have the right to do so. I think such an idea emerges only from the thought of European rationalism, since Buddhism holds that basically our lives are not our own. My existence is entirely something bestowed on me. To consider using the bestowed [existence] as I wish in this way or another is itself problematic and at the same time, things do not turn out the way they are planned. I think this is what is called the world of life in Buddhism. To put it bluntly, I think that it is the position of Buddhism, to accept it when life comes to its end due to a painful disease"* (quoted from Kitazuka, 2001, pp. 22-23). In view of Kitazuka's interpretation of the Ōtani-branch's statement of 1999, it could be argued that the crucial point of its reasoning resulting in the rejection of organ donation (level 1) can be identified as the use of a fundamental third-level-concept of the Buddhist worldview, "dependent origination". Yet, this argumentation lacks the use of Buddhist doctrines as intermediate principles. Although a second-level-argument is being constructed in form of the rejection of the "appropriation of life", the short and vague wording of the statement hardly succeeds in bridging the argumentative gap between the levels one and three.

### The Sōtō-school

The statement of the Sōtō-school, made public in 1999, differs from the Buddhist positions analyzed above in that it explicitly refrains from presenting its

clergy and lay followers an authoritative solution to the problem of brain death and organ transplantation. At the beginning of its statement, the Sōtō-school points out its conviction, that this problem is not a question easily to be answered with a clear yes or no – the decision rather has to be entrusted to each individual (Sōtō Shūmuchō, 1999, foreword). Since admittedly both positive as well as negative stances on this problem could be deduced from the doctrine of Buddhism, the Sōtō-school deems it impossible to proclaim a binding evaluation of the problem and therefore refrains from announcing a particular stance to its followers (Sōtō Shūmuchō, 1999, p. 3). In this regard, the Sōtō-school even warns against the exploitation and improper use of Buddhist teachings to justify a particular position for or against brain death and organ transplantation, and to impose that position on the general public (Sōtō Shūmuchō, 1999, p. 6). Therefore, the statement rather provides a discussion of several possible ways of interpreting the problem from a Buddhist point of view, intended as material for the individual process of decision-making. Consequently, in its statement, the Sōtō-school discusses at length and – compared to most of the official positions of other denominations – in a rather extensive and deeper going way, the various positions and arguments possible to derive from its doctrine and authoritative scripture.<sup>1</sup>

According to this kind of approach, in regard to organ donation, arguments both for and against are likewise introduced: “(1) Argumentation opposing organ donation: Buddhism teaches the “unity of body and mind” (j. *shinjin-ichinyo* 身心一如), the “non-duality of life and death” (j. *shōji-funi* 生死不二). This is a perspective, which in a way regards body and mind as monistic. As it is taught in the fascicle “Life and Death” (*Shōji*)<sup>1</sup> of the *True Dharma Eye Treasury* (*Shōbōgenzō*),<sup>1</sup> the body itself is the “venerable life of the Buddha” (j. *hotoke no on'inochi* 仏の御いのち) ‘Your present birth-and-death itself is the life of Buddha. If you attempt to reject it with aversion, you thereby lose the life of Buddha’ [quoted from Wadell and Abe, 2002, p. 106]. Therefore, even the organs are naturally the life of the Buddha, not mere parts of the body. In consequence, this means that under no circumstances these [the organs, i.e. the venerable life of the Buddha, T.B.] must get lost. (2) Argumentation in favour of organ donation: First of all, in accordance with the fundamental thought of Buddhism, the conception of the “temporary union of the five aggregates” (j. *goun-ke-wagō* 五蘊仮和合), Buddhism teaches “non-attachment” (j. *mushūchaku* 無執着) to the body itself. Consequently, the idea arises as to accept donating one’s organs without attachment in case someone should desire them. The next most emphasized concept is the “act of generosity” (j. *fusegyō* 布施行). The “act of self-immolation” ([literally, the “act of relinquishing one’s body”, T.B.] j. *shashingyō* 捨身行) taught in numerous Buddhist scriptures, is considered as the highest form of generosity. True generosity, however, is said to require “threefold purity” (j. *sanrin-shōjō* 三輪清淨), in other words giver, receiver, and gift – all three parties have to be ‘empty’ and pure. The giver must not become intoxicated in view of his own deed nor anticipate the receiver’s joy or gratitude. Likewise, by

no means, the receiver must indulge in expectations concerning the gift. Also the “act of generosity” taught in the fascicle “Four Elements of a Bodhisattva’s Social Relations” (*Bodaisattashishōbō*) is in accordance with this spirit. Further, for that “act of generosity” to be realized, the self-consciousness of being a follower of Buddhism must be made an imperative premise. If in this point things are made ambiguous, there is also the risk, that the act of generosity is made use of as a theory unnecessarily urging the general public to organ donation” (Sōtōshū Shūmuchō, 1999, pp. 26-27).

Interpreted from the perspective of the three-level-model, it can be observed that on the first level the Sōtō-school presents arguments derived from its doctrine and scripture both supportive and negative of organ donation as equally legitimate alternative options. As for arguments rejecting organ donation, the statement refers directly to fundamental level-three-concepts of Buddhist worldview and anthropology, e.g. the teaching of the “venerable life of the Buddha”, considered as being in conflict with the donation of one’s organs. Although this reasoning is supported by the reference to authoritative scripture of the Sōtō-school, no further intermediate principles of the second level are spelled out. Therefore, the argumentative leap from the fundamental Buddhist concepts (level 3) to the rejection of organ donation as their practical implications remains rather vague. Patterns of argumentation introduced by the statement in favour of organ donation however draw primarily on ethical concepts of the second level, the virtue of generosity and its particular form, the ideal of self-immolation. The concrete requirements for legitimately justifying organ donation by these second-level-concepts are also discussed. In addition, the also mentioned ideal of non-attachment to one’s body (level 2), another argument in favour of organ donation, is further supported by the anthropological concept of the “temporary union of the five aggregates”, which can be located on the third level of argumentation.

## Conclusion

In comparison with the perspective of the Christian churches in Germany on organ transplantation, the analysis of the solutions to this problem proposed by denominations of Japanese Buddhism affirms the latter’s broadness of the spectrum of positions uttered, as suggested at the outset of this paper. This diversity of Buddhist assessments of organ donation (level 1) is further reflected in a wide variety of arguments on second and third level, which the denominations draw upon in order to support their respective positions. From the comparison of Christian and Buddhist patterns of reasoning, it seems reasonable to suggest that precisely this diversity and polyphony of both positions as well as patterns of argumentation constitute one of the reasons for the lack of success of the Buddhist denominations to exert significant influence on the political discourse and the legislative process.<sup>1</sup> The revision of the Japanese Transplantation Law of 2009, especially its equation of brain death with human death, which virtually all Buddhist denominations take a critical view of, articulately demonstrates their failure to make their

positions heard. Also in regard to media attention and public awareness, the statements are apparently not communicated effectively. For example, a newspaper article of 1999 introducing the reactions of Japan's religions on brain death and organ transplantation, cites as Buddhist voices only the statement of the Ōtani-branch while giving the misleading impression that the other Buddhist denominations remain in a state of "bewilderment, caution, difficulties, silence" (Asahi Shinbun, 1999).

In regard to the Christian churches in Germany, it can be observed that it is not only their public demonstration of ecumenical consensus on organ donation which results in their far larger extent of public and political influence. It can rather be suggested that this success in making their voices heard, is also due to their reference to "love of neighbour" as a concise, widely known, acceptable and communicable social principle of the second level, evoking positive connotations in large parts of the public and the political decision-makers. Although in the Buddhist discourse on medical ethics, the virtue of "generosity" (j. *fuse* 布施) has emerged as one possible doctrine to support organ donation, the Buddhist denominations of Japan are yet to establish a similar consensus on an adequate Buddhist concept of the second level, in the light of which organ donation could be localized in Buddhism's doctrinal framework. In the current buddhological discussion, both affirmative as well as negative stances on the first level are deduced from the one and same doctrine of "generosity" as a second-level-principle (Bauer, 2006). As yet, the ongoing discussion within Japanese Buddhism, whether organ donation can truly be interpreted as an "act of generosity" or not, still has not arrived at a conclusion, thereby at present making it impossible for the Japanese Buddhists to present themselves to public and politics with an unequivocal statement on the problem.

In view of this diversity of possible patterns of reasoning in Buddhism and the fact that on the first level affirmative as well as negative conclusions can be derived from Buddhist doctrines, some denominations decidedly do not release any statement at all (Asahi Shinbun, 1999). Other Buddhist denominations explicitly refrain from issuing binding instructions on this matter and rather point out in their statements the individual responsibility to come to a personal decision on organ donation. As demonstrated above, one example of this reserved approach can be found in the statement of the Sōtō-school. At the outset of this statement, it is made clear that it is not intended as an imperative statement of a certain stance to be taken. Rather, although the individual decision on brain death and organ transplantation should be made on grounds of the Buddhist teachings, it is considered to be eventually a matter of individual responsibility: "In regard to brain death and organ donation, positive opinions and at the same time also negative views are possible to derive from the worldview of Buddhism or Zen. This is not a problem to which we as a Buddhist school could draw an either-or conclusion, answering with yes or no. This problem is a matter which should be decided only individually by the followers of our school on grounds of their self-consciousness and concern as religious persons. Accordingly, this report tries to point out in highly summarized form the most fundamental

conditions and directions necessary for such a decision" (Sōtōshū Shūmuchiō, 1999, p. 3).

A similar position is adopted by the buddhologist Yasuaki Nara in view of the fact that different and even contradictory positions on this problem are derived from Buddhist teachings and scripture. He calls for abandoning simplifying argumentations trying to deduce an authoritative answer "of Buddhism" from its doctrine, in favour of individual contemplation on this matter from a first-person perspective leading to statements in the form "I as a Buddhist ..." (Nara, 1991, pp. 10-11). Obviously, Japan's Buddhists are well aware of the methodological difficulties deducing first-level statements from traditional Buddhist teachings of the second or third level. It is such a problematic approach of religion to medical ethics, which – with regard to the European context – the German bioethicist Marcus Düwell criticizes to be a mere "exegetical exercise" (Düwell, 2008, p. 163) "In doing so, relevant passages from the holy scriptures of these religions and other contributions to their traditions are being consulted in order to derive answers to problems, which are completely beyond the horizon of experience of these holy texts' contexts of origin" (ibid, pp. 163-164).

However, recent tendencies in Japanese Buddhism actively engage this fundamental problem of the hitherto existing patterns of reasoning, and formulate alternative approaches in dealing with the dilemmas of medical ethics, by going beyond the mere deduction of positive or negative answers on organ donation from its traditional doctrines (Asahi Shinbun, 2009a). For example, the buddhologist Bunki Kimura proposes in his book *Buddhology of life and death: 'Human dignity' and its application* of 2007 for Buddhism to turn away from announcing either-or positions, and offers instead a Buddhist conception of "human dignity". On this basis, the various problems of medical ethics could be discussed in a way more flexible, and more in accordance with Buddhism's fundamental concern to relieve man from suffering. Kimura constructs this Buddhist concept of "human dignity" – in a much more detailed and extensive way than the Buddhist statements examined above – in contrast to its Judeo-Christian counterpart, from two fundamental concepts of Buddhist anthropology and worldview (level 3), "emptiness" (j. *kū* 空, skt. *śūnyatā*) and the above-mentioned "dependent origination" (j. *engi* 緣起, skt. *pratītya-samutpāda*). As Kimura subsequently tries to demonstrate using the example of organ transplantation, this Buddhist version of "human dignity" could constitute a solid principle of the third level, as a sound basis on which various questions of medical ethics could be discussed thoroughly.

One reason that Kimura's approach deserves further attention is that it tries to compensate the argumentative weakness of the Buddhist statements analyzed in this paper, in which the third level of argumentation is either not addressed or at best kept rather vague. In contrast thereto – as demonstrated above – the third level is not expounded on explicitly in the Christian context either, but the underlying theological reasoning and basic Christian concepts of the third level can be readily identified. In view of the inflationary use of the term "human dignity" in contemporary discussions on medical ethics and the ambiguity of its background in the context of Non-

Christian traditions such as Japan, it can be further suggested that another notable contribution of Kimura's construction of a Buddhist "human dignity" lies in clarifying its foundations, meaning and implications. Whether the construction of a concept of "human dignity" based on Buddhist teachings or the reference to traditional doctrines such as "dependent origination" (as in the interpretation of the Ōtani-branch's statement by Kitazuka) – the discussion of a solid third level of argumentation from which Buddhist solutions to concrete problems of medical ethics could be deduced, currently seems to be a promising and sustainable way to a stable and possibly also more influential form of Buddhist medical ethics.

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## Bioethics in France – Comparison with the Current Policy for Bioethical Issues in Japan

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### Abstract

As the existence form of regulations on bioethics, Japan is characterized by its frequent use of the guidelines made by the administration or academics and by having little use of restriction by legislation, whereas France is characterized by the point that shows clearly the judicial precedent from basic principles, which has constitutional value, to a concrete procedure. Clearly, there are differences between the systems of both countries. Thus, the example by France can become a reference regarding a restriction of the legislation level and the way in which specialists segregate those autonomous restrictions.

**Keywords:** Guidelines, Terminal care, Constitution, professional self-discipline, human dignity

### Foreword

It is well known that there is a comprehensive regulation in France with the so-called 'Act of Bioethics' (enacted in 1994<sup>61</sup>) that deals with all those

problems that advanced biosciences technologies may bring such as antenatal diagnosis, assisted reproduction technologies and organ transplants. In the revision of the act in 2004<sup>62</sup>, it clarified the legal situation to forbid human cloning, and brought many other changes in regulations, such as procedures or requirements related to the harvest or the use of materials of human origins, prohibit in principle of human embryo research (exceptions are allowed), permission of preimplantation diagnosis.

In contrast, in Japan, there are several individual laws in the area (Act on Organ Transplantation, Act of Restrictions of Cloning Technology), however, a string of problems including assisted reproduction technologies are regulated within the framework of guidelines or announcements by the government or academic societies. Therefore, it can be concluded that the regulatory status of the two countries is fairly different.

In this article, I would like to consider the bioethical related regulatory structure or the characteristics of the structure of France based on its Bioethics Act and the so-called Death with Dignity Act<sup>63</sup> (in the following paragraphs, the law may be referred to as the "2005 Act") from a point of view of an administrative law scholar, and make a comparative review combined with the situations in Japan.

### Regulatory Structure of Bioethics-Related Regulations in France

#### *Basic Structure Level Holding Constitutional Value*

If we would like to reach to the underlying principle of the Bioethics Act of France, we should take a look at the range of the decisions by Constitutional council of the French Republic (le Conseil constitutionnel) in 1994, in which the council found the constitutional value in human rights, from the point of view of legal interpretation. The 27<sup>th</sup> decision of 1994 by the Constitutional Council of the French Republic approves that the protection of the dignity of human rights as the principal right holding constitutional values when two of the three bioethical acts are referred, and at the same time, it explained the entire laws that are asked in the following way: "*The laws are covering the integral form of several principles, which include the superiority of the human beings, respect of the human beings from the beginning of their lives, inviolability, integrity and non-proprietary nature of the human body and the integrity of the human species. The principles that are confirmed here shall aim to secure the respect for the constitutional principle of human rights*"<sup>64</sup>.

In that way, the basic structure of substantive bioethical regulations in France is build based on the

<sup>61</sup> Loi n° 94-653 du 29 juill. 1994 relative au respect du corps humain, JO n° 175 du 30 juill. 1994; Loi n° 94-654 du 29 juill. 1994 relative au don et à l'utilisation des éléments et produits du corps humain, à l'assistance médicale à la procréation et au diagnostic prénatal, JO n° 175 du 30 juill. 1994; Loi n° 94-548 du 1er juill. 1994 relative au traitement de données nominatives ayant pour fin la recherche dans le

domaine de la santé et modifiant la loi n° 78-17 du 6 janv. 1978 relative à l'informatique, aux fichiers et aux libertés, JO n° 152 du 2 juill. 1994.

<sup>62</sup> Loi n° 2004-800 du 6 août 2004 relative à la bioéthique, JO n° 182 du 7 août 2004: D. 2004, pp.2089-2107.

<sup>63</sup> Loi n° 2005-370 du 22 avril 2005 parue au [JO n° 95 du 23 avril 2005](#).

<sup>64</sup> *Conseil Constitutionnel*, 94-343/344DC, 27 juillet 1994, Rec. p.100.

concept of “dignity of human beings” as a normative principle of the constitution.

**Difference between “Regulatory Structure by Legislation” and “Self-Governing Regulatory Structure by Experts”**

In the meantime, the problem of terminal care – which is often discussed in the name of bioethics - is not laid down in the Act of Bioethics in France. It means that there were careful discussions to decide objects of the regulation in law-making process. In France, reproductive medicine technology has been thought as the first thing that could not deal only with the “medical ethics” and intervention through legislation has been discussed to resolve the problem. However, on the contrary, the problem of euthanasia and death with dignity is considered as something that is inappropriate to the regulation by the government, and the problem was sent back to the area of “medical ethics” to be solved in the range of it. Then, the general line of objects and range of the regulation by the “Act of Bioethics” is clarified.

We have to keep in mind the characteristics in France, that those two systems - “regulatory structure by legislation” and “self-governing regulatory structure by experts” are working collaterally in bioethical or medical ethics regulatory architecture.

\* At the same time, the difference between the two systems is sometimes unclear. For example, traditionally it was the “Code de déontologie médicale” (Code of Doctor’s Ethics) - which is essentially a self-governing norm for physician - that has acted a great role in regulating doctors’ conducts and through the code, the better medical care is sought. In the code, the following things are included: respecting the will of patient’s refusal of care and duty of explanation in that regard, restraint from excessive treatment and to put emphasis on palliative care for patient in the terminal phase of the disease and respect for dignity. The problem of terminal care is considered primarily as the matter which could be, or should be, left in the hands of physicians’ autonomy.

However, active developments of movements to call on the rights to take palliative care or to not to die a lonely death (which lead to the Act of 9 June 1999<sup>65</sup>) or to call on the right to stand up for patients’ rights (which lead to the Act of 4 March 2002<sup>66</sup>) as a background, eventually, the Act of 2005 that sets more clearly about the right of patients’ to refuse life-prolonging therapy to respect their will, and at the same time it provides the procedures for the patients who seek passive euthanasia to include rules about patients’ advance directive was newly enacted.

Table 1: The Three Levels Structure in France

Three-Levels structure	Regarding respect for patient’s opinion (in respect with	Regarding responsibility of the doctor (in respect with
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	terminal care)	terminal care)
First Level: Concrete scene applied	Preparation for Various Procedures (prior instructional paper, people of the confidence and consultation, etc.)	Protection for the obedience in doctor’s occupational responsibility. Preparation for Various Procedures
Second Level: Intermediate Practical Principle	Respect for patient’s opinion	System of the self-discipline by the medical association
Third Level: Fundamental Concept and Principle	Public Freedom	Professional ideology, sharing a part between nation and occupational association

The concept, “respect for patient’s opinion”, regarding terminal care was clearly introduced into the legislative level by the Death with Dignity Act in 2005 through the Patient’s Right Act in 2002.

In its background there is a concept to respect “public freedom” (liberté publique) which is placed as a common human right. By the law or décret based on the law, it is stated the restricted standard which must be obeyed by medical staff: the concrete method to create respect towards intentions, keeping the prior instruction paper and selecting people of confidence, and the consultation procedure as an example. This concrete decision regarding the consultation procedure has been entrusted onto the Medical Association in consideration of the correspondence with effectiveness and existing regulations. Detailed regulations exist in the Occupational Ethics Code Article 37 which has revised in February 2006 (CSPR.4127-37). The explanation of the article by the medical association shows the action standards more in detail, and thus, it is believed that it will secure the respect towards patients’ intention effectively through these various standards.

In order for the patient’s rights stated above to be fully protected, it is indispensable for doctors and medical staff to obey imposed standards and to perform true to their duty. In France, traditionally, there is a system to secure autonomy like doctor’s professional ethics. The Medical Association (l’Ordre des médecins) as a professional group (ordre professionnel) has the duty to “protect obedience in duty like doctor’s professional ethics” (by the way, the Medical Association in France has a completely different organizational structure and aim for activities).

This duty upon professional ethics is stated in detail in “Ethical Code of Medical professional”, which is issued as “décret en Conseil d’Etat” by the medical association.

The content of professional ethics itself which a doctor is supposed to obey public opinion, which has set the movement of legislation as a core background, has been modified with time. In recent years, “patients benefit, and quality of treatment” is the factor that has been most valued, and thus, the prevailing idea has been “how to suit responsibility of the doctor into patient”. In other words, by keeping professional ethics which needs practical support, the activity of the

<sup>65</sup> Loi de n° 99-477 du 9 juin 1999 visant à garantir le droit à l’accès aux soins palliatifs, JO. 10 juin 1999.

<sup>66</sup> Loi de n° 2002-303 du 4 mars 2002 relative aux droits des malades et à la qualité du système de santé.

medical association can be seen as contributing to actualization of patient's benefit indirectly. Regarding terminal care, respecting the intention of the patient including declining treatment and emerging accountability in such cases, overshooting self-controlled treatment and easing the pain and protection of dignity has already been provided before the legislation in 2005.

Thus, in France, it can be seen that it is thought, "For the quality of doctor and medical care, the doctor oneself has to own the responsibility towards the society, and thus, one cannot shift the responsibility onto national policy and its act" through the activity of the medical association who strives for "continuation of professional ethics". Only to this respect, one can see a definite difference in ideology in principle, the core of the system.

### **Current Situation of Bioethical-Related Regulation in Japan: Various Regulatory Approaches**

When we look at the regulations of those bioethical problems in Japan, we could notice that many approaches are used. Other than the Act on Organ Transplantation (enacted in 1997, 1997 Act No. 104), for the handling of human embryos, there is the Act on Regulation of Human Cloning Techniques (enacted in 2000, 2000 Act No. 146). The latter act sets the prohibition of any implantation of four specific embryos including human embryo into wombs of human beings or animals and the violation of the act is punished with heavy penalty. At the same time, it allows research using specific embryos in the range of the guideline ("Guideline for the Handling of Specific Embryos" initially announced in 2001 (2001 Ministry of Education, Culture, Sports, Science and Technology announcement No. 173) and full revised in 2009 (2009 Ministry of Education, Culture, Sports, Science and Technology announcement No. 83)) made and announced officially by Minister of Education, Culture, Sports, Science and Technology. Here, the regulatory approaches of 'Law' and 'Guideline based on the Law' are used.

Moreover, the following guidelines such as "Guidelines for Establishment and Distribution of Human ES Cells" (August 21<sup>st</sup> 2001 Ministry of Education, Culture, Sports, Science and Technology announcement No. 156), "Guidelines for the Use of Human ES Cells" (August 21<sup>st</sup> 2001 Ministry of Education, Culture, Sports, Science and Technology announcement No. 157), "Ethical Guidelines for Studies about Human Genome and Gene Analyses" (March 29<sup>th</sup> 2001, Ministry of Education, Culture, Sports, Science and Technology, Health, Labour and Welfare Ministry, Ministry of Economy, Trade and Industry. Last revised on December 1<sup>st</sup> 2008), "Ethical Guideline for Epidemiological Study" (June 17<sup>th</sup> 2002 Ministry of Education, Culture, Sports, Science and Technology, Health, Labour and Welfare Ministry. Last revised on December 1<sup>st</sup> 2008) are so-called "administrative guidelines" and do not have the force of law. Therefore, if there appears someone who does not follow them, the government would not be able to approach the person with enforceable sanctions. However, there is a criticism that there is too much

regulation because those guidelines are enormously working as rules as a matter of practice.

Furthermore, it is very important to pay attention to the framework of "self-governing by academic societies". Operations of antenatal diagnosis, preimplantation diagnosis and assisted reproduction technologies have been mostly handled by the self-governing regulations (Announcements) of Japan Society of Obstetrics and Gynecology. For genetic technology there are "Guidelines for Genetic Screening" (2003) by more than ten academic societies including Genetics Counseling Society of Japan and "Ethical Guidelines for Commissioned Examination of Human Genome" by Japan Registered Clinical Laboratories Association which can be classified as an industry organization. For organ transplantation, there are guidelines such as "Guidelines about Ethical Problems of Medical Conducts that Use Human Tissue" (2002) by the Tissue Transplantation Society of Japan and "Ethical Guidelines of Transplantation Society of Japan" (revised in 2003), which attracted attention through the sick-renal transplantation problem in 2006 in Japan.

### **Some Thoughts on the Issue — From Comparison of the Systems of Japan and France**

One says, "The discussions in Japan about bioethical problems are very much dependent on that of the United States, therefore it seems to me when we consult other country's way, the way of thinking of the United States places a disproportionate emphasis on that matter".<sup>67</sup> Admittedly, if we compare the amount of information that is introduced to us about the legislation and their operations of the United States compared to that of France, it is an undeniable fact that there is a significant difference. However, as we all know, traditional legal approaches in Japan have been affected by continental law and for the actual format of law both Japan and France adopt a statutory law system. If our country would set regulation in the area of advanced life science and technology, whether it would be with legislation or with guidelines, I think that we could learn a lot about legislative technique from the regulatory system in France.

As stated above, we could see the phenomenon that many matters that are normally regulated with legislation in France are ruled by self-governing norms from academic societies in Japan (prohibit surrogate conception, the operational rules for preimplantation diagnosis and assisted reproduction technologies).

When the Act on Regulation of Human Cloning Techniques was enacted, there was a discussion referring the argument in France that claims for combined regulation in the field of cloning technology and assisted reproduction technologies. Personally, as for the future challenge, it seems that the area of assisted reproduction technologies can be regulated by legislation. In the first place, in European countries, they have prepared legislation in the field of assisted reproduction technologies from the 1990s and that

<sup>67</sup> Masa Takizawa, Bioethics regulations in France, *Jyochi Hogaku Ronshu*, 43-4 (2000), pp. 35.

means they had foundation for the cloning technology regulation as application issue. When we consider this difference, we could say that regulatory framework of Japan in which self-governing system by academic society plays a great role has also a good reason.

Moreover, in regard with restriction towards research, there is a theory insisting that it will be requested to be legitimate from the viewpoints such as how the context of the regulation is subjected to freedom of research related to human rights and how establishment of the rule may rather accelerate the research. However, principally, these must be entrusted with researchers themselves and autonomy and an independent judgment of the specialist. Thus, it is thought that legislative power and administrative power in the country must not interfere recklessly and must carefully correspond to the legal regulation. In that sense, it is undeniable that the regulation technique which is an indicator for an administrative guidance has a constant advantage.

Then, how about the medical scene? In France, as it has already stated before, legal control is treated as the main controller in advanced medical fields (assisted reproductive techniques, organ transplants from a brain-dead person, etc.). However, in "normal" conditions (the problem of terminal care, etc.), importance is placed on autonomous regulation by doctors and been entrusted with medical association.

It is obvious by seeing how the concrete regulation has been placed on doctor's obligations in terminal care in the logical code for occupation and on the contrary, it can be executed only under the law (Article 16 and 17, the Logical Code for Medical Occupation) regarding assisted reproductive technique and so on. And, again, under French legislation, there is the autonomous system towards the doctor to optimize the discretion judgment based on law regulations and with respect of patient's will. The condition of the patient varies and thus, medical scene cannot be bound with uniform restriction and has to depend on the discretion judgment of the doctor for some part. Thus, such a mechanism can contain a very important meaning.

On the other hand, regarding terminal care, "The first national guideline on terminal care and withdrawal of treatment in Japan" (May, 2007) was placed by Ministry of Health, Labour and Welfare. However, it is only to provide for some decision making procedure and not for a concrete content of measures. This is because of an idea that the content of the medical activity itself shall not be restricted beforehand under the regulations of medical law and other laws indicated as "Medical Activity, Doctor's autonomy and discretion as a core, would not be adapted to a previous uniform restriction by the law." These ideas must be the same as France. Nonetheless, an autonomous and effective regulation system like France cannot be found. In our case of "independent rule", it is recalled as by which each academic society or the medical association. However, in each case, its effectiveness is extremely weak due to a limitation as a virtual restriction by a private organization.

No matter how a legitimate restriction is placed by the law, under such situation, it is obliged to rest assured that the effectiveness will be ensured by the threat of the criminal punishment or interference by the public authority. The "doctor - patient" relationship as a high quality relation based on trust and guarantee the maximum right and profit of the patient who face advanced medicine or terminal care, is less emphasized.

The fact that how both structures, the restriction by legislation and autonomous restriction by the specialist, are working together inseparably is what we have to learn from France.

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## Three Levels Structure Analysis of the Oregon Death with Dignity Act

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### Abstract

The purpose of this chapter is to consider the Oregon Death with Dignity Act (ODDA) by the three levels structure analysis method. Based on 127.805§2.01, under certain conditions, adults may make a written request for medication for the purpose of ending his or her life. From this viewpoint, there is "respect for autonomy of patients" as the second level thing. In addition, Based on (1), (3), (7), (9), and(11) of 127.800§1.01. Definitions and 127.805§2.01, "Adult", "capable", "rationality", and "person" et al. are related to "an image of a rational person". In conclusion, there is "respect for autonomy of patients" as the second level thing, and there is "an image of a rational person" as the third level thing in the ODDA.

**Key Words:** Three Levels Structure Analysis, respect for autonomy, a rational person

### Introduction

Euthanasia has been an important theme in bioethics. In terms of physician's involvement in euthanasia, there are three main issues; withholding or withdrawing life-sustaining treatment, physician-assisted suicide, and active euthanasia. One of the most famous examples of physician-assisted suicide is the Oregon Death with Dignity Act (ODDA).<sup>68</sup>

In the USA, in Washington state (1991) and California state (1992), referendums were held about bills that allowed patients to ask doctors to execute voluntary active euthanasia, but in both cases, bills were voted down. As a result, in the Oregon state the movement of making a rule that patients ask doctors to prescribe a lethal injection under certain conditions

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<sup>68</sup> URL: <http://www.oregon.gov/DHS/ph/pas/ors.shtml>

occurs, a referendum was held in November 1994 and a bill was passed, and came into effect in October 1997.

The purpose of this chapter is to consider the ODDA by the three levels structure analysis method. This method was proposed by Takao Takahashi (2011, this issue). To clarify something for the second level or for the third level of ODDA, I considered the articles. In what follows, I will explain the considerations.

### The second level:

As a result of my analysis, "respect for autonomy of patients" is at the second level. The article concerned is 127.805§2.01. Who may initiate a written request for medication.

(1) *An adult who is capable, is a resident of Oregon, and has been determined by the attending physician and consulting physician to be suffering from a terminal disease, and who has voluntarily expressed his or her wish to die, may make a written request for medication for the purpose of ending his or her life in a humane and dignified manner in accordance with ORS 127.800 to 127.897.*

Based on this article, under certain conditions, adults may make a written request for medication for the purpose of ending his or her life. From this viewpoint, there is "respect for autonomy of patients".

### The third level

As a result of my analysis "an image of a rational person" is at the third level. The articles concerned and results of my considerations of them are below.

127.800§1.01. Definitions.

(1) *"Adult" means an individual who is 18 year of age or older.*

Thus an individual who is 18 years of age or older is mostly considered as a person entitled, who is a competent person under common sense. "Competency" is related to an image of a rational person.

(3) *"Capable" means that in the opinion of a court or in the opinion of the patient's attending physician or consulting physician, psychiatrist or psychologist, a patient has the ability to make and communicate health care decisions to health care providers, including communication through persons familiar with the patient's manner of communicating if those persons are available.*

The part "a patient has the ability to make and communicate health care decisions to health care providers" is related to an image of a rational person.

(7) *"Informed decision" means a decision by a qualified patient, to request and obtain a prescription to end his or her life in a humane and dignified manner, that is based on an appreciation of the relevant facts and after being fully informed by the attending physician of:*

- (a) *His or her medical diagnosis;*
- (b) *His or her prognosis;*
- (c) *The potential risks associated with taking the medication to be prescribed;*
- (d) *The probable result of taking the medication to be prescribed; and*

(e) *The feasible alternatives, including, but not limited to, comfort care, hospice care and pain control.*

The part "based on an appreciation of the relevant facts and after being fully informed by the attending physician of" is related to an image of a rational person.

(9) *"Patient" means a person who is under the care of a physician.*

The word "person" entails rationality, and is related to an image of a rational person.

(11) *"Qualified patient" means a capable adult who is a resident of Oregon and has satisfied the requirements of ORS 127.800 to 127.897 in order to obtain a prescription for medication to end his or her life in a humane and dignified manner.*

The word "a capable adult" entails rationality, and is related to an image of a rational person.

127.805§2.01. Who may initiate a written request for medication.

(1) *An adult who is capable, is a resident of Oregon, and has been determined by the attending physician and consulting physician to be suffering from a terminal disease, and who has voluntarily expressed his or her wish to die, may make a written request for medication for the purpose of ending his or her life in a humane and dignified manner in accordance with ORS 127.800 to 127.897.*

This article seems to be a summary of conditions for a person entitled. The parts, "who is capable" and "who has voluntarily expressed his or her wish to die" are related to an image of a rational person.

### Conclusion

In conclusion, there is "respect for autonomy of patients" as the second level aspect, and there is "an image of a rational person" as the third level aspect in the ODDA.

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