Problems of the Law on Organ Transplant and the Situation of Organ Transplantation in Japan

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Introduction

This article outlines the situation in Japan, where organ transplantation is making very slow progress, and discusses what can be done to facilitate smooth performance of organ transplantation.

The Law on Organ Transplant was enacted in 1997. This Law was a private member’s bill and subject to a free vote to reflect the independent will of each House member, and passed the House of Representatives and the House of Councilors. Article 2 of the supplementary provision of the Law states, “Concerning organ transplantation according to this Law, a comprehensive review should be made considering the actual implementation of the Law and necessary measures should be taken by approximately 3 years after implementation of this Law.” However, no amendment has been enacted to date, and defects in the Law and problems in the application of the Law are hindering the progress of organ transplantation in Japan, as compared with the situation in other countries. The sections below consider the treatment of this Law in the legislative body, focusing on whether and how the Law is expected to be amended.

Present State and Problems of Organ Transplantation

Because this Law was enacted based on a free vote of House members, any amendment to it should also be based on a free vote of House members. This Law deals with life and death issues. The votes of individual House members would depend on their views concerning such issues as life and death, the right to die with dignity, religion, and ethics. For this reason, a unanimous vote cannot be expected.

One of the most difficult problems is the change of Diet members. The House of Representatives is dissolved approximately every 3 years, and subsequent general election usually results in the replacement of about one-third of House members. The discussion with new House members must be restarted from the beginning, and any draft amendment developed through past discussion would be returned to the starting point. The House of Councilors is not dissolved. While the term of members is 6 years, election of half the members takes place every 3 years, and this results in replacement of some members. For this reason, the Investigation Committee on Brain Death, Bioethics, and Organ Transplants of the Liberal Democratic Party, which is the
ruling party, has examined the amendment of these proposals. However, the Law has been left unamended for much longer than 3 years after its enactment in 1997, and the legislative organ is responsible for this neglect of duty.

One of the key issues is the treatment of children under the age of 15. The Guidelines Concerning the Use of the Law on Organ Transplant contain provisions defining the age and other requirements for expressing wishes in writing. Organ transplantation from brain-dead donors under the age of 15 is not conducted in Japan, because the Guidelines specify that the wishes of persons at the age of 15 years or older should be respected, in concordance with the definition of ability to leave a will under the Civil Law. The Guidelines also specifies that legal determination of brain death should not be performed for the time being in the case that the potential donor is found to have mental retardation. This provision does not mention the age of the potential donor. These Guidelines effectively prohibit organ transplantation from brain-dead bodies under the age of 15.

Comparison with Situation in Other Countries

The situation in other countries is considered in this section. In many countries, including France, Sweden, the U.K., Australia, Germany, Denmark, Korea, Taiwan, and some states in the U.S., organ transplantation is permitted provided that the potential donor has expressed the wish to donate organs and the consent of relatives has been obtained. If the wishes of relatives are unknown, the consent of the potential donor alone is sufficient for performing transplantation. If the wishes of the potential donor are unknown, transplantation is possible if the consent of relatives is obtained. In France and some other countries, transplantation is allowed when the wishes of the potential donor and those of relatives are both unknown. When either the potential donor or relatives have refused, transplantation is usually not performed. In the case of children, most countries permit transplantation if the consent of relatives is obtained. In contrast, transplantation from child donors is not permissible in Japan.

Thousands of heart transplants are performed every year worldwide, including 2,198 cases in the U.S. (2000), 342 in France (2001), 217 in the U.K. (2000), 380 in Germany (2002), 41 in the Netherlands (2002), 70 in Australia (2002), 30 in Denmark (2002), 316 in Italy (2001), 314 in Spain (2001), 26 in China (2000), and 14 in Korea. In sharp contrast to the over 2,000 cases in the U.S., the number of cases in Japan was 3 in 1999 and 3 in 2000.

The number of patients in the waiting lists for organ transplantation in Japan is 74 for the heart, 79 for the lungs, 78 for the liver, 12,549 for the kidneys, 93 for the pancreas, and zero for the small intestines as of March 1, 2004. The past records of brain-death organ transplants in Japan include 21 cases of heart transplants, 18 cases of lung transplants, 25 cases of liver transplants, 2 cases of pancreas transplants, 13 cases of liver plus kidney transplants, 38 cases of kidney transplants, and 1 case of small intestine transplant; totaling 118 cases as of July 5, 2004. Thirty-one brain-dead donors provided organs in the period from October 1997 to December 2004.

As many as 30 patients under the age of 15 received heart transplantation in hospitals outside Japan, including 25 cases in the U.S., 3 in the U.K., and 2 in Germany, as of December 1, 2004. Forty-three patients (18 males and 25 females) wanted to receive heart transplantation in overseas sites after enactment of the Law.

Why There Are Few Transplants in Japan

1. Organ donation facilities

As mentioned above, heart transplants alone present many problems. We need to consider why there are few cases of transplants in Japan. One reason is the regulations concerning organ donation facilities. In Japan, organ donation must be performed in hospit-
tals falling under any of the following 4 categories: (1) hospitals attached to universities or colleges, (2) hospitals designated by the Japanese Association for Acute Medicine as centers for training preceptors, (3) hospitals designated by the Japan Neurosurgical Society as centers for training medical specialists and having adequate capabilities in terms of instructing physicians and the number of cases treated, and (4) designated emergency care centers. There are 306 designated institutions in Japan. It is a significant hurdle that potential donors cannot provide organs unless they are diagnosed as brain dead in these institutions. Unless this hurdle is lowered, patients with organ donor card cannot provide organs if they become brain dead in other medical institutions.

By the end of June 2002, there were 323 persons who were diagnosed as brain dead and had expressed their consent to organ donation. Of this total, 162 cases occurred in places other than organ donation facilities, and therefore were ineligible. Of the remaining 161 cases, 88 were reported before cardiac arrest and 73 were reported after cardiac arrest. Of the 88 cases, brain-death organ donation was performed in 19 cases, and organ donation was cancelled after legal determination of brain death in 1 case.

The remaining 68 cases did not end in organ transplantation for various reasons. The criteria of the diagnosis of brain death were not met in 23 cases. The organs were not suitable for transplantation due to other diseases in 16 cases. The consent of family members was not obtained in 14 cases. Other reasons included the attempt of resuscitation being continued before cardiac arrest, the patient’s condition hindering the determination of brain death, the patient’s wish to donate their body for medical research, the judgment to invalidate the patient’s wishes, and the hospital ethical committee’s decision to deny approval. Although there were a number of potential donors who had indicated their wishes on donor cards (in the period from October 1997 to June 2002), only a few of them remained after strict screening and examination.

2. Organ donors under the age of 15

What are the positions of various players related to this problem? On July 23, 2003, a nonpartisan group of Diet members called Parliamentarians Union of Bioethics Study conducted a questionnaire survey concerning organ transplants from donors under the age of 15. According to the answers from 191 persons, “brain-death organ transplants from donors under the age of 15 years” was supported by a great majority, 78% of Diet members answering that it “should be made possible.”

The Japanese Society of Legal Medicine has submitted the following opinion: “Appropriately and reliably diagnosed brain death should be defined as the death of a person. A patient in the state indicating brain death should be subjected to the criteria of diagnosis of brain death according to relevant criteria irrespective of whether organ donation is intended or not. If the patient is judged as brain dead, death should be declared without waiting for cardiac arrest. The legal determination of brain death does not require the patient’s written wishes or the consent of family members.”

Japan Federation of Bar Associations announced the following statement in October 2002: “The amendment of legislation partially negating self-determination, such as making special provisions to permit proxy consent of parents on behalf of children under the age of 15, should not be performed at present. Proxy consent of parents should be given only for the benefit of the child. Because the removal of organs never benefits the child, such proxy consent is not appropriate.” In addition, the Federation reinforced its objection by stating, “In the case of children, it is virtually impossible for them to express objections, and the spirit of self-determination would be neglected.”

The Japan Pediatric Society made a proposal on June 23, 2003. First, it “permits brain-
death organ transplants in children as a form of treatment.” Second, the Society stated, “As a prerequisite, we propose continued discussion of problems to improve the environment for such change.” It also proposed, “From the standpoint of protecting the human rights of children, it is desirable to promote the use of child donor cards to clarify the right of self-determination. As a prerequisite, we need to clarify the processes of informed consent concerning treatment for children, to implement educational programs concerning research and other activities, and to establish a neutral system to avoid intentional inducement. In addition, we need to train coordinators specializing in organ transplantation in children and also to lower the age limit for expressing wishes from 15 years old.” Recently, there have been some proposals to lower the age limit from 15 to 14 years old.

As a means to exclude brain-dead cases resulting from child abuse, the Society expressed the following opinion: “It has been pointed out that about 10% of children with head injury are potentially victims of child abuse. A period ranging from 2 weeks to more than 1 month may be required before the evidence of child abuse can be obtained, and the fact of child abuse may be overlooked in some cases. To exclude such cases, we need to encourage medical institutions to suspect that child abuse victims may be present among the group of injured children, and each case should be reviewed by an independent panel involving non-medical members. In particular, to avoid the danger of organ donation based solely on proxy consent given by a custodial parent, it should be clearly stated that brain-death organ donation from children is a special exception, strict procedures should be required, provisions including punishment for violations should be implemented, a specialized investigation organization should be established, and permission from such organization should be made a prerequisite.”

The President of the Japan Pediatric Society pointed out the following problems in organ transplantation in Japan: the number of organ donations is small, persons under the age of 15 cannot donate organs, and many living organ donations are performed. He also blamed the government for the fact that some lives could have been saved.

A physician at the Department of Pediatrics, Osaka Medical College stated, “The question of whether or not brain death should be regarded as the actual death of a person still remains medically unsolved, and defining brain death as the death of a person is problematic particularly in the case of children. Permitting organ removal from children under the age of 15 based on the consent of parents would be an infringement of the human rights of children. It would run counter to the Convention on the Rights of the Child assuring the right of the child to express his or her views freely in all matters affecting the child. The percentage of child abuse is considered high among the causes of brain death in children, but measures to counter child abuse have not been worked out.” The physician also pointed out, “Major rethinking is needed on the current legal criteria of diagnosis of brain death applied to 6-year-old and older patients, as well as the draft criteria of diagnosis of brain death in children (proposed in 2001), which involve problems regarding implementation systems and the number of cases. The families of donors and prospective donors should be given sufficient explanation concerning the activities of the body in the state of brain death, the actual procedures performed in organ removal, and the changes that would occur in the body during organ removal. A consensus that brain death is the death of a person has not been reached across various disciplines, including religious circles, and among the citizens of Japan.”

A professor of child psychology at Ochanomizu University stated, “An 8- or 9-year-old child can understand the state of physical death. I have heard of no research concerning the children’s understanding of
Based on experience, a professor of laws commented on testimonies given by children as follows: “What testimony, judgment, and explanation are given by a child depends on who performs the interview and in what ways. Interviews should be conducted not only by parents but also by independent specialists well versed in communicating with children. The interview must be recorded on audio or video media. Children can understand the concept of death at the age of 4 to 5 years, depending on experience. They gain the ability of decision-making probably when they are 4th or 5th graders. I have no objection, if children can receive an adequate explanation of the merits and demerits of transplantation, they can change their minds easily, and revisions are made at one-year intervals.” As he stated, 4th or 5th graders are able to understand various complex matters.

Proposals to Amend the Law on Organ Transplant

As discussed above, people in different positions and with different academic stances have different opinions. Considering this situation, the Investigation Committee on Brain Death, Bioethics, and Organ Transplants of the Liberal Democratic Party has compiled the outline of a draft bill to amend parts of the Organ Transplant Law and submitted a set of proposals. The following sections summarize the proposed changes.

1. Prerequisites for organ removal

The first part of the proposed amendment relates to the prerequisites for organ removal. The proposed text reads as follows: “A physician may remove the organs for use in transplantation from a dead body (including a brain-dead body), if any of the following conditions is met: (1) The deceased has expressed, in writing, the will to offer organs for use in transplantation, and either the family members of the deceased, after being notified of this fact, do not refuse the removal of organs or there are no family members of the deceased; and (2) The deceased has expressed, in writing, neither the will to offer organs for use in transplantation nor the lack of such will, and the family members of the deceased have provided written consent for the removal of the organs.” This provision would make possible organ removal when the will of the deceased is unknown.

In addition, there is a proposal stating, “The diagnosis of brain death does not require the written indication of the patient’s will or the consent of families.” At present, the process of the determination of brain death may not begin unless the patient and the families have provided written consent for beginning such process. The proposed provision would make such consent unnecessary. This translates to the notion that the determination of death should be made on a scientific basis even in the case of brain death.

Another proposal states, “The problem of whether or not brain death is the death of a person should be left to the judgment of the persons involved. Based on this understanding, organ removal should be permitted only when the deceased has expressed the will to offer organs in writing and the families do not refuse, or when the will of the deceased is unknown, in which case the matter should be left to the judgment of close relatives.”

2. Organ donation with priority given to related recipients

The second part of the proposed amendment would introduce “organ donation with priority given to related recipients.” On the basis of the above-mentioned possibility of removing organs for transplantation from a dead body (including a brain-dead body) and assuming the confirmation of the will to
donate organs, this proposal allows the written indication of the will to provide organs preferentially to the spouse or blood relatives within the second degree of kinship.

However, this notion has given rise to much controversy. The rationale for allowing organ donation in this form is respect for the will of the donor, but this respect for the will of the donor might compromise the ideal that the opportunity for receiving transplantation should be distributed equally. The scope of the relatives receiving priority is another problem. The proposal limits the scope to blood relatives within the second degree of kinship (grandparents, parents, siblings, children, and grandchildren), in addition to the spouse. In the implementation of the Law, the will expressed by persons aged 15 years or older would be respected. Concrete issues concerning the treatment and effectiveness of the will to give priority to relatives would be stipulated in the guidelines.

The proposal does not permit the indication of the will to deny donation to non-related recipients in the case that the organs are incompatible with the related recipient. However, concrete issues concerning the treatment and effectiveness of such indication of the will should be defined in the guidelines. The problem of whether or not the related recipient needs recipient registration would be treated not in the Law but in the guidelines, considering the coherence with the provisions in the existing Law. The Organ Transplant Committee of Disease Control Division, Health Sciences Council submitted the report “Treatment of the Living Will of the Donor Concerning the Recipients of Organs” to the Diet for discussion to form a conclusion. Although further debates are expected, this report provided a provisional conclusion to permit the living will to donate organs giving priority to the spouse and relatives within the second degree of kinship.

3. Issues concerning promotion and education

The third part of the proposed amendment contains a new provision stating, “As regards the issues concerning promotion and education, the State and local public bodies should take necessary measures for education and dissemination of knowledge concerning transplant medicine, such as indicating whether or not each person has expressed the will to donate organs for use in transplantation on driver’s licenses and health care insurance cards, so that the citizens can develop the understanding of and interest in transplant medicine at every opportunity.” At present, donor cards are available at convenience stores and other places. The Law should be amended to encourage more people to opt to have donor cards.

Finally, the fourth part of the bill would delete the temporary provisions concerning eye and kidney transplants.

Conclusion

While the contents of the proposed amendment are as outlined above, this draft bill must be used as a starting point for discussion by the nonpartisan Parliamentarians Union for Bioethics Study and the amendment must be passed in the form of private member’s bill. There will be a procedure for organ donation from donors under the age of 15 based on the consent of close relatives, and the procedures for diagnosis of brain death will be defined clearly in guidelines, such as the exclusion of infants within 12 weeks after birth. In addition, the promotion of transplant medicine will need to be supported by measures to reduce the burdens on patients, such as the expansion of health insurance coverage.

The most important thing is to save the precious lives of patients, who are waiting for the opportunity to receive an organ transplant, legally within the strict framework of regulations. It is strongly desired that the bill will be discussed and a vote taken during the ordinary session of the Diet.