Revised Organ Transplant Act and Transplant Surgeons


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Abstract
After nearly 5 years of lobbying, a bill amending the Organ Transplant Act (the so-called Nakayama plan; Plan A) was adopted without modification by both the House of Councilors and the House of Representatives in Japan. Diet passage of Plan A provided a glimmer of hope for many patients and their families who had long been waiting for an organ transplant, the only chance for life. The passage of this Act is, however, only the beginning, and does not bring full resolution of this issue.

Enforcement of the revised Act has resulted in a marked increase in the number of organ transplantations from brain-dead donors, but without a concomitant increase in the total number of deceased organ donations available or prompt initiation of organ donation from children. Although a dramatic increase in organ donations is hoped for in light of many patients who are now waiting for an organ transplant, transplantation medicine will never be fully established in this country unless it advances while the general public gains an adequate understanding of this issue. This article describes various problems which still need to be solved. It is important to carefully address and resolve each of these problems and thereby achieve public acceptance of transplantation medicine.

Key words Organ transplantation, Revised Act, Organ donation after brain death, Organ donation after cardiac arrest

Introduction
After nearly 5 years of lobbying, a bill amending the Organ Transplant Act (the so-called Nakayama plan; Plan A) was adopted without modification by both the House of Councilors and the House of Representatives in Japan. Diet passage of Plan A provided a glimmer of hope for many patients and their families who had long been waiting for an organ transplant, the only chance for life. The passage of this Act is, however, only the beginning, and does not bring full resolution of this issue. The revised Organ Transplant Act was enacted on July 17, 2010, and there had been 29 cases receiving organs from brain-dead donors as of December 2010. While this is a great source of hope for patients in need of organ transplantation, many issues await resolution.

Historical Review of Revision of the Organ Transplant Act
Before proceeding to the main subject, the author would like to describe his personal reasons for going into transplantation medicine.

The author learned of organ transplantation in the 6th grade of elementary school (age of 11) when he saw the news on Dr. Wada’s performance of the first heart transplant in Japan on TV. Dr. Wada was praised and admired when the patient got better after transplantation, but he was abruptly blamed as though he was a synonym for mistrust of medical services when the patient died. This left mixed feelings in child’s

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The biggest problem in the Wada heart transplant case was the fact that a transplant surgeon had diagnosed brain death at a time when the global discussion of brain death had only just begun. Seeing this case, the author began wishing that organs suited to individual patients could be created, rather than harvested from the deceased. This was the spark that prompted the author to go into medicine. Currently, almost 40 years later, this dream of organ creation has not yet reached a clinically applicable level. Even in heart, dozens more years will be required to make saving many patients’ lives by regenerative medicine a realization.

It was under these circumstances that the author pursued both clinical training and research activities. Seeing with his own eyes one life after another that could have been saved by transplantation being lost, the author decided to become a transplant surgeon more than 20 years ago. This meant giving up the initial aim of research on organ regeneration. However, still hoping to find ways to reduce the need for organ donations from people, the author also carried out experiments aimed at allowing heart transplantation from animals.

In 1997, the Organ Transplant Act (the former Act) came into effect. This Act had strict limitations stipulating that the donor’s written antemortem intention be respected to the maximum extent possible. Specialists in the field of transplantation regarded these limitations as the public consensus at that time, and prepared for the initiation of heart transplantation in Japan, believing in a possible review of the situation within 3 years.

On February 28, 1999, organ transplantation from brain-dead donors was begun in Japan. For the first case after resumption of heart transplantation, the author went to Kochi Prefecture and removed the donor heart. Although the author had experiences with removal of donor hearts during his stay in the US, the situation of organ removal in Japan was different from that in the US where the physician performing organ removal first meets the donor in the operating room. In contrast, in Japan the physician first examines the donor in the intensive care unit to determine the donor’s status. This resulted in the author experiencing an instinctive desire, as a physician, to somehow save the donor’s life, while simultaneously examining the patient as a potential donor. At the time the donor’s heart stopped beating by the author, his mind wavered as to whether the procedure was even justifiable. However, because the author as a physician was confident that brain death was indeed the death of the person, and because it was clear that the donor had intended to donate organs after brain death, the author was resolved to remove the donor’s heart. During the return flight by helicopter, although saving the life of a recipient would normally be a very rewarding experience for any physician, the author experienced intense emotional turmoil at the thought that the donor’s final heart beats had been stopped with his own hands. The author has never forgotten this feeling.

Given these intense feelings, the author performed heart transplantation with a sincere desire to observe the former Act. Through the efforts of many people involved in transplantation medicine, the outcomes of heart transplantation in Japan reached a top level worldwide. The author believed that publication of these outcomes would help the public better understand transplantation medicine, resulting in increases in the number of organ donor card holders. Patients requiring a heart transplant in the author’s hospital shared this belief and continued to wait without planning to go abroad.

However, there was no change in the number of donor hearts per population in Japan over the next decade, corresponding to only about 1/200 the level in Europe and North America and 1/20 the level in neighboring Korea. Thanks to the extraordinary generosity of donors and their families, 64 patients underwent heart transplantation under the former Act, but 90% had been maintained on an auxiliary artificial heart while awaiting transplantation. The waiting period became longer rather than shorter, and a wait of more than 1000 days with an artificial heart may currently be necessary for patients waiting a heart transplant. On the other hand, in the US, the waiting period for patients in the same condition is about 2 months.

Under the former Act, written antemortem intention to donate was valid when the donor was 15 years of age or older, the same as the testament. Therefore, children younger than 15 years of age were incapable of donating their organs after brain death under the former Act. Thus, physically small children were never candidates for heart or lung transplantation in Japan, and had to raise a large amount of money in order
to go overseas. However, among patients who actually underwent heart transplantation overseas, children with a small physique accounted for only about 40%. The remaining 60% were adults or children physically large enough for transplants available in Japan. This means that even patients who were eligible for transplantation in Japan had to go abroad to find a way to survive.

Various problems are involved in receiving heart transplantation overseas. First, Japanese children account for more than half of non-American children undergoing heart transplantation in the US. About 300 children per year undergo heart transplantation in the US, but at the same time, 60–100 children die annually while waiting for a transplant. If Japanese children did not go to the US for transplantation, the lives of more American children would be saved. Although the US still accepts Japanese children for transplantation, it is doubtful that this will go on indefinitely.

It is often heard that brain death and organ donation are well accepted in Western countries based on cultural differences between Japan and the West. However, American parents feel the same intense sorrow over the deaths of their children that Japanese parents do, and yet make the enormously generous decision to offer their children’s organs to save other children’s lives. Despite this, the news on overseas transplantation has usually focused on the burden of preparation and fund-raising before going abroad. Is this really the appropriate focus? If the US and Germany had stopped accepting children from foreign countries for transplantation according to the joint recommendation “Declaration of Istanbul” issued in May 2008 by the Transplantation Society and the World Health Organization while the former Act remained without revision, Japanese children who required heart or lung transplantation would have lost any chance of survival.

In hopes of achieving a breakthrough in this realm, movements to revise the former Act began to appear around in 2004. Through a 5-year process, Plans A, B, C, and D were proposed in the House of Representatives, and Plans A’ and E in the House of Councilors. After deliberation, Plan A was adopted. Plan A prescribed that organ donation from a brain-dead donor is possible when there is written consent from the donor’s family, even if the donor’s intention is unclear. Because there was no age limit, this opened the way to heart or lung transplantation for children in Japan.

**General Problems after Revision of the Organ Transplant Act**

**Has revision of the Act actually increased the number of organ donations?**

There were 109 kidney donations after cardiac arrest in fiscal 2008. Among them, cannulation was carried out after diagnosis of brain death in 51 cases in 4 legitimate types of hospitals. Thus, revision of the Act would have accounted for an estimated 46.8% (51/109) of kidney donations after cardiac arrest with brain death. Namely, if the Act had been revised in 2008, the number of organ donations from brain-dead donors would have totaled 61, adding actual 10 cases after brain death to the aforementioned estimate of 51. Because there is a natural annual increase of 10% at present, the estimate for 2011 is 81 organ donations after brain death.

In fact, there were 29 brain-dead organ donors within about 5 months after revision of the Act, suggesting the actual figure to be much the same as the estimate. During this period, there were 36 organ donations after cardiac arrest. Although the total number of organ donations from donors with brain death and cardiac arrest was similar to previous years, the total number of donors in the latter half of 2010 showed an increase of about 20% as compared with previous years. However, the increase in the total number of donors is not as substantial as the increase in brain dead donors. Further observation is necessary to ascertain whether organ donation after cardiac arrest will increase in the future.

**Problems in transplant facilities**

**System construction in transplant facilities**

The availability of transplant facilities in response to a possible marked increase in organ donors is an issue of concern, considering the previous situation that 4 organ transplantations were carried out in a single transplant facility on the same day and simultaneous organ donations from more than 2 brain-dead donors occurred 6 times, even when organ donations from brain-dead donors were only about 10 cases annually. System construction in each transplant facility and
expansion of transplant facilities specific to each organ may be necessary. Enhancement of cooperation among transplant facilities at the time of organ removal and transplantation is also an important issue.

Although current expansion of transplant facilities is reducing the burden on each facility, it is necessary to lay out a framework for maintaining the quality of transplantation medicine.

Improved management of waiting patients
With the increase in organ donors, the waiting period may be decreased, but the number of patients for organ transplantation is anticipated to increase, and thus the number of waiting patients would rise. Because heart and lung transplantations in children are now available, it is important to address this issue. Insurance coverage of implantable artificial heart (that allows patients to wait at home) and auxiliary artificial heart for children is urgently needed.

Improvement of labor conditions and training and support for transplant physicians
In cases receiving organ transplantation from a deceased donor, organ removal is also an urgently performed operation, and often takes place during the night or on Sundays or holidays. Nevertheless, formation of two teams, one for removal and another for transplantation, is necessary. Unless labor conditions including salaries are improved, numbers of transplant physicians, not a very popular specialty, may further decrease.

If organ donation increases, transplant physicians will have more opportunities to work, together with increases in the number of physicians involved in transplantation (transplant surgeons, internists, pediatricians, pathologists, etc.). However, systems to train and support such physicians have not been fully established. Transplant physicians are required to have a broad range of knowledge including immunosuppressive therapy, prevention and treatment of infectious diseases, mental care of patients, and social aspects (gratitude to donors and their families, public enlightenment regarding transplantation activities, and others) in addition to surgical aspects with organ removal and transplantation. Although it is desirable for surgical societies dedicated to each organ to take charge of education and training for organ-specific surgical techniques, in developing the human resources for general transplant physicians, educational systems should be set up by the Japan Society for Transplantation.

Recipient coordinators
To improve patient management during the waiting period and after transplantation, it is necessary to adopt organ-specific recipient coordinators (RCo). The formulation of a system for RCo qualification in cooperation with the Japanese Nursing Association is also urgently needed.

Japan Organ Transplant Network (JOT)
Personnel training and augmentation of donor coordinators
Because organ donation from brain-dead donors has become possible with consent from the family, the psychological burden on the donor’s family has increased. Therefore, while maintaining the quality of donor coordinators (DCo) who can properly understand the intention of the donor’s family, the number of DCo should be increased to cope with the future rise in organ donation. Some transplant physicians praise a “good” DCo for achieving a high rate of organ donation, but it is more important for a DCo to properly understand the thoughts and feelings of the donor’s family on site even if organ donation is ultimately impossible.

Setting of donor mediation costs
The income of the JOT consists only of public expenditures, registration fees from patients for transplantation, and coordinator costs at the time of procurement and allocation. Furthermore, public expenditures have been decreasing annually. In addition, various costs including those for personnel exceed the current coordinator cost in every case of organ procurement and allocation. The excess cost should be compensated; otherwise, fair and impartial organ procurement and allocation and donor evaluation and management will no longer be feasible.

According to various cost estimates including those for confirmation of the intention of the donor’s family, donor evaluation and management, selection of recipients, cardiorespiratory management during surgical organ removal, organ transfer, family support after donation and media correspondence, organ donation costs approximately 4.8 million yen (US$62,338)2 per brain dead-donor. Assuming 4 recipients per

2 Yen/US dollar exchange rate: 1 US$≈77 yen.
donor, the health insurance assessment is 120,000 points per recipient. With this figure, we applied to the Association of Social Insurance Committee of Surgeons for inclusion in the insurance coverage list for fiscal 2010.

**Exclusive coordinators for donor family support**

Because the donor’s family members live long after the loss of their loved one, it is necessary to exert maximal effort to keep them content after donation. Conventionally, it has been the general practice that JOTCo or prefectural Co involved in acquisition of consent visit the family periodically and thank them by placing a letter of appreciation in their hands, but this is far from adequate. In addition, the donor’s family members may suffer posttraumatic stress disorder due to the bereavement, and a system that provides informal counseling exclusive to JOTCo at any time should therefore be formulated. It is also important to establish a framework for cooperation with psychologists and psychiatrists.

**Organ donor facilities**

To reflect the donor’s intention to the maximum extent possible, formulation of a system involving donor evaluation and management is important. In Japan, in cases of organ donation after brain death, more than 5 organs are offered on average by a single donor (5.8 organs per donor in the last 10 cases), ranking first worldwide, owing to the efforts of specialists in donor evaluation and management (medical consultants, MCs) sent to the donor facility. A nationwide system should be established to maintain figures at this level and good outcomes after transplantation. Although MCs currently go to the donor facility and carry out donor evaluation and management, a support system that can reduce the burden on the donor facility including cardiorespiratory management during surgical organ removal should be formulated.

**Commending of donors and families**

It is also important to provide a national system for commending organ donors, e.g. by making May 17 Bridge of Life Day as a national day. The goal is to make Japan a country where donor’s family can live with pride. This is an important theme for the Future Planning Committee of the Japan Society for Transplantation, as reflected in the theme of the 2008 Annual Congress of the Society: “Life, Hope, Thankfulness: A New Era for Transplantation.”

**Improvement of emergency medical system**

When brain death is diagnosed after saving as many lives as possible, there is a pathway to organ donation. Although the details are not described in the present article, national infrastructure development is necessary for the improvement of emergency medicine (preparation of life-saving facilities before brain death and means of conveyance), helping abused patients (saving patients from death due to abuse), and support for grieving families after suffering the death of a loved one regardless of whether organ donation is possible or impossible.

**Conclusion**

Although the number of organ donations from brain-dead donors has obviously increased since promulgation of the revised Organ Transplant Act, it cannot be said that the total number of organ donations from deceased donors has actually increased. No organ donation from a child donor has yet occurred. Although a rapid increase in organ donors is anticipated and hoped for by patients waiting for transplants, transplantation medicine will not be established in this country unless it advances based on the general public gaining an adequate understanding of this field. It is important that transplantation medicine be accepted by Japanese people, and this can only be achieved by carefully addressing and solving each of the aforementioned problems.

**References**