

The current status and future perspectives of organ donation in Japan: learning from the systems in other countries

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Abstract The revised Organ Transplant Law came into effect in Japan in July 2010. The law allows for organ procurement from brain-dead individuals, including children, with family consent from subjects who had not previously rejected organ donation. Nevertheless, the number of cadaveric organ donations has not increased as expected. The Spanish Model is widely known as the most successful system in the field of organ donation. The system includes an earlier referral of possible donors to the transplant coordination teams, a new family-based approach and care methods, and the development of additional training courses aimed at specific groups of professionals, which are supported by their corresponding societies. South Korea, a country which neighbors Japan, has recently succeeded in increasing the rates of organ donation by introducing several systems, such as incentive programs, an organ procurement organization, a donor registry, and a system to facilitate potential donor referral. In this review, we present the current status of organ donation in Japan and also explore various factors that may help to improve the country's low donation rate based on the experiences of other developed countries.

Keywords Organ donation · Opt-out · Opt-in · Potential donor referral · In-house coordinator

Introduction

The revised Organ Transplant Law came into effect in Japan in July 2010. The law allows for organ procurement from brain-dead individuals, including children, with family consent if the subject had not previously refused organ donation. The amended law also allows individuals to prioritize family members to receive their donated organs after death. However, the number of cadaveric organ donations has not increased as expected following the implementation of this law.

In this review, we present the current status of organ donation in Japan and also explore factors that might improve the situation based on the experiences of other developed countries.

The current status of organ donation in Japan

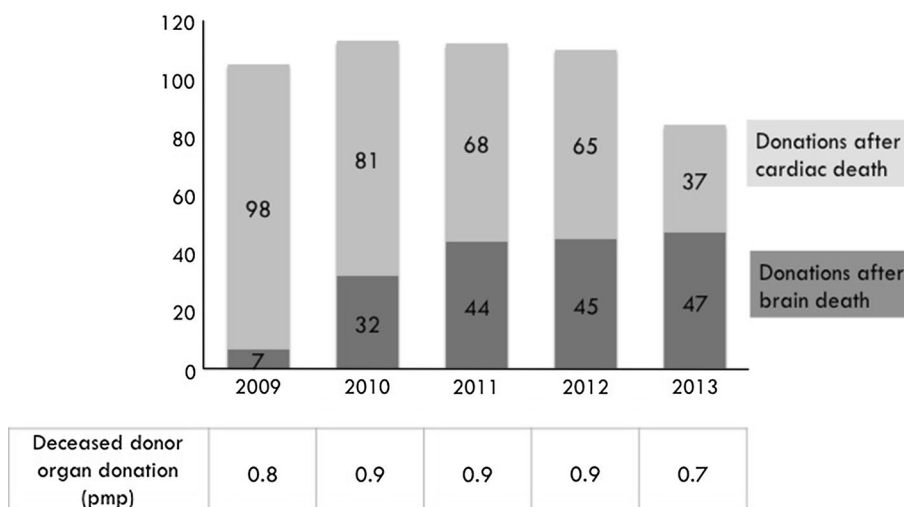
The Japanese Organ Transplantation Act for brain-dead donation was introduced in October 1997. The act required living written consent for future brain-dead organ donation. The act did not allow brain-dead donation from children younger than 15 years of age. After the enforcement of a revised law in 2010, the number of brain-dead organ donations increased from 13 to 44 cases in 2011 [1]. However, the number of brain-dead organ donations did not increase as far as expected. The rate of deceased organ donations per million population (pmp) has remained at less than one even after the revision of the law (Fig. 1). As a result, the number is still extremely low in comparison to other developed countries [2].

According to a 2012 survey of 1855 subjects (age >20 years) by the cabinet office of the government of Japan, 43.1 % of respondents showed positive intentions regarding organ donation [3]. In contrast, only 12.6 % of

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Fig. 1 The number of deceased donor organ donations in Japan



the population possessed an organ donation decision card. If a family member provided consent to donate their organs after brain death, 87.0 % of respondents expressed their respect of the family member's wishes. Even when a family member did not express their wish to donate the organs after brain death, 38.6 % of respondents reported that they would still consider and accept organ donation.

Although the number of brain-dead organ donations in Japan has been extremely low in comparison to other developed countries, the number of organs procured per donor is higher in Japan than in other countries. To maximize the limited organ transplant opportunities, special transplant management doctors ("medical consultants") have been sent to donor hospitals to assess organ function and to identify transplantable organs [4]. These medical consultants also support the intensive care of patients. The number of organs procured from each donor increased from 4.5 to 6.8 after the application of this system [5]. In contrast, the mean number of organs transplanted per donor in the United States was 3.2 in 2012 [6].

The Spanish Model

For many years, Spain has had a donor rate over 30 per million population. As a result, Spain is widely known to be the only example of a large country that has seen a continuous increase in deceased organ donation for over 20 years (from 14.3 donors per million population in 1989 to 33–35 donors per million population since 1999) [7]. In addition, a parallel increase in the number of solid organ transplantations was achieved (from 1300 per year in 1989 to more than 4200 per year in 2011) [7].

The sustained increase in deceased donation followed the implementation of a set of measures, mainly of an

organizational nature, which is known internationally as the Spanish Model of Organ Donation and Transplantation [8]. The Spanish Model includes an earlier referral of possible donors to the transplant coordination teams, a family-based approach and care methods, and the development of additional training courses aimed at specific groups of professionals. Consensus documents to improve knowledge about the safety limits for organ donation have been developed to minimize inappropriate discarding of organs [9].

An opting-out system from consent to donation has been in place since 1979, when The Spanish Transplantation Law was first enacted. In practice, however, relatives are always approached and have the right to a final veto [10]. The core principle of the Spanish Model is a systematic and organizational approach to the process of deceased donation. The transplant coordinators (TCs) appointed at each procurement hospital are considered to be a key element of the Spanish Model. The TCs in Spain are in-house professionals and staff members of the procurement hospital. Most of the TCs are involved in donation activities on a part-time basis, which enables them to be appointed even at hospitals with low deceased donor potential. It is noteworthy that the majority of TCs are critical care physicians [9].

The Quality Assurance Program in the Deceased Donation Process has become an essential tool for the Spanish Model [9]. The program aims to monitor the deceased organ donation potential, evaluate performance, and identify key areas for improvement. The program is based on a continuous clinical chart review of all deaths occurring in critical care units. The program includes an internal audit performed by TCs in their hospitals and an external audit carried out by expert TCs belonging to a region other than the hospital being evaluated.

Training is also an essential component of the model. Training courses focus on the entire process of deceased donation. To date, over 11,000 professionals have been trained through these courses in Spain [11]. The training courses have now been reproduced in many other countries.

Finally, hospitals are reimbursed for their donation and transplantation activities. The corresponding regional health authorities allocate a specific budget to cover both the human and material resources needed for the effective development of these activities at every hospital [9].

Organ donation in South Korea

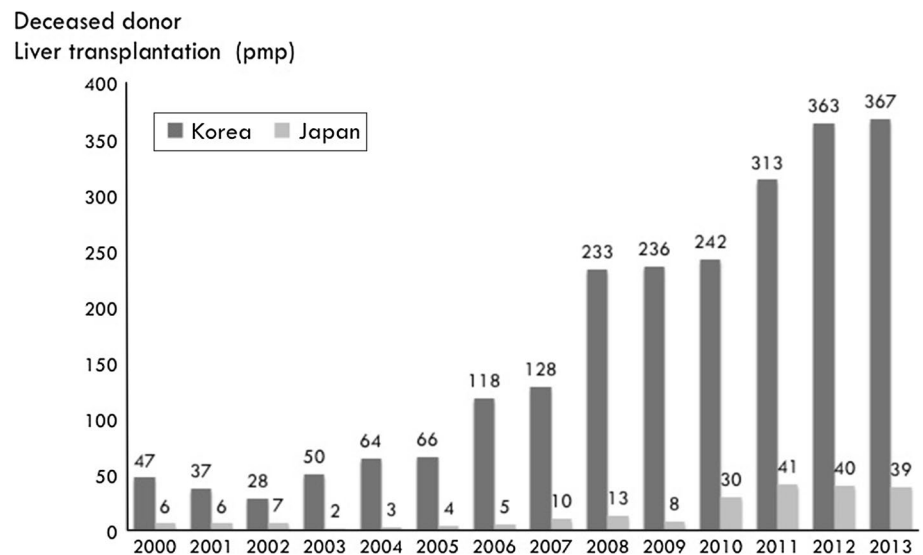
South Korea, a country neighboring Japan, has recently succeeded in increasing its organ donation rate after introducing several systems, such as incentives programs, an organ procurement organization (OPO), a donor registry and a potential donor referral system. The number of brain-dead liver transplantation cases in South Korea and Japan is shown in Fig. 2 [12]. The Organ Transplantation Act came into effect in 2000, establishing the Korean Network for Organ Sharing (KONOS) with a centralized authority for organ procurement, as well as for the approval of donors and recipients to ensure fair organ allocation [13]. However, since there was no increase in the number of organ donations, the organ procurement system was changed to introduce an incentive system. Under the incentive system, if a transplantation hospital formed a committee for brain death evaluation and a hospital organ procurement organization, it could receive a kidney from a brain-dead donor as an incentive, regardless of the waiting list. After the

introduction of the incentive system, the number of brain-dead donors increased from 36 in 2002 to 68 in 2003. The number of brain-dead subjects per hospital also increased from 3.4 to 7.8.

In 2007, the government also introduced a volunteer organ donation pledge on driver's licenses. The government also launched a pilot brain-dead donor registry program to strengthen hospital organ procurement organizational activity. The establishment of an independent organ procurement organization has markedly contributed to increasing the number of brain-dead donors. The Korea Organ Donor Agency (KODA) was established in 2009. The KODA helps make the procedures of organ donation more effective. All potential brain-dead patients in local hospitals are to be reported to the KODA, which determines whether the patients are truly brain-dead and persuades the family members of the brain-dead patients to agree to organ donation. As a result of the above-mentioned efforts, the number of organ donations by brain-dead patients in South Korea reached about 10 per million people in 2013.

During the development of the organ donation system, the decision of a famous professional boxer to donate his organs received a great deal of publicity. Yo-Sam Choi was a world champion boxer who died in 2008 as a result of injuries sustained while defending his World Boxing Council (WBO) inter-continental flyweight title. Although he defeated his challenger on December 25, 2007, he collapsed shortly after the fight ended. He went into a coma, and was taken off life support 9 days later. His heart, liver, kidneys, and corneas were donated and were used to treat six people [14]. After this news was reported, organ donation from brain-dead donors increased from 148 in 2007 to 256 in 2008.

Fig. 2 The brain-dead liver transplantation rates in South Korea and Japan



Opt-in and opt-out

Opt-out consent systems are considered to bridge the gap between people's intentions and their behavior by removing the need to undertake any actions to become an organ donor [15]. In addition, opt-out consent legislation may increase people's willingness to donate their organs by altering their beliefs regarding the recommendations of policymakers [15]. In contrast, in countries where the default choice was not to be a donor, 'the opt-in consent countries,' people generally believe that policymakers do not recommend organ donation [16]. Furthermore, organ donation may be regarded as more meaningful and important in opt-out countries than in opt-in countries [17]. As a result, many countries are considering whether introducing opt-out consent would increase the organ donation rates. Shepherd et al. reported an international comparison of deceased organ donation and transplant rates in opt-in and opt-out systems [18]. The deceased donor rates (pmp) were higher in opt-out consent countries (median = 14.2) than in opt-in consent countries (median = 9.9). As a result, the implementation of opt-out consent led to a relative increase in the total number of transplanted livers and kidneys.

Shepherd et al. also recently reported the importance of people's awareness of their countries' legislation to improve the donation rates [19]. The study compared people's willingness to donate their organs from 19 opt-out and 10 opt-in consent countries in Europe ($n = 29,288$). The proportion of people who were willing to donate their organs did not differ significantly between the opt-in (65.97 %) and opt-out (66.37 %) countries. However, when people were aware of their nation's legislation, the proportion of the subjects who were willing to donate their organs was greater in the opt-out (85.26 %) countries than in the opt-in (80.72 %) countries. Based on these results, Shepherd et al. concluded that opt-out consent countries should increase people's awareness of their legislation to improve the donor rates.

Potential donor referral

In Japan, the option to donate organs from brain-dead patients is not regulated by the law, and depends on the decision of the physicians in charge. In contrast, many developed countries, such as the United States, France, Spain, Belgium, The Netherlands, Germany, and South Korea have adopted legislation regarding potential donor referral.

As described in the previous section, in the United States, the Center for Medicare and Medicaid Service (CMS) requires hospitals to refer all deaths and imminent deaths to the local OPO in a timely manner [20]. For cases of imminent brain death, hospitals should report as soon as the patient shows one or more of the imminent death triggers, including

the following: ventilator dependency, a GCS of 4 or less, plans to discontinue ventilator or pharmacological support and three or more clinical signs (pupils fixed and dilated, no cough, no gag reflex, no spontaneous respiration, and no purposeful movement in response to noxious stimuli) [21].

The nurse plays an essential role in the organ and tissue donation process in the United States. Without the nurse's referral to the OPO, the hospital and family will not have access to the essential services that the OPO provides. The hospital that takes ownership of the donation process identifies and refers potential donors early, and recognizes that the early referral is not "giving up on a patient"; rather, it is an opportunity to provide families a chance to donate. The inability to obtain consent remains one of the major obstacles to converting potential donors into organ donors. To establish organ donation as part of routine health management, the roles of healthcare providers other than the physicians in charge are also important, and greatly affect the potential for donor referral.

In-house coordinators

The importance of in-house coordinators has been widely recognized [22, 23]. In-house coordinators improve the donation process by interacting with families and staff earlier and more often during potential organ donations and improve the donation systems by building closer relationships with hospital staff [23]. Salim et al. reported that the introduction of in-house coordinators (IHCs) was associated with a significantly lower family decline rate (6 vs. 18 %, $p < 0.001$), a significantly higher consent for research rate (8 vs. 0.4 %, $p < 0.001$), and a significantly higher conversion rate (77 vs. 63 %, $p < 0.007$) in comparison to the rates before the introduction of IHCs. The conversion rate was calculated as the number of actual donors divided by the number of eligible deaths, and is represented as a percentage. In addition, a significant increase in referrals per day (0.35 vs. 0.27, $p < 0.05$) and organs transplanted per eligible death were noted after the introduction of IHCs.

In Japan, most prefectures commission hospital staff members in the procurement hospital to become IHCs. They in turn make their hospital staff aware of organ donation and support organ procurement. Konaka et al. conducted a letter-based survey using a self-designed questionnaire. A total of 756 IHCs (40 %) completed the questionnaire. The majority of the respondents were nurses (66 %), followed by physicians (18 %) and other staff members (16 %). Only 2 % were full-time IHCs. These staff members mainly played a role in preparing their own manual for organ procurement (57 %), providing in-hospital lectures (44 %) or providing their own simulation exercises (29 %), as well as coordinating donation cases [24]. The proposal of organ donation is a

patient’s right, and is the essential step for increasing organ donation. Although the physician in charge mainly proposes the organ donations in Japan, the IHC is in charge of the proposal in many developed countries. In France, with support of the government, 96 % of transplantation hospitals have a full-time IHC. Although the increased personnel cost of is a problem that remains to be solved, the provision of government support, as occurs in many European countries (including France and Spain), should be considered.

Education

Attitudes based on a well-established education are supposed to contribute to the development of improved organ donation rates. Healthcare professionals who play a role in donation or transplantation are offered training to maximize donation rates through donor detection, brain-death diagnosis, donor management, approaching the family, communicating bad news, grief counseling, management of refusals, cultural issues, organ allocation, approaching the media and legal issues.

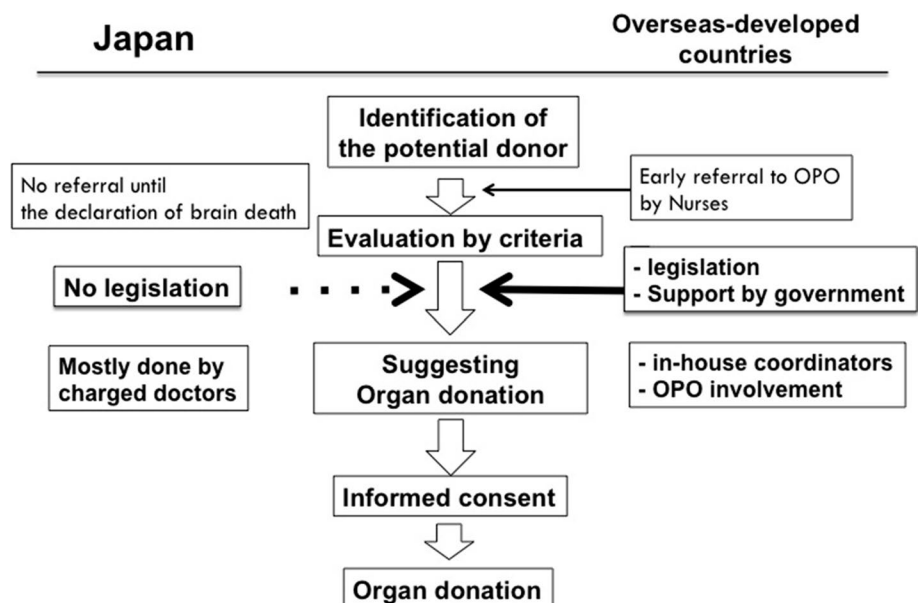
The attitudes of intensive care unit (ICU) staff play an important role in organ donation advocacy. According to a report by Lin et al., before training in the theory of planned behavior (TPB), there was no difference in the attitudes and intentions of the control and experimental groups of ICU staff members. After training in TPB, however, the nurses significantly changed their attitudes and intentions regarding the advocacy of organ donation, both immediately ($P < 0.01$) and 2 months after the education program ($P < 0.01$). In addition, a multivariate analysis indicated that TPB training was significantly associated with a change of attitudes ($P < 0.01$)

and intentions ($P < 0.05$) toward organ donation advocacy. Lin et al. concluded that TPB education programs enhanced the ICU nurses’ attitudes and intentions toward organ donation advocacy. Repeated education is advised to increase the participation of ICU nurses in organ advocacy [25]. An in-house donation coordinator-initiated education program that leads to referral, rather than referral by other parties, results in higher tissue donation rates after asystolic death [26].

Incentives

The payment of primary care physicians for counseling and recording of an individual’s wishes regarding organ donation would help ensure that informed consent for donation was provided, and would reduce the likelihood that consent would be revoked by family members in the event of neurological brain death [27]. Financial incentives for organ donation (from living or brain-dead donors) have been considered ethically acceptable by some authors, and have been accepted locally in some countries. In the United States of America, eight federal proposals have been rejected, while some kinds of incentives have been approved at a local or state level. During the development of the organ donation program in South Korea, the organ transplant act prohibited any financial rewards for organ donation between the recipient and donor, but permitted financial incentives by the government. In the case of brain-death donations, they included a funeral expense, a hospital fee, and a consolatory amount totaling \$4500 US that could be given to the family [13]. There is still widespread concern that the acceptance of economic incentives could lead to the commodification of the human body, and lead

Fig. 3 The differences in the approaches to the process of organ donation between Japan and other countries



to a “slippery slope” toward organ commercialism [28]. In addition, the organ allocation criteria based on the organ donation incentive system appear to be unfair, because the criteria do not fit the principles of distributive justice. In the future, the organ donation incentive system itself may need to be reexamined [29].

Conclusion

To improve the current situation with regard to the low organ donation rate in Japan, the introduction of various measures that have increased the organ donation rates in other countries should be considered. In principal, no major differences exist between Japan and the other developed countries in the process of organ donation (Fig. 3). The process includes the identification of a potential donor, the declaration of brain death, the suggestion of organ donation to the family, obtaining informed consent from the family, and then donation of organs. Early referral is a key to success in increasing the rate of organ donation.

The incorporation of consent for organ donation into routine health management should be associated with an increase in organ donation. Similarly, consent for organ donation should be sought at the time of any hospital admission and should be integrated with routine end-of-life care planning [27].

Continuous education for healthcare providers is important. Furthermore, besides the physicians in charge and the nurses, the placement of full-time in-house coordinators and the introduction of an OPO are considered to be important factors that for increasing the number of organ donations.

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