Revised Organ Transplant Act and Critical Care Physicians

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Abstract

The revised Organ Transplant Act permits organ donation from brain-dead donors based on family consent even when the brain-dead patients have not declared their intention to donate organs or in the cases of children. Formerly, medical transplantation was considered only in the presence of a written consent. From July 2010, medical professionals have been required to be more active in explaining and proposing options leading to transplantation. Physicians and nurses, after doing their best to treat a patient, naturally feel reluctant to suddenly switch to discussing the possibility of organ donation with the patient's family. In addition, if the potential donor is a victim of child abuse by parents, the parents are not allowed to opt for organ donation and brain death cannot be the basis for determining the death of the child. Hospitals need the organizational ability to detect and respond to child abuse. These issues are integral to the process of terminal care and the care for dying patients, and at present it is necessary to develop the organizational ability of hospitals for providing appropriate terminal care through team medicine.

Key words Revised Organ Transplant Act, Critical care, Hospital care, Brain death, Child abuse

Introduction

A partial amendment to "The Organ Transplant Act" (hereinafter, "the revised Act") was passed in July 2009. This revised Act, legalizing organ donation from brain-dead patients based on the decision of the patients' families, took effect in July 2010. Although a rapid increase in the actual organ donation from child organ donors is not likely to occur, one projection[1] suggests that the number of donors obtained during the first year following the enforcement of the revised Act may exceed 80 cases, which is comparable to the number of cases in the preceding 10 years, and the actual situation seems to be in line with this projection.

Problems in the organ transplantation process have been examined, and the development of standard protocols has been discussed. The proposal from the Council of Societies Related to Organ Transplantation[2] and the protocols of the Japan Organ Transplant Network (JOT)[3] have been published. In addition, the government has started a major revision of various documents under the old Act, such as "The Manual for Organ Donor Facilities" (issued on October 1, 1999).[4]

This article explains the problems for critical care physicians working at organ donor facilities in relation to brain-dead organ donation, which has already become part of clinical practice, according to the Guidelines for the Operation of the Organ Transplant Act (hereinafter, "the Guidelines") as partially revised on July 17, 2010 under the revised Act.

Standard Protocols for the Process Leading to Organ Transplantation

In this paper, the author reviews the discussion based on the flow chart shown in the protocols by

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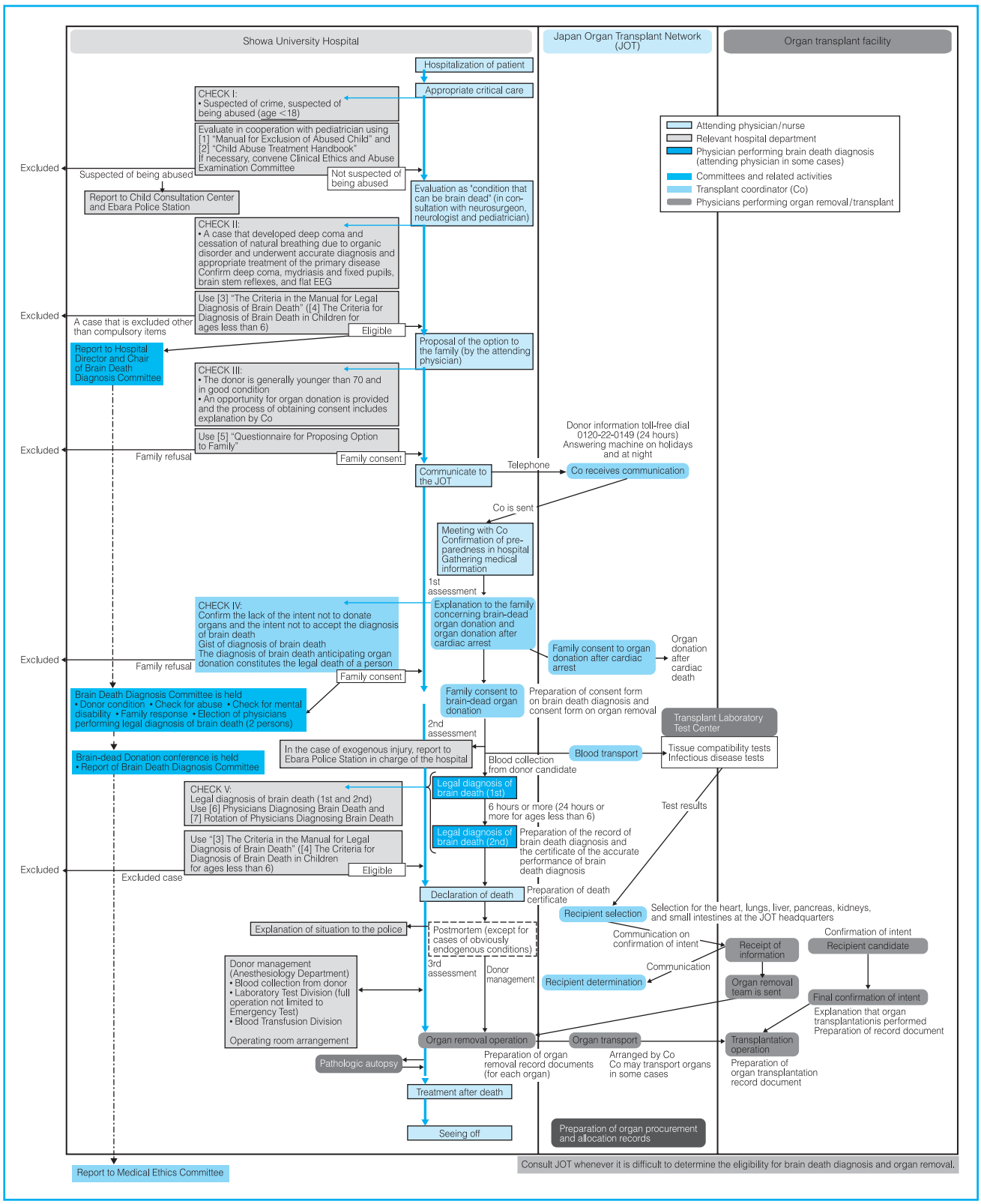

Fig. 1 Brain-dead organ donation after the enforcement of the revised Organ Transplant Act—Flow chart at Showa University Hospital

JOT[3] and then presents the flow chart of Showa University Hospital, which was developed later (**Fig. 1**). The crucial parts in this flow are Steps (1) through (5) outlined below.

Step (1) When the patient is considered to have lapsed into irreversible whole brain failure, i.e., brain death, proceed to Step (2). The diagnosis of this condition is made following the description in "The Proposal (Guidelines) Concerning Terminal Care in Critical Care Medicine" by the Japanese Association for Acute Medicine.[5] Here, the acts of medical professionals that have been continued to treat the patient are clearly distinguished from the life-prolonging measures after the diagnosis of brain death. The attending physicians and other members of the medical team understand Step (2) and later steps as part of the terminal care.

Conventional kidney donation under cardiac arrest is possible based on family consent without the patient's declaration of intent. However, confirmation of brain dead condition and other necessary procedures have been conducted when highly invasive measures are taken for the purpose of kidney protection. The Steps (1) through (5) shown here are based on this past practice. The number of brain-dead donors has been projected similarly based on past experience.[1]

Incidentally, the term "clinical brain death" used in the old guidelines was deleted in the partial amendment on July 17, 2010, because this term, though it may seem medically meaningful, caused confusion in practice.[2,6]

Step (2) It is explained to the patient's family that the patient has lapsed into the condition in Step (1).

Step (3) If the patient's family understands the development of the condition and agrees to Step (2), the medical team considers the termination of life-prolonging measures and other actions. Here, the attending physicians and other relevant persons tell family members about "the possibility of organ donation" as an option according to Part 6, "Matters Concerning the Standard Protocols Leading to the Diagnosis of Brain Death in the Case of Organ Removal from the Body of a Brain Dead Person" in the Guidelines , in which the description under "1. Attending Physician and Other Relevant Persons" (1) requires "oral or written announcement."

The method for giving this information can be chosen from several options depending on the situation of individual facilities. For example, the attending physician may explain the availability of this option to family members on the instance or family members may be asked to answer a questionnaire including this option (**Fig. 1**: CHECK III [5]). Providing brochures describing general explanation of organ donation in the waiting room may be helpful. Some facilities ask the families of all patients about the intention to donate organs in advance, "just in case."

Some argue that hospitals should be staffed with donor coordinators. The provision of such specialists or functions in the hospital may need consideration. This matter is discussed in detail in the next section.

Step (4) If the family wants to discuss in more detail, they are referred to JOT or prefectural organ transplant coordinators. Many facilities are considered to have established rules for this action.

Step (5) If the family intends to donate organs, the subsequent flow is the same as that practiced in the past. For example, the time of the second legal diagnosis of brain death is defined as the time of death.

A frequently mentioned issue specific to children is the possibility that a patient might be a victim of child abuse. While organ donation from a person undergoing exogenous death inevitably involves police intervention, hospitals always notify the police of any cases suspected of exogenous causes early at the time of hospitalization, whether or not abuse is suspected and whether or not brain death might occur. In the case of brain damage leading to brain death, the police are responsible for identifying the assailant. However, the attending physicians and other persons involved are generally expected to provide information on the possibility of child abuse from the clinical standpoint, and they need to provide greater support to the family of a child organ donor than in the case of an adult donor. The author discusses this matter later.

Issues Concerning Standard Protocols

Issues concerning the proposal of "the possibility of organ donation" as an option

Some specialists at critical care and neurosurgery departments have been proposing the option in Step (3) described above, using individual discretion and making individual efforts. However, in

Table 1 Tasks of critical care physicians in terminal care and development of organizational hospital care

[1] Abandonment of treatment/giving explanation ⇒ Obtaining understanding and agreement of family (move to terminal care)

[2] Once brain death occurs, "the patient must be informed of organ transplantation"
⇒ The family (in lieu of the patient) receives explanation of the possibility of transplantation

[3] Helping the family find peace of mind in "attending the dying patient" ("Collaboration" with the patient and the family)
⇒ Propose the possibility of transplantation (as an option)
[1] is a must.
[2] in addition to [1]?
[3] in addition to [1]? (Is [2] a must?)

[4] The attending physician has psychological reasons to feel difficulty in "performing [2] and [3]) (even in [1])!
⇒ The option should be proposed as part of organizational hospital care. (In this case, [2]? / [3]? / [2] and [3]?)

* "Financial aspect/hospital crisis management" → How?
The hospital should perform [2] and [3] as an organization! → Assigning in-hospital coordinators, other measures

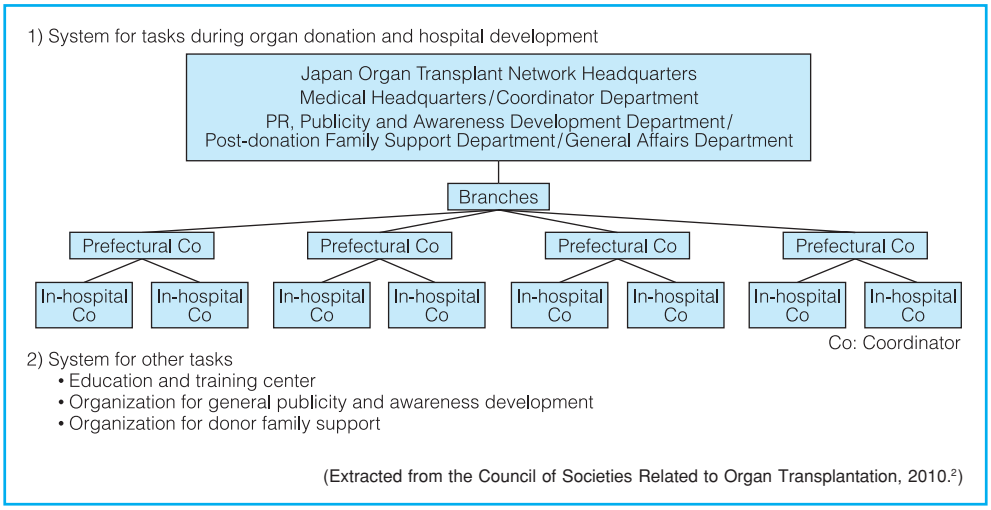

Fig. 2 Organizational setup supporting the organ transplant network system

view of the severe work environment and busy daily practice of many critical care physicians,[7] it is often unreasonable to demand that they "propose the option." Above all, we should understand that the attending physician and other members of the medical team are bewildered by the precipitous change in the orientation of their minds from doing their best to save life to asking about the intention to donate organs.

As a hospital as an organization needs to provide organizational medical services in a terminal care situation, the author needs to consider the following:

First, when the patient lapses into irreversible whole brain failure, the attending physician explains to the patient's family that further treatment has to be abandoned. If the family agrees, the situation enters the terminal care stage as defined by the Japanese Association for Acute Medicine (**Table 1** [1]). Next, all patients are en-

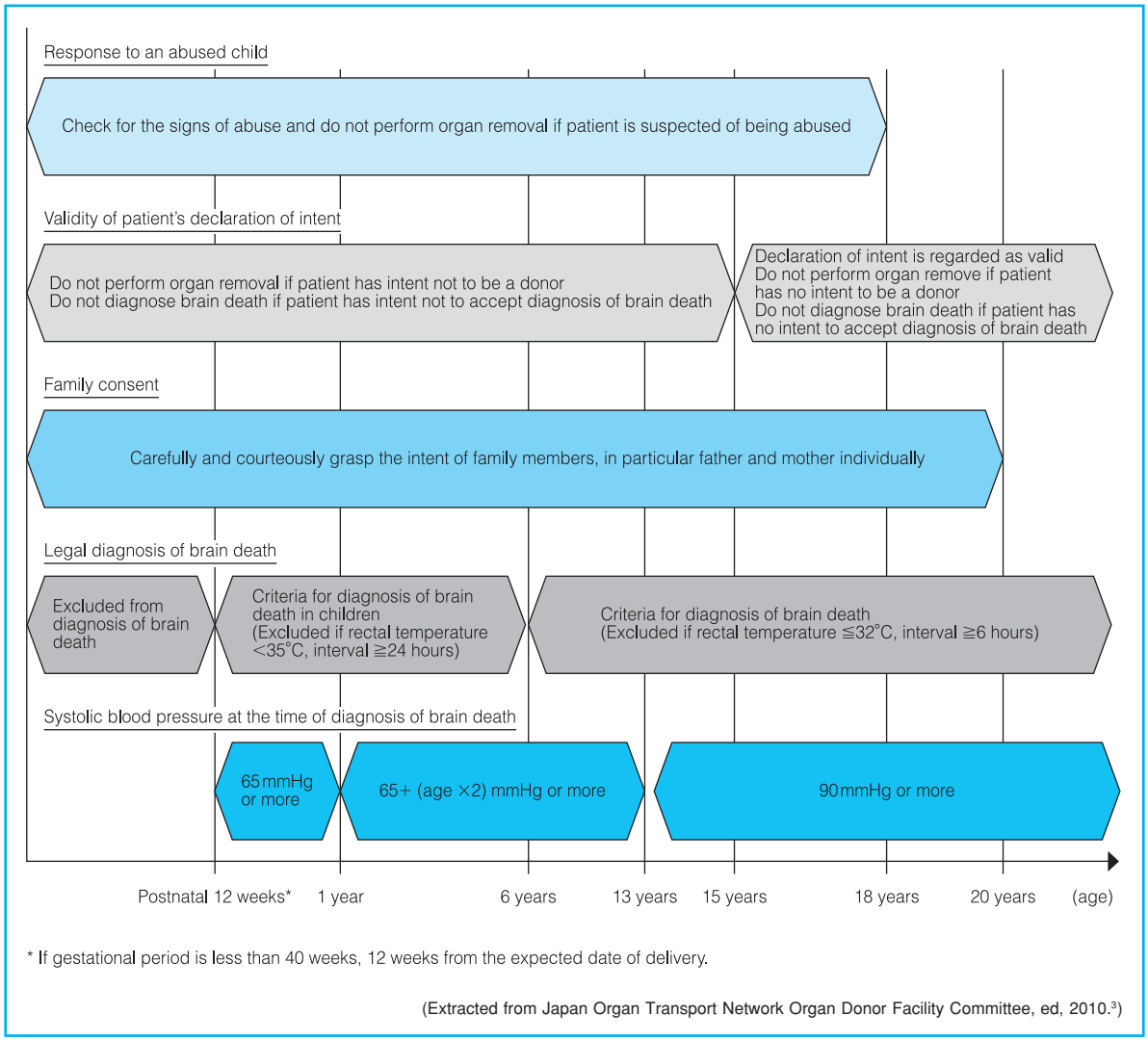

Fig. 3 Treatment of donors at different ages

titled to receive an explanation from the attending physician about the condition and treatment of their illness, and this enables them to seek a second opinion. Therefore, brain-dead patients similarly have the right to be given an explanation of the diagnosis and to know about the possibility of the organ donation. Such patients must be given an explanation of the facts about their own health, but because brain-dead patients are unable to understand the explanation, it is given to their families and other persons concerned (**Table 1** [2]).

The attending physician and the medical team who have been working to save life have difficulty in proposing the option directly, as discussed above. Such proposal should be made as part of the organizational medical services of the hospital. In attending a dying patient, it is also necessary to help the patient's family find peace of mind (**Table 1** [3]). One possible solution is that the organ donation option is proposed by a team (in-hospital coordinators) separate from the medical professionals that has worked hard to save life (**Table 1** [4], **Fig. 2**).

Support to patient's family

As part of nursing care for family members of a brain-dead patient in the terminal stage, the

patient's family is sometimes invited to the bedside and allowed to participate in the bed bathing of the patient's body. Family members sometimes start to talk about the intentions of the patient on such occasion. Because the attending physician is rarely present at such spontaneous conversations, the role of the nurse in attendance within the medical team is important.

After the option has been presented and the process leading to organ transplantation has started, psychological support to the family can be provided by organ transplant coordinators belonging to prefectures or the JOT. However, these coordinators cannot take part when the family refuses organ donation. Intervention of the nurse in attendance may also be necessary when opinions on accepting the option differ among family members and the argument may linger.

As discussed above, nurses play a major role within the medical team in providing the mental and psychological care for the patient's family, the importance of which continues to increase. This also applies to the case of child organ donors at present.

However, nurses are not specializing in family support, but are providing such support in their spare time, so to speak. Medical facilities with religious backgrounds seem to provide greater family support whether or not organ donation is involved. The matter of family support should be discussed more deeply, as it is a function that should be provided at all organ donor facilities. The scheme discussed in the first subsection above, in which an organization other than the team working to save life proposes the option to the family, is inseparable from the provision of support to families.

Discussion concerning child organ donors and child abuse

Several precautions concerning child organ donors have been identified as shown in **Fig. 3**. One focus of discussion has been the case of brain death as a result of child abuse by parents. In general, victims of domestic violence are not limited to children, but in the process of brain death and medical transplantation, the decision to donate organs is made by the patient's family and the time of the diagnosis of brain death is regarded as the time of death. However, parents who inflict brain damage on their children are not qualified to make such a decision. As the background of this problem, it may be pointed out that many organ donor facilities are not sufficiently prepared to respond to issues of domestic violence.

If brain damage resulting in brain death is suspected to have been caused by a crime and an autopsy is expected, the case is not considered for organ donation. In the case of patients younger than 18, we need to rule out the possibility of child abuse (**Fig. 1**: CHECK 1, **Fig. 3**). As mentioned above, the police are responsible for identifying the assailant. Physicians need to treat children arriving at the emergency department with exogenous conditions considering the possibility of child abuse, in addition to cooperating with the police and other authorities. The author understands that the revised Act has further increased the need for such cooperation.

Expansion of Organ Donor Facilities and Support to Front-line Medical Professionals

The Guidelines define the categories of facilities where organs for transplantation can be removed from brain-dead donors. These include the 4 previously defined categories of university hospitals, medical advisor certification facilities of the Japanese Association for Acute Medicine, specialist physician training institutions of the Japan Neurosurgical Society (Item A), emergency and critical care centers, and the newly defined 5th category of facilities affiliated with the Japanese Association of Childrens' Hospitals and Related Institutions (JaCHRI). Of the 474 facilities (as of Fiscal 2008) under the previously existing 4 categories, 338 (71%) answered that they had organizational systems for organ donation in response to the inquiry from the Ministry of Health, Labour and Welfare.

When the facilities in these 4 categories are combined with specialist physician certification facilities of the Japanese Association for Acute Medicine and specialist physician training facilities of the Japan Neurosurgical Society (Item C), the total number exceeds 1,600. Cases of brain death also occur among the approximately 1,200 facilities outside the 4 categories. According to a questionnaire survey, about 70% of these facilities are willing to cooperate in organ donation from brain-dead donors, provided that conditions are met in terms of personnel support and other

aspects.[8] Enabling brain-dead organ donation at these facilities is consistent with the basic concept of respecting the patient's intentions, which is the primary purport of the Act.

In the first place, to diagnose brain death is synonymous with to evaluate brain pathology accurately and treat it. In other words, we physicians can provide aggressive treatment because we can discern a condition where we cannot but give up. Specialist physicians at the facilities outside the 4 categories are actually treating brains. They can express their willingness to participate in brain-dead organ donation because they are providing appropriate treatment. This is the critical care physicians' real intention.

In reality, it takes as long as 2 days from the diagnosis of brain death to the completion of the operation to remove organs for transplantation. Even among the facilities in the above 4 categories, 30% have not established preparedness. Considering this fact, it is logical to provide support to the facilities where specialist physicians are performing appropriate brain treatment so that they can participate in organ donation from brain-dead donors.

Conclusion

The author has considered the problems faced by front-line critical care professionals in consequence of the revised Act and how they can be addressed, including how hospitals can respond as organizations.

Where critical care is the first step leading to organ transplantation, problems are compounded in relation to organ transplantation involving children. Further cooperation of the people concerned and the accumulation of knowledge in this field are desired.

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