Legal Determination of Brain Death

JMAJ 54(6): 363–367, 2011

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Abstract

Revisions to the Organ Transplant Act have made it possible for the organs of a brain-dead patient to be donated for transplantation with the permission of the patient's family only, even if the patient's desires regarding donation have not been set out in writing, in all brain-death cases unless the patient has expressly indicated that they do not wish to be an organ donor. However, there has fundamentally been no change in the "legal determination of brain death"; the main changes to the Act are those related to the broadening of the age range for organ donor eligibility.

Under these revisions, age divisions have also been set at ages 6 and 18 as well as the original 15, and the criteria and conditions for organ donor eligibility in each age group have become more complicated.

Under the original Act, in cases where there is damage to a patient's eardrum, vestibular reflex was deemed to be impossible to perform and a legal determination of brain death was not made. However, under these revisions, regardless of the patient's age, it is now possible to perform tests to ascertain brain death using sterile physiological saline.

In fact, from a medical standpoint the legal determination of brain death has a limited range of discretion, and since some matters such as the order in which tests are performed may be trivial medically, they may hold significant meaning legally and is required utmost care.

Key words Organ Transplant Act, Brain death, Diagnosis

Introduction

Revisions to the Organ Transplant Act have made it possible for the organs of a brain-dead patient to be donated for transplantation with the permission of the patient's family only, even if patient's intention regarding donation have not been expressed in writing, in all brain-death cases unless the patient has indicated that they do not wish to donate organs. Despite this major legal revision, however, only limited changes have been made to the "legal determination of brain death"; there has been fundamentally no change to the criteria for determining brain death, with the main changes to the Act focusing on items related to the broadening of the age range for organ donor eligibility.

There is a difference between the diagnosis of brain death as a clinical stage diagnosis and the legal determination of brain death for the purpose of organ donation from a brain death donor. While the former is an academic diagnosis left to the discretion of individual physicians, the latter is a determination performed in accordance with the Act and presupposes organ donation. Accordingly, from a medical standpoint the legal determination of brain death has a limited range of discretion, and since some matters such as the order in which tests are performed may be trivial medically, they may hold significant meaning legally; thus meticulous care needs to be taken. This paper addresses the determination of brain death in accordance with the Act.

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This article is a revised English version of a paper originally published in the Journal of the Japan Medical Association (Vol.139, No.12, 2011, pages 2521–2524).

Table 1 Legal determination of brain death according to age

<table>
<tr><th>Age</th><th>12 weeks* to under 6 years</th><th>Age 6 years to under 15 years</th><th>Age 15 years to under 18 years of age</th><th>Age 18 years and above</th></tr>
<tr><td>Criteria for brain death determination</td><td>Ministry of Health and Welfare Criteria for the Determination of Brain Death in Children 1999[4]</td><td colspan="3">Ministry of Health and Welfare Criteria for the Determination of Brain Death 1985[5]</td></tr>
<tr><td>Brain death determination manual</td><td colspan="2">None</td><td colspan="2">None
(Previous Act: Legal Determination of Brain Death Manual 1999[1])</td></tr>
<tr><td>Facilities where determination is performed</td><td colspan="4">Type 5</td></tr>
<tr><td>Physician performing determination</td><td colspan="4">2 or more specialist physicians belonging to 6 academic societies</td></tr>
<tr><td>Interval between initial determination and second determination</td><td>24 hours or more</td><td colspan="3">6 hours or more</td></tr>
<tr><td>Exclusion of child abuse cases</td><td colspan="3">Required</td><td></td></tr>
</table>

* In the case that gestational age is less than 40 weeks, the 12 weeks is calculated from the due delivery date.

(Extracted from Japan Organ Transplant Network Organ Donation Facilities Committee, ed. (2010) and modified.[3])

The Act and its Operation

The Organ Transplant Act does not operate independently of other Acts, and its operation is prescribed by multiple official documents. The National Diet passes the “Act,” but in order to put the Act into operation, the Ministry of Health, Labour and Welfare prepared the “Ordinance for Enforcement of the Act” (ministerial ordinance) as well as “Guide for Operation of the Act” (guidelines) to ensure the smooth operation of the Act. In order to implement the Act, understanding of all three of these documents is necessary. However, it has been pointed out that these documents contain various points that are unclear and can be difficult to decipher, even when read carefully.

In the legal determination of brain death is important that criteria are complied with; that is to say, not complying with these criteria may lead to accusations of legal violations. In clinical settings, however, speed is also required. At organ donation facilities, there is no time for reading through three different types of documents for every case. In order to reduce as far as possible the heavy responsibility placed on these organ donation facilities and enable appropriate legal determination of brain death to be performed, the “Manual on the Legal Determination of Brain Death”[1] was compiled in 1999, two years after the enactment of the 1997 Organ Transplant Act.

With the revision of the Act, a new ministerial ordinance and guidelines have been formulated, but since a new manual had not been compiled at the time of this writing, Item 8-1 of the guidelines states that operations of the Act are to comply with the 1999 “Manual on the Legal Determination of Brain Death.” However, it seems a little strange for operations of the Act to have to comply with a manual that was formulated based on the pre-revision version of the Act. Moreover, the guidelines also state that operations of the Act are to comply with the 2009 Health and Labour Sciences Research Grant Special Research Project Report “Study on the Determination of Brain Death in Children and Organ Donation, etc.”[2] Thus in reality medical professionals at organ donation facilities need to read through three types of documents in order to operate the Act. Prompt amendment of the manual is highly desirable.

A guide that can be used until the manual has been amended is the “Protocol for Organ Donation Facilities” compiled by the Japan Organ Transplant Network (JOT); it can be downloaded from the JOT website.

Table 2 Patient status required for the legal determination of brain death (preconditions)

1. Cases in which the patient is in a deep coma and has ceased breathing naturally due to organic encephalopathy
2. Cases in which the primary disease has been diagnosed definitely
3. Cases in which have been diagnosed that there is absolutely no possibility of the patient recovering even if all appropriate medical treatment currently available were used

Ages and Criteria

Prior to the revisions, persons aged 15 years or older were eligible to become brain death organ donors under the Organ Transplant Act and there were no special differences in the criteria applied for donors of different ages. As shown in **Table 1**, under these revisions, age divisions have also been set at ages 6 and 18 as well as the original 15, and the criteria and conditions for organ donor eligibility in each age group have become more complicated.

The division at age 6 may appear to have been created as a result of the formulation of criteria for the diagnosis of brain death in children,[4] aimed at small children aged under 6 years who were excluded under the so-called "Takeuchi Criteria,"[5] but in fact it is thought to be more appropriate to understand this division as being due to the special characteristics of young children. In contrast, the division at age 18 is intended to exclude abused children, the division that was introduced with these revisions. Since the reasons for these changes are complicated in any case, a thorough understanding of **Table 1** is necessary.

Preconditions and Exceptions

Before legal determination of brain death can begin, the following three requirements must be fulfilled.

1) Preconditions for brain death determination (**Table 2**) must be completely fulfilled;
2) All exceptions (**Table 3**) must be excluded without fail; and
3) Of the prerequisites for legal brain death determination, all items (Items 1–4 of **Table 4**) except for cessation of natural breathing (arrested respiration test) must be confirmed.

Table 3 Cases in which legal determination of brain death is not performed (exceptions)

1. The patient has expressly indicated that they do not wish to be an organ donor
2. Patients aged under 12 weeks (in the case that gestational age is less than 40 weeks, the 12 weeks is calculated from the due delivery date)
3. The patient is an abused child, or is aged under 18 years of age and it is suspected that they have been abused
4. Patients who are intellectually disabled and whose disability makes it difficult for them to effectively express their wishes regarding donating their organs for transplantation.
5. Patients confirmed to be in a deep coma and ceased breathing naturally due to an acute drug overdose
6. Patients confirmed to be in a deep coma and ceased breathing naturally due to a metabolic or endocrine disorder
7. Low body temperature (rectal temperature)
   Under 6 years of age: less than 35 degrees Celsius
   Age 6 years and above: less than 32 degrees Celsius
8. Low blood pressure (systolic)
   Under 1 year of age: less than 65 mmHg
   Above 1 year and under 13 years of age: less than 65 + (age × 2) mmHg
   Age 13 years and above: less than 90 mmHg
9. Critical arrhythmia

Table 4 Preconditions for determining brain death

1. Profound coma
2. Dilation of both pupils of 4 mm or more; pupils are fixed
3. Loss of brain-stem reflexes
   • Loss of light reflex
   • Loss of corneal reflex
   • Loss of ciliospinal reflex
   • Loss of oculocephalic reflex
   • Loss of vestibular reflex
   • Loss of laryngeal reflex
   • Loss of cough reflex
4. Isoelectric electroencephalogram
5. Cessation of natural breathing (arrested respiration test)

A patient's condition in which 1–4 of **Table 4** were confirmed was referred to as "clinical brain death" in the pre-revision guidelines, but in the revised guidelines, the expression used to describe legal brain death is "a condition in which the patient has been deemed to be brain dead following a determination of brain death conducted in accordance with the Act." This definition was changed in the guidelines because general clinicians frequently also explain diagnoses of brain death with their own criteria as a "state of clinical brain death," making the two states easily con-

fused, as well as because there are also patients who fulfill preconditions 1–4 in **Table 4** but are able to breathe on their own.

With regard to exceptions, especially body temperature and blood pressure, since it is possible for the patient to enter a condition during the course of treatment where a legal determination of brain death may be carried out, it is important to be aware of the patient's condition, which can change by the minute.

Changes Made to the Legal Determination of Brain Death under these Revisions

(1) In order to respond to cases of brain death in young children, conditions regarding blood pressure and body temperature at the commencement of testing are prescribed in detail (**Table 3**). Conditions for measuring the brain waves of children aged under 6 years (interelectrode distance, electroencephalograph sensitivity, body earth, electrode attachment, and testing conditions) are also prescribed in detail.[2]

Furthermore, apnea testing for children aged under 6 years is to be performed by removing the respirator and administering 100% oxygen (6 L/min.) using a t-piece instead of the method prescribed for adult patients (insufflation) in which oxygen is administered via a catheter is inserted through the tracheal tube.

(2) In the case of adults, determination of brain death is to be carried out twice at an interval of 6 hours or more, while for young children aged under 6 years, determination of brain death is to be carried out twice at an interval of 24 hours.

(3) Under the original Act, in cases where there is damage to a patient's eardrum, vestibular reflex was deemed to be impossible to perform and so a legal determination of brain death was not made. However, under these revisions, regardless of the patient's age, it is now possible to safely perform tests to ascertain brain death using sterile physiological saline in compliance with criteria for the diagnosis of brain death in children[2] and explanations of questions concerning brain death determination.[6]

Furthermore, the following 3 regulations regarding vestibular reflex have been added under the revisions.[2]

1) Both ears are examined using an otoscope to confirm that there are no foreign objects in the external canals.
2) The amount of cold water injected is 25 mL for children aged under 6 years, and 50 mL for patients aged 6 years or above.
3) There is an interval of more than 5 minutes from the conclusion of testing on one ear to the commencement of testing on the other ear.

Points to Note of Legal Determination of Brain Death that have not Undergone Legal Revision

Of the requirements for a determination of brain death (**Table 4**), one important point that has not been changed under the revisions is that an arrested respiration test must be performed following all of the items for determining brain death.

Moreover, deep body temperature at the commencement of arrested respiration testing is to be 35 decrees Celsius or higher, and so care must be taken as this differs from the preconditions for patients aged 6 years or above at the commencement of overall legal brain death determination (deep body temperature of 32 degrees Celsius or higher).

Records

Records of observations of the patient's condition must of course be made during the legal determination of brain death, making sure that nothing is omitted, and it is important that documents such as the Brain Death Determination Record Form prescribed under the ministerial ordinance is completed correctly.

Organ donation facilities are required to complete additional documents such as the Format for Verification Documents for Organ Donation from Brain-dead Donors (Verification Format),[7] which is submitted to the Verification Meeting for Cases in Which Organs Are Donated from Brain-dead Patients, which is held following the legal determination of brain death and donation of the brain-dead patient's organs. This document is often sent after the legal determination of brain death and donation of the brain-dead patient's organs, but as described below, it has been pointed out that there are problems with the current version, dated March 17, 2008. The current verification format states that post-arrested respiration test blood pressure and oxygen saturation

(SaO2) are to be measured 10 minutes before and after the recommencement of artificial respiration, but this is not prescribed either on the Brain Death Determination Record Form or in the Manual on the Legal Determination of Brain Death. This format is regarded as being an important record for confirming the patient's recovery after the arrested respiration test in cases where low oxygen and low blood pressure levels are observed during the test; however, neither the Record Form nor the Manual even touches on this subject. Since brain-dead patients whose organs are being removed for transplantation are normally attached to a monitor constantly, certainly no problems occur in the vast majority of cases, but that fact that in many cases it is uncertain whether the data has been kept or not is great inconvenience for organ donation facilities. If this subject is required to be recorded on the Verification Format, then it is desirable that it also be properly included in the Record Form and Manual.

Furthermore, the current Verification Format requires that the time that the clinical diagnosis of brain death performed prior to the legal determination of brain death is concluded be recorded (although this is not included on the "Record Form"). It requires that each time at the completion of the clinical diagnosis of brain death and the commencement of the initial legal determination of brain death be clearly stated, that checks are made during this time to ascertain whether there have been any changes in the clinical findings, and that these results be described in the patient's medical records. The times at the beginning and the completion of the clinical diagnosis of brain death performed prior to the legal determination of brain death are frequently not clearly recognized in many cases and require careful attention.

Although it is difficult to comment on the above since at this point after the Act was revised, Verification Format has not yet been released, as of the time of this writing no changes have been made to the Format. It is highly desirable that improvements are made as quickly as possible in order to also lighten the burden on organ donation facilities.

Conclusion

Determinations of brain death based on the Act should be performed in compliance with items prescribed by the Act and other legal documents. At present, organ donation facilities are operated under a burden. In reality, confusion is being kept to a minimum through the strong support of the JOT and prefectural coordinators, which is delegated the task by JOT. These are also moves in related academic societies to establish regional support organizations. While it is important that an adequate support network be established, should not the revision of manuals and the Verification Format be carried out first? These are tasks that should have been completed when the revised Act came into force.

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