Enforcement of Amended Organ Transplantation Law

June, 2011

Office for Organ transplantation
Health Service Bureau
Ministry of Health, Labor and Welfare
Number of heart-beating cadaveric Donors
（Oct,1997～30 June, 2011）

Amendment was enforced on 17 July, 2010
Number of Cadaveric Donors
(Oct, 1997 ~ 30 June, 2011)
Number of Deceased and Living Donors per a million people (2007)

Reference: Transplantation Procurement Management (TPM) International Registry Organ Donation and Transplantation
Outline of Organ Transplantation Law

1. Philosophy
   Respect for one’s own will of organ donation
   Security for voluntary donation
   Fairness about the chance of transplantation

2. Organs
   Heart, Lung, Liver, Kidney, Pancreas, Intestine, Eye

3. Organ retrieval
   (Please see the next slide.)

4. Others
   ▪ Prohibition of trafficking
   ▪ Authorization of organ procurement and allocation organization


### Requirements for Organ Procurement in the Law

<table>
<thead>
<tr>
<th>Family Patient</th>
<th>Consent</th>
<th>Decline</th>
<th>Unknown or not existence</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>○</td>
<td>×</td>
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</tr>
<tr>
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<td>○</td>
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<td>×</td>
<td>×</td>
</tr>
<tr>
<td>unknown</td>
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<td>×</td>
</tr>
</tbody>
</table>

**July 17, 2010**

O: Procurement is permitted  ×: Procurement is prohibited
## Comparison of the former and current law

<table>
<thead>
<tr>
<th></th>
<th>Former Law</th>
<th>Current Law</th>
<th>Enforcement Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Donation to Relatives</td>
<td>Permitted, if the wish was presented in writing</td>
<td>17.Jan. 2010</td>
</tr>
<tr>
<td>2</td>
<td>Requirement for Determining Brain Death and Organ Procurement</td>
<td>Patient’s writing consent and no denial of family or no existence of family</td>
<td></td>
</tr>
<tr>
<td></td>
<td>About Children (under 15)</td>
<td>Same condition as shown in left box or No denial of patient and Writing consent of family</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Promotion and Enlightenment</td>
<td>Donation from the aged 15 or under is permitted if their family consent in writing</td>
<td>17.July. 2010</td>
</tr>
<tr>
<td>4</td>
<td>About Abused Child</td>
<td>Donation decision format will be printed on the back of driver’s license or health insurance card. Etc.</td>
<td></td>
</tr>
</tbody>
</table>

- Donation to Relatives: Remain to be considered in the former law, permitted if the wish was presented in writing in the current law.
- Requirement for Determining Brain Death and Organ Procurement: In the former law, written consent and no denial of family or no existence of family is required. In the current law, it is similar to the former condition, but with the addition of writing consent of family.
- About Children (under 15): Writing consent by children under 15 is not valid in the former law, whereas it is valid if the family consents in writing in the current law.
- Promotion and Enlightenment: (None) in both the former and current laws.
- About Abused Child: (None) in both the former and current laws.
Organ donation decision card

1. Either in the case of brain death or cardiac arrest, I will donate my organs for Transplant

2. Only in the case of cardiac arrest, I will donate my organs for Transplant

3. I will not donate my organs

Choose organs if you have some organs you would not like to donate

Heart / Lung / Liver / Kidney / Pancreas / Intestine / Eye

Date
Signature
Family signature
Criteria for Brain Death in Japan

【Prerequisite】
1. Patient who are in deep coma by structural brain injury and placed ventilator
2. An etiology has been established. (Imaging (CT, MRI etc.) is mandatory.)
3. There is no possibility of functional recovery with all currently available interventions in all aspects

【Exclusion】
1. Patient considered to be unable to express one’s own will (eg. mental retardate)
2. Newborn under 12 wks
3. Children(<18yrs) suspicious to be abused
4. States that can mimic brain death:
   - Locked-in syndrome, Drug intoxication, Poisoning of sedatives, hypnotics or anticonvulsants, Neuromuscular blocking agents, Sever hypothermia (core Temp < 32°C), Endocrine and metabolic diseases
Criteria for Brain Death in Japan②

【Neurological Examination】
1. Deep coma: Japan coma scale 300, Glasgow coma scale 3
2. Absence of papillary responses to light and pupils at mid position with respect to dilatation (greater than 4mm diameter)
3. Absence of brainstem reflex (corneal, ciliospinal, oculocephalic, vestibular, pharyngeal, cough)

【Flat EEG: Electrocerebral inactivity】
Recordings for at least 30 minutes.

No EEG reactivity to intense somatosensory or auditory stimuli.
ECI at levels higher than 2μV with the instrument set at a sensitivity of 2μV/mm.

【Apnea test】Absence of respiratory drive at a PaCO2 level greater than 60 mmHg

【Observation period】
Re-evaluation is essential. The interval between exams is 6 hours or longer
(for children < 6 yrs, 24 hours)