### Regular Article

# Beyond the Twilight Zone: A Comparative History of Brain Death Policies in Japan and the United States

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#### Abstract

In Japan and the United States, brain death policy development has resulted in a situation where two opposing positions co-exist regarding the notion that "brain death is human death." Although discussions on this topic have only taken shape in the United States this century, similar discussions were already underway in twentieth-century Japan. This paper explores how public debates in the United States caught up with those in Japan. Comparative analysis of the processes leading to the development of brain death criteria reveals that, in Japan, the creation of medical evidence-based criteria occurred in a smooth, sequential manner—first addressing cases with a short "alpha period" (i.e., the period from brain death leading to cardiac death), with many brain death cases defined as those caused by primary lesions, unlike in the United States where lesions (i.e., multisystemic disorders) were deemed responsible for a majority of brain death cases. By clarifying the historical context, this study shows how this difference in definition has led to the co-existence of two opposing policies. In Japan, various technological developments extended the "alpha period" by the 1990s, while controlling it with appropriate ethical considerations. This period—referred to as the "twilight zone"—was never widely accepted in the United States, but Japanese attempts to extend the "alpha period" were incorporated into bioethics commission reports in the 2000s.

Keywords: Bioethics policymaking, Brain death, Comparative history, Harvard Criteria, Takeuchi Criteria

## 1. Introduction

According to Eelco F. M. Wijdicks, "brain death" is the vernacular expression for irreversible loss of brain function (2002: 20). In the United States, brain death was accepted as human death in the 1980s through a number of policy debates surrounding the official recognition of criteria for the determination of brain death. In 1968, the Ad Hoc Committee of Harvard Medical School to Examine the Definition of Brain Death (hereinafter, Harvard Ad Hoc Committee) published a set of criteria for defining an irreversible coma (hereinafter, Harvard Criteria) (Ad Hoc Committee of the Harvard Medical School to Examine the Definition of Brain Death 1968). In 1981, the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research established in 1978 (hereinafter, President's Commission) submitted a report entitled, *Defining*  *Death: A Report on the Medical, Legal and Ethical Issues in the Determination of Death* (President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research 1981). These publications paved the way to validate a framework that accepted brain death as human death on the basis of neurological criteria (Bernat et al. 1981).

However, criticisms of this framework emerged in the 1990s (Emanuel 1995; Shewmon 1998; Singer 1994; Truog 1997), resulting in further public debate in the 2000s. In 2001, the George W. Bush administration appointed an advisory committee, known as the President's Council on Bioethics (hereinafter, President's Council), to replace the National Bioethics Advisory Commission. In 2008, the President's Council published a report—Controversies in the Determination of Death: A White Paper-in which the majority of committee members continued to support the conventional neurological criteria, while the minority sided with aspects of the recent criticisms (President's Council on Bioethics 2008). The incorporation of these criticisms resulted in the report's inclusion of opposing positions regarding the acceptance of brain death as human death.

Policies drawn up in the United States in the twentyfirst century—in which two opposing arguments regarding brain death co-exist—are similar to the final Japanese brain death policies developed at the end of the twentieth century. In Japan, the criteria for determining brain death were developed in 1985 by the Brain Death Study Group, under the purview of the Ministry of Health and Welfare (MHW; now Ministry of Health, Labour and Welfare). Named after the head researcher,

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these criteria are known as the "Takeuchi Criteria" (Ministry of Health and Welfare 1985). In 1990, the Prime Minister's Office (PMO; now Cabinet Office) established the Provisional Commission for the Study on Brain Death and Organ Transplantation (hereinafter, Provisional Commission on Brain Death), which submitted a report entitled "Important Issues Regarding Brain Death and Organ Transplantation: A Report" in 1992 (Provisional Commission for the Study on Brain Death and Organ Transplantation 1992). While many committee members supported the acceptance of brain death as human death, this report also devoted an entire chapter to clarifying the stances of the minority who oppose this idea.

Although Margaret M. Lock (2002) conducted a similar analysis of the changing understanding and criteria of brain death over the twentieth century, few have compared the historical development of brain death criteria in Japan and the United States, or dealt with recent twenty-first century developments when doing so. In the United States, related studies have primarily focused on the process of creating neurological criteria in the last century (Bagheri 2003; Kimura 1991; Leflar 1996; Morioka 2001), leading researchers to conclude that the formation of a social consensus on equating brain death to human death has progressed smoothly. However, given the recent situation in both countries (i.e., the co-existence of opposing arguments), it may be fair to say that Japan was more deeply engaged in this discussion well ahead of the United States. As such, it is meaningful to revisit the process leading up to the public discourse divergence on the acceptance of brain death by

additionally considering recent events that contributed to the formation of a social consensus. Accordingly, this study presents a more adaptive, up-to-date historical account of how the composition of brain death policies in the United States evolved to resemble those of Japan. This is achieved through a comparative analysis of the processes leading to the development of brain death criteria in Japan and the United States from the 1960s to the 2010s, as well as of the discourses related to these processes.

# 2. The Process of Developing Brain Death Criteria in Japan and the United States

This study begins with a comparison between the processes that led to the creation of brain death criteria in Japan and the United States. Table 1 summarizes the development of brain death criteria in both countries from 1968 to 2011. In Japan, sequential steps were followed: first, by addressing cases of brain death caused by primary lesions in the brain, and then by expanding the scope of review to include those cases categorized as having a poorer prognosis (Takeuchi Criteria and their variations). Meanwhile, in the United States, neurological diagnostic criteria were adopted first, and the accepted medical standards were then revised according to the most recent cases. This approach was taken in the United States because the cumulative number of cases of brain death due to secondary lesions (i.e., multisystemic disorders) exceeded that involving primary lesions. Inevitably, both types of cases were handled together in order to verify the medical validity of the Harvard Criteria.

In Japan, the criteria for determining brain death caused by primary lesions—which result in conditions such as brain contusion, brain hemorrhage, and brain tumors—were established by academic societies in the 1970s and based on case studies from neurosurgical facilities. Established by the MHW in 1969, the Council on Organ Transplantation published an interim report in 1971 that mentioned both the argument equating brain death to human death and the opposing position that regards only cardiac death as constituting death (Tokizane 1975). The report suggested the following regarding the need to formulate standards to determine brain death:

Regarding the timing of the pronouncement of death, the idea that "brain death" should be regarded as "human death" instead of the conventional definition of "cardiac death" has attracted public attention with the opportunity to consider cardiac transplantation. We have spent a lot of time discussing this idea...but reached no conclusion that represented the position of the Council. However, some argued that even if it were justifiable to treat "brain death" as "human death," at this stage, we have no choice but to use the conventional definition that equates "cardiac death" to "human death," as there currently exist no established criteria for determining "brain death" (Tokizane 1975: 74).

**Table 1.** Chronological Table of Key Publications Related to the Development of Brain Death Criteria in Japan and the United States (1968–2011)

Year	Japan: Publications; Organizations	United States: Publications; Organizations
1968		A Definition of Irreversible Coma: Report of the Ad Hoc Committee of the Harvard Medical School to Examine the Definition of Brain Death [Harvard Criteria]; Ad Hoc Committee of the Harvard Medical School to Examine the Definition of Brain Death
1971	<i>Interim Report</i> ; The Council on Organ Transplantation, Ministry of Health and Welfare (MHW)	
1974	Criteria for the Determination of Brain Death in Acute Major Primary Lesions of the Brain [Prototype of the Takeuchi Criteria]; Japanese Society of Electroencephalography and Electromyography	
1977		An Appraisal of the Criteria of Cerebral Death: A Summary Statement (Harvard Criteria, revised edition); Joint Study Led by the National Institute of Neurological and Communicative Disorders and Stroke
1981		Defining Death: A Report on the Medical, Legal and Ethical Issues in the Determination of Death; President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research
1985	Guidelines and Criteria for Diagnosis of Brain Death [Takeuchi Criteria]; Brain Death Study Group, MHW	
1987		Guidelines for the Determination of Brain Death in Infants and Children (first edition); American Academy of Pediatrics (AAP)
1992	Important Issues Regarding Brain Death and Organ Transplantation: A Report; Provisional Commission for the Study on Brain Death and Organ Transplantation, Prime Minister's Office	
1995		Determining Brain Death in Adults (first edition); American Academy of Neurology (AAN)
2000	Criteria for the Determination of Brain Death in Children [Takeuchi Criteria Pediatric Version]; Study Group on the Criteria for the Determination of Brain Death in Children, MHW	
2008		Controversies in the Determination of Death: A White Paper; President's Council on Bioethics
2010		Determining Brain Death in Adults (second edition); AAN
2011		Guidelines for the Determination of Brain Death in Infants and Children (second edition); AAP

With regard to the notion that "brain death should be considered as human death," both sides of the argument have co-existed in Japan from the outset of public debate. Addressing this, the Japanese Society of Electroencephalography and Electromyography (currently, the Japanese Society of Clinical Neurophysiology) provided case studies from neurosurgical facilities in 1974, the results of which were used to create criteria for determining brain death (Ueki 1974). Since most cases collected in this study were based on primary lesions, the scope of the criteria was inevitably limited to those cases (Takeuchi and Bai 1985). As Kazuo Takeuchi, a medical scientist who cooperated in this project, recalled:

> When we developed the criteria of the Japanese Society of Electroencephalography and Electromyography, we collected roughly 200 cases; most cases involved the three major primary lesions in the brain (brain contusion, brain hemorrhage, and brain tumor) that cause brain death. Certainly, there were a few cases involving secondary lesions, but even if we were to conduct a retrospective study, the number of those cases was so small that we wouldn't have been able to say, responsibly, that "these criteria should be fine" (Takeuchi and Bai 1985: 40).

According to Takeuchi, his presentation of these results at the Congress of Neurological Surgeons received the following comment: "This type of study is valuable, because special circumstances exist in Japan that involve, first of all, different types of brain damage compared to other countries—especially the United States" (Takeuchi and Bai 1985: 46).

In the 1980s, some consideration was given to

expanding the scope of the aforementioned criteria to include cases of brain death resulting from secondary lesions, such as cardiac arrest and asphyxia leading to brain hypoxia. In 1983, Takeuchi became the leader of the MHW's Brain Death Study Group and conducted a nationwide case study targeting centers other than neurosurgery facilities (Takeuchi et al. 1987). This study revealed that 660 of the 718 cases (91.9%) collected up to that point were due to primary lesions, while only 58 cases (8.1%) resulted from secondary lesions. Moreover, among 20 cases, in which more than 15 days had passed between the onset of brain death and cardiac death, four (20.0%) were cases of children younger than six years of age. A set of criteria excluding these pediatric cases was published in 1985. The so-called Takeuchi Criteria covered both types of lesions as the causes of brain death subject to assessment. However, these criteria merely functioned as a tool to medically determine brain death and included an annotation that the criteria themselves are not meant to propose a new concept of "human death."

In its 1992 report, the Provisional Commission on Brain Death requested the formulation of criteria for determining brain death in children younger than six. Consequently, a new version of the Takeuchi Criteria applicable to pediatric cases was created in the 1990s. As leader of the Brain Death Study Group examining pediatric cases, Takeuchi responded by initiating another nationwide study in 1998, leading to the publication of the corresponding criteria in 2000 (Takeuchi et al. 2002). In the 1998 study, cases in which the duration from the onset of brain death to cardiac arrest was  $\geq$ 30 days were defined as "long-term brain death"; 25 of 116 cases (21.6%) met this definition.

Compared to these developments in Japan, brain death criteria in the United States did not necessarily come under scrutiny in a step-by-step fashion in terms of medical validity. Indeed, Henry K. Beecher, a medical scientist who served as the Chairman of the Harvard Ad Hoc Committee and wrote the first criteria of this kind, barely referred to actual cases of brain death. In fact, he was more heavily focused on contributing to the development of a social consensus, while ensuring that the medical validity of the criteria was of secondary importance (Beecher 1969). Nonetheless, in 1972, the Task Force on Death and Dying of the Institute of Society, Ethics, and the Life Sciences (hereinafter, Hastings Center)-of which Beecher was a memberpublished a report collating the conditions that brain death criteria should provide ("Refinements in Criteria for the Determination of Death" 1972). However, their recommendations failed to reflect the increasing number of brain death cases. Reflecting on this limitation, the group noted "evidence building" as a challenge for the future. Around the same time, a collaborative research group of the National Institute of Neurological and Communicative Disorders and Stroke (NINCDS: currently, the National Institute of Neurological Disorders and Stroke) conducted a nationwide case study in an attempt to verify the validity of the Harvard Criteria. This study found that only 230 of 503 (45.7%) patients had brain death caused by primary lesions, while 273 (54.3%) had brain death due to secondary lesions, accounting for more than half of all cases ("An Appraisal of the Criteria of Cerebral Death" 1977). Thus, in the United States, brain death criteria were verified in their original form, which included the "secondary" aspect in their scope (i.e.,

brain death caused by secondary lesions), without going through a process in which the focus was first placed on developing criteria in line with the pathology of primary lesions, as was the case in Japan.

In the 1980s, an attempt to reach an agreement regarding neurological criteria for brain death was made at a national level, while simultaneous efforts were made to develop a framework that would gradually improve the medical validity of those criteria. The President's Commission reviewed existing guidelines in the process of publishing a report on the definition of death in 1981, recommending that brain death criteria be established in compliance with the accepted medical standards at the time. Thereafter, and until relatively recently, academic societies began expanding the latest knowledge on brain death resulting from primary lesions without changing the outline of the neurological criteria approved by the Commission. Reviewing available cases, the findings of the American Academy of Pediatrics (AAP) and American Academy of Neurology (AAN) were reflected in the respective brain death criteria for pediatric patients and adult patients (American Academy of Pediatrics 1987; Wijdicks 1995). This development was repeated even after the President's Council published a new report on the controversies surrounding the definition of death in 2008. Subsequently, the AAN and AAP both revised their criteria in 2010 and 2011, respectively, in accordance with the review of brain death cases to conform to the latest medical standards (Nakagawa et al. 2011; Wijdicks et al. 2010).

# 3. Historical Factors Influencing Brain Death Policies in Japan and the United States

In Japan, medical evidence on the prognosis of brain death grew in conjunction with the criteria for determining brain death. However, these developments did not occur in the same way in the United States. The reason for this discrepancy is that the academic discourse on how to handle a body during the period between brain death and cardiac death emerged during the development of the Takeuchi Criteria in Japan. Although similar insights were beginning to emerge in academia in the United States, their impact was not significant enough to influence the updating of the Harvard Criteria. Just one and a half months after the world's first successful heart transplant surgery in South Africa in December 1967, Koichi Bai, a Japanese legal scholar, coined the term "alpha period" in reference to the period from the onset of brain death to cardiac death (Bai 1968). With regard to legitimizing both the offer of an individual to donate an organ prior to the pronouncement of brain death, as well as the act of extracting the individual's heart upon cardiac death on the basis of familial consent, Bai proposed the following:

With regard to heart extraction, what if we suppose there is another period—the "alpha period"—between life and death, rather than approaching this in a manner that separates two scenarios ([removing the heart] from the living body vs. from the dead body)?...If this "alpha period" is brought up as an issue, the beginning should be the onset of brain death, and the end should be the onset of cardiac arrest...In reality, this may represent a very short time. However,

by logically acknowledging this brief period, proper adjustment of one's rights and obligations regarding the removal of organs as an act of disposal of the body during this period is attempted (Bai 1968: 20).

At one point, Bai placed his proposal on hold after being questioned on the feasibility of the brain death criteria upon which his idea was premised, which was in accordance with medical standards at the time (Bai 1970). Later, attending a meeting of the Provisional Commission on Brain Death as an expert in October 1990, Bai introduced the concept of the "alpha period" as requiring reevaluation by committee members in light of the circumstances leading to the establishment of the Takeuchi Criteria. Elaborating on his views, Bai noted that there was a considerably close association between his theory and the negative stance toward the criteria ("they not only provide a medically valid means to determine brain death but also point to a new concept of human death") (Provisional Commission for the Study on Brain Death and Organ Transplantation 1991).

When the criteria were published in 1985, Takeuchi noted that, in clinical practice, he was mindful of the way bodies were handled during the period between the onset of brain death and that of cardiac death. Indeed, he confessed that in the neurosurgery ward of Kyorin University Hospital, where he served as Director, the 30 to 40 patients who suffered brain death each year all remained in their beds until they reached the point of cardiac death, with no attempts made to encourage organ donation.

> Since I myself have a "wet" feeling common to neurosurgeons, at present, we do not unplug respirators. Hence, we do not harvest organs

from brain-dead patients. I have no doubt that all physicians in our facility, myself included, are in consistent agreement with the idea that we "wait for cardiac arrest"...Of course, when brain death is pronounced, we also prepare ourselves for the moment when the heartbeat stops ("the heart will soon stop beating") at the same time, but that period is..."necessary as a sort of ceremony," so to speak. In other words, it is the grace period before the heart stops (Kato et al. 1986: 40–41).

Granted, the legal scholar's notion of accepting the "alpha period" had some correlation with the clinical attitude of the medical scientist who had spearheaded the development of brain death criteria. However, the circumstances that allowed academic discourse to continue in a manner that transcended the barriers between legal and medical disciplines may have also promoted the sequential development of brain death criteria. Consequently, the scope of the criteria that initially addressed cases with poor prognoses (i.e., those with a short "alpha period") was expanded to include those with a longer "alpha period."

Meanwhile, a similar discourse regarding the appropriate means of handling the body of an individual transitioning between life and death started developing in the United States following the publication of the Harvard Criteria, primarily among members of the Hastings Center. In 1970, medical scientists like Robert S. Morison and Leon R. Kass openly debated whether the Harvard Criteria really deserved their status as the standards for judging human death (Jonsen 1998). While Morison argued for a greater focus on the process of an individual gradually approaching death, Kass maintained that the period between life and death should be regarded as an "event" (Kass 1971; Morison 1971). As such, Kass adhered to the traditional understanding of the concept of death, as follows:

> There is no need to abandon the traditional understanding of the concept of death: Death is the transition from the state of being alive to the state of being dead...There is no real need to blur the distinction between a man alive and a man dead or to undermine the concept of death as an event. Rather, we should ask, in the light of our traditional concepts...whether the persons in the twilight zone are alive or not, and find criteria on the far side of the twilight zone in order to remove any suspicion that a man may be pronounced dead while he is yet alive (Kass 1971: 699–700).

Kass used the term "twilight zone" to describe the period of transition between being alive and being dead in the context that this transition represents a continuous event. In order to dispel the concern that the patient may be pronounced dead while still alive, Kass argued that the brain death criteria instituted should have sufficient validity to overcome this "twilight zone."

The term "twilight zone" was also used by Hans Jonas (1974), a philosopher, who opined that an individual on the verge of death should not be considered dead so long as they remain "the organism as a whole"—that is, as long as they maintain circulatory and other functions. Accordingly, Jonas made the following assertion:

> Reality of certain kinds—of which the life-death spectrum is perhaps only one—may be imprecise in itself, or the knowledge obtainable of it may be...I am challenging the undue

precision of a definition and of its practical application to an imprecise field...In short, what is here kept going by various artifices must with the caution due in this twilight zone—be equated with "the organism as a whole" named in the classical definition of death much more so, at least than with any mere separable part of it (Jonas 1974: 136–137).

Jonas maintained that in situations in which the lifedeath spectrum itself is in an "imprecise field," the definition of death should not be applied to this "twilight zone" before adequately securing the validity of brain death criteria. Both Kass and Jonas were deeply insightful about the handling of the body during the period between brain death and cardiac death. Similar to the "alpha period" proposed in Japan, the term "twilight zone" can be understood as a concept representing this period in the United States.

However, there is no clear evidence indicating that these academic discourses had any influence on the subsequent creation of the Harvard Criteria. In 1972, Kass and Alexander M. Capron, a legal scholar, published a proposal that equated the spontaneous cessation of brain function with death only when traditional cardiac death does not apply due to the artificial maintenance of respiratory and circulatory functions (Capron and Kass 1972). Capron later became the secretary-general of the President's Commission, where he advanced the position that the cessation of brain function was accepted as the only neurological basis for the definition of death. In 1974, Willard Gaylin, a medical scientist, proposed the term "neomort" to refer to a brain-dead individual, focusing on the potential of utilizing his or her body (Gaylin 1974).

However, Jonas condemned this proposal, stating that such an idea could give rise to a "simulated life" that falls between life and death, and that it was an attempt to prolong this state as long as possible in order to bring about various benefits (Jonas 1974). Consequently, the term failed to gain traction or elicit further academic debate (Youngner et al. 1985).

# 4. Subsequent Development of Academic Discourse Regarding Brain Death in Japan

In 1992, when the Provisional Commission on Brain Death submitted a report to the Prime Minister, Japan had made some developmental advances in medical technologies that improved the circulatory dynamics of brain-dead patients, thereby prolonging the period leading to cardiac death. Consequently, concerns were raised about whether attempts to prolong this period were necessary, while bioethical discussions to address this issue were initiated with extraordinary speed. As such, it is worth further exploring developments in the academic discourse surrounding brain death in Japan.

Published in 1985, the Takeuchi Criteria omitted children younger than six years of age—who tend to have a relatively favorable brain death prognosis (i.e., longer "alpha period")—from its scope. Following the publication of these criteria, Yasuhide Nakamura, a medical scientist, and members of the pediatric science group at Tokyo Metropolitan Neurological Hospital conducted a pioneering study in which they observed changes in the pathological conditions of the brain in two pediatric patients using head computed tomography (CT) scans: one patient (male, aged one year and three months) spent 109 days in the "alpha period," while the other (male, aged one year and six months) spent 60 days in this state (Nakamura et al. 1986). This study suggested that a deeper understanding of circulatory dynamics during this period may promote the refinement of the aforementioned criteria. As the authors asserted:

> These two patients in our study are excluded from the [scope of] criteria set forth by the Brain Death Study Group of the MHW due to their ages. However, there is no age limit on the state of illness (i.e., brain death) itself...At least, it is not currently possible to deny the possibility that some kind of nerve control may exist in circulatory function even after brain death, and we anticipate that we will obtain further insight on the circulatory dynamics in the period from brain death to cardiac death (Nakamura et al. 1986: 2146–2147).

A similar study was conducted by Tsuyoshi Sugimoto, a medical scientist, and the emergency medicine group at Osaka University following the publication of the Takeuchi Criteria. In 1986, this led to the discovery that co-administration of epinephrine or antidiuretic vasopressin (an hormone) with catecholamine could help maintain the circulatory function of brain-dead patients for an average of 24.1 hours (Yoshioka et al. 1986). By the mid-1990s, they had discovered that even after a patient reaches a state of brain death, their organs-with the exception of the liver and lungs-could essentially maintain normal functioning without any major changes over the course of many months (Sugimoto 1995). Reflecting on the history of the University's technological developments, Sugimoto argued that their attempts were only possible in Japan, where it is strongly recommended or accepted

that the families of brain-dead patients seek to prolong the "alpha period" rather than acknowledge patient death. As Sugimoto stated:

> Fortunately or unfortunately, brain death is not yet recognized as human death in Japan, and organ transplantation is also unlikely to be performed on a large scale for the time being. Many families wish for physical life extension even if the patient is brain dead, so it is often necessary to keep the body (patient) alive for several weeks before they can accept death... In developed countries in Europe and the United States, when brain death is pronounced, the decision is made either to harvest the organs or let the patient die. Thus, it is not possible to study the very changes that occur in the braindead body. In that sense, we think that our study is important and meaningful (Sugimoto 1995: 118–119).

However, in opposition to this trend, a bioethics collaborative at the University of Tokyo initiated a new debate in 1991. Led by Akira Akabayashi, a medical scientist, and Masahiro Morioka, a philosopher, the collaborative claimed that unnecessarily extending the "alpha period" of a brain-dead body might conflict with the ethical principles of the "dignity of the remains," asserting:

> One assumption is that the "dignity of the remains" must be respected. What viewpoint should be adopted with regard to the BDB [brain-dead body] when its use involves significant medical "invasion"? Does this constitute legal "damage" of the body?...The concepts of invasion and damage were used

before the notion of BDBs arose. Invasion was used in reference to the "brain alive" and damage was used in reference to the "heart dead"... Would the use of a BDB for storage and as a factory be considered a violation of the dignity of the remains, even though such uses do not, in themselves, constitute invasion? Is time a factor? The option "the shorter the time of use the better" may derive from concern about the dignity of the remains (Akabayashi and Morioka 1991: S534–S535).

The collaborative clearly distinguished the concept of legal damage based on the moment of cardiac death from that of medical invasion performed on the patient before brain death. In this way, the collaborative attempted to increase the integrity of the arguments of Bai (i.e., that the process from the onset of brain death to the end stage of damage is a series of events) and Takeuchi (i.e., that the extent of invasion of brain-dead patients should be minimized) from a bioethics perspective. In doing so, they presented a framework that could help address the development of advanced technologies, while reducing the concern raised by critics-like Sugimoto-that such highly technical attempts to maintain the circulatory function of the body during the "alpha period" might constitute the futile prolongation of that period. In this context, the challenge was the application and advancement of the arguments of Gaylin and Jonas regarding the appropriate use and treatment of human bodies.

# 5. The Co-Existence of Positions in Supporting and Opposing Brain Death in the United States

This section explores recent developments in brain

death policies in the United States, with a focus on comparing them with those in Japan. In the process leading to the President's Council submitting a new report regarding the definition of death in 2008, "Position One"—that is, that brain death should not be recognized as human death—was newly established in a way that reflected Japan's development of brain death criteria, as well as the views based on cases of long-term brain death. Simultaneously, "Position Two"—which supported neurological criteria in deference to the demand for organ donors—was also maintained, thus resulting in the representation of both positions in policymaking.

The President's Council accelerated its efforts to discuss brain death policies in 2005, when Edmund D. Pellegrino, a medical scientist, was elected chairman. Presenting his arguments to the Council, D. Alan Shewmon, a medical scientist, had a particularly large influence on the Council's 2008 White Paper regarding controversies in the determination of death (Rubenstein et al. 2006). Shewmon (1998) collected 175 cases of brain death from across the world, all of which involved a duration of one week or longer from the onset of brain death to cardiac death. Citing the Takeuchi Criteria, he summarized the characteristics of primary and secondary lesions as the causes of brain death. According to this study, 24 of the 56 cases (42.9%) for which sufficient clinical information was available had been attributed to primary lesions, while 24 cases (42.9%) had been attributed to secondary lesions; the remaining eight cases (14.2%) were due to unknown causes. Based on these findings, Shewmon (1998) advocated that the cessation of brain function does not directly lead to human death. This study included the

case of a male patient diagnosed as brain-dead at the age of four years and six months. When Shewmon introduced this case at a President's Council meeting in November 2007, the patient had been in this state for thirteen and a half years (President's Council on Bioethics 2007). Apart from this case, the main focus of Shewmon's presentation was on the case of a Japanese boy at Showa University who was brain-dead and transitioning to home care (Abe et al. 2006). As Shewmon explained:

> A boy aged six years and four months experienced acute necrotizing encephalopathy at the age of one year and one month. The patient was clinically diagnosed as brain-dead. However, his heartbeat had been sustained and he was transferred to a home mechanical ventilator therapy at the age of four years and seven months. Despite his requirement for pituitary hormone administration and tube feeding, he was placed on a home mechanical ventilator therapy while receiving treatment from his home doctor (Abe et al. 2006: 1682).

Shewmon showed images of the child to Council members and discussed his physical development. He effectively delivered his perspective through this Japanese long-term brain death case, arguing that "Any biologist would say, 'Well, of course this is a living organism. This is a comatose apneic living organism" (President's Council on Bioethics 2007).

In his personal statement appended to the 2008 report, Pellegrino referred to Jonas' argument, which states that an empirical understanding is required about the transition from life to death; that is, the "imprecise field" or "twilight zone." Similarly, he positioned Shewmon's theory as powerful support for "Position One." However, he also conceded that disregarding Two"—which "Position relies on traditional neurological criteria-is unrealistic and dismissible considering the social demands surrounding organ donation (Pellegrino 2008). Consequently, Pellegrino suggested that opportunities to provide organs for transplantation should be secured, provided that the Dead Donor Rule (DDR)-that is, that the organ is removed upon the pronouncement of death (Robertson 1999)-be upheld, by developing methods to keep organs viable for as long as possible. As such, public discussions on brain death converged to comprise both supporting and opposing positions in the United States, with prospects similar to the stance of Japan towards the development of medical technologies (as advocated by Sugimoto in 1995).

## 6. Limitations

The present analysis was carried out with a focus on the intricacies of brain death policies. Therefore, discourses regarding relationships between these policies and the practice of organ transplantation were excluded as being beyond the scope of this study.

## 7. Conclusion

This study compared the processes that led to and shaped the development of brain death criteria in Japan and the United States. Compared to the United States, Japan established medical evidence-based criteria in a smooth and sequential manner, initially focusing on cases with a short period between the onset of brain death and cardiac death. What this analysis shows is that experts in the twenty-first century United States gradually caught up with the pioneering efforts of twentieth-century Japan, including technical advances that had extended the "alpha period" and the development of measures to address them. Such an attempt by bioethics pioneers to understand the "twilight zone" holds a lesson for future generations, particularly from the perspective of promoting international communication, collaboration, and consensus-building.

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