Delays in Brain Death Certification in an Opt-out Deceased Organ Donation System: Causes, Ethical Problems, and Avoidance

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Received: 27 March 2018 / Accepted: 8 October 2018 / Published online: 28 October 2018
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Abstract

Brain death certification can be a clinically and ethically challenging affair. Healthcare workers are expected to refer patients for brain death certification to identify potential organ donors, but family members may be ill-prepared for this turn of events. Already distraught families may not appreciate delays in brain death certification, but such delays are common because of the need to manage the patient's altered physiological state to allow testing. Opportunities for donation are sometimes lost because of the unnecessary delay. With focus on an opt-out organ donation law, we discuss causes of delays in brain death certification, and the ethical issues faced by clinicians in using tests to certify patients. To resolve the issues, we argue for the use of supplementary confirmatory tests as part of a more protocol-driven approach to brain death certification to avoid delays. Such tests should be regarded as part of the donation process funded by the state.

Keywords Brain death · Organ donation · Brain Death Certification

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Introduction

Brain death or death by neurological criteria is widely recognized both medically and legally as death of a person. While a distinct assessment, brain death remains controversial because of its association in clinical practice with deceased organ donation; its declaration is the principal prerequisite to allow removal of organs for transplantation. In view of competing conceptions of what it means to be dead, the ethical debate on brain death has focused on whether this is the appropriate point for deeming a person dead for the purpose of donation (Truog and Miller 2013). This paper will discuss the ethical and moral issues arising from delays in brain death testing in Singapore, where clinical tests are relied on without turning to appropriate use of supplementary tests for radiological evidence of brain death. Delays in brain death certification (BDC) can be defined as delays that prevent the establishment of a brain death diagnosis within a reasonable amount of time. While it should be based on certainty in terms of removing all clinical doubts, BDC should be established as soon as possible to obtain closure for families. At the same time, in the context of ethical issues discussed in this paper, delays can unnecessarily compromise the viability of potential organs procured.

The jurisdictional and policy context of Singapore with respect to how death is defined and certified and how deceased organs may be procured is important in understanding the ethical and social issues at hand. The first definition of death was enacted in 1987, under Section 3 of the then Human Organ Transplant Act (HOTA) (Kaan 1992). This adhered to the common law medical definition widely espoused, as a cessation of circulation, which is also known as “heart death.” However, since a brain-dead patient can be kept “alive” artificially, the common law definition of death came into question, and in 2002, the Interpretations Act came about that defines death in its Section 2A(1): “For all purposes, a person has died when there has occurred either a) irreversible cessation of circulation of blood and respiration in the body of the person; or b) total and irreversible cessation of all functions of the brain of the person” (www.parliament.gov.sg). Subsection 6 of the Interpretations Act 2A provides for the requirement for two independent and qualified practitioners to carry out the determination of brain death, while Subsection 7a allows the Ministry to prescribe the “criteria for determining the total and irreversible cessation of all functions of the brain of a person...”

The Interpretation Act sets out the Interpretation (Determination and Certification of Death) Regulations, which in turn set out conditions to be satisfied before brain death is to be determined and certified and the clinical criteria for doing so. The regulatory requirements and standards notwithstanding, brain death testing and certification can be a clinically and ethically challenging affair. Brain stem death causes a series of pathophysiological changes, such as hypernatremia, hypotension, and diabetes insipidus, all of which need to be managed to enable diagnosis and to optimize organ procurement (Gill 2004). As a prelude to deceased organ donation, BDC can be difficult and circuitous, and prone to variable performance (Bratton and Chestnut 2014). Delays in BDC can affect the viability and quality of organs procured, and cause distress to already distraught families and other loved ones awaiting BDC and closure (Goila and Pawar 2009). Before the HOTA was introduced, which provided for the current “opt-out” donation system, deceased organs for transplants in Singapore were procured through opt-in donations under the Medical (Therapy, Education and

Research) Act (MTERA) which was enacted in 1972. However, the MTERA proved inadequate to meet the organ transplant needs of the population. The HOTA has undergone several amendments (in 2004, 2008, and 2009) to increase donation rates. Amendments included the extension of coverage to other organs—liver, heart, and corneas—in addition to kidneys; inclusion of non-accidental deaths; inclusion of Muslims, who were previously exempted due to religious reasons; and removal of the upper age limit of 60 years for deceased donors. Under the Act, all citizens and permanent residents who have not opted out of the HOTA will be required to have their organs donated in the event that they die in a hospital, their organs are deemed suitable for transplant, and there are suitable recipients. With this background, the ethical and social concerns can be better understood when delays occur in the process of BDC, which, as a clear precursor of deceased organ donation, is not clearly defined (Rosenberg 2009).

Our interest in this paper is to make an ethical case for a protocol to ensure the prompt confirmation or certification of brain death. We locate our argument within the context of Singapore's opt-out donation system, and stringent clinical criteria and procedures for BDC (Chin and Kwek 2007). We first describe the wide variability in neurological criteria and procedures for BDC at the international level. We then explain why delays in BDC often happen, and why clinicians may be reluctant to carry out certain interventions, such as rapid hypernatremia control, to avoid delays in certification. On the basis of avoidance of harm to families, clinicians, and potential transplant recipients, we argue that delays in BDC should be avoided as much as possible through a more systematic, protocol-driven approach. Supplementary radiological tests to confirm BDC should be used as part of the protocol and such tests should be funded by the State as part of potential donor management.

Brain Death Certification: International Variability

Brain death occurs when a person suffers an irreversible, catastrophic brain injury which may be caused by an accident or illness. Some countries adopt the criteria of “whole brain” (total and irreversible loss of all brain functions, including the brainstem) for BDC, whereas others regard cessation of brainstem reflexes as sufficient (Chua 2015). Other than variation in neurological criteria, diagnostic testing requirements vary worldwide in “the need for repeat neurological examinations, the minimum interval between examinations, the minimum interval between examinations, and the number and type of personnel needed for certification” as well as confirmatory testing as a requirement (Kaan 1992).

As Chua et al. write, the current international variability in criteria and procedures for BDC presents “a rather disconcerting state of affairs” given the critical decisions and implications that follow diagnosis (Chua 2015). When brain death is certified, families will be asked to accept that their loved one has died, and that further treatment is futile and should be withdrawn. In an opt-in system, if the patient's vital organs are assessed as viable for transplantation, cardiopulmonary support may be maintained, and families are informed of the dead person's prior expressed wish to donate, or they would be asked to agree to donation. Under the HOTA's opt-out system, all Singaporean citizens and permanent residents who turn 21 years of age and who have no

psychiatric disorders will be automatically enrolled as deceased organ donors, unless they opt out from donation. Under the current system, transplant coordinators will broach donation as a consequence of the law with the family, after a combined end-of-life conversation with physicians, where the physicians shall declare the patient brain-dead and offer condolences (Chin and Kwek 2014).

For sure, BDC should be rigorous and accurate; premature declarations, which had happened in certain countries, harm or wrong the patient and may erode public trust in deceased organ procurement as an ethical and legitimate practice (Burkle and Pope 2015). In an era where many countries experience a profound shortage of transplant organs, it is also important for BDC to be done with urgency yet as precisely as possible for ethical and moral reasons. Reduction in the management time of potential organ donors, which may be broken down into the time from the injurious event causing brain death to brain death certification, and the time from brain death certification to organ retrieval, will increase donation and reduce distress to families and clinicians, as described below (Kwek et al. 2009).

Delays and Distress

In a 2001 Editorial in *The New England Journal of Medicine*, Alexander Morgan Capron wrote that “If one subject in health law and bioethics can be said to be once well settled and persistently unresolved, it is how to determine death has occurred” (Capron 2001). Before determining brain death, numerous clinical criteria should be fulfilled: a serious damage should have occurred, the patient must be unconscious with no cranial reflexes, breaths should not be spontaneous other than preserved by a ventilator, there should not be any confounding drugs or metabolic conditions causing such a state, etc. Once these factors are ruled out, further clinical tests are carried out for confirmation (Wijdicks 2001). Brain death testing and certification is thus a complex process with a series of testing procedures to ensure a correct diagnosis. There is certainly no consensus among legal jurisdictions on the determination of death, especially in Asian countries, where cultural norms and contexts may weigh in on the acceptance of a patient’s brain death when the heart is still beating, particularly when organs are to be taken as mandated by law. Herein lie the ethical and social tensions that can arise when delays occur in confirming brain death. In the context of Singapore, such tensions may be exacerbated by policy (made in relation to the practice of the HOTA) whereby discussion of organ procurement or mention of the law to the family is not permitted until the patient is officially certified as brain-dead (elaborated below).

Despite decades of progress in the medical field after the first publication of the Harvard Report on the definition of irreversible coma, there is still uncertainty on what constitutes an irrefutable determination of brain death. Even in the Uniform Determination of Death Act in the USA, there is no clear definition of the specifics of the clinical diagnosis. Brain death is assessed clinically by obtaining irrefutable evidence of catastrophic brain damage that can lead to brain death, and also by performing a battery of clinical bedside tests required to test brain stem reflexes (Chin and Kwek 2007). Initial testing is conducted, usually by members of the primary care team (such as the intensivist) when a patient’s neurological condition is suspected to have evolved to brain death. If brain death is diagnosed, the primary care team will inform the family of

their diagnosis, and independent verification will be carried out if the patient is a potential donor under the HOTA. As mentioned, it is mandated by the Interpretation Act that for BDC involving removal of organs for donation, two medical practitioners with prescribed postgraduate medical qualifications in BDC, and who are independent from care of the patient and his or her potential organ donation (to avoid conflict of interest), are needed to review and confirm the diagnosis.

While BDC need not be a protracted affair, it is difficult and circuitous in many cases as the patient's bodily state is often not appropriate for BDC. This includes normal vital signs, temperature, and blood tests. During the brain death process, a series of physiological alterations will occur that contribute to the patient's hemodynamic and metabolic instability (Moraes 2009). Electrolyte imbalances are often severe and rapid after brain death. Within a few hours, serum sodium levels can be elevated to hyponatremia levels. This is primarily due to severe paucity of a crucial hormone from the pituitary gland which ceases to function immediately at brain death (Burkle and Pope 2015). Getting the independent certifiers on site will take time, and during that time, the elevated sodium level needs to be as close to normal as possible for BDC, which applies equally to whole brain death or brain stem criteria. Control of hyponatremia is also important to preserve the quality of any donor organs; studies have shown poor graft outcome in transplanted organs from hyponatremic patients (Kotloff 2015). Hyponatremia can be artificially corrected by means of a dextrose infusion which dilutes the blood. However, clinicians may not find this ethically acceptable, as it may be regarded as treating a patient with a specific blood test not in the his or her interest to achieve the required result for brain death testing.

Delays in BDC may also arise because of biochemical interference. Opioids and sedatives are often initially given to patients with serious brain injury, e.g., anti-epileptic medication for all traumatic brain-injured patients prior to their deterioration to brain death. The drug effects need to clear off as they may confound the results of brain stem death testing. This may take many days, and patients often succumb to cardiac death before BDC is completed. Although the HOTA covers cardiac death donation, recovery of organs does not usually occur in these cases because of their poor viability for transplantation.

Lastly, an overly fastidious approach to BDC creates delays. Whether a patient satisfies physiological and biochemical preconditions for BDC is a matter of clinical judgment, and physicians, particularly those inexperienced with brain death testing, may want the patient to be in an "ideal" condition to declare brain death. Kwek et al. (2009) wrote:

Unfamiliarity and variability in the conduct of brain death certification, often leads to delays in confirming brain death, either through unnecessary checking and correction of biochemical parameters or from unnecessary ordering of supplementary tests. These delays often result in anger and frustration among families of potential donors who may already be lukewarm or openly hostile to organ donation. Some may even at this juncture withdraw their consent to donation and request for withdrawal of cardiopulmonary support. (Kwek et al. 2009).

Kwek et al.'s claims are consistent with the experience of two of the authors of this paper (Siddiqui and Ng) who practice as ICU physicians. (Chin and Kwek 2014). Like

other intensivists, they are professionally expected to test for brain death for those who fit the criteria, identify potential donors to transplant coordinators who would request for formal certification by two independent certifiers (rostered for BDC by the hospital), and provide organ preservation interventions for the potential donor, as an implementation of the HOTA. In their experience, family distress produced by delays in BDC is exacerbated by the family's (initial) unawareness of the relationship between diagnosis and the organ donation. Under current policy, those involved in the care of the patient are not allowed to communicate this relationship, which, as mentioned, is performed by transplant coordinators. Whether intensivists should take a leadership role in facilitating agreement with organ donation with the family, given their closer relations, has been the subject of ethical debates, although it is practiced in countries like Spain (Streat 2004). The aforementioned two authors have experienced families' anguish, anxiety, stress, and distress which amplified the longer they waited in uncertainty about their relative's brain status in the period between initial diagnosis and confirmation. Delay also plays a role in feelings of betrayal to the family experienced by both parties by the turn of events as transplant coordinators bring up the requirements of organ donation under the HOTA following BDC.

Ethical Grounds to Prevent Delays in BDC

It should be obvious by now that a key reason for avoiding delays in BDC is to reduce the risks of losing potential donors and preserve the quality of the organs procured, which in turn affects the mortality and morbidity of patients receiving the organs. Although this point—it is ethically undesirable to lose organs for transplant that could save or improve lives—may be trite analysis-wise, it is still an important one to make: to draw the link between BDC and downstream ethical consequences to society of not taking a prompt and timely approach to overcome its technical hurdles. At the time of writing, many patients are waiting for organs with organ failure (<http://www.liveon.sg/>), which also causes diminishing public resources for dialysis treatment for kidney failure patients (the most common group of patients needing a transplant) due to the rising incidence of chronic diseases like diabetes (Khalik 2017); the average waiting time for a kidney donation is 9 years. (It may be noted that there are significant barriers to improvements in deceased donation rates in Singapore, including the fact that the country has one of the world's highest life expectancies (National Registry of Diseases, Singapore 2013).) Even if it results in more organs retrieved, avoiding procedural delays in BDC, to reiterate, does not justify taking away the time required to ensure that the BDC is done properly and accurately.

The second ethical reason is a physician's moral duty to minimize distress to families. Wilkinson (2011) has argued that family distress produced by lack of power to disagree with donation of their deceased relative's organs should not be morally trivialized; imposition of further distress on the family at an already difficult time is a wrong in itself. He also argues that the consequentialist reason of losing donors as a result of public knowledge or scandals involving family distress, supported by a family's claim against imposition of such distress, may outweigh the prior expressed wish of the relative to donate and his or her "personal sovereignty" over his or her body. In an opt-out system, there is an unavoidable degree of uncertainty over the deceased's

actual wish or preference. Despite existing for many years and extensive public education, a significant number of people in these countries remain unaware of the opt-out law or are ignorant about what it means and entails (Kwek et al. 2009). Uncertainty of a patient's wishes or ignorance of the law had played a part in the distress of families and their conflict with hospital staff following enforcement of the law in some countries (Koh 2012).

While the opt-out law will be enforced in most circumstances in these countries, families would be given time to accept brain death as death of their relative and deceased donation, to the extent that this accommodation does not significantly affect the viability and quality of the organs for donation. By minimizing management time from brain death occurrence to BDC, family are likely to be afforded more time to be counseled, and to grieve and accept organ recovery, which would alleviate their distress.

Specific Measures to Avoid Delays in BDC

Currently, there exist no institutional guidelines on medical futility, and many practitioners are in dispute within specific medical contexts regarding futility. The diagnostic process involved in BDC is lengthy, confusing, and time-consuming. Whether strategies to avoid delays in BDC will be implemented depend on the “buy in” of clinicians who are involved in care of dying or brain-dead patients and in brain death testing and certification. Clinicians' moral disagreement with the HOTA has been noted and is a reason why they are reluctant to make referrals for BDC; cardiopulmonary support may be withdrawn to avoid brain death testing and the possible imposition of a perceived “double tragedy” on the family (Khalik 2015). Such behavior could also be explained by a fragmented understanding of the roles they occupy in the healthcare system or seeing their primary role as advocates of the patient's best interest (which donation may not be due to uncertainty of the patient's wishes) rather than serving society in helping to procure organs (Kwek et al. 2009 and Qing 2015). The ethical significance of the grounds to prevent delays can be further drawn out from the following points which flesh out what we consider to be an ethical approach for BDC:

1. Understandably, it may be psychologically difficult for clinicians who have been so involved in the care of the patient to switch from patient-centered care to potential donor management mode. To act in their patient's interest, clinicians should attempt to obtain certainty while at the same time retain urgency in BDC. Clinicians should consider the dignity of the person in death (by not prolonging inappropriate life support) as reasons against delays in BDC. A survey on BDC in certain countries with clinicians on hospital BDC roster found that the majority regarded rapid correction of hyponatremia and use of drugs to reverse the effects of opioids or sedatives solely to allow BDC as unacceptable (Chin and Kwek 2007). Reasons were not given in the quantitative survey, but it is likely that they found these interventions counterintuitive to patient care, as the patient is not as yet clinically recognized as dead. Furthermore, preconditions for BDC may not necessarily be achieved with the use of the interventions: sodium levels may climb steeply despite correction, precluding confirmatory testing (Machado 2010). Importantly,

- hypernatremia correction, if done rapidly, may cause cerebral edema and worsen the brain conditions to the point of contributing to brain death itself (Kim 2006).
2. Strategies could be implemented to avoid delays in BDC that would lessen a clinician's moral discomfort and risk of harm to patients. For example, the above survey on BDC in Singapore recommended the incorporation of threshold values of physiological and biochemical preconditions that clinicians in general would find acceptable to proceed with brain stem reflexes testing into the BDC protocol which would help reduce an overly cautious approach (Chin and Kwek 2007). The mandated clinical tests and criteria for BDC as set by the Interpretation (Determination and Certification of Death) Regulations leave a wide margin of uncertainty and delay due to the physiological irregularities that may occur in certification and meeting the prerequisite conditions before BDC. Other than causing distress, delays can be deemed as unfair from the families' perspective.
 3. Due to the various formalities required, the clinical tests can at times not be performed. When appropriate physiological and biochemical thresholds cannot be attained to test brain stem reflexes during independent certification, definitive supplementary or auxiliary tests for radiological evidence of brain blood flow could be used to confirm the primary care team's diagnosis of brain death, the latter of which should be performed according to strict clinical criteria and guidelines. Most certifiers however defer supplementary tests to the clinical tests. An empirical study could be done to understand why but cost may a factor—again, clinicians may not see the value of such a test in a patient-centric mode.
 4. It should be noted that Section 3A of the Interpretation (Determination and Certification of Death) Regulations states that BDC *shall* be established by either one of these supplementary tests – cerebral angiography or radionuclide scan – together with the clinical criteria when any of the criteria cannot be satisfied; or, when the suspicion “that the person's condition is due to depressant drugs, hypothermia or metabolic and endocrine factors” cannot be removed, or if it cannot be satisfied “that the person's cessation of spontaneous respiration is not caused by neuromuscular blocking agents or other drugs.” In other words, the regulations may be read as not only authorizing but as providing for the requirement of the use of supplementary tests for BDC under certain conditions. This is because it recognizes that under these conditions, these tests provide sufficient evidence that the criteria for brain death are already met. To the degree that this is so, we argue that such tests should be funded by the State, which is consistent with existing policy in Singapore (<http://agc.statutes.gov.sg>), donor's family will not be charged for hospital bills for any organ removal-related procedures and tests. As part of potential donor management, supplementary tests to confirm brain death should not be charged to the family, even if donation does not proceed. Such a policy could be justified on the grounds of reducing harm to families and promoting solidarity and reciprocity in deceased organ donation.

Conclusion

We have discussed here ethical and practical reasons against certain procedures for the prompt diagnosis of brain death. BDC could however be done in a way that balances

certainty of brain death and promptness in certification. We argue here that supplementary tests to confirm brain death should be done as soon as possible to avoid delays so as to facilitate closure for the family; to prevent complications and build-up of public opposition to an opt-out system; and to obtain good-quality organs for recipients in a timely manner. To the extent that use of supplementary confirmatory testing is consistent with the spirit and provisions of the Interpretative Act and its regulations and with the HOTA, it should be funded by the State. Our recommendation for a protocolized approach for avoiding delays in BDC should result in improving family acceptance and prevent further emotional and moral distress caused by the delays to the families as well as to the medical team, thereby indirectly aiding a smoother transition to deceased organ donation.

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