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Chapter

Ethical Controversy Surrounding the Revision of the Uniform Determination of Death Act in the United States

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Abstract

This chapter reviews fundamental ethical controversy surrounding the ongoing effort to revise the Uniform Determination of Death Act in the United States. Instead of focusing on the process of the revision itself, the chapter explores the underlying ethical debate over brain death that has been ongoing for many decades and finally culminated in this revision. Three issues are focused: the requirement for consent and personal exemptions before applying brain death for the diagnosis of death; redefining the areas of the brain that have ceased to function in the definition of brain death; and codifying the American Academy of Neurology as the authority to issue the standards of the diagnosis of brain death. The chapter concludes that allowing the personal choice of death determination gives a pragmatic compromise to the disputed definition and practice of diagnosing brain death. So long as all risks and imperfections of the diagnosis are accepted through the consenting process, there is nothing ethically objectionable to continuing the current practice of diagnosing brain death as a successful tool to facilitate heart-beating organ donation without violating the dead-donor rule. By contrast, precluding personal choice and imposing legal restrictions to consent and exemptions would further erode public trust.

Keywords: brain death, uniform determination of death act, informed consent, conscientious objection, organ donation

1. Introduction

"An individual who has sustained either (1) irreversible cessation of circulatory and respiratory functions, or (2) irreversible cessation of all functions of the entire brain, including the brain stem, is dead. A determination of death must be made in accordance with accepted medical standards" (The Uniform Determination of Death Act 1981).

The Uniform Determination of Death Act (UDDA—as quoted above) is, as of middle 2023, under review by the Uniform Law Commission (ULC) for revision.
The uniform laws in the United States are meant to be a non-binding model law, which can guide each state to legislate its statutes [1]. The current UDDA was drafted by the President’s Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research and approved by the ULC in 1981. Subsequently, 36 states, the District of Columbia, and the US Virgin Islands have adopted the UDDA. The remaining states have enacted similar legislation or court decision [2]. While the concept of brain death was introduced in the 1950s and ’60s as an irreversible coma [3], the UDDA formally codified this concept throughout the United States. The UDDA has been pivotal since its adoption to guide medical practice in neurocritical care and organ transplantation. Below the surface of this “uniformity” of the acceptance of the UDDA, however, it has been rigged by vigorous and persistent controversies and genuine and sound disagreement from the beginning [4]. From the standpoint of bioethics, this controversy itself has always been a major area of ethical deliberation, but what has made this controversy further more challenging is the fact that brain death has been successfully integrated into clinical practice. Without this practice, heart-beating organ donation would have been almost impossible, and the intensive care unit would have been overcrowded with patients whose disposition is uncertain. This stark contrast between clinical success and unresolved ethical disagreement makes this debate on the definition of death so entangled.

The purpose of this chapter is not to update the ongoing effort to revise the UDDA. The revision should have been completed by the time this chapter is read. Moreover, it is entirely unclear how many states are willing to enact the revised UDDA. It is possible that the issues taken up in this revision will continue to be debated at state levels. Instead of focusing on this short-term development, this chapter concentrates on the ethical analysis of three focal points that triggered the current revision: (1) persistent functioning of the hypothalamus despite the requirement of the cessation of all functions of the entire brain; (2) specific professional organizations are designated as the sole authority for the standards of the diagnosis of brain death; and (3) notification to the next to kin and consent is required to initiate the evaluation for brain death [5]. While these points have emerged recently in medical-legal cases, underlying ethical issues that culminated in them have been debated for decades. The main focus of this chapter is those fundamental ethical controversies underlying the current revision of the UDDA. Of particular, the third item, consent and related issue of exemption, is most pertinent to clinical ethics, and this will be discussed in detail.

The plan of this chapter is as follows. The next section discusses the controversy surrounding the consent and exemption for diagnosing brain death. The issue is not just a narrow procedural question, even if the ULC might leave it to state levels if they view it as a relatively minor point. The fundamental ethical issue underlying the consent and exemption about diagnosing brain death is the personal choice of how we die, or death is determined. It is at the core of end-of-life ethics. The third section discusses the problem of brain regions being included for irreversible cessation. The fourth section discusses the possible revision to add specific medical organizations as the sole authority of the protocol for diagnosing brain death. While these two sections deal with some technical issues, there are also important ethical concerns. The final section will concisely present overall moral viewpoints of this long-standing controversy over brain death, which is just rekindled by the revision of the UDDA, and final thoughts for a pragmatic solution.
2. The ethical controversy over the consent and exemption of brain death

2.1 Background of consent and exemption about brain death

The overarching concept of consent and exemption is the personal choice regarding brain death. Should individuals be allowed to choose whether they are diagnosed and declared dead by neurologic criteria? Some commentators, notably Veatch, Ross, and others [6, 7], have long advocated personal choice among three definitions of death: circulatory, whole-brain, and higher-brain. They have argued that personal choice of the definition of death should be legally permitted. However, the higher-brain definition has never gathered broad support. It defines irreversible coma, or persistent vegetative state (PVS), as death. However, there are many technical difficulties: First, the diagnosis of PVS or the irreversibility of coma is notoriously inaccurate, with up to 40% of diagnoses turning out to be errors. Moreover, even when the diagnosis is correct, up to 24 percent of cases regain consciousness in 2 years. Although functional imaging tests have been used to increase the accuracy of diagnosis and prognosis, no reliable data is available for the rate of false positives in long-term follow-up [6]. Although Veatch and Ross continue to favor the higher-brain definition, they acknowledge that it is not a feasible option until we know more about how to diagnose irreversible coma without false positives. Therefore, we will focus on the first two definitions. Moreover, since circulatory death has been the traditional definition and is still by far the most widely used one, it is the default definition unless brain death is used. For this reason, we will only focus on whether there should be any personal choice to avoid using brain death as the definition of death (and by default, circulatory death is chosen).

2.2 Argument for personal choice

In this section, we will examine common reasons that personal choice for brain death—through exemption or consent—is desirable. So far, personal choice is not admitted to the use of neurologic criteria for death diagnosis except for several states where exemption is possible: New Jersey [8], New York [9], California [10], and Illinois [11]. All mention religion as the reason for exemption, consideration, or accommodation in using neurologic criteria to remove life support. California also mentions cultural practices and New York mentions moral objection. Before going into the details of exemption and consent, let us consider why personal choice is desirable. In general, the current trend in clinical medicine is to accommodate patients’ preferences so long as it does not create secondary problems, such as violating others’ rights and excessive resource allocation. That is precisely why patients generally prefer “personalized” medicine and informed consent or decline in almost every aspect of clinical medicine. Of course, the diagnosis and definition of death are quite different from other therapies and diagnoses. However, the question is whether there are specific reasons for excepting death diagnosis and what is common and different from other therapies and diagnoses.

The final moment of human life is profoundly personal, spiritual, and valued. How a person is judged to have expired and classified as deceased is a moral value judgment. As Veatch and Ross appropriately pointed out [6], no matter how precisely neurological criteria identify an irreversibly non-functional brain and how many reasons are given that a body without a functioning brain is equivalent to a dead
body, neurology or any other knowledge of medical science cannot and should not
determine that the person who possesses that brain is alive or dead. That judgment is
totally one of value, answered by each person’s moral, philosophical, and religious
convictions. Death is fundamentally a process, not a momentary event [12]. It is only
made to appear a moment for the convenience of the law and society. If there is room
for personal choice for such a moment, society and the law should accommodate it.
Of course, that does not mean that anyone can arbitrarily decide the moment of their
death. We already have a universal and indisputable moment of death since immemo-
rial: death by circulatory criteria. It is a sudden departure introduced by brain death
from this time-honored tradition over the past several decades that triggered all
these challenges. This discord is not necessarily from certain cultural, religious, or
philosophical traditions but the tradition of the entire humanity. It is only a matter
of fundamental morality to accommodate such a value choice in our multi-cultural,
value-diverse, and democratic society, as opposed to suppressing any diverse values
through “physician power” [13].

2.3 Argument for consent before applying the neurologic criteria of death

It is unclear at this time whether the personal choice for the definition and
diagnosis of death is considered by the ULC morally important in our society. If
they consider it important enough, the ULC might incorporate personal choice as an
exemption because several states have already implemented it. Regarding consent,
the current proposal is only about its rejection, stating that “consent is not required to
initiate an evaluation [of death by neurologic criteria]” [5]. Such a clause has already
been adopted by the state legislature in Nevada [14]. Whether the revised UDDA
would incorporate these points or leave it to state decisions is unclear. Regardless, let
us consider using informed consent before diagnosing brain death because informed
consent is primarily a matter of medical ethics, and the law plays a role when a legal
dispute arises.

From the viewpoint of the proponent of informed consent before performing
the diagnostic procedure of brain death, it is plain that informed consent is required
as much as any other medical procedure of similar importance [15]. Needless to say,
informed consent is used in almost every aspect of clinical medicine today, as long
as the intervention involves any risk or significant consequences to patients. Consent
is not limited to physical and mental risk but the risk of diagnostic errors, the conse-
quences of false positives and negatives, and the setback of personal interest.

Obviously, most patients and families want to avoid a false-positive diagnosis
of death or classifying a living patient as dead. Compared to other diagnostic tests,
knowing the risk of false positives is paramount. They will likely require their
physicians to rule it out completely. In this regard, three critical pieces of informa-
tion must be disclosed to the family before the diagnostic protocol of brain death
is initiated. First, unlike other diagnostic tests, we do not have well-controlled
clinical trials to accurately evaluate the rate of false positives and negatives of the
diagnosis of brain death. This lack of definitive data is because almost every case
of brain death is disposed of promptly after the diagnosis, either by terminating
life-support or removing vital organs for transplantation. There have been anecdotal
rare cases that were kept on life support, such as pregnant women and those cases
whose families insisted on life support. There has been no systematic study to repeat
the diagnostic test for brain death in intervals to see if the diagnosis is reproduc-
ible. Second, repeated reports of violating established diagnostic protocols [16–18]
implicate procedural risks. Additionally, there are several reported cases of diagnostic errors [19, 20].

As with other medical procedures, the procedural risk of the apnea test, which is crucial to diagnosing brain death, is an indispensable part of informed consent. The apnea test induces hypercapnia by stopping the ventilator after full oxygen saturation. Hypercapnia triggers the respiratory drive if the brainstem is still functioning. If there is no respiratory movement in the chest and abdomen, the test is positive and consistent with brain death. The risk comes mainly from the fact that hypercapnia can raise intracranial pressure, which is part of the causative pathophysiology of brain death [21]. The test can further aggravate already elevated intracranial pressure, perpetuating the underlying pathophysiology of brain death. It also causes hypotension and arrhythmia, which could be fatal.

The risk from the apnea test may indeed be small, but it is not negligible. Many very low-risk diagnostic procedures, such as treadmill exercise tests and lumbar puncture, are routinely done with informed consent. The magnitude of risk is always compared to the benefit of the procedure. It is this relative magnitude of the risk versus benefit that decides whether the procedure is acceptable or not. As long as the apnea test involves greater than zero risk, it has to be compared to the zero benefits of the apnea test for most patients. For them, this risk/benefit ratio becomes infinitely large. It is also true that the diagnosis of brain death could be beneficial if the patient is known to have the wish to become a heart-beating organ donor. This fact can be ascertained, and the risk/benefit ratio is estimated during the conference for informed consent only before the procedure.¹

2.4 Argument against informed consent before initiating the diagnostic procedure of brain death

Opponents of the consent requirement, who proposed to state explicitly that consent is not required in the proposed revised UDDA [5], give several reasons. According to Lewis and Pope, (1) consent will limit “physicians’ power to determine death,” (2) “inciting families to seek injunctions to continue organ support after brain death,” and (3) “forcing hospitals to dispense valuable resources such as ventilators, beds, medications, and clinician time, to dead patients” [13]. In a separate paper, Lewis, Bonnie, and Pope [22] give the following four reasons: “[Requiring consent would] (1) challenge the integrity of DNC [death by neurologic criteria]; (2) increase the number of objections to DNC; (3) necessitate allocation of health care money and resources to patients who may be dead in lieu of those who are alive; and (4) create a double standard for death determination, given that consent is not required for determination of death by cardiopulmonary criteria.”

These points can be grouped under three headings: (1) Integrity argument, or the challenge to physician’s unrestricted “power to determine death”; (2) Symmetry argument, or consent requirement has to be the same for brain death and circulatory death; and (3) Utilitarian argument, or consent requirement will prolong the hospital stay and incite family’s objections by delaying the diagnosis of brain death and consume more resources. In what follows, we will examine each of these three objections.

¹ Information provided before informed consent does not necessarily have to be comprehensive, but because the risk is misdiagnosing life as death, the standards can be the highest for some patients. Also, some families may forego informed consent due to poor prognosis, and as with other informed consent, patients have every right to waver informed consent at any time and for any reason.
2.4.1 Integrity argument

This argument stems from a typical confusion and conflation between declaring death, which is a legal procedure and diagnosing the state of the brain as brain death, which is a medical procedure. It is true that the legal declaration of death follows the medical diagnosis of death in usual circumstances, but not always. The most well-known example is when the patient is pregnant. A physician may medically diagnose brain death but may not legally determine that the patient is dead. Nor does the law require physicians to declare death immediately after the diagnosis of death. If that were the case, all dying patients would have to be admitted to the ICU to avoid missing the moment they die. But, of course, it is absurd, and many patients die at home, and a physician declares death probably the following day. It is left to the discretion of physicians when they make a diagnosis of death. Informed consent is entirely about the medical diagnosis and has no force over the legal determination of death. Only after the diagnosis of death has been made does the legal duty to issue a death certificate starts. Consent or refusal does not directly affect the “physician’s power” to legally determine death. A physician has full power to declare death whenever necessary information becomes available for death. If the patient declines the test for brain death, the physician still has the full power to declare death when the patient’s heart stops irreversibly.

The revised state law of Nevada [14] states, “brain death determination is a clinical decision that does not require the consent of the person’s authorized representative or the family member with the authority to consent or withhold consent.” It is unclear why “a clinical decision” does not require consent when other numerous clinical decisions routinely require consent, including a clinical decision as simple as removing a wart. The ULC should be astute enough to spot this logical flaw.

2.4.2 Symmetry argument

The argument claims that because consent is not required for the diagnosis of circulatory death, neither should it be for the diagnosis of brain death. There are several problems in this argument. First, it is incomprehensible why two different practices must be symmetrical in consent requirements. The diagnosis of circulatory death and brain death is indeed the diagnosis of death. But that does not entail that the consent requirement must be the same. There is no logical or practical reason for this symmetry. This argument is equivalent to demanding the same consent requirement for a colonoscopy and a stool blood test because they both diagnose colon cancer. It is false because a colonoscopy involves much more risk than a stool blood test even when they diagnose the same condition.

Second, this argument neglects the fundamental reason a certain intervention does not require consent. Besides the risk of intervention, as already discussed above, the presence of an alternative is critical. If there is no alternative to an intervention, consent is moot. Almost every medical intervention has an alternative: no intervention. The diagnosis of circulatory death is a rare exception: no alternative. Everybody acknowledges that someone has undergone circulatory death when they do. The body becomes cold and rigid, followed by putrefaction. Nobody can ignore this reality. There is no qualm that the permanent cessation of the heart and breathing is the exceptionless human destiny.

The opponents of the consent requirement want to argue that brain death also comes with no alternative. But of course, unlike circulatory death determination and
like any other medical intervention, a valid alternative for diagnosing brain death exists: not to do it. No intervention means not proceeding to the diagnostic procedure of brain death and continuing life support, waiting for circulatory death unless the condition improves, preparing for non-heart-beating organ donation if the patient is a qualified donor, or transitioning to palliative care. They also neglect that circulatory death sometimes requires consent. When a do-not-resuscitate (DNR) order is placed, circulatory death is diagnosed without confirming its irreversibility. In this case, there are clear risks (the heart could still be restarted if resuscitation was done) and an alternative (trying to restart the heart). Consent for this protocol of diagnosing circulatory death makes perfect sense exactly because there are risks and alternatives. It is false to claim that circulatory death is always diagnosed without consent.

2.4.3 Utilitarian argument

As quoted above, the opponents of the consent requirement have argued that consent would “necessitate allocation of health care money and resources to patients who may be dead in lieu of those who are alive” [22]. It is true that the sooner we diagnose a patient dead, the more we can spare healthcare resources. Should we reallocate resources from “patients who may be dead” to those who are alive by diagnosing death sooner than later? What is problematic about this apparently correct argument? Nobody would disagree that it is important to spare medical resources and refrain from wasting them. However, it would be controversial to do so by diagnosing someone as dead hurriedly when the family has no idea why the patient is dead before the heart stops. The family wants to have a death diagnosis later than sooner. By definition, circulatory death never precedes brain death. It is logical for an unprepared family to choose circulatory death, which is the latest and default death. It is against the fundamental moral principle of clinical medicine to ignore such a basic human desire to delay the death of the loved one maximally. We cannot arbitrarily test every near-death patient for death sooner than later. The family wants to have a death diagnosis later than sooner.

Of course, that does not mean we must continue futile treatment indefinitely. There is a better way to conserve resources than unilaterally classifying a patient dead: transitioning to comfort care after a full agreement with the family. By doing so, there is no need to allocate the ICU resources and physician time to make an extra effort to make an unnecessary and risky diagnosis of brain death. Known organ donors are, of course, exceptions. If the patient is considered a heart-beating donor, diagnosing brain death could be beneficial to achieve his or her known wishes. There are no qualms about proceeding to the diagnosis of brain death. However, for most other cases, particularly when the patient is known to decline organ donation, it would be wasteful to test for brain death. Such patients are best handled with palliative care followed by the determination of death by circulatory criteria if further treatments are deemed ineffective.

What about “inciting families to seek injunctions to continue organ support after brain death,” which is one of the reasons not to offer consent, as quoted above? When we review those families who were “incited” and sought legal injunctions to continue organ support, such incitement was triggered not by well-conducted informed consent but by the lack thereof. In fact, there has been no informed consent before
brain death determination in those cases known from the court record. Consent was never the reason for inciting those families that took their cases to court. On the contrary, unilateral declaration of death by neurologic criteria without any agreement is the reason. Those cases are more of the reason that we need to explain in detail what entails brain death diagnosis, and all questions are answered before proceeding to the procedure.

Additionally, such disagreement about death determination often comes from those families in cultural, religious, and racial minorities who hold different values from the dominant social groups of the United States, such as many physicians and lawyers who are highly educated and belong to a higher socioeconomic class than those families. Instead of compassionately understanding their values and seeking common grounds through a conference for informed consent, those opponents of consent treat them simply as “incited families” and try to override them by “physician power.” Even when informed consent was not required, more compassionate and sincere communication before a brain death diagnosis might have averted such legal actions.

2.5 Argument for exemption from applying the neurologic criteria of death

Most proponents of personal choice for the definition of death, such as Veatch [6], have focused their argument not on informed consent but on the legal exemption from applying the neurologic criteria for death determination. In such arguments, the public is encouraged to decide in advance how death is determined so that this advance directive is honored when death comes. As mentioned in 2.2, four states, New Jersey, New York, California, and Illinois, provide exemption, consideration, or accommodation based on religious, cultural, or moral reasons. Exemptions are not in the proposed revision of the UDDA, but since they are already incorporated in several state laws, the ULC might incorporate them into the revised UDDA.

Before brain death was introduced, such diverse differences in death judgment among different traditions were rare. This was because circulatory death is mostly transparent and uniform with few and rare exceptions. There is little room for disagreement regarding death determination by circulatory criteria. Brain death is entirely different. The diagnosis of brain death and the determination of death by neurologic criteria are so removed from the transparency that unless the family and surrogate blindly trust the words of physicians, acceptance of death at the sight of numerous signs of life is an enormous challenge. Policy- and lawmakers may or may not consider the diversity of values, but certainly, a significant portion of the population would raise concern about treating a person whose brain is non-functional as dead if they knew the reality of the state of a brain-dead person. It is this diversity of values in this multicultural, multi-ethnic society of the United States that makes value-based exemptions much more important than in smaller and more homogeneous countries.

2.5.1 Argument for religious and cultural exemptions

The religious exemption has a special place in the United States due to the First Amendment of the US Constitution that separates the church and state. Under this special treatment of religion, it is often difficult to legally enforce some decisions, particularly those related to personal medical decisions, against religious beliefs. For example, the traditional Jewish view is that death occurs upon the separation of the
soul from the body. Some Jews accept only irreversible cardiopulmonary cessation as the definition of death. On the other hand, religion exceptionalism may be viewed as discrimination against non-religious people. Moreover, religion is notoriously difficult to define because it is inherently a cluster concept without sharp demarcation from non-religion. Religiosity is often a matter of degree. It needs to be clarified how a state defines religious objection and how it is determined and implemented. Is it necessary for a person to belong to a specific religious organization, or is occasional affiliation sufficient? Some people are raised in the family or culture of a certain religion. Is that enough to consider an objection from such people religious? Given such potential challenges surrounding the treatment of religion in uniform ways, an introduction of sweeping religious exemption may not be an ideal solution. Again, in our value-diverse society, a broader conception of the value-based objection, including moral, philosophical, conscientious, as well as religious objection, seems more desirable.

2.5.2 Argument for non-religious exemptions

In contemporary secular society, giving privileged status to any decision framed as “religious” became more controversial when the same privilege is denied if the decision is framed as non-religious. Aforesaid, California mentions cultural practices as a reason to “make reasonable efforts to accommodate”; New York mentions moral objection as the reason for “reasonable accommodation to the determination.” No state mentions philosophical reason or, more broadly, personal reason. That means that no state under the current UDDA will consider any objection based on a personal belief that brain death is not that person’s death.² Or suppose someone questions the sensitivity, specificity, and safety of the procedure of brain death diagnosis, or on the grounds of simple and basic risk-benefit analysis in medicine, and wants to opt out of such a death determination. In that case, there is no recourse for exemption from death determination by brain death. That is why Veatch and Ross [6] advocate all-encompassing conscientious clause or conscientious objection, as opposed to religious, cultural, or philosophical exemption.

2.5.3 Argument against exemptions from neurologic criteria of death

The same objections against consent can also apply to exemption. Many cases of extended somatic survival, such as Jahi McMath [23], invoked religious exemption in New Jersey. As long as the cost of sustaining somatic life is funded by health care insurance, which is the case in New Jersey, the utilitarian argument can also apply to exemptions. On the other hand, since exemptions are often invoked after the diagnosis is made, the integrity argument and symmetry argument against consent may not apply to exemption. Moreover, since religion has a special status in the US Constitution, opponents of consent do not voice their opposition to religious exemption, at least in the same tenor and rigor.

While this is not exactly the opposition, several practical and technical difficulties are involved in exemptions. First, how many of the general population would bother to register their preferences regarding the definition of death when brain death is

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² Brain death is deeply rooted in the Cartesian mind-body dualism that says that the thinking mind is the essence of being a human. Euroamerican centrism in philosophy tends to forget that this belief is only one species of metaphysical views among many others in the world.
relatively rare and often unimaginable? When only one-third of the population uses advance directives (AD) for end-of-life care [24], how much more is it unlikely that they think seriously about the definition of death? Brain death can happen regardless of age, for example, due to sudden subarachnoid hemorrhage, devastating brain trauma, drowning, and complications from surgical procedures. That means it is likely that brain death happens in a population without established AD. For this reason, it is further more difficult to register such a choice in advance before such an unexpected and rare event falls upon them.

Second, as many empirical studies indicate, the general public does not adequately understand the meaning and significance of brain death [25]. It is not uncommon that they confuse brain death with a coma and (persistent) vegetative state, such as Terri Schiavo. Laypeople (and most likely even many physicians) cannot differentiate between coma, vegetative state, brain death, and even locked-in syndrome by viewing bedside appearances of photos and video clips of those patients. With this level of general understanding of brain death, how can medical professionals rely on an AD of a patient regarding their preference for the definition of death? Third, as a well-known problem of AD, there are always difficulties finding such directives on time when brain death becomes rapidly imminent. Such an exemption status is only known through well-informed family members or other surrogate decision-makers who are familiar with the AD.

And lastly, it is unclear whether exemptions are also applied to minors. Those state laws do not say explicitly about minors. This is probably because the minor’s religious commitment is not reliable enough to grant a religious exemption. As often seen in cases of Jehovah’s Witness parents who refuse blood transfusions for their children, parental religious exemptions are often overridden by the court. It is unclear about the definition of death, but if New Jersey is any guide, unlike cases of Jehovah’s Witnesses, parental religious exemptions are granted for their children.

2.6 Exemption versus consent

The above contrast between exemption and consent has several important implications. First, informed consent is not a ceremony of signing paperwork. Informed consent is a process of bidirectional information exchange and frank dialog between the medical team and the family or surrogate to reach a common ground or shared decision-making. Exemption never comes with such a deliberative process between the family and medical team. If informed consent is done correctly, the resulting shared decision is based on precise information on the patient’s medical condition. It also reflects the particular preferences of the patient and the family facing the patient’s imminent death.

These patients have several options, depending on the patient’s condition and the availability of appropriate medical programs. First, as long as the patient is an organ donor, the diagnostic protocol for brain death can be started in a timely manner to fulfill the patient’s wishes to donate vital organs. If the patient is not deemed a heart-beating donor, they could still receive medical treatment with an expectant observation for spontaneous improvement, though this is uncommon as long as the patient is judged in imminent brain death. Once the family agrees that the prognosis is extremely poor regardless of brain death or not, transitioning to palliative care and eventually withdrawing life support is an important option. Of course, it is also

3 For an up-to-date review of changing classifications of the disorders of consciousness and other conditions that mimic brain death, refer to Kondziella and Stevens [26].
common that patients who miss the diagnosis of brain death for various reasons soon succumb to circulatory death. For those not candidates for heart-beating donation, a donation after circulatory determination of death without diagnosing brain death can also be discussed before transitioning to palliative care.

These are not abstract decisions on exempting from brain death in advance and are expressed in AD without any specific information regarding the context of the medical events and alternative choices. In contrast, religious exemptions and accommodations in current state statutes mostly refer to a special treatment regarding the timing of the removal of life support after the diagnosis of brain death. Of course, some religious exemptions, such as those of the orthodox Jewish community in New Jersey, are well known to local medical providers, and in such special situations, the entire process of diagnosing brain death may be exempted. In most other cases of religious and conscientious exemptions and accommodations, brain death is already diagnosed, but death is not legally declared, and life-supporting treatment continues. This fact is crucial for the utilitarian argument. Since consent or decline takes place before the diagnosis of brain death, it is improbable that those cases that decline brain death end up with a very long process of somatic support. They have several alternatives to brain death. In contrast, religious exemption cases, such as Jahi McMath case, have only one option: indefinitely continue life-support until cardiac arrest. Moreover, consent can achieve the purpose of exemptions and conscientious objections in most cases. Even if exemption status is unknown at the time of acute brain injury, and AD has not been established or located on time, consent can cover all the needs of exemptions and AD, as long as the surrogates properly execute their roles and decline consent.

From the viewpoint of the value of individual choice in medical care, and death determination in particular, all instruments are desirable, including AD with conscientious objection clauses and religious and cultural exemptions. Informed consent or decline immediately before the diagnostic procedure can ensure that the stated choice of these instruments is respected. However, it is unlikely that these will be incorporated into the revised UDDA. A likely scenario is to read that “consent is not required to initiate an evaluation” as given in the proposed revision [5]. If so, the issue of personal choice could be discussed at the level of state legislators.

Nevertheless, that does not mean the family cannot request informed consent. This proposed revision does not say that consent is prohibited. That means that the family may still request consent. If this happens, can the medical team refuse consent? It is an important open question in clinical ethics. Consent is not legally required, but what about a moral requirement, particularly if the family explicitly requests it? The law does not directly dictate most informed consent in clinical settings. Medical ethics primarily covers it. Depending on how the revision is worded and state laws are amended, medical ethicists might face the question of whether the medical team can refuse consent when the family requests it. Ethicists in Nevada might start seeing such cases since Nevada is so far the only state that explicitly mentions in the state law that consent is not required.

3. The controversy over the anatomic regions of the non-functional brain

3.1 The hypothalamic functions in brain death

The possible revision of the brain region pertains to a long-standing debate about whether “the cessation of the all functions of the entire brain” is indeed a necessary
and sufficient condition of human death. There are three categories of challenges. The first is that human death is only the irreversible cessation of circulatory and respiratory functions (the first definition of the UDDA), the second is the irreversible cessation of all functions of the entire brain (the second definition of the UDDA), and the third is the cessation of so-called the higher brain. As mentioned in 2.1, the higher brain definition has minimal support and is not considered for this revision. The debate continues, but by the legal authority of the UDDA, the whole brain criteria have been accepted for brain death, while the overwhelming majority of the population die from circulatory death. However, recent legal cases and case reports increasingly challenged the whole brain criteria because it became clearer that there are important areas of the brain that are not entirely non-functional in cases of brain death. Particularly at issue is the hypothalamus. Michael Nair-Collins group [27, 28] provided an extensive literature review, demonstrating that this part of the brain often survives brain death and continues functioning.

The hypothalamus is only a small part of the brain but has many integrative functions that are indispensable not only for the brain function but for the vital functions of the whole body. The hypothalamus controls the energy metabolism, fluid and electrolyte balance, thermoregulation (including fever responses), and the homeostasis of the neuroendocrine system. It controls the secretion of pituitary hormones, including gonadotropins, adrenocorticotropic hormone, thyroid-stimulating hormone, growth hormone, and prolactin.

One of the most important hormones for patients undergoing the pathophysiology of brain death is the synthesis of arginine vasopressin, which is sent through the axon to the posterior pituitary and released into circulation. Vasopressin maintains the homeostasis of plasma osmotic pressure. When this hormone becomes insufficient, diabetes insipidus (DI) follows. While DI is frequently seen in patients with brain death who continue to receive ventilator support, Nair-Collins’s group demonstrated that up to about half of the reported cases showed detectable vasopressin blood level, consistent with at least partially functioning hypothalamus [27]. Moreover, while quantification is difficult, reported cases of long-term somatic support after the diagnosis of brain death demonstrated puberty, menstruation, body growth, and temperature regulation, all of which would have been impossible without at least partially functioning hypothalamus and the pituitary gland.

3.2 Three options for revision

Given the possible survival of the hypothalamus after the diagnosis of brain death, there are roughly three options to address this problem. First, the test for the hypothalamic function is included in the revised UDDA to maintain the language of “all functions of the entire brain.” For example, the law will read, “... including the brainstem and hypothalamus.” The second option is to abandon the concept of “all functions of the entire brain” and to narrow the anatomical area to the brain stem, leaving off the cerebrum, including the hypothalamus, and the cerebellum without direct evaluation. This definition has been adopted in the code of practice for the diagnosis of death in the United Kingdom (UK) and is often called “irreversible apneic unresponsiveness,” an apt syndromic name. The third option is to keep the status quo, acknowledging that the hypothalamic function may remain in some cases. It is also possible to keep the current wording except for adding, “... excluding the hypothalamus.”

The proposed revision seems to combine the second and third options above [5]. The proposal keeps the current “all functions of the entire brain” but adds “leading
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DOI: http://dx.doi.org/10.5772/intechopen.1002031

...to unresponsive coma with loss of capacity for consciousness, brainstem areflexia and the inability to breathe spontaneously.” This version works in both ways: It is still about “all functions of the entire brain,” but the focus is only apneic unresponsiveness. It ignores the hypothalamus, but if it is challenged about its preservation, one could contend that “the focus is only the brain stem and apnea, not hormones.” At the same time, if it is challenged that this revision narrows brain death from the whole brain criteria to the brain stem criteria, it tries to escape the challenge by saying that the revision still keeps the language of “all functions of the entire brain.” They also propose a backup option to explicitly exclude “hormonal function” while keeping the whole brain language.

The first option to include the hypothalamus in “all functions of the entire brain” may not be seriously considered, probably because such a change requires the assessment of the hypothalamic function to be added to the protocol of brain death diagnosis. Such an addition would be a new challenge because the irreversible cessation of the hypothalamic function is probably more difficult to establish promptly than other brain functions, and further research is likely necessary.

3.3 Ethical analysis of the brain region to be evaluated

If the proposed revision that does not mention the hypothalamus but adds the language of apneic unresponsive coma were adopted, it would certainly face above mentioned challenges. The replies would be evasive at best and could be outright contradictory in that “all functions of the entire brain” is subtly narrowed to exclude the hypothalamic hormonal function and focus only on the brain stem and apnea. This version would not escape the criticism of an ad hoc makeshift revision only to smother the inconvenient fact.

Nevertheless, as mentioned earlier, “brain stem death” has been adopted in the UK all along [30]. This definition narrows down the brain region required to cease functioning irreversibly to the brain stem. One advantage of brain stem death is that the US definition becomes streamlined with the UK definition, foreshadowing the worldwide standardization of diagnosing brain death. Historically, there was a debate across the Atlantic in the 1970s and early 80s whether the brain stem criteria in the UK are equivalent to the whole brain criteria in the US. The difference between these two criteria appeared very significant, and some US physicians argued that the UK criteria would misclassify those who might recover later. There were anecdotal cases from the US where those diagnosed as brain death by the UK criteria were not quite brain dead, though these cases were later disputed [31].

In the end, however, this difference is, technically speaking, not so significant. First, these definitions only refer to the function, not the pathology of the brain. Brain stem death does not mean the pathology is limited to the brain stem. It only means that the evaluation is limited to the loss of brain stem functions, deep unresponsiveness, and positive apnea test. Second, the rest of the brain is inferred to have ceased to function based on the depth of coma, confirmation of severe enough lesions inside the skull by imaging tests, and exclusion of other miscellaneous conditions that mimic brain death. Historically, this is how the UK criteria evaluated the cerebrum, albeit indirectly, without ancillary tests such as EEG. In contrast, the US criteria for many years used ancillary tests, particularly EEG and brain blood flow tests, to ensure

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4 Karl Popper, one of the most influential philosophers of science, considers an ad hoc theory repair in the face of falsifying evidence is a mark of pseudoscience [29].
there is no electrical or perfusion activity in the cerebrum. However, in recent years, particularly after the revision of the American Academy of Neurology (AAN) guidelines in 2010, which discouraged ancillary testing except when a clinical examination is incomplete, the US guidelines are very similar to that of the UK.

The most important ethical question is whether the actual practice is what the UDDA stipulates. If the language of “all functions of the entire brain” is kept unchanged, yet in practice, the protocol leaves out the hypothalamus, it is a downright contradiction. For this reason, it is also possible to adopt a narrower version of the brain stem death and abandon “all functions of the entire brain.” Conceptually speaking, it is impossible for all brain regions at once to stop functioning at the time of diagnosis. Additional areas of functional survival can be discovered in some cases of brain death. Whether this fact is acceptable is a matter of value judgment and something physicians alone cannot and should not decide. It should be evaluated by those involved in the decision through informed consent and eventually by the informed public. Such uncertainty and inevitable imperfection of the diagnosis are more of the reason that informed consent and conscientious exemption are indispensable in diagnosing brain death.

4. Codification of the guidelines published by the AAN and affiliated organizations as the sole authority of the “accepted medical standards”

The proposed revision suggests codifying the current guidelines for brain death diagnosis published by the AAN and affiliated professional organizations as the sole standards. These guidelines would replace the “accepted medical standards” in the current UDDA. While most neurologists follow the AAN guidelines of 1995 [32] and its updated 2010 version [33], some specialists other than neurologists and particularly older practitioners still use the predecessor of the AAN guidelines, the Harvard criteria of 1968 [3].

The major differences between the Harvard Criteria and the AAN Guidelines are twofold: The former strongly recommends confirmatory EEG, which should be flat, and a repeat examination in 24 hours is required. When the UDDA was issued in 1981, medical consultants of the President’s Committee published their guidelines based on the UDDA in JAMA 1981 [34]. It was almost identical to the Harvard criteria, except that the observation period was shortened from 24 to 12 hours, except for anoxic brain damage. For example, one of the most authoritative textbooks of neurology, Principles of Neurology by Adams and Victor [35], gives the following instruction on the diagnosis of brain death in 1985, 4 years after the UDDA was released:

*The EEG is a valuable indicator of cerebral death and most institutions require proof of electrocerebral silence (ECS), also called a flat or isoelectric EEG... When examination has disclosed that all brain functions are absent, it should be repeated in 6 h, to confirm that the state is irreversible (p. 258).*

The first version of AAN Guidelines 1995 still recommended a repeat clinical evaluation 6 hours later, but it is now “optional.” Confirmatory tests are “not mandatory but desirable,” though EEG was no longer the first choice, replaced by cerebral angiography [32].

In the update of 2010, a repeat examination is no longer recommended, and an ancillary test is not required except when the clinical examination is incomplete for
various reasons [33]. This progressive minimization of the protocol bewilders those who have practiced neurology for decades. The only reason to justify this change is the assertion that there has been no case of diagnostic error (or classifying patients who are not dead as dead). As many critiques have already pointed out [36], and even the President’s Council recognized [37], the current practice of diagnosing brain death is a self-fulfilling prophecy: The patient is dead because we diagnosed so. There is no independent proof that such a diagnosis is not false positive because the evidence is all erased by promptly disposing of the body or subjecting it to organ procurement. As mentioned in 2.3, anecdotal cases of diagnostic errors have been reported [19, 20]. Moreover, the AAN’s main journal, Neurology, reported many reports of non-compliance to their guidelines [16–18].

Why has this ethical problem of the AAN guidelines persisted? The reason is that the guidelines were not created in a moral vacuum. It cannot remove itself from underlying professional interests: efficiency and ease of use. As mentioned in 2.4.3, the proponents of the AAN guidelines are eager to save resources by promptly disposing of any patients who might have brain death. The history of the brain death guidelines shows this priority of efficiency: The number of physicians was reduced from two to one, the number of examinations was reduced from two to one, and the use of ancillary tests was minimized from strongly recommended to none unless necessary. The only justification is always the same: no reported case of diagnostic error, even when there is no way of identifying diagnostic error.

However, as any physicians who have had the most basic education of the sensitivity and specificity of diagnostic tests know, if the specificity of a test is crucial, such as classifying the patient dead as opposed to alive, the test should have the highest specificity even at the cost of sensitivity. In other words, even if we may miss a case that is truly brain dead as still alive, we want to and must be positive not to misclassify a single case that is still alive as brain dead. A simple calculation of the specificity of repeat testing shows that the overall specificity of repeated testing is always greater than singular testing. If one wants to make sure to achieve the highest specificity, even if we do not know the value of specificity itself, repeating the test always increases the specificity and thus safety.

There is always a risk in legally authorizing one organization or a vested interest group as the sole authority of critically important medical practice. It is, of course, natural and understandable to maximize their vested interest, but there should be checks and balances against the inherent conflict of interest. At a minimum, such guidelines require close oversight by entirely independent ethicists and laypeople who have not participated in any practice of the legal, medical, or ethical aspect of diagnosing brain death. Such an oversight organization is critically important to judge whether the protocol is ethically acceptable given the nature of this diagnostic test, which defies formal evaluation for its safety, specificity, and sensitivity required for any other medical tests.

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Sp_{1\&2} = 1 - [(1 - Sp_1) \times (1 - Sp_2)] = Sp_1 \times Sp_2 - Sp_1 \times Sp_2. 
\]

This value is always greater than Sp_1 or Sp_2 alone; thus, the specificity of repeated testing (Sp_1\&2) is always greater than singular testing (Sp_1 or Sp_2). It is also the rationale to increase the specificity of a negative COVID-19 home test by repeating it in 48 hours.\footnote{Suppose Sp_1 is the specificity of the first test, Sp_2 is that of the second test, and Sp_1\&2 is the cumulative specificity of repeated test 1 and test 2 (we assume that Sp_1 and Sp_2 are different because the first and second brain death evaluation has different specificities due to rapidly changing condition of those patients). Sp_1\&2 = 1 – [(1 – Sp_1) \times (1 – Sp_2)] = Sp_1 \times Sp_2 – Sp_1 + Sp_2. This value is always greater than Sp_1 or Sp_2 alone; thus, the specificity of repeated testing (Sp_1\&2) is always greater than singular testing (Sp_1 or Sp_2). It is also the rationale to increase the specificity of a negative COVID-19 home test by repeating it in 48 hours.}
5. Insights into the ethical controversies behind the revision of the UDDA

5.1 Value or science

Several insights from this brief review can be extracted. The first insight is that the fundamental problem of the “science” behind the diagnosis of brain death is that it is “unscientific.” The diagnosis of brain death is indeed based on a large body of accumulated scientific knowledge regarding severe and devastating brain damage. That is not an issue. The issue is that the science of brain death confuses itself, whether intentionally or unintentionally, with a fundamental value judgment of what constitutes life and death. Humanity has many millennia of experiences and moral intuition to classify who is alive and dead. No doctors or scientists are required to classify these two distinct conditions. It has been done without any medical knowledge throughout the history of humanity. The alleged science of brain death has imposed its value in the name and the “clothing” of science to override this fundamental moral intuition.

It is sometimes pointed out that the debate over brain death parallels the debate over abortion. Of course, there is a morally relevant difference between the two. In abortion, the values of two lives (mother vs. fetus) are involved, whereas, in brain death, it is the value of the life of one brain-damaged person. However, an important moral feature is common in both abortion and brain death. It is primarily a value decision, not a medical or scientific decision. No amount of scientific and medical argument can overturn the underlying value judgment. Abortion seems to have already been treated under this assumption, yet the ethical debate of brain death has not reached this maturity. We are still under the illusion that, somehow, the science of brain death can tell that it is a person’s death. Under this illusion, those who do not accept brain death are considered “uneducated, unscientific”; therefore, their voices can be silenced by the legal and medical authorities. The proposal under review by the ULA suggests that the proponents of this revision want to enforce that brain death is primarily a medical and legal decision, and the value judgment of the patients and families is pushed behind.

Of course, that does not mean that personal values can define human death any way we want. We already have an excellent universal definition of death: circulatory death. Most people do not want to propose any further complex definition of death; most just want to die with a default definition, and indeed most do.

5.2 Brain death as a critically important and necessary instrument of medicine

What is the actual value of diagnosing brain death, then? Why must we diagnose brain death as soon as it is suspected in a patient with a devastating brain injury? The insight given from this review is that we need to come to this fundamental question. The answer is a logical consequence of what we have been doing over the past several decades: It is almost entirely to conserve healthcare resources and procure vital organs for transplantation. Diagnosing brain death is now an indispensable tool for these important utilitarian goals. Besides, there is nothing inherently and morally wrong in pursuing these goals per se. What is morally wrong with the proponents of the current proposal of denying consent and neglecting the specificity of the brain death testing is to disguise this practice as morally equivalent to diagnosing traditional circulatory death by making the practice appear “symmetrical” between brain death and circulatory death. Their naïve logic is that because we do not do this for circulatory death, we should not do this for brain death. Because of this superficial disguise by arranging the same practice for circulatory death and brain death, many inconsistencies came
out through legal cases and falsifying clinical cases. Instead of further enforcing this false narrative through legislation, it is necessary to come down to the actual goals of this medical practice: an ethical disposition of cases with devastating brain injury with dismal prognoses and heart-beating organ donations.

5.3 Pragmatic solutions to the current difficulties of brain death practice through informed consent

The above two insights, brain death as a value judgment and brain death as a crucial utilitarian instrument, suggest that informed consent before diagnosing brain death can solve most difficulties that the current effort to revise the UDDA addresses [38]. It is a voluntary contribution to the utilitarian goals through the consenting process. In other words, consenting patients are volunteering to be heart-beating organ donors through the diagnosis of brain death due to an extremely poor prognosis, whether or not they believe that brain death is equivalent to circulatory death for them.

5.3.1 Consent can subsume religious and conscientious exemption before the diagnosis

The first advantage of consent is that, as discussed in detail in 2.5, it takes place immediately before the procedure is prepared. The process of informed consent is a bidirectional information exchange, and what is discussed is entirely specific to what has happened to the patient here and now, as opposed to a hypothetical and abstract consideration about something that may not happen at all. Whether the exemption is religious, cultural, conscientious, or technical, the answer is the same: They are all given a chance to say “no” at the moment of the final pathway. Since the diagnosis of brain death never happens if the consent is declined, those patients who want to claim exemptions can have their end-of-life care most appropriate to their cultural and personal values instead of being labeled as “brain dead” after a diagnosis as Jahi McMath was.

5.3.2 Consent can facilitate organ donation of consented heart-beating donors

Informed consent can also facilitate heart-beating organ donation. For those donors, it is crucially important to perform the diagnostic protocol of brain death promptly to meet their wishes to donate fresh organs for successful transplantation. At the same time, diagnosing brain death has no value for non-organ donors, whether by preference or for medical reasons. For them, it is entirely unnecessary. The current practice of nondiscriminatory brain death testing wastes precious medical resources. Those cases should eventually be transitioned to palliative comfort care to die peacefully from cardiac arrest instead of inhumane, unnecessary brain death testing followed by unilaterally removing life support and forcing the heart to stop. Additionally, those who might be organ donors but are undecided about the diagnosis of brain death might be good candidates for non-heart-beating donation, and this can be offered along with the option for palliative care.

5.3.3 Consent can cover other issues being considered in this revision

Consent is a powerful tool for information exchange. If the conference is appropriately held, the topic of brain region can be briefly discussed. Whether the whole brain formulation or the brain stem formulation is adopted, it is impossible to ensure that all the brain tissue is dead at diagnosis. The family and surrogate should
have a good understanding that the diagnosis of brain death is only through “sampling” the functions of the brain stem to infer the death of the entire brain. Whether the hypothalamus is included or not, some part of the brain might inevitably remain functioning, and the decision-makers should be aware of this prior to consent. It is an inherent risk that a consented patient needs to accept. The consenting conference could also cover the problem of the AAN protocol. While we are using this protocol, the medical team could repeat the test in 6–24 hours to ensure the reproducibility and specificity of the result by simply calculating the specificity of the test, even if the AAN protocol does not require it. Conscientious practitioners can meet the desire of the family if they want. As long as the family and prospective patients in public understand the risk involved in diagnosing brain death, the consenting process can safeguard against the excessive and overzealous application of brain death diagnosis.

6. The final thoughts and conclusion

Over the past 40-plus years, the UDDA has succeeded in one sense but failed in another. It is a success in enabling heart-beating organ donation that saved countless lives. At the same time, it created persistent moral and philosophical dissensions due to the unsettled epistemic and metaphysical nature of brain death. To overcome persistent disagreements, the proponents of the current practice made every effort to convince the public that brain death is not just a state of the brain but death that is no different from the irreversible stoppage of the heart and respiration. That is proven to be a failure. The underlying metaphysical and epistemic differences between brain death and circulatory death are unmistakably conspicuous to the families witnessing every detail of the loved one being diagnosed as brain dead. No amount of science can convince those families that the warm and perspiring body with a beating heart is medically the same as a cold and rigid corpse that died of circulatory death. It is those families who persisted in the deeply-held intuition of human life, those who questioned the fundamental discrepancy and raised voices and brought the case to the judicial system, and it is such families that shook up the established system of brain death backed by the UDDA.

There are limited options if our society wishes to continue heart-beating organ donation from brain-dead donors. Making ad hoc adjustments, such as excluding hypothalamic function while precluding the patient and family from opting out of the definition and practice of brain death by eliminating consent, is an option pursued by the proponents of the current practice. As we reviewed, there is a better way to solve all disagreements: allowing the personal choice of death determination through consent and exemption. With this simple and well-established ethical practice, there will be no need for the ethically objectionable practice of imposing the diagnosis of brain death against the wishes of families and surrogates. At the same time, willing patients and families, particularly consenting organ donors, have full access to the diagnosis of brain death followed by organ donation. So long as all risks and imperfections of the diagnosis are accepted through the consenting process, there is nothing inherently and morally objectionable to continuing the current definition and the practice of diagnosing brain death as a tool to facilitate heart-beating organ donation without violating the dead-donor rule. On the other hand, precluding personal choice and imposing legal restrictions to consent would further erode public trust. Regardless of the outcome of the revision, these ethical debates will and should continue beyond the current revision, probably at state levels.
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DOI: http://dx.doi.org/10.5772/intechopen.1002031

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