Imminent Death Donation: Ethical and Practical Policy Considerations

Jordan Potter

For the past several years, the Ethics Committee for the United Network for Organ Sharing (UNOS), which is the private, non-profit organization that administers the United States Organ Procurement and Transplantation Network (OPTN), has been deliberating upon a relatively new organ donation proposal known as Imminent Death Donation (IDD). This proposal has been rather controversial ever since its inception, because it does not necessarily fit into either of the two "normal" molds of organ donation: cadaveric organ donation from the recently deceased or living organ donation from healthy, living donors. Rather, this organ donation proposal deals with Life Support Withdrawal Donors (LSW Donors), who are living donors near the end of life that both have a desire to donate their organs and have previously (and separately) decided to withdraw all life-sustaining treatment and passively die.[1] But instead of waiting for the patient's inevitable death to procure the patient's organs, which involves significant uncertainty and requires inefficient methods of organ procurement, this proposal advocates for non-vital organ donation from the living donor prior to withdrawal of all life-sustaining treatment. While the UNOS Ethics Committee has recently supported the similar practice of living organ donation by those with certain fatal diseases, they concluded in March of 2016 that there was not sufficient justification for further pursuing IDD in patients without decision-making capacity at this time due to concerns regarding harming the public perception and trust of organ donation, lack of community support, and significant potential challenges in the implementation of such a policy.[2]

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This article gives policy recommendations and a comprehensive ethical analysis regarding the potential of IDD as an ethically justifiable method of organ procurement in those patients who are near the end of life and are willing to donate an organ prior to the withdrawal of all life-sustaining treatment. The article starts by giving the medical context of the debate and providing a backdrop for the rationale of favoring this proposal over other methods of organ procurement, specifically Donation after Cardiac Death (DCD). In the next section, the article transitions to an ethical analysis of IDD in capacitated patients. This section argues that IDD in capacitated patients is an ethically justifiable method of procurement that should be considered a standard of practice, because not only does it promote beneficence and maximal utility, i.e. extra donated organs with higher overall quality, it also respects and advances patient and donor autonomy. Finally, the article ends with an ethical analysis of IDD in incapacitated patients, and this section argues that while this method may be ethically appropriate in certain, specific circumstances, there are several issues and potential risks with this policy proposal that make the utilization of IDD in incapacitated patients as a standard of practice unjustifiable, including significant concerns with the potential exploitation of a vulnerable population and the potential risks to public trust and acceptance of organ donation, especially in minority populations.

The Context of IDD

Understanding the medical context of organ donation, specifically brain death versus cardiac death, is critical for discussing this new proposal of IDD, because the necessity and justification of this proposal rely and

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focus on this crucial moral and practical distinction in the definition and type of death. Ever since the controversial case of Bruce Tucker in 1968, the concepts of "death," "brain death," and "organ donation" have been intrinsically linked. Due to developments from this controversial case, today the concept of death is largely associated with the cessation of brain function, either in part or in whole, though in some cases the lack of a beating heart is still integral to certain conceptions of death, as is discussed below.[3] The legal definition of death, which has been accepted by every state in the U.S. as set forth by the Uniform Determination of Death Act, requires either (a) irreversible cessation of circulatory and respiratory functions, or (b) irreversible cessation of all functions of the entire brain, including the brain stem, to be considered legally dead.[4]

This conception of brain death is defined as the whole-brain concept of death. Though it is by far the most common and popular conception of death, it is rivaled by other competing concepts of death that are not quite as stringent in their requirements. For example, the higher-brain conception of death argues that only those activities associated with the higher components of the brain, such as human consciousness, including dreaming states, are required to be lost to be considered truly dead. There is also the more traditional and historical conception of death associated with the cessation of the functioning of the heart and lungs, and consequently the loss of breathing and blood flow, and as seen above, it is still one way of determining death legally. It is widely assumed that increased scientific knowledge regarding the brain's functioning led to a fundamental shift in our conception of death in the late twentieth century.[5] But others have a more cynical explanation that claims that the addition of the concept of brain death is merely just a way to increase the cadaveric organ donor pool and ultimately solve a social problem by "gerrymandering" the lines between life and death. This explanation would come with the additional benefits of providing clearer, more distinguishable conditions (which are easier to diagnose), clearer prognoses, and the allowance of smoother transitions between life and death.[6]

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But it might be asked — why are these conceptions of death so important for the concept of organ donation, especially this new proposal of IDD? This is primarily due to two reasons. First, the dead donor rule, which is discussed in more detail below, requires donors to be deceased before removing vital organs.[7] This deontological rule limits the utilitarian justifications that can be justified in the process of organ donation, and it is a vitally important moral norm that keeps organ donation and transplantation balanced as an ethically justifiable medical intervention. It also ensures and maintains public trust in organ donation by providing clear and distinguishable limits for when organs can be removed from a patient's body, either in cases of explicit informed consent in live donation or after the person has been declared dead in cadaveric donation. So the exact timing of death is crucial in this regard. Second, brain death organ donation is the clear "gold standard" for organ donation, because it allows for the removal of virtually every abdominal and thoracic organ in a controlled environment before removing the cadaver from the mechanical life/oxygen support that is continuing respiration, and consequently blood flow, that keeps the organs a high quality and absent of ischemia, i.e. a lack of blood flow that damages the organs. Thus, the diagnosis of brain death leads to the best possible scenario for the procurement of organs.

But brain death organ donation is not the only type of organ donation practiced today. In patients that do not meet the conditions of brain death, either as conscious, capacitated patients or incapacitated patients in comas or persistent vegetative states, there is still the possibility of Donation after Cardiac Death (DCD) once life support has been decided to be withdrawn.[8] Depending upon the particular conception of death one is operating under, there are two differing conditions that must be met before DCD can take place: (a) the amount of time before autoresuscitation of the heart is impossible, and/or (b) the amount of time that is required for the loss of circulation to lead to irreversible brain loss, and ultimately brain death. Depending upon the specific DCD protocol one is following, the amount of time that is recommended/required to wait for these two conditions to supposedly occur has mainly ranged from 90 seconds (and even shorter periods in more controversial propos-

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als) to a full 10 minutes, which highlights part of the imprecise and controversial nature of this method of organ procurement. Beyond this impreciseness, there are also numerous other ethical issues involved with DCD, including issues of consent, questions regarding whether or not the patient is truly deceased during DCD, and potential harm and/or moral distress for the caregivers and family.[9]

DCD is also practically inefficient in several ways: (a) it generally only procures abdominal organs and not thoracic organs due to the ischemic injuries sustained by the thoracic organs during the cardiac death; (b) if the patient does not die quickly enough after the withdrawal of life support, DCD is not able to procure even abdominal organs due to the development of ischemic injuries;[10] (c) many times procured organs from DCD are of lower quality due to suffering longer ischemic times, which can lead to organ injury and delayed graft function; and (d) there are only rudimentary, unreliable methods capable of determining which patients will die within the specified timeframe of the DCD protocol, meaning there is no surefire method to determine optimal DCD candidates. It is also impractical because many times DCD usually requires life support to be withdrawn in the operating suite (or the cadaver rushed there as soon as death occurs) due to the time constraints imposed on surgeons trying to procure the organs successfully in a timely fashion to minimize ischemic injuries, which makes things very difficult and awkward for both the patient and especially the family.[11] This could significantly affect patient/family experience in end-of-life care, let alone the overall societal perception of organ donation, especially with the volatile emotional states that are characteristic of both patients and their families during this time. These issues then highlight the controversial and impractical nature of DCD and the need for new proposals of organ procurement, such as IDD, to avoid whenever possible these practical and ethical issues that arise in DCD cases where patients do not meet the criteria for brain death.

Outside of the medical context, there are also certain ethical norms that are specific to organ donation that are relevant to this new proposal of IDD. Obviously, the well-known bioethical principles of bodily autonomy (the right to self-determination regarding what happens to one's own body before or after death, as assured by the use of informed consent procedures), beneficence (the benefitting of others, such as donating an organ), non-maleficence (the obligation to avoid, prevent, and/or remove harm), and justice (the assurance of the fairness of the distribution of benefits and burdens) are relevant to this proposal. But beyond these more commonly known ethical principles is the previously mentioned ethical norm of the dead donor rule. Though the well-known principles of principlism are intrinsically linked to the ethical regulation of organ donation, the dead donor rule has been the primary, guiding ethical norm for the practice of organ donation throughout most of its existence, because it is the normative rule most associated with the practice of organ donation.[12] The dead-donor rule has two main, related obligations that correspond to the two differing main types of organ donation. The first obligation corresponds to cadaveric organ donation, and it requires organ donors to be deceased before the procurement of organs begins. The second obligation corresponds to live organ donation, and it requires that organ procurement itself may not cause the death of the donor. From both an ethical and a practical perspective, then, this principle has long shaped how organ donation is perceived and practiced in the United States.[13]

Two other ethical principles that further regulate the process of organ donation and transplantation and are related to the two obligations of the dead donor rule, but are separate principles in themselves, should also be mentioned. The first of these is the ethical principle requiring brain death prior to the removal of organs, at least in cadaveric organ donation. As described above, the definition of death has been a contentious issue recently, but most people subscribe to some sort of version of brain death, meaning the onset of brain death is the earliest one should begin procuring organs from a cadaver in order to not violate the first obligation of the dead donor rule.[14] The second ethical principle is the overall prohibition on killing, which is an extension of the principle of non-maleficence discussed above, though it is specifically aimed at the killing of patients by their physicians. This corresponds to the second obligation of the dead donor rule that prohibits the act of organ donation and procurement from killing the patient.[15] Thus, these two separate ethical principles act as outside justification for the ethical obligations imposed by the dead donor rule, giving the dead donor rule further validation as a useful normative tool in organ donation and transplantation.

Capacitated Donors

With both the medical and ethical backgrounds and contexts of organ donation laid out, the two differing types of this new proposal of IDD can now be ethically analyzed. When LSW Donors are discussed with regard to IDD, many might assume that both brain dead and non-brain dead individuals are included in this population. However, practically this is not the case, because as previously mentioned brain dead

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donors are already dead and do not engender the same type of controversy as non-brain dead LSW Donors. This is because brain death organ donation is ultimately the "gold standard" and preferred method of cadaveric organ donation today. Differently, due to the ethical obligations imposed by the dead donor rule, non-brain dead LSW Donation engenders significant controversy, and this is one of the main reasons why the UNOS Ethics Committee ultimately discontinued work on Living Donation Prior to Planned Withdrawal (LD-PPW, i.e. IDD) of life support, at least at this time.[16]

IDD is a type of organ donation that occurs in patients who have previously, and separately, decided, either themselves or via their surrogate, to withdraw all life-sustaining treatment. Generally, this type of organ donation occurs in terminally ill patients at the end of their lives who are dependent upon mechanical ventilation, such as an end-stage ALS patient. But IDD can also occur in patients who are not ventilator-dependent, or even patients who are not terminally ill but for one reason or another have still decided to withdraw all life-sustaining treatment, such as in the case of a patient in a persistent vegetative state. These patients are neither brain dead nor ideal candidates for DCD, which makes cadaveric organ donation virtually impossible. This type of organ donation then functions by procuring the organ(s) from the still living donor and withdrawing all life-sustaining treatment soon after the operation is over when the patient is stabilized.[17]

Since this type of organ donation is completed before life-sustaining treatment is withdrawn while the patient is alive and non-brain dead, it is considered living organ donation, which entails that the second obligation of the dead donor rule is applicable to IDD, i.e. the process of procurement should not kill the patient. Due to this obligation imposed by the dead donor rule, at the present time discussion of this type of organ donation has been limited to one kidney at a time, because it is believed that it is extremely unlikely that excising one organ, especially a kidney, would cause, or even hasten, the death of the patient, though many ultimately believe that more organs could (and should) eventually be donated from these types of patients prior to withdrawing care.[18] It should also be noted that the practice of IDD is both conceptually and (per the dead donor rule) morally distinct from the more controversial practice of Organ Donation Euthanasia (ODE), which is a practice where the act of organ procurement itself is the proximate cause of the donor's death. Due to this practice's promise of maximizing the number of high-quality organs that would otherwise go to waste under the practice of DCD, this new proposed form of organ donation has been gaining prominence in the literature of late.[19] However, given this article's acceptance and utilization of the dead donor rule, which is diametrically opposed to the practice of ODE, the discussion of the ethical justifiability of ODE is outside of the scope of this article.

IDD then comes in two forms, too, with each having distinct ethical components. First, it may occur in patients who are conscious and have sufficient decisional capacity to make such a decision. Decisional capacity is a notoriously difficult concept to fully determine, categorize, and define, but ultimately it represents the ability of patients to make autonomous, informed decisions regarding their healthcare. In fact, the criteria for determining capacity largely mirrors the steps of informed consent, specifically ensuring understanding of information and the voluntariness of the decision.[20] A patient with decisional capacity can (a) appreciate and understand the information being relayed, (b) make a decision that is free from coercive influences, and (c) consistently use their values and preferences to make logical, i.e. reasonable, healthcare decisions. Further, rather than being a bifurcated system of capacity versus incapacity, a patient's decisional capacity functions more on a sliding scale with differing levels of capacity, which is why differing types of healthcare decisions can require differing levels of decisional capacity to fully comprehend and deliberate upon.[21] This is contrary to the legal notion of competence, which is bifurcated into an "either/or" scenario.[22]

To many, this practice is a fairly straightforward and ethically justifiable scenario in cases of patients with sufficient levels of decisional capacity. Not only does IDD respect and promote patient autonomy with only minimal concerns of voluntary, non-coercive informed consent, it also promotes significant acts of beneficence via donation of organs of much higher quality than can be procured during DCD. It also engenders much good for both the donation recipient and the dying patient, who receives the joy and comfort that comes from altruistic acts, which is very welcomed at the end of life when knowledge of one's own impending mortality generally robs the patient of these emotions. This beneficence is even more apparent for the patient's family. For example, though not specifically discussing cases of IDD, James Childress has noted the benefits and positive effects that organ donation generally has for the donor's family, who at the time of donation is still mourning the loss of a recently deceased loved one, or in the case of IDD emotionally preparing for the inevitable imminent passing of a loved one. In one family's own words, "This was the

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best thing we could have ever done. Whoever the people are that got the organs, we are just grateful to them to keep part of him alive in this way. We are grateful they are living."[23] In this sense, many families view organ donation as a way of keeping their loved ones "alive" and "present" in another body. Said in another way, this practice "could provide patients and families a middle ground — a way of avoiding futile medical care, while also honoring life by preventing the deaths of other critically ill people."[24]

Of course, there are still several ethical components that some may take issue with in this form of IDD. For example, more conservative individuals might still find issue with the notion of withdrawing life support, even though it is currently widely accepted in the realm of medical ethics as an ethical action and ultimate right of bodily autonomy for patients. But even if one holds this position, this type of IDD is not necessarily affected by that stance, because the act of live organ donation is conceptually separate from the act of withdrawing life support. There is no real conflict between the two. Another issue that has been brought up is the fear that IDD could effectively offer up fewer overall viable organs for transplantation than the method of DCD. This is because while IDD is subject to the obligations of the dead donor rule, which limits the types of organs that can be procured via this method, i.e. only abdominal organs without thoracic organs, DCD is not held to that same obligation due to the donor already being deceased at the time of procurement. This was a specific concern that the UNOS Ethics Committee received in feedback from various Organ Procurement Organizations (OPOs) from across the country during their recent investigation of the issue.[25] Thus, some argue that DCD is always preferable to IDD due to this possibility of recovering more overall organs.

But this is a concern that is misguided for several reasons. First, as was shown above, DCD is a fairly unreliable and unpredictable method of procuring organs due to a dearth of effective predictive tools, so while there may be a higher *possible* range of organs to procure from DCD, there is also the very real chance of procuring no organs at all due to the patient not dying quickly enough or increased/faster rates of ischemic injury to organs. Further, while DCD can technically procure both abdominal and thoracic organs, in practice the transplant team almost always only procures abdominal organs, just like IDD, due to the rapid development of ischemic injury in thoracic organs after cardiac death.[26] So while IDD offers a lower range of organs procured from the donor, the success rate and confidence of successfully and safely acquiring the organs is much higher in IDD than in DCD.

Second, while discussion of IDD is currently limited to considering procurement of a single kidney, some argue that in many cases virtually all of the abdominal organs, or at the very least both kidneys, could and should be procured in IDD, meaning there would be a significant number of organs procured from a single act of organ donation.[27] This is because while the kidneys, liver, pancreas, etc. all serve vital bodily functions, the cessation of their function and/or their removal would take some time, meaning days to weeks, to ultimately seriously harm and kill the patient. Yet since the patient is actively dying anyways, in cases where the estimated time of death is reasonably soon, such as minutes to hours after withdrawal, it can be morally justifiable to procure all of these organs, since these organs would not necessarily be causally connected to the death of the patient (more on this below). So as long as the transplant team is reasonably sure that the patient can survive a major surgery and the patient's comfort, i.e. lack of unreasonable and unnecessary pain, can be assured in the final hours before death, the majority of the abdominal organs can be procured in IDD while still being consistent with the dead donor rule. And finally, IDD does not necessarily entail that DCD will not occur, as well. In fact, In fact, both methods could be utilized to maximize the gains of organ procurement, so the fear of widespread practice of IDD ultimately offering fewer overall organs than DCD is not warranted or compelling, since it is not even necessarily a bifurcated, "either/or" choice.[28]

Others may worry that this type of operation might actually cause death in the terminally ill, which would violate the second obligation of the dead-donor rule. But it seems well supported that the excising of most non-thoracic organs, e.g. the kidneys, liver, pancreas, etc., would not ultimately cause the death of the patient, since the patient is actively and imminently dying very soon after removing the life-sustaining treatment anyways.[29] Still, others worry that though death might not be an immediate result of this operation, these types of major operations might still hasten death to some degree or cause extra, unwarranted pain to the donor while they are actively dying (which very well could occur in certain contexts), and this would ultimately turn this concept into a slower version of ODE, similar to the proposal discussed earlier. But once again, it seems well supported that this type of operation would neither cause nor hasten death, even if additional pain after the surgery could ultimately arise — though it would be controllable. And even in rare cases where complications do occur during or after surgery that actually do hasten the death of the patient, it could ultimately be justified by the

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normative tool known as the principle of double effect. The principle of double effect is a normative tool that combines a deontological framework with utilitarian reasoning and principles to create an ethical framework that determines when an action that has both good and bad consequences can be morally justified. It determines this by filtering actions through four required conditions:

1. The action, considered by itself and independently of its effects must not be morally evil …
2. The evil effect must not be the means of producing the good effect … The evil effects … are simply unavoidable by-products of [actions] designed to produce the good effects …
3. The evil effect is sincerely not intended, but merely tolerated.
4. There must be a proportionate reason for performing the action, in spite of its evil consequence … According to a sound prudential estimate, the good to be obtained is of sufficient value to compensate for the evil that must be tolerated.[30]

If the action successfully makes it through the four conditions, then it is considered an ethical action that merely has some bad, unintended consequences, even if they were foreseen consequences. In bioethics, intensive pain management at the end of life is the paradigmatic example of the principle of double effect in action, because there may be times when the proper use of intensive pain management unintentionally hastens the death of the patient. Yet as long as the death of the patient was not the true intention of the physician but rather an unfortunate and unintended side effect or consequence of the pain management remedy, then it is still a morally justifiable act, at least according to the principle of double effect.[31] And just as in intensive pain management, as long as the true motive in IDD is procuring an organ rather than hastening the patient's death, then this act is ethically justifiable via the moral reasoning of the principle of double effect.[32]

Another area that might be of ethical concern to IDD in capacitated patients is the route taken to find patients who are willing to undergo IDD. Specifically, this concern deals with potential conflicts of interest with the medical team, which has significant potential to harm public trust in organ donation. For example, in this context a strong emphasis needs to be put on the clear separation of the decision to withdraw life-sustaining treatment from the decision to donate an organ. This separation should be both *temporal* and *agent-centered*, meaning members of the medical team should never be the ones to bring up the possibility of organ donation to the patient to avoid any potential conflict of interest, because this could give the patient and/or the patient's family the impression that the medical team is more interested in the patient's organs than their overall health, which as will be shown below is already a pervasive problem in the public perception of organ donation. This responsibility should always fall on the organ procurement specialist, whose job it is anyway. The organ procurement specialist should also always wait to approach the patient and/or the patient's family regarding organ donation (including IDD when appropriate) until *after* the decision to withdraw all life-sustaining treatment has been made, which further avoids any conflict of interest charge and additionally ensures that the patient's decision to withdraw all life-sustaining treatment is not unduly influenced by some outside factor, such as the possibility or "moral requirement" to donate an organ.

So as long as the decision to undergo IDD is completed in an ethically appropriate way to avoid potential conflicts of interest and the harming of public trust in organ donation, this form of IDD in capacitated patients is certainly morally licit and should most definitely be considered a standard of practice that is performed when autonomously requested by patients and widely promoted by transplant teams. And with the help of the principle of double effect, more aggressive IDD procurement strategies should even be implemented to maximize the potential viable organs garnered from each individual, though of course this must be balanced against the patient's overall well-being and safety and the practical realities associated with national organ procurement policies and regulations.

One final issue that must be discussed in this section due to its ever-increasing presence and standing in American medicine and healthcare is IDD prior to Physician-Assisted Death (PAD). At first glance, some may wonder why this proposal would be controversial at all, because (a) the element of PAD is not necessarily causally connected to the organ donation, (b) there is no question about capacity, since decision-making capacity is a prerequisite for the legal approval of PAD, and (c) the mode of death is not really relevant to the procurement of organs in normal situations. But for some it might be difficult to separate perspectives of PAD from perspectives of organ donation due to their interaction in this particular form of IDD, so some might conflate the issues and have problems justifying organ donation in this context from an ethical perspective. Thus, it needs to be addressed. This was even an explicit point of discussion at several recent UNOS Ethics Committee meetings due to the expanded

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legality of this practice in several U.S. states and the District of Columbia and the need to clarify the Committee's position on the matter as it relates to IDD and organ donation as a whole.[33]

So the question is this — is this an ethical form of IDD that should be promoted and encouraged, specifically by OPOs and healthcare organizations that function in areas with laws allowing for PAD? Even if one finds PAD ethically wrong in itself, it is difficult to find something ethically dubious with this form of IDD. This is because the act of organ donation is conceptually distinguishable and separate from the method of death itself, and there is nothing conceptually hypocritical about being an advocate for organ donation in these cases, while still finding the act of PAD immoral. That is, though certainly the patient's impending death provides extra motivations to consider organ donation, the act of organ donation itself in this case is not causally related to the act of PAD, because the act of organ donation itself can just as easily occur if the patient is not considering PAD. So it does not logically follow that moral opposition to PAD would necessarily entail moral opposition to this form of IDD prior to PAD.

A practical example can verify this line of reasoning. Many cases of brain death actually occur from suicide attempts that deprive the brain of oxygen for a substantial amount of time, and recent research suggests that around 3.8% of all brain death scenarios are caused by suicide attempts. Moreover, the families of these suicide brain dead patients exhibit a much higher rate of consent to organ donation than families of non-suicide brain dead patients, which means that a substantial minority of brain-dead donors come from suicide victims.[34] So if there is no moral hesitancy to accept organ donation in these patients, which inherently involves a much clearer causal connection between the act of suicide and cadaveric organ donation, then there should be no moral hesitancy to accept the ethicality of this form of IDD in potential PAD donors. For the most part, then, this form of IDD in potential PAD patients is ethically similar to the standard form of IDD in capacitated patients, and as long as these patients and/or families are approached in ethically appropriate ways, IDD in capacitated patients, including PAD patients, is an ethically justifiable and charitable action that should be standard practice when autonomously requested by patients and regularly utilized and encouraged by transplant teams across the nation.

Incapacitated Donors

A second and more controversial option of IDD is in permanently unconscious patients — those in a permanent vegetative state or those with a devastating neurologic injury that is considered irreversible, though not necessarily being considered brain dead — or patients in a severely incapacitated state where surrogate decision-makers would make this decision to donate the organ(s) after making the decision to withdraw all life-sustaining treatment. The main issue with this option of IDD involves the use of surrogate decision-making. There are two main and relevant standards of surrogate decision-making: the substituted judgment standard and the best interests standard. Sometimes a distinction is made between the prior, explicit articulation of the patient's relevant preferences to the surrogate on the one hand and actual substituted judgment based more off of analogical reasoning from differing known preferences of the patient on the other hand, which creates an entirely new standard of surrogate decision-making; however, here they are both funneled under the broader substituted judgment standard.[35] Traditionally, the substituted judgment standard has been the preferred standard for surrogate decision-making, because it is theoretically based upon the subjective and previously known preferences of the incapacitated patient. This standard then requires the surrogate to use the known preferences and values of the incapacitated patient to make the most proper medical decision according to what the patient would ultimately want if they were making the decision for themselves.[36]

The problem is that IDD is a unique and rare medical intervention that is not well-known to the general public, so the chances of patients previously and

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explicitly discussing their preferences for this procedure with surrogates are minimal at best. Of course, there is always the possibility of this occurring, and prior, explicit articulation of the patient's relevant preferences for this procedure of IDD would surely need to be followed. But realistically the chances of explicit articulation of this preference are slim, meaning surrogates will most likely have to come to a conclusion regarding IDD via substituted judgment based upon the patient's relevant values, interests, and preferences on other related issues. But this brings up other issues and concerns.

Several recent studies have found that the substituted judgment standard is not nearly as accurate and reliable as it was once thought to be. For example, there is significant discrepancy in the actual preferences of the patient versus the judged preferences of the patient by the surrogate, meaning surrogates are sometimes judging the patient's preferences wrong and thus making decisions that are counter to what the patient really would have wanted. One study even found that surrogates are only correct in their judgments about 68% of the time, which is still a majority of the time but far from the overwhelming accuracy that this standard was once thought to possess.[37] What is even more troubling in this regard is the unclear status of IDD. While IDD is without a doubt an example of live organ donation, this practice is not necessarily equivalent to standard living organ donation in healthy individuals, let alone cadaveric organ donation, which is certainly a relevant factor for patient preferences regarding the procedure. For example, it is conceivable that a patient would be more willing to be a live donor in the case of IDD than in the case where the patient was fully healthy, because IDD does not contain the recovery time and burdens that would come with the post-operative process for a healthy, live patient. And similar arguments could be made in the other direction with certain patients being more willing to be a live donor as a healthy person than as a person who is preparing for death that is not wanting to take on additional medical interventions and operations during their final hours or even days.

This then raises substantial questions and concerns about the required threshold of evidence that surrogate decision-makers would need to meet in order for them to justifiably conclude through the substituted judgment standard that the incapacitated patient would truly want IDD in this situation. For example, questions that would necessarily need to be answered to come to such a conclusion include:

- Did the patient show any sort of preference toward cadaveric and/or live organ donation?
- How much prior preference and interest should be shown by the patient in organ donation for the surrogate to justifiably make an affirmative decision on IDD?
- Is expressing a favorable stance towards organ donation enough justification for the surrogate, or is more needed to justify this decision? How much more?
- Is the patient explicitly expressing the wish to be an organ donor enough, or should the patient have shown enough interest in organ donation that they were previously registered as an organ donor and/or evaluated for the possibility of being a live organ donor?
- What about other forms of altruistic behaviors? Can a generally altruistic character be sufficient justification to pursue IDD in an incapacitated patient, even if the authorized surrogate decision-makers have no knowledge regarding the patient's preferences for organ donation?
- Who is the potential organ recipient — a close relative? An acquaintance? A stranger? Is this even morally relevant?

Complicating things even further, along with the recent research suggesting the increased fallibility of the substituted judgment standard, there is also evidence that patients' preferences evolve and significantly change over time, especially with regard to end-of-life issues, meaning surrogates' knowledge regarding past preferences of the patient might not be accurate or up to date. Prior preferences also may not necessarily even be of primary importance to patients in end-of-life scenarios, because patients highly value the opinions of family and their doctors, who they want involved in the decision-making process, even if they might have opinions and recommendations that contradict the patient's past preferences.[38]

Other factors are also relevant to organ donation and past preferences, including the possibility of certain components of advance directives making it difficult for patients to donate their organs upon their death, even if they expressly mark their preferences for organ donation. This is because certain medical interventions that are many times needed to ensure the viability of the organs for donation, such as ventilator use for continued oxygen supply, the administration of the anticoagulant heparin, etc., can be interpreted as life-sustaining treatment that may temporarily extend the patient's life, which would be expressly prohibited by the advance directives. This is why Robert Veatch has recently argued that amendments or addendums to advance directives should be utilized to assure the medical team that these treatments are in fact consis-

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tent with the patient's preferences for organ donation, so long as that is the primary purpose of the medical intervention. He even advocates for an amendment to advance directives that is specific to IDD, which states:

> Let it also be known that, if this directive is acted upon, I desire at the time to be a living organ donor. I would like a kidney [or all organs that the procurement team is willing to take] procured prior to forgoing life-support and consent to the procurement as well as any medical treatments that will facilitate that procurement provided my surrogate does not consider such treatment too burdensome for me.[39]

Thus, outside of those rarer instances where advance directives or surrogates have direct, explicit information regarding the patient's preferences for IDD, there are substantial hurdles to overcome with the substituted judgment standard and the necessarily high threshold of evidence required for surrogates to justifiably pursue IDD. While it might be standard practice in cadaveric organ donation to simply consider the patient's general values and altruistic characteristics as adequate grounds for surrogate consent to organ donation (absent explicit knowledge of the patient's preferences for organ donation), this should not necessarily be the case in IDD. Since IDD in incapacitated patients is both more morally problematic and more burdensome than cadaveric organ donation (due to IDD actually occurring in a live patient), a higher threshold of confirmatory evidence is also required for surrogates to make such a decision to pursue IDD, which general values and altruistic characteristics may or may not be sufficient to justify. And given that this threshold of evidence is murky and not well-defined, along with being somewhat subjective and based upon the particular medical and psychosocial factors of the case, IDD in incapacitated patients is not a practice that can justifiably be considered *a standard of practice that is regularly practiced, sought out, and promoted by transplant teams*, though this does not necessarily preclude all acts of IDD in incapacitated patients in specific situations, as is detailed below in the conclusion.

But what if no prior relevant preferences or values are known for the patient, such as in the case of a patient without a surrogate or a patient who has been estranged from his family, leaving them in the dark regarding his values and preferences? In these types of cases the best interests standard of surrogate decision-making is relied upon, and unfortunately this standard does not seem to fare much better here. This standard of surrogate decision-making states that surrogates should make healthcare decisions according to the patient's objective "best interests" when no prior relevant preferences from the patient are known, and these interests should be separate from the surrogate's own views and preferences.[40] This standard is also supposed to be based upon what a "reasonable person" in this situation would want.[41] Immediately, then, this standard of surrogate decision-making can be nullified as justification for pursuing IDD, because since this type of procedure would provide no objective benefit whatsoever to the patient, but only additional harm and burden, there is no objective interest in performing this donation from the perspective of the incapacitated patient.

One other issue that should be mentioned here is the distinction between those patients who at one time had capacity but lost it due to some sort of ailment or accident and those patients who never had capacity at any point in their life. Specifically, this refers to newborns, especially profoundly disabled newborns, and the severely mentally handicapped. Since these individuals never had the opportunity to develop decision-making capacity, along with preferences, desires, and values, the substituted judgment standard is of no use for surrogate decision-making in these individuals, and the best interests standard would be the primary guide for surrogate decision-making.[42] As just stated, in most cases the best interests standard firmly denotes IDD as not in the best interests of patients, because it does not benefit the patient whatsoever, while simultaneously requiring significant burdens and bodily harms. So this specific population should be categorized with the realm of incapacitated patients without surrogates where the best interests standard is utilized and, at least for the vast majority of cases, in strong opposition to the moral justifiability of IDD in incapacitated patients based off of the patient's best interests.

Of course, some might argue that the benefit lies in the non-directed altruism and beneficence that is engendered through the donation, making this some sort of "moral benefit" that is in the best interests of both the patient and society at large. But this perspective is problematic in several ways. First, the altruism and beneficence in this scenario is not coming from the patient; it is coming from the surrogate who is actually making this decision. So how can this be a benefit for the patient or in the patient's best interests? In short, it cannot be. As Katherine Brown-Saltzman and the UCLA Medical Center Ethics Committee commented on a similar case of surrogate consent to living organ donation (i.e. IDD), "The decision to donate an organ cannot be construed as benefiting this patient because he will never regain consciousness to realize that he

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provided the gift of an organ. Thus, alternative ethical reasoning is needed to justify performing the organ donation based on surrogate consent."[43] The only way this would be a benefit for the patient is if IDD honored the patient's prior preferences and values (either explicitly or through analogous reasoning), but this would then fall under the substituted judgment standard rather than the best interests standard, making this a separate and distinct issue that is not consistent with the type of non-directed "moral benefit" to the patient and society at large that is being argued here. (This specific type of scenario of IDD based on the patient's past altruistic values is discussed in more detail in the conclusion and a subsequent endnote.)

Second, the medical intervention of organ donation is a rather intrusive and burdensome violation of bodily integrity that generally requires express informed consent from patients with strong decision-making capacity. This is especially true for live organ donation, more so than cadaveric organ donation, due to the extra potential consequences of this intervention for the patient, because even in IDD in incapacitated patients there is the possibility of certain complications that may bring extra burdens, pain, or suffering to the patient, along with the rare instance of actually hastening the patient's death. And while in cases of capacitated patients (who can freely *consent to* and *benefit from* such a procedure) the principle of double effect may justify this method of organ donation (even if it does happen to hasten the death of certain patients in rarer instances), this moral justification is much less clear in IDD in incapacitated patients due to the proportionality of the act being unbalanced, which is the final condition of the principle of double effect that was discussed above. Though there are significant benefits to IDD in incapacitated patients for the recipient(s) of the organ(s) and perhaps even surrogates and/or patient families, there is no objective benefit to patients themselves, meaning the proportionality of this action is substantially unbalanced to the individual who is actually shouldering all of the burden.

This is a violation of the principle of justice discussed above, because there is an unfair distribution of burdens and benefits in this act. And essentially this amounts to exploitation of a vulnerable population that has no means of protecting themselves, which goes doubly for the specific populations of newborns and the severely mentally handicapped that were discussed earlier, because others are extracting benefits from incapacitated patients while not necessarily sharing in the burdens of the intervention. In a Kantian sense, this then treats these patients instrumentally and merely as a means rather than an end in themselves, which would be a major violation of the types of Kantian moral obligations to others, i.e. to not treat others merely as a means to some other end, that are fairly well-accepted today.[44] Thus, combining the lack of explicit consent from the patient with the lack of practical benefits of the intervention, clearly no supposed non-directed "moral benefit" can justify this type of violation of bodily integrity and additional surgical burden in an incapacitated patient that had no known relevant prior preferences or values that would reasonably lead a surrogate to suspect the patient would ultimately want to pursue IDD.

In addition to these significant issues with surrogate decision-making, there is also the crucial issue of public perception and trust in organ donation to consider. With the United States organ donation system's (current) reliance on voluntary, altruistic organ donation, the public perception and trust in organ donation is critical to ensuring high rates and acceptability of organ donation. Yet along with general misunderstandings about brain death and the organ donation process, one of the most substantial reasons that many people do not register to become an organ donor is a fear and mistrust of doctors and the assumption that they will receive lesser care in emergency or end-of-life situations due to the desire for their organs for transplantation in other patients.[45] For example, in a 5,100 participant online survey created by Donate Life America, which is a non-profit special interest group aimed at increasing organ donation, at least half of the respondents indicated that this was a specific fear that they had regarding registering as an organ donor, especially if their doctors had knowledge of their donor status.[46] Even anecdotally, this author has had numerous students in ethics classes taught throughout the years who have explicitly stated that they, or their family members, were never going to register as an organ donor due to the fear that doctors would give them subpar care, or even actively attempt to end their life, in order to harvest their organs.

This is an even more pervasive and prevalent attitude in minority communities, which is an issue that the UNOS Ethics Committee only minimally addressed in its report. Beyond the substantial minority disparities in access to healthcare, there are other significant minority disparities in healthcare that are related to internal bias, discrimination, and a lack of trust within the healthcare system. Many of these minority disparities occur from conscious or unconscious prejudices and biases of healthcare providers that affect the ways they treat or make healthcare decisions for their patients of a minority group.[47] For example, several studies have shown an association between race and socioeconomic status and the likeli-

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hood of receiving surgery for the treatment of cancer, including the disparity of African-Americans being significantly less likely to receive surgical resection for the treatment of non-small cell lung cancer compared to their white counterparts.[48] Similar disparities have been found in minority populations in the management of pain. Interestingly, in one study male physicians prescribed higher doses of pain medication for white patients over black patients, with the opposite being true of the female physicians.[49] Other studies have corroborated these minority disparities in pain assessment and pain management, including everything from pain originating from cancers and chest pains to chronic back pains.[50]

These disparities, among other social and historical issues, have helped lead to the well-known and documented distrust of the white-dominated U.S. healthcare system by African-American communities, and this distrust and suspicion is present in the realm of organ donation and transplantation, too.[51] In fact, there is substance to some of these concerns based on racial discrimination, with several studies suggesting that black Americans are routinely much less likely to be referred to transplant services, considered good candidates for transplantation, and placed on organ waiting lists than white Americans, even with all other factors in consideration and accounted for.[52] The combination of this distrust with actual discrimination has led to major disparities in organ donation and allocation within this population, and there has been little improvement in the last several decades in this regard.[53] Further, a continued reluctance towards organ donation in this population, due in large part to this overall distrust of the healthcare system, has sustained this organ transplant disparity due to a lack of histocompatible viable organs for transplants in African-Americans.[54]

So with the effectiveness and success of organ donation programs relying so heavily on public perception and trust in organ donation, this is a substantial concern that must be taken into account. Due to the controversial and convoluted nature of this form of IDD and the fact that there are already numerous public misunderstandings and elements of distrust regarding organ donation and transplantation, there is significant risk of this proposal being misconstrued by the public as a "power grab" of sorts to harvest more organs from vulnerable patients who do not have the capacity to consent to such a procedure. This would be especially true in minority communities, who already have heightened levels of distrust in the organ donation process and feel disenfranchised and of lesser value compared to their white donor and recipient counterparts. And with major disparities in organ donation and transplantation already present in minority communities, let alone the larger overall disparity in organ supply compared to organ demand, adopting such a controversial proposal as a standard of practice could increase these disparities by spurring even more distrust and skepticism in the organ donation process.

Of course, it should be mentioned that certain evidence has recently surfaced suggesting public trust and acceptance of organ donation in the imminently dying may be on the rise. For example, one study published in 2015 by Nair-Collins, Green, and Sutin found that when using plain language to describe a scenario where the act of organ donation would cause biological death in an imminently dying patient, "the American public was largely in support of organ removal, even though it cause[d] death in this scenario."[55] While this study didn't focus on IDD in particular, this type of public view and perception of organ donation in the imminently dying would contradict the dead donor rule, which was established and enforced to protect this notion of public trust and acceptance of organ donation, and it would further seemingly lessen these concerns regarding the widespread practice of IDD in incapacitated patients damaging public trust and acceptance of organ donation, especially in minority communities.

However, being a singular study this newfound evidence is insufficient in itself to overcome these concerns regarding the regular practice of IDD in incapacitated patients and the effects it would have on the public trust and acceptance of organ donation. Much more research and confirmatory evidence is needed before ultimately disbanding the dead donor rule and establishing expanded organ procurement techniques in the imminently dying as a standard of practice. Also, while the study aimed to accurately represent the United States demographic, the actual studied sample ended up significantly whiter, more educated, less religious, and younger than the general population, and these are all factors that are positively associated with more favorable perceptions of organ donation and/or actual increased consent rates to organ donation, which certainly could have affected the results.[56] Thus, given this need for more confirmatory evidence and the potential ramifications that widespread adoption of this practice could have, it seems clear that instituting and promoting a controversial policy like IDD in incapacitated patients *as a standard of practice* that is always pursued when requested by surrogates is neither morally nor practically justifiable given its significant risks and meager overall benefits compared to its possible negative consequences.

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Conclusion

So it must be seriously taken into consideration what widespread promotion and utilization of IDD in incapacitated patients would do to both (a) surrogate decision-makers in their attempt to interpret the patient's obscure preferences, and (b) the public perception and trust in organ donation, especially in minority communities who are already dealing with significant distrust issues and organ donation and transplantation disparities. This is basically the position of the former chairman of the UNOS Ethics Committee, Dr. Peter Reese, when he says that IDD "could erode public trust in donation in general."[57] This primary concern in the public perception of IDD — among other issues, such as practical worries surrounding the challenging implementation of such a policy, the need for better guidance for when to offer IDD over DCD, and the need for better models to predict how allowing IDD would impact the number of viable organs available for transplant — led the UNOS Ethics Committee to conclude in March of 2016 that IDD in incapacitated patients was not something to pursue further at this time.[58]

As a *general* policy, this author concurs that this is the correct public position to take regarding IDD in incapacitated patients, because instituting IDD in incapacitated patients as a standard of practice that is widely sought and utilized by transplant teams could have devastating effects on the overall public trust and acceptance of organ donation, especially if any problems or complications occurred during an operation and/or with an emotionally-charged family that were leaked to the media. Yet this approach does not necessarily require a total prohibition on this method of organ procurement either, because certainly there may be circumstances when surrogate decision-makers have indisputable evidence or other good reasons that prove that IDD would be ethically justifiable and what the patient, or at least a rational and reasonable patient, would want. There are then several specific scenarios where IDD in incapacitated patients might still be ethically justifiable, including situations when:

1. The patient recorded their preference for IDD in an advanced directive prior to losing decision-making capacity, such as Veatch's recommendation that was discussed above.
2. There is no advance directive from the patient, but the surrogate decision-maker has significant and compelling evidence that the patient ultimately would want IDD in this situation, such as a case where the patient was a vocal organ donor proponent that at one time had been tested to become a live organ donor.
3. The patient has a close relative, such as a child, sibling, etc., that needs a kidney, and the patient is a compatible match for the relative. Under these circumstances, it *might* (depending upon other factors of the case — such as the donor's character, values, and relationship with this individual) be justifiably concluded that the patient would subjectively want IDD in this situation to aid their close relative, even if there is no other evidence available that suggests a specific preference for organ donation.[59] This might even be justified under a best interests standard for those populations that never had capacity, such as newborns or the severely mentally handicapped who have an especially close relative (like a sibling) in need.

And there are probably several other contexts where IDD might be ethically and practically justifiable in incapacitated patients. So while this should not be a standard practice that transplant teams actively seek out and promote in every case where IDD might be medically indicated for an incapacitated patient,[60] individual hospital ethics committees (or some type of specialized committee/subcommittee dedicated solely to the purpose of reviewing IDD requests) should have the ability to approve or disapprove of surrogate requests for IDD per their discretion after a thorough ethical investigation and analysis of the case. And though many incapacitated patients will probably not be ethically justifiable candidates for IDD, they might still have the opportunity to donate their organs, or at least other tissues, via DCD, so it is not as if this denial of IDD in most incapacitated patients will completely deny patients the chance to donate their organs and/or tissues and rob the transplant community of a valuable scarce resource. Furthermore, the transplant community as a whole will still greatly benefit from the promotion and utilization of IDD in capacitated donors, which was argued in the first half of the article. But with the potential to severely harm public trust and acceptance of organ donation and the very precarious position that it forces surrogate decision-makers to make life-altering decisions from, IDD in incapacitated patients is not a policy that should be implemented and adopted as a standard of practice for transplant teams across the country. Rather, OPOs should further educate the public and institute awareness campaigns that are aimed at increasing the discussion of organ donation, specifically regarding IDD, in both advance directives and with the patient's surrogate decision-makers.

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10. Generally, patients must die within one to two hours after the withdrawal of life-sustaining treatment, depending upon the specific DCD protocol, in order to remain a candidate for DCD.
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27. Veatch, *supra* note 18, at 273-274; and Morrissey, *supra* note 18, at 515-517.
28. Wilkinson and Savulescu, *supra* note 19, at 42-43.
29. Veatch, *supra* note 18, at 273-274; Morrissey, *supra* note 18, at 515-517; and Wilkinson and Savulescu, *supra* note 19, at 42-43.

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59. This scenario is similar to the case mentioned briefly earlier from the UCLA Medical Center Ethics Committee. In this case, the ethics committee allowed surrogate consent for IDD based upon both (a) a close relative (first cousin) needing a kidney who was a match with the patient, and (b) the patient's previous character and values, which were thoroughly demonstrated by the family to be significantly altruistic (e.g. the patient was a firefighter). This is despite the fact that neither the family nor friends had knowledge of the patient's preferences and values regarding organ donation. More difficult scenarios would be whether to allow surrogate consent for IDD in this case if (a) the potential recipient was a stranger rather than a relative, or (b) the potential recipient was a relative, but there was no substantial evidence of the patient's prior altruistic character, which treads into a moral gray zone. For more detail on this case, see: K. Brown-Saltzman, A. Diamant, I. C. Fineberg, H. A. Gritsch, M. Keane, S. Korenman, M. Lewis et al., "Surrogate Consent for Living Related Organ Donation," *JAMA* 291, no. 6 (2004): 728-731.
60. In cases where an incapacitated patient is a registered organ donor, it is ethically appropriate and justifiable for the transplant team to approach the patient's surrogate decision-makers regarding the possibility of IDD. Given the patient's past preferences for organ donation, this justifies the transplant team inquiring about the possibility of IDD in order to best respect the patient's preferences and values. Of course, as already detailed above, a positive organ donor status does not necessarily justify pursuing IDD on its own, and more positive evidence is required to justifiably pursue IDD from an ethical perspective; however, a positive organ donor status does at least justify an inquiry regarding IDD to the surrogate decision-makers.

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