Living Donation by Individuals with Life-Limiting Conditions

Lainie Friedman Ross and J. Richard Thistlethwaite

Traditionally, living donors were very healthy, passed extensive physical and psychosocial evaluations, and gave a voluntary consent to donation. However, as the supply-demand gap grew, transplant programs became more accepting of less healthy donors. Medical criteria of age, weight, and blood pressure have all been loosened.¹

This paper, however, focuses on whether and when individuals who have life-limiting conditions (LLC) should be considered for living organ donation. Specifically we consider: 1) donation by individuals with advanced progressive severe debilitating disease for whom there is no ameliorative therapy; and 2) donation by individuals who are imminently dying or would die by the donation process itself. We examine the ethical issues using cases from the literature.

Scenario 1: Living Kidney Donation from Donors with LLCs

The first scenario involves living organ donation by individuals with advanced progressive severe debilitating disease for whom there is no ameliorative therapy. Consider Case A one of 5 case reports from the University Medical Center, Rotterdam, The Netherlands:

Case A: This patient [a 48-year old man] was diagnosed with a stage III GOLD chronic obstructive pulmonary disease and severe

Lainie Friedman Ross, M.D., Ph.D., is the Carolyn and Matthew Bucksbaum Professor of Clinical Ethics, Professor, Departments of Pediatrics, Medicine and Surgery, Associate Director, MacLean Center for Clinical Medical Ethics, University of Chicago, Chicago IL. J. Richard Thistlethwaite, M.D., Ph.D., is Professor Emeritus, Department of Surgery and the MacLean Center for Clinical Medical Ethics, University of Chicago, Chicago IL. emphysema. He was being treated by a pulmonologist, used a wheel chair because of respiratory insufficiency. In 2010, he requested and underwent psychosocial screening for [non-directed] living donation. The reason for donation was based on his opinion that, at the moment, he was physically and mentally still healthy enough to donate a kidney. Moreover, he was aware of the fact that kidneys from living-donors function better than those from deceased donors. He reported: "By doing this I can give something back to society, just like my Mother would have done, because she was a really helpful person. I am sure she would have been proud of what I am going to do." Based on the interview and psychologic complaint questionnaire, no psychosocial problems were detected, and sense of reality was normal.²

The other four case reports in this article also involved persons with LLC who requested to serve as nondirected living donors: two had Huntington Disease but were judged to have the capacity to consent for donation, and two had recurrent brain cancers that were not thought to be transmissible by organ transplantation.³

The authors described four safeguards. First, "all donors are well informed and made the decision about unspecified donation by themselves."⁴ That is, the individuals voluntarily sought out the opportunity and gave an informed consent. Second, the donation was consistent with the donors' lives. Evidence included that all had previously registered in the Dutch organ donation register for deceased donation before stating interest in living donation. Third, the physicians consulted with the patients' independent medical specialists and found that "None of them had an objection to the donor nephrectomy."⁵ Fourth, all passed the psychological evaluation component of screening just as their healthy donor counterparts.⁶

The authors claimed that the three-month postdonor nephrectomy evaluation by the transplant coordinator validated their decision to allow the individuals to serve as living donors. All of the donors stated that the donation lived up to their expectation and would do it again. Although none reported abnormal post-nephrectomy pain or fatigue, two of the five donors reported worse health status. Of note, during the post-donation follow-up, two died by euthanasia which is legal in the Netherlands (at 0.6 years and 4.9 years post-donation) and one died from his LLC (at 2.4 years post-donation). The other two were doing well in their last yearly medical follow-up.⁷

Contrast the cases from the Netherlands with the case of W.B. (Case B) from Madison, Wisconsin described by surgeons in *The Atlantic Monthly*. W.B. was a 56-year-old previously healthy man who was recently diagnosed with amyotrophic lateral sclerosis (ALS) with compromised respiratory function. He approached the University of Wisconsin's transplant program as a prospective organ donor. As the surgeon-authors explain:

Case B: Initially, W.B. had assumed that he would arrange for his organs to be procured when he died, but then he read that kidneys from a living donor work better and last longer than kidneys from a deceased donor. For one thing, the death process takes a toll on organs, between the decreased flow of blood and oxygen and the release of inflammatory proteins. For another, kidneys that are removed after death inevitably endure "cold time" — when they are outside the body, on ice, without any blood flow at all.

"Why not fork out a kidney before it becomes compromised by all the meds I am taking?" W.B. asked us when we met him in June.⁸

The Wisconsin surgeons refused to remove W.B.'s kidney because they were not sure that in his weakened state he would tolerate the surgery or that even if he tolerated the surgery, whether he would be able to be extubated. While W.B. was willing to assume those risks, and he had the support of his neurologist, the surgeons objected: "If we were to remove one of W.B.'s kidneys, and he died one, two, or even six months after surgery, his death would be a very public black mark on our program."⁹

An Ethical Framework

Dr. Joseph Murray who performed the first successful living donor kidney transplant in 1954, was of two minds about his success, noting that "we make a basic qualitative shift in our aims when we risk the health of a well person, no matter how pure our motives."¹⁰ Today, we continue to permit – even encourage – living donation because of the inadequate organ supply, knowing that donors are exposed to short-term risks (e.g., pain, bleeding, infection, and even death) as well as a small but calculable increased risk of longterm health problems including hypertension, chronic renal failure, and pre-eclampsia.¹¹ As such, the question is not whether but how much risk is the transplant community and society at large willing to expose an individual? Additionally, it asks which candidates should be allowed to assume these risks?

Elsewhere we proposed a moral framework involving five principles for exploring the ethics of living donation.¹² The first three are principles modified from the principles of human subjects protections in research as articulated in the Belmont Report: 1) respect for persons; 2) beneficence; and 3) justice.¹³ The fourth principle is adapted from Kenneth Kipnis' work in which he argues that the focus on vulnerable groups in the Belmont Report is inadequate and offers instead a typology of the various types of vulnerabilities that individuals may face in research.¹⁴ We have modified this typology to apply to living donors (see Table 1).¹⁵ The fifth principle focuses on the concepts of special relationships and special responsibilities. In his book, Protecting the Vulnerable, Robert Goodin starts from the premise that vulnerability is relational and assigns special responsibilities for protecting the vulnerable on those with whom the vulnerable are in special relationships: "we bear special responsibilities for protecting those who are particularly vulnerable to us." In living donor transplantation, then, the donor's health care team are moral agents who are responsible for empowering prospective donors to address their vulnerabilities, and/or for protecting those who cannot by disqualifying them from donation.¹⁶

How do these five principles play out in the case reports from Rotterdam (Case A) and Wisconsin (Case B)?

Consider, first, the principle of respect for persons which is operationalized in the concept of informed consent. The individuals from Rotterdam and Wisconsin had decision making capacity at the time they sought to be a living donor. All actively sought to donate, and their decision was consistent with other life decisions (e.g., signing a donor card). The principle of respect for persons would support the voluntary and informed decisions of these patients.

Table 1 Eight Vulnerabilities of Potential Living Donors *

Trait	Research	Living donor transplantation
Cognitive (aka Incapacitational)	Does the C-S have the capacity to deliberate about and decide whether or not to participate in the study?	Does the potential living donor have the capacity to deliberate about and decide whether or not to participate as a living donor?
Juridic	Is the C-S liable to the authority of others who may have an independent interest in that participation?	Is the potential living donor liable to the authority of others who may have an independent interest in that donation?
Deferential	Is the C-S given to patterns of deferential behavior that may mask an underlying unwillingness to participate?	Is the potential living donor given to patterns of deferential behavior that may mask an underlying unwillingness to participate?
Social	Does the C-S belong to a group whose rights and interests have been socially disvalued?	Does the potential living donor belong to a group whose rights and interests have been socially disvalued?
Medical	Has the C-S been selected, in part, because of the presence of a serious health- related condition for which there are no satisfactory remedies?	Has the potential living donor been selected, in part, because of the presence of a serious health-related condition in the intended recipient for which there are only less satisfactory alternative remedies?
Situational	Is the C-S in a situation in which medical exigency prevents the education and deliberation needed to decide whether to participate in the study?	Is the potential living donor in a situation in which medical exigency of the intended recipient prevents the education and deliberation needed by the potential living donor to decide whether to participate as a living donor?
Allocational	Is the C-S or proxy lacking in subjectively important social goods that will be provided as a consequence of participation in research?	Is the potential living donor lacking in subjectively important social goods that will be provided as a consequence of participation as a donor?
Infrastructural	Does the political, organizational, economic, and social context of the research setting possess the integrity and resources needed to manage the study?	Does the political, organizational, economic, and social context of the donor care setting possess the integrity and resources needed to manage living donation process and follow-up?

Abbreviation: C-S = Candidate-Subject

*This table was first published in L. F Ross and J. R. Thistlethwaite, "The Prisoner as Living Organ Donor," *Cambridge Quarterly of Healthcare Ethics* 27, no. 1 (2018): 93-108, at 97. Reprinted with permission from Cambridge University Press.

However, this principle must be balanced against the other principles. The principle of beneficence would support donations provided that the benefits outweigh the harms. Whether living organ donation from a person with a LLC fulfills this principle is controversial. Some would argue that the benefits of successfully being an organ donor outweigh the harms of undergoing surgery and the risks of postoperative complications even if one has only a short life-expectancy. They may also argue that the physicians may be harming someone like W.B. psychologically in thwarting his goals even as they protect him physically. Others, however, would argue that most of the benefit can be achieved by post-mortem donation and one cannot justify taking a patient with a LLC to the operating room if the individual has a serious

risk of an adverse outcome from the elective surgery, as might be expected in an individual with stage III Gold chronic obstructive pulmonary disease (Case A) or ALS (Case B).

The third principle to consider is justice understood as fairness in participant selection. Traditional living donors were adult biologically related family members, but today programs encourage patients to find living donors from a wider pool: from spouses and friends to acquaintances located on social media and even strangers. Participants were traditionally very healthy to minimize both short-term peri-operative risks and long-term health risks although today programs accept less healthy individuals.¹⁷ While longterm risks are of less concern in individuals with a LLC, some individuals with a LLC are at increased short-term risks (e.g., W.B. was at risk of becoming ventilator dependent). If transplant programs were to target persons with a LLC,18 this might raise suspicions of discrimination and devaluation. But one must recall that WB approached the transplant center on his own volition as did all of the individuals described in Rotterdam, and all were seeking to donate nondirectedly. This is an important distinction. The proposed donations are not the brainchild of transplant programs (and/or families) who may suggest donation because they de-value the life of those with LLCs and are willing to expose such individuals to risk because they have "less to lose." Rather, these cases involve individuals with LLC who autonomously propose living donation to give meaning to their numbered days. Non-directed donation by individuals with LLC is consistent with the principle of justice (although a campaign to encourage such donations would not be). It is fair because it treats all adults with decisional capacity equally in respecting their right to decide whether to serve as a living donor.

While the principles of respect for persons, beneficence, and justice are all consistent with respecting the donation request, such a conclusion raises discomfort in part because of the potential vulnerabilities of those with a LLC. Below we consider each of the vulnerabilities enumerated in Table 1.

In both the descriptions from Rotterdam (Case A) and Wisconsin (Case B), the work-ups did not find the potential donors to be cognitively vulnerable. Rather all were able to give an informed consent. Nor were there any juridic (overriding authority who had an independent interest in the donation), deferential (patterns of behavior that may mask unwillingness), medical (serious health-related condition in the intended recipient) or situational (time pressure that would interfere with donor education or deliberation) vulnerabilities as the idea to donate was their own and they had chronic illnesses but were not imminently dying.

We believe that the donors from Rotterdam and the potential Wisconsin donor possibly had allocational vulnerability — lacking in subjectively important social goods that would be gained by donation. First, many were described as unfit for work, and several were quoted as saying that the donation would make them "useful" suggesting that they lacked social respect which they hoped could be gained by donating.¹⁹ This does not seem heavily persuasive as donation would be a one-time event, unlikely to maintain an ongoing sense of productivity or self-worth. A second important social good is the sustaining of relationships. A major fear of critically ill individuals is abandonment by their families and health care providers.²⁰ Again, this does not seem persuasive as kidney donation by

such individuals would create short-term relationships with new health care providers that would be unlikely to help maintain family relationships and, if anything, would temporarily supplant and risk interfering with relationships with ongoing health care providers. In additional, family members' responses may be mixed — while some may view the donor as a self-sacrificing hero; others may think the donor is "crazy" or "reckless."²¹

The potential donors from Rotterdam and Wisconsin were also potentially socially vulnerable because of their illness and/or disabilities. The medical profession has a long history of abandoning dying patients, as do some friends and families,²² and this is one way that patients may seek to be engulfed into relationships out of a position of strength and not of vulnerability.

The threats of social and allocational vulnerability must be examined against the backdrop that these donors had approached the transplant programs on their own initiative. In both Cases A and B, the donors decided by themselves that they (and society) would get more benefit from their donating a kidney as living donors rather than wait until their death when their declining health or the dying process might make the organs unusable for transplantation. Permitting living donation in individuals with LLC empowered the individuals in Rotterdam to achieve their goal of helping a third party through organ donation at a time when they themselves felt that they had few other opportunities to contribute to society.

The concerns that the individuals' vulnerabilities adversely interfere with their ability to consent voluntarily to living organ donation requires careful evaluation by a skilled independent living donor advocate or living donor advocate team (LDA[T]).²³ Since 2007, the LDA(T) is a mandated component of all living donor evaluations in the US.24 For any potential living donor, the LDA(T) must assess the various vulnerabilities delineated in Table 1. While all potential donors have potential vulnerabilities, when the potential donor has a LLC, some vulnerabilities may be exacerbated and different vulnerabilities may be at issue. The LDA(T) should ensure that the potential donor is informed, is acting consistent with his or her own values, understands his or her right to renege, and that the vulnerabilities have been evaluated and addressed. Using Goodin's concepts of special relationships and special responsibilities, this means that the LDA(T) is responsible for evaluating all the different types of vulnerability threats that the potential donor may experience and for ensuring that they are adequately addressed in order to empower the potential donor to give a voluntary and informed consent.

Even if the LDA(T) determines that the donor is acting freely and without undue pressure, the surgeons are moral agents and in the Wisconsin case, they stated that they have a responsibility to minimize harm and leaving a donor ventilator-dependent post-operatively is not consistent with their interpretation of their obligations in the elective living donor setting.25 The Wisconsin surgeons were also worried about institutional reputation.26 While their decision may conflict with their patient's interest, it is important for the community of patients for whom they provide care. Thus, the Wisconsin surgeons, as moral agents, can and did refuse to accommodate W.B.'s desire to be a living donor. As Carl Elliott so eloquently explained: a physician as a moral agent decides "not simply whether a subject's choice is reasonable or morally justifiable, but whether he [the physician] is morally justified in helping the subject accomplish it."27

In sum, Cases A and B describe cases in which competent adults request to serve as living donors. The donations only differ from the standard non-directed donor in that the non-directed donor is usually very healthy with a long life expectancy. While the potential donor with a LLC may be more socially and allocationally vulnerable, the donation can be consistent with their own life goals. A thorough living donor work-up including evaluations by mental health providers and LDA(T) are essential. While morally permissible for the Rotterdam physicians to respect the donation decisions by individuals with decisional capacity who have a LLC, the physicians in Wisconsin, as moral agents, were also within their right to refuse to take W.B. to the operating room if they thought they would leave him seriously worse off.

Interestingly, all the donors from Rotterdam and Wisconsin were seeking to donate non-directedly. Although not described in detail in this published manuscript, Rakké and colleagues in Rotterdam noted that they had also procured kidneys from two individuals with Huntington's Disease who donated to a specified recipient.28 Directed living donation from individuals with LLC potentially may generate deferential vulnerability concerns (for example, if the idea is proposed by another family member to whom the individual with the LLC is deferential). The need for an organ by a family member also raises concerns about medical and situational vulnerabilities. On the one hand, the individual with a LLC may be selected by the family as more expendable than others, and the individual may feel pressured to donate quickly before his or her symptoms worsen and make him or her ineligible to be a living donor. On the other hand, the donor may also experience significant benefit in knowing that he or she has helped a family member, and it may

increase his or her social standing within the family.²⁹ As such, potential directed donors with LLC raise both similar and different vulnerabilities than potential donors with LLC who seek to donate non-directedly. Both require careful evaluation by an LDA(T) to assess donor understanding, voluntariness, and that the vulnerabilities are appropriately addressed.

Did Rotterdam go too far? We don't think so. Agreeing to accept donations from donors with LLC is consistent with the ethical framework that we enumerated. While safeguards are necessary for all living donors, the potential donor with a LLC may have some additional vulnerability risks that require careful assessment by an LDA(T). It will be an uncommon request, but its fulfillment may help individuals give meaning to their lives as they struggle to live with progressive and ultimately fatal debilitation. However, such donations should be limited to persons with decisional capacity who voluntarily and independently raise this option. Public endorsements or campaigns by transplant professionals to attract such candidates for either directed or non-directed donation should be avoided.

Scenario 2: Pre-Mortem Donation from Individuals with Devastating Neurologic Injuries

In the United States, under the Uniform Declaration of Death Act, death is determined by either (1) irreversible cessation of circulatory and respiratory functions, or (2) irreversible cessation of all functions of the entire brain, including the brain stem.³⁰ In all cases of deceased donor transplantation, the donor must be dead and not merely dying (what is colloquially known as the "Dead Donor Rule" [DDR]).³¹ The DDR "is neither a law nor a regulation - it is a description of an ethical norm."32 It expresses the idea that all human life is valuable and that persons are treated and cared for as living patients until death is declared. Only after death is declared do providers switch from treating the patient to focusing on the procedures necessary to prepare the decedent for organ donation. As Arnold and Younger explain, the requirement that:

persons must be dead before their organs are taken has two distinct connotations: 1. Patients must not be killed by organ retrieval;...and 2. Organs must not be taken from patients until they die.³³

Most deceased organ donors are declared dead by irreversible cessation of neurological function. A physician evaluates the patient to ensure that he or she lacks brain stem reflexes and fails an apnea test. The decedent is kept on the ventilator for organ oxygenation until organs are removed in the operating room. Both thoracic and abdominal organs can be procured.

In the case of death after irreversible cessation of cardio-circulatory function, there is a waiting time between the declaration of death and the procurement of organs to ensure auto-resuscitation does not occur.³⁴ Donation after circulatory death (DCD) are usually attempted in individuals who suffer a catastrophic injury (e.g. from trauma or stroke), require life-sustaining treatment, and have a neurological prognosis inconsistent with recovery. Only after the decision is made to withdraw life-sustaining treatment is the option of DCD raised. Consider, for example, the case described by Paul Morrisey in the *American Journal of Bioethics* in 2012.

Case C: A 28 year old man suffered severe irreversible brain injury in an industrial accident but was not expected to progress to brain death. The family and team agreed to withdrawal of treatment. The patient had a signed donor card and the family agreed to attempt donation after circulatory death (DCD). The family requested that upon procurement, one kidney would be allocated to a family member and agreed that the liver and second kidney would be allocated according to the wait list. Thoracic organ donation was not considered.³⁵

Most DCD protocols require that the individual undergoes cardiorespiratory arrest within a given period of time after withdrawal of life support. If the potential donor survives for a longer time period, the organ retrieval procedure is aborted. In fact, even when potential DCD donors die within the allotted time, the number of organs actually procured and transplanted will depend on many factors. In the case described by Morrisey, procurement was not attempted:

Upon extubation in the operating room, he maintained normal blood pressure and heart rate despite low oxygen saturations. After 60 minutes the transplant team requested further observation in the operating room for asystole. After an additional 30 minutes of hypotension and hypoxia, organ recovery was abandoned and the patient was returned to the intensive care unit. He died four hours later.³⁶

The requirement that the patient be declared dead before donation may thwart potential donors from realizing their desire to donate. To circumvent this, Morrisey proposed that our current organ donation policies should be revisited in the situation of an elective withdrawal of life support for a neurologically devastated patient, and that the donor's surrogate be given the option of pre-mortem kidney donation:

Case D: The process begins as before with the identification of a suitable candidate for DCD: explicitly an individual with severe, irreversible brain injury. The family decides to withdraw life-sustaining treatments with the expectation of the patient's imminent death. A DNR [Do Not Resuscitate] order is entered. The family provides informed consent for kidney donation to be followed by end-of-life care. The patient is transported to the operating room for kidney recovery. Both kidneys are recovered via midline laparotomy with vascular control, equivalent to bilateral nephrectomy in a neurologically intact patient. General anesthesia and standard analgesic care are administered, as would be given to a trauma victim with severe head injury undergoing surgery. The patient returns to the intensive care unit. A suitable interval from the operating room to the palliative care setting would enable the medical team to administer analgesia and sedation appropriate to end-of-life care without concern that an anesthetized patient is being extubated. End-of-life care is instituted according to the family's request, in a more relaxed time period without the requisite "rush" to organ retrieval following asystole required by DCD. This protocol enables the family to grieve and spend time with the decedent after death.³⁷

Morrisey proposes that individuals with severe irreversible brain injury who are not expected to progress to brain death (and may die too slowly after extubation to meet DCD criteria) undergo pre-mortem bilateral kidney donation under anesthesia. Although Morrisey is only proposing the procurement of kidneys, one could imagine other organs, for example, a living liver lobe or single lung could also be procured. After the procurement, the patient returns to the intensive care unit, gets appropriate palliative care, and then has treatment withdrawn.³⁸

Morrisey's article was followed by a number of commentaries. Smith and colleagues objected because Morrisey's proposal failed to protect the donor's interests, but, if Morrisey's proposal were modified to require first-person donor consent, then they would support it.³⁹ Wynn Morrison also supported the idea of pre-mortem donation in principle, but objected to the removal of both kidneys: The suggestion that bilateral nephrectomies be performed is the most ethically troublesome aspect of this protocol. The medical team's ability to predict, on an individual basis, the time frame within which a patient will die is imperfect. Removing both kidneys not only guarantees that the patient will die within a few weeks following the withdrawal when death otherwise might not have occurred, but iatrogenic renal failure also has the potential to complicate the symptom management of the dying patient.⁴⁰

Morrisey is not the only one to raise the issue of "imminent death donation" (IDD). In 2014, the Ethics Committee of the United Network for Organ Sharing (UNOS) coordinated an inter-committee work group to consider the ethical implications of IDD — that is "the recovery of a living donor organ immediately prior to an impending and planned withdrawal of ventilator support expected to result in the patient's death."⁴¹ According to the Ethics Report, IDD applies to at least two types of potential donors:

(1) IDD might be applicable to an individual with devastating neurologic injury that is considered irreversible and who is not brain dead. The individual would be unable to participate in medical decision-making; therefore, decisions about organ donation would be made by a surrogate or might be addressed by the potential donor's advanced directive.

(2) IDD might also be applied to a patient who has capacity for medical-decision making, is dependent on life-support, has decided not to accept further life support and indicates the desire to donate organs prior to foregoing life support and death.⁴²

Case D above is an example of a potential type 1 IDD. An example of a type 2 IDD was described by Arnold and Younger in 1993. The hypothetical case (**Case E**) involves a ventilator-dependent patient with ALS patient who has requested termination of life support which is planned for the following day. In their hypothetical case, the patient then requests that prior to termination of life support that he be taken to the operating room and be allowed to donate multiple abdominal organs under anesthesia. He would then be transported back to the intensive care unit where his ventilator would be disconnected at the arranged time, long before the patient would die from the organ removals.⁴³

The UNOS Ethics Committee did not discuss the ethics of type 2 cases of IDD, but focused exclusively

on type I cases of IDD and "ultimately determined that there could be circumstances where LD-PPW [living donation prior to planned withdrawal] may be ethically appropriate and justified by the potential benefits to donors, donor families and recipients."⁴⁴ However, nine other UNOS committees objected to their proposal and the proposal was subsequently withdrawn.⁴⁵

But IDD is not the farthest point on the spectrum. The next step would be to consider whether individuals who are imminently dying (or their families) can ask that the physicians not withdraw the ventilator and procure the organs post-declaration of death but rather, that the dying individual be taken to the operating room on the ventilator and have their organs (including vital organs) removed under anesthesia (Case F). IDD limits which organs can be procured and their quality in comparison with death by organ procurement in which all organs, can be procured and avoids what might be considered a charade of returning the imminent death donor to the ICU to remove cardiorespiratory support to allow death to proceed. Although this has not yet occurred, there are bioethicists who have argued in its support.46

Ethics Framework for Imminent Death Donation (IDD)

Case C is ethically straight-forward because the family gives permission for the patient to become a DCD donor (which, in this case, we know is consistent with the patient's signed donor card). Case D is more ethically controversial because the patient's tragic condition was acute and the patient had no time to consider how he would want to be treated if he became severely brain injured and was not expected to recover. A proxy decision-maker, usually a family member, must decide what he would have wanted. The proxy can also authorize DCD donation if this is what the patient would have wanted. It is not clear that the proxy can consent for the patient to serve as a living solid organ donor without going to court.⁴⁷

The five principle framework can be used to evaluate IDD by an individual who lacks decisional capacity (Case D).

Consider, first, the 3 principles from the *Belmont Report.* Case D differs from all the earlier cases because consent for living donation is being given by a surrogate and not by the patient. Respect for persons requires that we respect the wishes of a patient with decisional capacity and protect those who lack capacity.⁴⁸ Whether the patient in Case D would have wanted to be a living donor and undergo surgery prior to treatment withdrawal is not known. Given his incapacity and lack of stated wishes, the principle of respect for persons requires protection even from well-meaning family members and transplant professionals and would not support donation. Pre-mortem donation is also not consistent with the principle of beneficence. The procurement would clearly not be for his medical benefit and may even cause physical harm (pain), without any potential psychological benefit. This contrasts with Cases A and B in which psychological benefit of being a donor was an important motivation for the individuals to serve as living donors. Given the lack of prior stated wishes in Case D about living donation, it is hard to justify exposing him to any risks of pain or discomfort to benefit an unknown third-party. Justice arguments also support limiting living organ donation to individuals who can provide their own voluntary and informed consent.

The vulnerabilities analysis also must be re-evaluated in light of the potential donor's cognitive vulnerability which means he cannot consent for himself and differentiates him from the donors in Cases A and B above. The patient is also socially vulnerable because his neurological prognosis is poor, even if he were maximally treated. The data show that the severely disabled are frequently disvalued.49 The patient in Case D also clearly has situational vulnerability: the severe brain injury prevents the education and opportunity to deliberate about whether to participate as a living donor. If there were a known potential transplant candidate in the family, the patient may also have medically vulnerability: the family may seek to procure the organ for their loved one pre-mortem to avoid the possibility of an aborted DCD donation due to the patient's prolonged survival after withdrawal of life support.

While cases of IDD type 1 do not violate the letter of the DDR, we believe they do violate its spirit. The main reason for the individual to donate pre-mortem is because DCD may not come to fruition. In contrast, we believe that the harms of surgical intervention in the last hours of life - not for the benefit of the patient, but for the benefit of a third-party, cannot be justified. As moral agents, transplant providers should invoke the DDR to protect dying patients. IDD is being done to circumvent the DDR which protects dying patients because it requires pre-mortem care to be focused on the patient as a person (an end-in-oneself) and not solely as a potential source of organs (as merely a means to another's ends).⁵⁰ IDD also threatens public trust in the transplant and palliative care enterprises. We do not support IDD type 1.

Cases of IDD type 2 (Case E) differ from Cases of IDD type 1 (Case D) because the hypothetical individual in Case E has decisional capacity and makes the request for and by himself. While this makes him less vulnerable, he is still quite socially vulnerable given his severe disability.⁵¹ Again, IDD is only being considered because DCD may not be actualized due to many factors beyond the control of the patient and transplant team. Thus, cases of IDD type 2, like cases of IDD type 1, are ethically problematic because they also attempt to circumvent the DDR and the protections it affords to those who are dying.

Case F is slightly different than IDD as described by the UNOS Ethics Committee because in this case, the individual whose death is imminent does not die shortly after donation but actually the donation is the proximate cause of death. Case F challenges the premise of the DDR. It promotes organ procurement from individuals who are not dead but only "nearly dead" or "as good as dead."⁵² That is, Case F forces one to ask what protections does the DDR provide in a case where life-sustaining treatment will be removed in the near future with imminent death expected.

The utilitarian asks whether the benefits of obtaining organs from dying patients before they die and violating the DDR outweighs the harms. While the donors (or their families) in these cases might say that the benefits outweigh the harms, we must ask what society at large would think and whether such actions would reduce public trust, not just in transplantation, but also in medical care of the dying. Some may be concerned that permitting donation by those with LLCs suggests that their lives are expendable, or at least they are perceived as expendable by health care providers. Thus, although procuring organs from the dying may increase organ procurement in the shortrun, if public trust is lost, it may cause fewer organs to be procured in the long-run. Thus, utilitarians may or may not support living donation by the imminently dying – depending on their assessment of the anticipated consequences, both intended and unintended. Other utilitarians may argue for at least a trial to determine what impact donation of the dying would have on the overall number of organ donations.

From a deontological or principle-based perspective, it is not enough to ask whether the benefits outweigh the harms, but to consider certain fundamental principles of bioethics that must be satisfactorily addressed. One such principle is whether death by organ procurement is consistent with respect for persons or whether it is treating the moribund donor as a means (a source of organs) and not focused on the patient as a person or an end-in-him- or herself.⁵³

There is also a logistical problem: Transplant surgeons may not be willing to be the proximate cause of the patient's death. In the spirit of the DDR, patients are declared dead by health care providers not involved in the organ procurement, and the transplant team only gets involved after the patient is declared dead.

The Journal of Law, Medicine & Ethics, 47 (2019): 112-122. © 2019 The Author(s)

But what if transplant surgeons were willing to take patients to the operating room and procure their organs as a form of physician-assisted suicide rather than waiting until after a patient's death by natural causes after life support is withdrawn, should it be permitted? Currently it is not legal, and we believe that death by organ procurement should remain illegal because it circumvents important safeguards: the separation of patient care and patient care decisions from organ procurement as well as the separation of the determination of death from organ procurement.⁵⁴ These separations are important to ensure respect for the dying patient and to maintain patient and community trust in the transplant enterprise, and the medical system more broadly.

In sum, the DDR helps to ensure respectful and

Our answers are case-dependent. Case C is a classic example of DCD and raises no red flags (provided adequate time has elapsed after cessation of circulation to ensure both that auto-resuscitation cannot occur and that cerebral brain function has ceased).55 Cases A and B are cases of living donation in individuals with LLC who have decisional capacity and are not imminently dying. Living donation is being considered as a viable option because of the primacy placed on the principle of respect for persons in modern Western bioethics. But respect for persons incorporates both respect for the autonomy of those with decisional capacity as well as protection for those who lack decisional capacity (i.e., those who are cognitively vulnerable) or have other vulnerabilities that merit protection. In cases of living donation, the transplant team, including an

We began by considering cases of individuals with decisional capacity who are currently "healthy enough" to donate organs despite having an LLC. We then proceeded to the living donor who was imminently dying and the potential for IDD and lastly the case of the person who seeks to die by organ procurement (see Table 2). The appearance of these cases in the literature implies some degree of legitimacy that makes them worthy of examination. They force us to ask whether the cases represent a permissible small step along what admittedly could become a slippery slope or whether they are themselves a step too far in our quest to expand the organ donor pool.

appropriate care for the dying. There is value in maintaining a clear division of responsibilities between end of life care and organ procurement with two separate medical teams involved even though it means that the organs suffer a warm ischemic insult because the patient must die before his or her organs are removed.

Concluding Remarks

We began by considering cases of individuals with decisional capacity who are currently "healthy enough" to donate organs despite having an LLC. We then proceeded to the living donor who was imminently dying and the potential for IDD and lastly the case of the person who seeks to die by organ procurement (see Table 2). The appearance of these cases in the literature implies some degree of legitimacy that makes them worthy of examination. They force us to ask whether the cases represent a permissible small step along what admittedly could become a slippery slope or whether they are themselves a step too far in our quest to expand the organ donor pool. LDA(T), must evaluate all of the potential donor's vulnerabilities enumerated in Table 1. When the potential living donor has a LLC, some of these vulnerabilities may be augmented. As Elliott stated, the transplant physicians must decide not only whether the decision to donate is reasonable but whether they should assist.⁵⁶ As we saw in Cases A and B, different transplant physicians will come to different decisions about the morality of organ procurement from particular individuals with LLCs.

IDD (Cases D and E) and death by organ procurement (Case F) violate the DDR which protects the dying by requiring that "Organs must not be taken from patients until they die."⁵⁷ To-date, there are no reports in the literature describing the actual performance of IDD or death by organ procurement, and we believe they would represent a step too far.

Table 2 Summary of Cases

Case	Case description	Is the outcome ethical?
A	First person consent for living donation by individuals with decisional capacity and a life limiting condition (Rotterdam)	Yes, living donation is permissible provided that patient vulnerabilities adequately explored and patient gives an informed and voluntary consent
В	First person consent for living donation by individuals with decisional capacity and a life limiting condition (Wisconsin)	Yes, transplant team as moral agents can decide that the risk of harm is too great despite consent
С	DCD with surrogate consent	Yes, surrogates can consent when decision is consistent with prior wishes of decedent. Consistent with DDR.
D	Pre-mortem donation authorized by surrogates for a patient who is imminently dying (possibly followed by DCD)	No, attempts to circumvent DDR and thereby exposes vulnerable individuals to unnecessary harms
E	First person pre-mortem donation (possibly followed by first person consent to DCD)	No, attempts to circumvent DDR and thereby exposes vulnerable individuals to unnecessary harms
F	Death by organ donation authorized by first person or surrogate consent	No, removes protections from a vulnerable class of people. Inconsistent with DDR

Abbreviations: DCD = Donation after circulatory death; DDR = Dead Donor Rule

Note

Drs. Ross and Thistlethwaite received funding from the Robert Wood Johnson Investigator Award in Health Policy.

References

- M. J. Bia, E. L. Ramos, G. M. Danovitch et al., "Evaluation of Living Renal Donors: The Current Practice of US Transplant Centers," *Transplantation* 60, no. 4 (1995): 322-327; and D.A. Mandelbrot, M. Pavlakis, G. M. Danovitch et al., "The Medical Evaluation of Living Kidney Donors: A Survey of US Transplant Centers," *American Journal of Transplantation* 7, no. 10 (2007): 2333–2343.
- 2. Y. S. Rakké, W. C. Zuidema, M. T. Hilhorst et al., "Seriously Ill Patients as Living Unspecified Kidney Donors: Rationale and Justification," *Transplantation* 99, no. 1 (2015): 232-235 at 234.
- 3. *Id.*
- 4. *Id.*, 234.
- 5. *Id.*, 233
- 6. *Id.*
- 7. Id.
- J. Mezrich and J. Scalea, "As They Lay Dying," *The Atlantic*, April 2015, *available at* http://www.theatlantic.com/magazine/archive/2015/04/as-they-lay-dying/386273/ (last visited January 23, 2019).
- 9. *Id.*
- J. E. Murray, "Organ Transplantation: The Practical Possibilities" in G. E. W. Wolstenholme and M. O'Connor, eds. *Ethics* in Medical Progress: With Special Reference to Transplantation (Boston, MA: Little, Brown and Company): 59.
- See, for example, H. N. Ibrahim, S. K. Akkina, E. Leister et al., "Pregnancy Outcomes after Kidney Donation," American Journal of Transplantation 9, no. 4 (2009): 825-834; A. B. Massie, A. D. Muzaale, X. Luo et al., "Quantifying Postdonation Risk of ESRD in Living Kidney Donors," Journal of the American Society of Nephrology (JASN) 28, no. 9 (2017): 2749-2755; G. Mjøen, S. Hallan, A. Hartmann et al., "Long-term Risks for Kidney Donors," Kidney International 86, no. 1 (2014): 162-167; and A. D. Muzaale, A. B. Massie, M-C. Wang et al., "Risk of End-stage Renal Disease Following Live Kidney Donation," JAMA 311, no. 6 (2014): 579-586.
- 12. L. F. Ross and J. R. Thistlethwaite, "An Ethical Framework for Living Donor Transplantation," (2018) In submission.

- 13. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (Washington DC: Government Printing Office, April 18, 1978), *available at* http://www.hs.gov/ohrp/humansubjects/guidance/belmont.html (last visited January 23, 2019).
- K. Kipnis, "Vulnerability in Research Subjects: A Bioethical Taxonomy," in The National Bioethics Advisory Commission (NBAC), *Ethical and Policy Issues in Research Involving Human Participants Volume II Commissioned Papers and Staff Analysis* (Bethesda, Maryland, August 2001): G1-13; and K. Kipnis, "Seven Vulnerabilities in the Pediatric Research Subject," *Theoretical Medicine and Bioethics* 24, no. 2 (2013): 107–120.
- L. F Ross and J. R. Thistlethwaite, "Prisoners as Living Donors: A Vulnerabilities Analysis," *Cambridge Quarterly of Healthcare Ethics* 27, no. 1 (2018): 93-108.
- C. Elliott, "Doing Harm: Living Organ Donors, Clinical Research and the Tenth Man," *Journal of Medical Ethics* 21, no. 2 (1995): 91-96.
- 17. See Mandelbrot et al., *supra* note 1.
- R. A. Denu, E. A. Mendonca, and N. Fost, "Potential Yield of Imminent Death Donation," *American Journal of Transplantation* 18, no. 2 (2018): 486-491.
- 19. See Rakké et al., "Seriously ill patients," *supra* note 2.
- 20. A. L. Back, J. P. Young, E. McCown, et al. "Abandonment at the End of Life from Patient and Clinician Perspectives: Loss of Continuity and Lack of Closure," *Archives of Internal Medicine* 169, no. 5 (2009): 474–479; and D. Koon, "Meet the Woman Who Cared for Hundreds of Abandoned Gay Men Dying of AIDS," *OUT*, 2016, *available at* https://www. out.com/positive-voices/2016/5/19/meet-woman-who-caredhundreds-abandoned-gay-men-dying-aids (last visited January 23, 2019).
- J. Challenor and J. Watts, "It Seemed Churlish Not to': How Living Non-Directed Kidney Donors Construct their Altruism," *Health* 18, no. 4 (2014): 388-405; and C. L. Jacobs, D. Roman et al., "Twenty-Two Nondirected Kidney Donors: an Update on a Single Center's Experience," *American Journal* of Transplantation 4, no. 7 (2004): 1110-1116.
- 22. See, for example, Back et al., *supra* note 20; Koon, *supra* note 20; and J. M. Pohl, C. W. Given, C. E. Collins et al. "Social Vulnerability and Reactions to Caregiving in Daughters and

medical information commons \bullet spring 2019

Daughters-in-Law Caring for Disabled Aging Parents," Health Care for Women International 15, no. 5 (1994): 385-395.

- 23. D. LaPointe Rudow, "The Living Donor Advocate: A Team Approach to Educate, Evaluate, and Manage Donors Across the Continuum," Progress in Transplantation 19, no. 1 (2009): 64-70; and J. L. Steel, A. Dunlavy, M. Friday, et al. "The Development of Practice Guidelines for Independent Living Donor Advocates," Clinical Transplantation 27 (2013): 178 - 184.
- 24. Department of Health and Human Services, "Part II. Centers for Medicare & Medicaid Services 42 CFR Parts 405, 482, 488, and 498 Medicare Program; Hospital Conditions of Participation: Requirements for Approval and Re-Approval of Transplant Centers to Perform Organ Transplants; Final Rule. Rules and Regulations," *Federal Register* 72, no. 61 (March 30, 2007): 15198-15280; and United Network for Organ Sharing (UNOS)/ Organ Procurement and Tissue Network (OPTN), Appendix B, Section XIII, 2007.
- Mezrich and Scalea, "Lay Dying," supra note 8. 25.
- 26.Id.
- 27.
- Elliott, *supra* note 16, 95. Rakké et al., "Seriously Ill Patients," *supra* note 2 at 234. 28.
- 29. See, for example, C. Jacobs, E. Johnson, K. Anderson et al, "Kidney Transplants from Living Donors: How Donation Affects Family Dynamics," Advances in Renal Replacement Therapy 5, no. 2 (1998): 89-97; C. L. Jacobs, C. R. Gross, E. E. Messersmith, et al. on behalf of the RELIVE Study Group, "Emotional and Financial Experiences of Kidney Donors over the Past 50 Years: The RELIVE Study," Clinical Journal of the American Society of Nephrology 10, no. 12 (2015): 22-231; R. G. Simmons, S. K. Marine, and R. L. Simmons, Gift of Life: The Effect of Organ Transplantation on Individual, Family, and Societal Dynamics (Oxford: Transaction Books; 1987).
- 30. National Conference of Commissioners on Uniform State Laws, Uniform Determination of Death Act, Drafted July-August 1980, approved by the American Medical Association October 19, 1980, Approved by the American Bar Association February 10, 1981, adopted by the states throughout 1981, available at <http://people.bu.edu/wwildman/courses/thth/ projects/thth projects 2003 lewis/udda.pdf> (last visited January 24, 2019).
- N. Fost, "Organs from Anencephalic Infants: An Idea Whose 31. Time has Not Yet Come," Hastings Center Report 18, no. 5 (1998): 5-10; and J. A. Robertson, "Relaxing the Death Standard for Organ Donation in Pediatric Situations," in D. Mathieu (ed.), Organ Substitution Technology: Ethical, Legal, and Public Policy Issues (Boulder, CO: Westview Press, 1988): 69-76.
- R. M. Sade, "Brain Death, Cardiac Death, and the Dead Donor Rule," Journal of the South Carolina Medical Associa-32.tion 107, no. 4 (2011): 146-149, 147.
- R. M. Arnold and S. J. Youngner, "The Dead Donor Rule: 33. Should We Stretch it, Bend it, or Abandon it?" Kennedy Institute of Ethics Journal 3, no. 2 (1993): 263-78, 264-265.
- Ethically, the "hands-off" period between the cessation of pulse and respiration and procurement should also ensure 34. that brain function has also ceased because one would not want to be declaring a person dead, or procuring their organs if they were still conscious. This is discussed in R. M. Veatch and L. F. Ross, Defining Death: The Case for Choice (Washington DC: Georgetown University Press, 2016): 76-78.

35. P. E. Morrisev, "The Case for Kidney Donation Before Endof-Life Care," American Journal of Bioethics 12, no. 6 (2012): 1-8, 1.

- 38. While not mentioned by Morrissey, it is clear that if the patient dies quickly enough after treatment is withdrawn, that he would support the family's authorization to return the person to the operating room for DCD procurement of other organs.
- 39. M. J. Smith, D. Rodríguez-Arias, and I. Ortega, "Avoiding Violation of the Dead Donor Rule: The Costs to Patients,' American Journal of Bioethics 12, no. 6 (2012): 15-17.
- 40. W. Morrison, "Organ Donation Prior to Death - Balancing Benefits and Harms," American Journal of Bioethics 12, no. 6 (2012): 14-15, 15.
- L. Boulton on behalf of the OPTN/UNOS Ethics Committee, 41. "Ethical Considerations of Imminent Death Donation," 2016, 1, available at <https://optn.transplant.hrsa.gov/media/1918/ ethics_ethical_implications_of_idd_20160815.pdf> (last visited January 24, 2019).
- 42. *Id*, 1.
- See, Arnold and Youngner, supra note 33, 271. 43.
- 44. See Boulton, supra note 41, 1.
- See Boulton, supra note 41, 2. 45.
- 46. F. G. Miller and R. D. Truog, Death, Dying and Organ Transplantation: Reconstructing Medical Ethics at the End of Life (New York: Oxford University Press, 2012); and D. Wilkinson and J. Savulescu, "Should We Allow Organ Donation Euthanasia? Alternatives for Maximizing the Number and Quality of Organs for Transplantation," Bioethics 26, no. 1 (2012): 32 - 48
- 47. S. L. Nygren, "Organ Donation by Incompetent Patients," University of Chicago Legal Forum 2006, no. 1 (2006): 471-502, available at <http://chicagounbound.uchicago.edu/uclf/ vol2006/iss1/16> (last visited January 24, 2019).
- See, National Commission, supra note 13. 48.
- 49. C. J. Gill "Disability, Constructed Vulnerability, and Socially Conscious Palliative Care," Journal of Palliative Care 22, no. 3 (2006): 183-189; D. Stienstra and H. M. Chochinov, "Vulnerability, Disability, and Palliative End-of-Life Care," Journal of Palliative Care 22, no. 3 (2006):166-174.
- 50. I. Kant, Grounding for the Metaphysics of Morals, 1785, translated by J. W. Ellington (Indianapolis: Hackett Publishing, 1981).
- See Gill, supra note 49; and Stienstra and Chochinov, supra 51. note 49
- 52.See Miller and Truog, supra note 46, 144-147.
- See Kant, supra note 50. 53.
- 54. R. M. Kotloff, S. Blosser, G. J. Fulda et al., for the Society of Critical Care Medicine/American College of Chest Physicians/ Association of Organ Procurement Organizations Donor Management Task Force, "Management of the Potential Organ Donor in the ICU: Society of Critical Care Medicine/ American College of Chest Physicians/Association of Organ Procurement Organizations Consensus Statement," Critical Care Medicine 43, no. 6 (2015): 1291-1325.
- See, Veatch and Ross, supra note 34, 76-78. 55.
- 56. Elliott, supra note 16, 59.
- Arnold and Youngner, supra note 33, 264 and 265. 57.

Id., 1. 36.

^{37.} Id., 2.