



# The Ethics of Organ Donation: First, Do No Harm?

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# The Ethics of Organ Donation: First, Do No Harm?

*Submission for  
Honors in a Special Field*

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*“But, if we recall the version of the maxim, ‘at least do no harm,’  
we may see it not so much as a morality of lower limits,  
but as an admonition to humility.”*

Albert R. Jonsen (1978)

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### **Acronyms**

CPR – Cardiopulmonary resuscitation  
DBD – Donation after brain death  
DCDD – Donation after the circulatory-determination of death  
DDR – Dead donor rule  
UDDA – Uniform Determination of Death Act

## **Abstract**

The dead donor rule (DDR) stipulates that donors must be dead before life-sustaining organs are removed. Its normative basis is to protect organ donors from suffering unacceptable harm. The central ethical consideration should therefore not be whether or not a donor is dead: it should be whether the harm of vital-organ retrieval is justified. In this thesis, I argue that under certain circumstances it can be ethically permissible to grant consenting donors exemption from the DDR so long as the retrieval of vital organs would do no *wrongful* harm.

## Part I. Context

### Cape Town, South Africa

On December 3<sup>rd</sup>, 1967 Dr. Christiaan Barnard performed the world's first successful heart transplant. The *New York Times* heralded it as “one of the peaks of modern scientific achievement” (Editorial Board 1967). A decade had gone by since the first kidney transplant, but the riveting story of a dying young woman giving her heart to save a stranger's life enraptured audiences worldwide, introducing organ transplantation into public discourse to for the first time (DeVita, Snyder, and Grenvik 1993, p. 114). The donor was 25-year-old Denise Darvall. She was struck by a speeding drunk driver the previous evening and suffered severe head trauma which left her unconscious (McRae 2006, p. 186). At the Groote Schuur Hospital she was found to have multiple skull fractures which the attending neurosurgeon deemed “beyond treatment” (Ozinsky 1967, p. 1268). Denise's father, aware of the prognosis, gave the surgeons permission to remove his daughter's heart after he reflected on what Denise would have chosen for herself. “If you can't save my daughter,” he told them, “you must try and save this man” (McRae 2006, p. 189).

The recipient miraculously survived, but amid the fanfare some wondered how exactly Denise Darvall died *before* Barnard resected the heart. After all, her heart started beating in the recipient's chest, suggesting that the donor was not entirely cadaveric—or at least that she was alive enough to sustain healthy organs (Rosenfeld 1968). Yet if the heart had been resected from a non-deceased body, then, as one newspaper alleged, procuring the heart was “murder” (Editorial Board 1968). Then, less than a year later, a transplant surgeon in Japan sparked public outcry and faced criminal charges after removing a heart from a brain-injured donor who many perceived to still be alive. As a result of the controversy, the Japanese public lost trust in organ transplantation for decades (Haberman 1987).

The ethical quandary caught physicians by surprise. Rapid scientific advances in the 1950's led to mechanical ventilation, an advent which redefined the set of homeostatic checks-and-balances

necessary to sustain human life (Greenberg 2001). A patient on a ventilator could suffer the permanent loss of all brain activity—including the drive to breathe—and yet remain physiologically intact for years (Shewmon 2001). At the same time, transplantable organs were increasingly scarce and it seemed reasonable to obtain organs from permanently-comatose persons. What puzzled the medical profession was whether ventilator-dependent patients were themselves alive: if so, then to procure life-saving organs would itself kill the donors. Is it always wrong for physicians to remove healthy organs from a living person? One commentator opined, “As the need for donors grows larger, the definition of death must be carefully redefined. When are you dead enough to be deprived of your heart?” (Smith 1968, p. 721). Some, including pioneers in transplant surgery, pushed back. “We should not jeopardize the possible survival of the recipient while we are waiting around to made a decision whether the cadaver, as you call it, is dead or not ” (Cooley 1968).

Sensing that, “obsolete criteria for the definition of death can lead to controversy in obtaining organs for transplantation,” in 1968 Dr. Henry K. Beecher convened the Ad Hoc Committee of the Harvard Medical School to reexamine the meaning of death (p. 85). Their response was to “define irreversible coma as a new criterion for death” because “for all practical purposes” anyone with “a *permanently* nonfunctioning brain” is dead (p. 85). By definition, then, anyone declared brain dead is truly dead, regardless of other homeostatic processes. The Ad Hoc Committee’s definition of death successfully stymied the swelling controversy. It permitted individuals in end-of-life circumstances to voluntarily donate their life-sustaining organs, and it dispelled ambiguity about whether doctors kill to obtain transplantable tissue.<sup>A</sup>

The delineated concept of brain death and later circulatory death enabled the transplant community to enforce an initially-informal norm known today as the “dead donor rule” (DDR) (DeVita, Snyder, and Grenvik 1993). The late John Robertson, perhaps the most celebrated proponent of the DDR, describes it as a requirement that organ procurement itself not intentionally cause death (1999, p. 6). Put differently, physicians cannot cause death when procuring vital organs for transplantation. Other commentators articulate the DDR with a different connotation (Arnold and Youngner 1993, p. 264-5). For instance bioethicist James Bernat states that the DDR is the rule that

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<sup>A</sup> Historian Martin Pernick argues that Beecher developed brain death out of “pragmatic utility” to “not only promote organ donation, but also to protect the profession against transplantation’s critics” (1999, p. 12). Among other points, he cites a letter Beecher sent in 1967 to the Dean of Harvard Medical School proposing the Ad Hoc Committee. Beecher writes, “The time has come for a further consideration of the definition of death. Every major hospital has patients stacked up waiting for suitable donor[s]” (p. 9). In response the Dean warned, “The connotation of this statement is unfortunate, for it suggests that you wish to redefine death in order to make viable organs more readily available” (p. 9). Some critics argue that brain death was merely “conceptual gerrymandering” (Arnold and Youngner 1993, p. 267).

vital organs can only be removed after the declaration of death (2013, p. 1289). A bright-red-line definition of death is necessarily to comply with either version of the DDR.

Justification for the DDR can be divided into three categories: ethics, law, and public trust (Robertson 1999, p. 6). Ethical justifications generally argue that violations of the DDR are unacceptable because physicians harm donors by depriving them of continued life. Thus, even with a donor's consent, violations of the DDR disrespect the principle of nonmaleficence. Legal arguments emphasize the fact that it is a criminal offense to intentionally cause death for any reason. Barring legislative action, the transplant system has no choice but to enforce the DDR.<sup>B</sup> The third category of justification emphasizes the need for societal trust in transplantation: for the members of the public to voluntarily register as donors, they must have confidence they will not be killed for their organs.

There has always been uncertainty as to whether the historic heart transplant in Cape Town would have violated the yet-unarticulated DDR. Barnard's initial case report hardly comments on Denise Darvall, stating only that the donor was "certified dead (electrocardiogram had shown no activity for 5 minutes and there was absence of any spontaneous respiratory movements and absence of reflexes)" prior to the operation (Barnard 1967, p. 1269). Then a few years after Christiaan Barnard passed away his brother Marius Barnard, a surgeon who also operated on the donor, finally spoke out (McRae 2006, p. 332). The procurement team was aware that after halting mechanical ventilation, a gradual rise in hypoxia might jeopardize organ viability. When all life-sustaining measures were ceased and Darvall's heart did not immediately progress to asystole, Marius is reported to have administered a solution of potassium to halt electrical activity in the donor's heart (McRae 2006, p. 191). Five minutes later, Denise Darvall was pronounced dead and her heart was placed on bypass to provide oxygenation until Christiaan Barnard was ready to remove the organ (Barnard 1967, p. 1271). If true, the revelations offer reassurance that Denise Darvall was dead before her heart was removed, but they raise alarm that her doctors caused her death without professional authorization.

I do not support unauthorized transgressions of the DDR. But in what follows, I argue that the ethical motivations for the DDR would support professionally-sanctioned exemptions to the rule under certain circumstances, specifically when organ retrieval would do no *wrongful* harm. While the majority of my argument focuses on the relationship between the principles of medical ethics and the DDR, the following two sections offer a survey of the key empirical considerations.

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<sup>B</sup> I will not contest this assertion.



## Pathways to Organ Donation

In 1981 the President's Commission drew from the Ad Hoc Committee's report and endorsed the Uniform Determination of Death Act (UDDA) which is now law in forty eight states (Burkle, Schipper, and Wijdicks 2011, p. 841). The UDDA states, "An individual who has sustained either 1) irreversible cessation of circulatory and respiratory functions, or 2) irreversible cessation of all functions of the entire brain, including the brain stem, is dead. A determination of death must be made with accepted medical standards" (1997). The law introduces cardiopulmonary death as an alternative to brain death. It also entrusts physicians with the authority to develop criteria for each definition. The two current procedures for obtaining vital organs are molded by these definitions in order to ensure that—in compliance with the DDR—death precedes procurement.

The first option available to eligible patients is donation after brain death (DBD). Guidelines from the American Academy of Neurology establish the clinical criteria of brain death. The declaration of brain death requires that a patient be in an irreversible coma from a known cause with absent brainstem reflexes and no drive to breathe (Wijdicks et al. 2010, p. 1914-16). Whenever a patient is declared brain dead, state and federal law mandate reporting this be reported to an organ procurement organization (p. 1916). If there is valid consent to donation, the deceased donor's mechanical ventilation is not withdrawn until after her transplantable organs are removed. This ensures organs receive adequate oxygenation throughout the procurement process. However, brain death often occurs in physiologically unstable patients. In the United States, only 1.4-1.5% of deaths allow potential donors to undergo DBD (Organ Procurement and Transplantation Network 2015, p. 46).

Amid worsening organ shortages, patients wait-listed for a transplant increasingly depend on the alternative protocol, donation after the circulatory-determination of death (DCDD). While fewer than two percent of deceased donors utilized DCDD in 2000, the protocol was used for one out of every five successful donations in 2017 (Organ Procurement and Transplantation Network 2018). When a patient dependent on life-support consents to DCDD, she is taken to an operating room where life-sustaining therapy is halted. After two to five minutes of pulselessness the patient is pronounced dead, and only then organs are resected (Steinbrook 2007, p. 210).<sup>c</sup> Mainstream bioethicists believe that two-to-five minutes of pulselessness is sufficient to satisfy the

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<sup>c</sup> The exact waiting period depends on prevailing consensus. Doctors in the United States generally respect a five-minute waiting period, but Europeans wait for two minutes. Because very few neonatal hearts are available for transplantation, doctors in Colorado recently performed two DCDD-heart procurements after one minute and 15 seconds of pulselessness (Boucek et al. 2008, p. 711).

cardiopulmonary criterion for death. After this time period the loss of function is considered *permanent*: while the circulation might be restorable, if there is no plan to administer resuscitation, then “permanent cessation serves as a valid stand-in for irreversible cessation” (Bernat et al. 2010, p. 965).<sup>D</sup> If the heart does not stop, organs are not removed. Accordingly, they reason, the declaration of death precedes vital-organ procurement and so DCDD complies with the DDR.

The cessation of life-sustaining therapy, however, often does not immediately result in cardiac arrest. As a result, willing donors are unable to actually donate any solid organs in as many as half of the situations where DCDD is attempted (Manara, Murphy, and O'Callaghan 2012, p. 113). Even when a patient does progress to asystole within a reasonable time period, lack of ventilator support causes progressive hypoxia and ischemic organ damage. As a consequence, patients allocated a DCDD-liver for instance are at significantly greater risk for graft failure and premature death than DBD-liver recipients (Doshi and Hunsicker 2007, p. 127, Merion et al. 2006, p. 558). Out of concern for recipient welfare, compared to DBD donors on average fewer organs are retrieved per DCDD donor (Organ Procurement and Transplantation Network 2018). In fact, the kidneys are the only DCDD-solid organ that is regularly transplanted (Organ Procurement and Transplantation Network 2018).

Given the relative advantages of DBD, it is generally viewed as the preferred pathway for vital-organ donation. However, DBD is not an option for every willing donor. Consider a situation where life support will soon be withdrawn from a patient with a catastrophic brain injury who hoped to donate as many life-saving organs as possible. She is irreversibly unconscious and would meet all criteria for brain death but for a single brainstem-mediated reflex still intact. According to professional consensus she is not dead, thus the only pathway available to her is DCDD. After extubation, if her heart continues to beat on its own, the donor's end-of-life wishes must soon be abandoned altogether. It is required by the DDR.

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<sup>D</sup> This assertion is not without controversy. As Dan Brock writes, “The common sense understanding of the irreversibility of death is that it is not *possible* to restore the life or life functions of the individual, not that they will not in fact be restored only because no attempt will be made to do so” (1999, p. 298)

## Public Trust and the Dead Donor Rule

Every day in the United States, approximately 22 people die on the transplant waiting list (Organ Procurement and Transplantation Network 2018). At the same time, organ donation is voluntary and uncompensated. Everyone is free to refuse to donate their organs for any reason. The number of people willing to register as an organ donor rests on the prevailing attitudes about donation. From a public health perspective, public opinion is therefore pertinent to any proposed policy change. Accordingly, a common objection to permitting vital-organ procurement before the declaration of death is that it would breach the public's trust in organ donation (Bernat 2013, Magnus, Wilfond, and Caplan 2014, Robertson 1999).<sup>E</sup> As Bernat writes, modifying the DDR “will lead fearful patients to lose trust in physicians and confidence in the organ donation system and will result in an overall decline in organ donation” (2013, p. 1290). After all, relaxing the DDR would ease the existing moratorium on killing people for their organs.

Occasionally the DDR is construed as a reflection of the prevailing values in society. For instance, a perspective piece in the *New England Journal of Medicine* alleges that any proposal to change the DDR is “far out of touch with currently accepted medical and legal standards and public opinion” (Magnus, Wilfond, and Caplan 2014, p. 893). In this sense, the DDR describes a widely-shared intuition or moral judgement. Other commentators differ on the nature of the DDR's relationship to public opinion. Bernat contends that the DDR “strengthens public trust and confidence in our voluntary system of organ donation” (2013, p. 1289). Here the implication is the DDR *acts on* public opinion. This subtly deviates from the first argument's assertion that public opinion is *captured by* the DDR. These explanations are not mutually exclusive. A less generous factor might be that in superseding dissent, the DDR maintains trust by keeping the operative details of DBD *out of* the public spotlight.<sup>F</sup> At any rate, all similarly predict that a change to the DDR would cause public backlash with a resulting decrease in the per-capita rate of organ donation. Considering the potential to spark misunderstanding and fear, Robertson stipulates that any proposal to alter the DDR must be evaluated according to its likely effect on public trust (Robertson 1999). Therefore, amending the DDR would constitute irresponsible stewardship over a life-saving medical resource.

Crucially, this argument takes the form of an empiric slippery-slope: its persuasiveness depends entirely on its factuality. Yet these concerns are unsubstantiated by the three most recent

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<sup>E</sup> For the sake of brevity, I refer to generally to these as “public-trust” arguments

<sup>F</sup> Some observing DBD might not consider the donor truly dead until exsanguination results in asystole.

articles to review the sizeable body of pertinent research (DuBois and Anderson 2006, Bastami et al. 2013, Shah, Kasper, and Miller 2015). Instead, the existing evidence indicates that most people do not understand—or do not share—the medical profession’s definition of death. The most recent of these reviews included 43 studies involving 18,603 participants and concluded that, “[D]espite scholarly claims of widespread public support for organ donation from brain dead patients, the existing data on public attitudes regarding brain death and organ transplantation reflect substantial public confusion” (Shah, Kasper, and Miller 2015). In one topical study, virtually all participants were familiar with the concept of brain-death, yet two thirds of respondents did not believe a person declared “brain dead” is “legally dead” (Siminoff, Burant, and Youngner 2004, p. 228). Three quarters of these respondents instead believed the brain-dead patient is “as good as dead,” and yet they were just as likely to support vital-organ procurement as the respondents who believed that the brain-dead person was legally dead (p. 228).

One reason for the state of confusion might be that the UDDA defines death by expert consensus rather than by its common-sense meaning. The public might not see a distinction between someone who is brain dead and an apneic patient in a coma: both feel warm to the touch, both have an audible heartbeat, and both appear to be in a deep slumber—few would guess that the law does not ascribe them equal rights. Journalists face a daunting challenge when a story highlights a divergence between the medical criteria of death and its meaning in ordinary language. For example, in 2005 a pregnant woman in Virginia was declared brain dead and subsequently maintained on a ventilator until her pregnancy reached term. One headline read simply, “Brain-Dead Woman Gives Birth, Dies” (Smith 2005). This conveys the belief that the brain-dead woman was alive for some time, which is nonsensical according to accepted medical standards—but how can a cadaver birth a healthy baby? The still-evolving case of Jahi McMath might further erode public confidence in the medical profession’s determination of death. It is without dispute that McMath met the criteria for brain death in 2013 (Magnus, Wilfond, and Caplan 2014, p. 891). However, her mother refused to terminate care. The ensuing legal battle and ultimately her cross-country transfer to New Jersey thrust the story into the public spotlight. In the most recent twist, Alan Shewman, a widely-respected neurologist, submitted court documents attesting, “Jahi McMath does not currently fulfill the accepted medical stands for brain death” (Winkfield v. Benioff Children's Hospital Oakland 2017, p. 3). At the time of this writing, the front page story on *The New Yorker* is about Jahi McMath—its running title asks, “What Does It Mean to Die?” (Aviv 2018). Exactly fifty years after the Ad Hoc Committee’s report on brain death, posing this question to a well-education audience suggests there is deep uncertainty if

the declaration of death is actually the end of life (Shewmon 2004, p. 292). Some members of the public might therefore reasonably assume that existing transplant policies permit the retrieval of organs from still-living donors in violation of the DDR. To many, then, exempting comatose donors from the DDR with their or a family member's consent might seem more ordinary than abhorrent.

This might explain the results of a recent study of attitudes towards organ donation in end-of-life circumstances (published after the literature reviews noted above). A nationally-representative group of participants was given the following scenario;<sup>6</sup>

“[...] As a result of the [car crash], Jason is completely unconscious [...] and his condition is irreversible. He also cannot breathe without mechanical support [...]. Although he will never wake up [...] Jason is still biologically alive. Before the injury, Jason wanted to be an organ donor. The organs will function best if they are removed while Jason's heart is still beating and while he is still on the breathing machine. If the organs are removed while Jason is still on the machine, he would die from the removal of organs (in other words, the surgery would cause Jason's biological death)” (Nair-Collins, Green, and Sutin 2015, p. 298-99).

Among the 1096 participants, 14% felt that it should be illegal for patients like Jason to donate his organs while 71% believed that organ donation should be legal (the remainder were unsure) (Nair-Collins, Green, and Sutin 2015, p. 299). Similarly, only 16% disagreed with the statement, “Doctors should be legally allowed to remove organs from patients like Jason, assuming consent.” Among respondents who said they were personally willing to donate their organs, fewer than one in ten said they would not want to donate their organs if they were in a situation like Jason's (supplementary appendix S15). At the same time, eight out of ten registered organ donors said they would want to donate their organs if they were in a situation like the one described in the scenario.

This study demonstrates that a substantial majority of Americans support exemptions to the DDR for imminently-dying and consenting donors. The conclusion is at odds with widely-cited assertions that the DDR reflects popular opinion and that any change to the rule would erode public trust. On the contrary, that such a large proportion of respondents would personally choose this option, were it available, suggests that modifying the DDR might not actually undermine public willingness to undergo voluntary organ donation.

In response, commentators might cite transplant scandals as evidence to support the trust-based justification of the DDR. Bernat characterizes the public support for the transplantation as

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<sup>6</sup> I omit descriptions of the medical conditions and interventions for brevity.

“broad but shallow” (Bernat 2013). Wrongdoing can sway the public discourse surrounding organ donation, like in 2007 when a California physician was accused of administering drugs to hasten the death of an organ donor (Caplan and DeVita 2007). While the medical profession has a responsibility to learn from its mistakes, these examples do not illustrate how sanctioned DDR-exempt organ retrieval would affect public confidence because only one of these situations involve a *breach* of professional and societal expectations. If an amendment to the DDR were to be transparent, effectively communicated, and widely supported, then adhering to the new set of norms is unlikely to cause the same chilling effect as an unauthorized transgression of the DDR.

The existing data are not definitive but, at the very least, they cast doubt on the empirical claims described earlier and thereby question the soundness of public-trust justification of the DDR. Insofar as a sizeable proportion of the general public misunderstand deceased organ procurement to routinely violate the DDR for irreversibly-unconscious donors, and insofar as society supports giving donors in end-of-life circumstances the option seek exemption from the DDR, it seems plausible that amending the rule might not erode public trust. This says nothing as to whether any exemptions ought to be granted—for this I must first analyze the DDR strictly on its normative merits.<sup>H</sup>

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<sup>H</sup> Some might object that the public-trust argument for the DDR is normative rather than empiric. First, I would respond by noting that the wrong-making property in these arguments is a decline in the number of organ donors. This is a consequentialist consideration, which conflicts with assertions that the DDR is deontological in nature (Bernat 2013, Robertson 1999). Second, even if it were a normative argument, its soundness still depends on the truth of its premises. Insofar as the public-trust argument is unsound, it should not be favored over more-salient ethical considerations.

## Part II. Ethical Considerations

### What Justifies the Dead Donor Rule?

The dead donor rule (DDR) was initially informal; the exact reason for its development can only be inferred (Arnold and Youngner 1993, p. 264). Its proponents observe that the norm is deontological (Bernat 2013, Robertson 1999). I will assume that the DDR is motivated by the medical profession's moral commitments. I focus my analysis on the two core principles most relevant to the ethics of organ procurement: autonomy (respect for persons) and nonmaleficence (*primum non nocere*, or “first, do no harm”).

The principle of autonomy recognizes the domain people have over their bodies. Human dignity entails the right to be free from unwanted bodily intrusion. So, everyone can choose not to donate organs. This principle also obligates medical providers to respect each prospective donor's authentic wishes. This duty is operationalized through the doctrine of informed consent. For instance, in the United States when a patient volunteers to undergo kidney or split-liver donation, hospitals must provide an advocate “to assist the potential living donor in obtaining and understanding information about the consent process, the evaluation process, and the surgical procedure” (United Network for Organ Sharing 2018, p. 101). Because they promote the alignment between medical intervention and personal preferences, these types of rules are motivated by the principle of autonomy.

On first glance, the DDR also appears to act as a safeguard for autonomy. After all, the rule intuitively prohibits killing vulnerable persons for their organs (Truog and Miller 2008, p. 674). Fundamentally, however, the DDR is unrelated to the principle of autonomy. Robertson notes that, “Removal of organs necessary for life prior to demise would violate the dead donor rule regardless of the condition or consent of the donor” (1999, p. 6). Even with a donor's valid consent, the DDR does

not permit vital-organ procurement until after death has been declared. At the same time, strictly speaking the DDR permits organ procurement against a person's wishes—so long it is not responsible for causing death. The purview of the DDR is only confined to whether the donor is alive or dead. There is no consideration for the donor's values and preference, which may include a strong desire to be exempt from the DDR. This, phrased in Kantian terms, does not treat donors as ends unto themselves (Miller, Truog, and Brock 2010, p. 306). The DDR's normative foundation is the not principle of autonomy, it is nonmaleficence.

### **The Dead Donor Rule Prevents Harm**

*Primum non nocere* encapsulates a core moral tenant of the medical profession (Jonsen 1978, p. 827). What exactly constitutes a harm? In *Principles of Biomedical Ethics*, Tom Beauchamp and James Childress define harm as “a thwarting, defeating, or setting back of some party's interests” (2013, p. 153). Interests vary from person to person, so the harmfulness of any particular action might depend on the circumstances (p. 193). However, it can be safely assumed that everyone has “welfare interests,” a bare-minimum set of foundational interests which must be fulfilled in order to pursue the things she values (Kleinig 1978, p. 30). This includes a universally-held interest in life itself. “If we are to make sense of the view that to die is bad,” American philosopher Thomas Nagel argues, “it must be on the ground that life is a good and death is the corresponding deprivation or loss, bad not because of any positive features but because of the desirability of what it removes” (1979, p. 64). By virtue of being alive, people have an interest in not being deprived of the experiences attendant to life. Because this universal desire is thwarted by death, removing life-sustaining organs from a living donor necessarily constitutes harm and thereby undermines the principle of nonmaleficence.

It is not always immoral to cause harm (Beauchamp and Childress 2013, p. 153). Principlism is a pluralistic moral theory: the weight of each moral principle depends on the circumstances, and so when *prima facie* duties conflict, their relative stringency in that particular situation determines whether the act is right or wrong (Ross 1939, p. 144). Practicing the art of medicine constantly involves a balance between the demands of *primum non nocere* and those of principle of beneficence, or the duty to promote good. The help provided by intervention always incurs risk, so physicians aspire to offer treatment only when the harms are commensurate for the benefits. The patient-doctor relationship also engenders an asymmetric relationship between the principles nonmaleficence of autonomy. For



instance, in a non-life threatening situation it is morally wrong for a physician to harm a patient without consent, but imposing harm of the same magnitude can be acceptable with valid consent (Shiffrin 2012, p. 364). Just as the expected outcome of treatment can outweigh the physician's obligation to not harm, the principle of autonomy can also lessen relative stringency of nonmaleficence.

Nonetheless, the duty not to harm is particularly weighty in the context of organ donation. It differs from perhaps every other professionally-accepted intervention: donors do not stand to clinically benefit from the resection of healthy organs. With no possibility of making the donor better off, any degree of harm is ethically disproportionate. The principle of nonmaleficence, as the reasoning goes, is therefore especially stringent in transplant contexts (Wilkinson and Savulescu 2012, 37). Doctors have an overriding obligation to do *no* harm through vital-organ removal.

In clinical settings, this responsibility constrains the range of professionally-accepted practices. In a position paper on caring for organ donors, the American College of Critical Care Medicine states, "Therapy that is harmful to the dying patient should be avoided even if it might improve organ viability" (2001, p. 1830). It is wrong to inflict harm to a living donor, even with good intentions. This presents a problem of how to determine which interests are relevant, but the guidelines highlight a bright-red-line; "Organ procurement must not cause death, and death must precede procurement of unpaired organs or both paired organs. This practice is intended to prevent harm to the donor" (2001, p. 1830). When a pre-mortem intervention thwarts a universally-held interest, ethically it is never recommended.

Put together, the discussion above explains the rationale underlying the DDR. Removing life-sustaining organs causes death, undermining a universally-shared interest in life, and therefore vital-organ procurement is necessarily harmful to living donors. In contrast, cadavers have already been deprived of the future—the further loss of biologic integrity cannot thwart their interests.<sup>1</sup> As such, the deceased are not owed the same set of moral protections from harm. By stipulating that death must occur prior to vital-organ procurement, the DDR ensures that the only donors who undergo an (otherwise-harmful) operation cannot suffer harm. The motivation for the DDR, then, to prevent ethical transgressions of the principle of nonmaleficence in a context where the duty not to harm is stringent. Put succinctly, the DDR is derived from medicine's credo, *primum non nocere*.

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<sup>1</sup> The ancient Greek philosopher Epicurus wrote, "Death [...], the most awful of evils, is nothing to us, seeing that, when we are, death is not come, and, when death is come, we are not," suggesting that after death there is no subject suffer harm (1966). Joel Feinberg contests the view, arguing that the dead can suffer harm (1985). To get around the Epicurean problem of a subject, he holds that, "harm to an interest is better defined in terms of the objective blocking of goals [...] [rather] than in subjective terms" (1984, p. 84)

Robertson did caution that the DDR is not logically necessary (1999, p. 13). Because the DDR is not itself an absolute moral requirement, “as medical, ethical, and social conditions and perceptions change,” exempting certain donors from the rule might adequately respect its normative foundations (p. 13). When societal values shift over time so too does the relative weight of each ethical principle.<sup>J</sup> Transplantation has uncontroversibly changed over the preceding decades. Today vital-organ donation is a routine practice in end-of-life care. To understand if the DDR infringes or denies its core values, the relevant consideration is not the timing of the declaration of death, but whether the harm of vital-organ retrieval is ethically justified. In the next two sections I explain some of ways the ethical rationale for the DDR mischaracterizes the harmfulness of exceptions to the rule.

### **The Stringency of the Principle of Nonmaleficence is Overstated**

Historically organ recipients were assumed to be the sole beneficiaries of transplantation. Even at the turn of the 21<sup>st</sup> century the majority of transplant centers did not allow living kidney donation among strangers (Spital 2000, p. 1731). Over the prior decades physicians believed that a person’s desire to altruistically donate a kidney was a self-evident sign of psychopathology (Hamburger and Crosnier 1968, p. 37). A rational person would not voluntarily undergo risky organ donation for no personal benefit, and so until recently ethicists questioned the validity of donor consent.<sup>K</sup>

The rationale underlying the DDR shares the same conviction. As Norm Fost observes, “Resistance to organ removal from unconscious dying patients, while still alive, is based partly on the perception that it involves a bodily invasion that is not in the interests of the patient” (Fost 2004, p. 252). Imagine that vocal and lifelong advocate for organ donation is unconscious and ventilator dependent at the end-of-life. Rather than attempt DCDD, applying substituted judgement her family requests exemption from the DDR because the patient would have wished to save as many lives as possible through organ donation. Honoring the request clearly endangers the patient’s *medical* interests. However, insofar as the preference is a valid expression of the patient’s autonomy, to assert the patient

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<sup>J</sup> For example, the notion of what constitutes a good death is fluid. Arguably, in palliative settings the value ascribed to being in control at the end of life gives autonomy heightened salience to compared to recent decades.

<sup>K</sup> To be sure, the health risks of living kidney donation were heightened in the 1950’s–1960’s. On the other hand, by the early 1990’s, long-term follow-up studies had already established that even 20 years post-operatively, the health status of donors did not differ from non-donor counterparts (Najarian et al. 1992, p. 807). The eventual acceptance of living unrelated kidney donation did not correlate improvement in surgical risk, either (Segev et al. 2010, p. 961).

cannot gain personal benefit from the advancement of her interests is a pernicious strain of hard paternalism (Beauchamp and Childress 2013, p. 217). Everyone has a right to define their own version of the good. A person can determine she would be better off while completely aware of a near-certain clinical setback. The principles of autonomy and beneficence entail an obligation to align end-of-life care with each patient's values and preferences. The interests of a vital-organ donor are no less deserving of respect, both when she is alive and dead (Zeiler et al. 2008, p. 527). Despite the palliative backdrop of vital-organ donation, the justification underlying the DDR does not ascribe any domain to the principles of autonomy or beneficence. Yet in at least some cases the benefits of realizing a patient's autonomous wishes can offset the stringency of the principle of nonmaleficence.

Moreover, those closest to a dying patient might also derive meaning from the donation process. As a parallel, consider the provision of care when surrogates request medically inappropriate or "futile" cardiopulmonary resuscitation (CPR). Like with organ procurement, providers are asked to harm for disproportionate clinical results. Robert Truog wrote compellingly about a situation in which he ordered resuscitation for a child whose parents, with full apprehension of the likely outcome, asked "that everything be done" (2010, p. 477). He observed that, "Family members may live for years with the psychological aftereffects and regrets of end-of-life decisions. In these situations, the interests of the surviving family members may take priority" (p. 478). Treatment can provide benefits unrelated to pharmacologic efficacy. Families might remember CPR at the end of life as an expression of their non-abandonment. Similarly, the families of donors might find great comfort in knowing that death did not reduce their loved ones to inanimate matter. So long as the intervention honors the patient's own end-of-life wishes, the benefits experienced by those closest to the donor can mitigate the stringency of the duty not to harm organ donors. The justification for the DDR does not recognize the salience of any such consideration. Here too, then, the rationale for the DDR overemphasizes the stringency of the principle of nonmaleficence.

### **Deceased Organ Donation is Just as Harmful**

The second questionable assumption justifying the DDR is that it confuses causation for culpability, arbitrarily privileging some harms over others. Note that DCDD culminates in transplantation *if and only if* the donor dies—otherwise the determination of death would not precede vital-organ procurement. Because death thwarts a universally-shared interest in life, DCDD is

responsible for inflicting this harm on consenting organ donors. At the same time, DCDD is considered an “ethically acceptable practice of end of life care” (Bernat et al. 2006, p. 22). Therefore, insofar as the harm from a DCDD-donor’s death is morally permissible, so too is the harm of DDR-exempt organ donation.

To help illustrate this final point, imagine that Andrew and Sal are admitted to the ICU on mechanical ventilation following a car accident. A few weeks later, their families choose to redirect the goals of care. Andrew’s advanced directive indicates his preference to undergo DCDD. Sal’s expresses his desire to seek a professionally-sanctioned exemption from the DDR. Eventually, both undergo donation and their altruism successfully saves several lives. Nonetheless, both Andrew and Sal died over the course of the donation process. Neither Andrew nor Sal is more or less harmed by this: death deprives them both of a future equally.<sup>L</sup> The harm prohibited by the DDR in the case of Sal is also suffered by Andrew. In this scenario, undergoing DDR-exempt organ retrieval causes no greater harm than undergoing DCDD.

Supporters of the DDR are likely to contest the moral equivalency of these scenarios by drawing a distinction between *causing* as opposed to *allowing* death. This is to say that it is worse to harm through an *action* than through an *omission*. Commentators might explain this by noting that the mechanical ventilator was all that kept Andrew alive, and so when care was withdrawn his disease progressed unfettered until it caused his death. The physicians are not morally responsible for depriving him of a future because, in the eloquent words of Daniel Calahan, “People will, one way or another, die of some disease; death will have dominion over all of us. To say that a doctor ‘kills’ a patient by allowing this to happen should only be understood as a moral judgement about the licitness of his omission, nothing more” (1992, p. 53). In contrast, death was denied its dominion over Sal. While it was imminent and inevitable, human intervention causally pre-empted the course of nature. Thus, as the reasoning goes, Andrew was allowed to die whereas Sal was killed: the principle of nonmaleficence permits the harm of one death but not the harm of the other.

However, this line of response posits the existence of a morally-relevant distinction between causing and allowing death. Other commentators reject the fundamental premise of the rebuttal (Rachels 1975, Brock 1992, Quill 1993). Patients are killed by terminal extubation—Dan Brock

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<sup>L</sup> Some might object that because all lives are valuable, the harm of one death always equals another. Nagel explains that the tragedy of death is *relative* to what is otherwise expected (1979, p. 68). He argues it is more misfortunate when a young person is deprived of a future than when an elderly person with a rich past is deprived of the future. Both are harmed by death, but the setback is of different magnitudes. In the case of Andrew and Sal, because both will soon pass away regardless of donation, the misfortune of death does not meaningfully differ.

dismisses misleading claims to the contrary as “transparent sophistry” (2001, p. 237). Andrew would not have died if not for the termination of life support. There is no possible scenario which permits vital-organ retrieval but which does not counterfactually depend on his death. Yet proving a causal relationship beyond all doubt would nonetheless fail to demonstrate that DCDD is *therefore* morally responsible for killing Andrew. The inference confuses causation for culpability. And by this very same token, the fact that Sal’s death is causally traced to human intervention does not speak to their moral character (Beauchamp and Childress 2013, p. 176). Ascriptions of culpability depend on other ethically-germane aspects of the situation. Considerations relevant in this context include valid consent, professional authorization, and safeguards to ensure that no one undergoes donation except those who otherwise plan to halt life support (Truog and Miller 2008, p. 675).

Granted, an action causing harm or death is often morally worse than an omission with the same outcome. However, the problem is that by oversimplifying moral culpability, the cause/allow distinction fails to perfectly track with its motivating ideals. The President’s Commission describes the distinction as “a useful rule-of-thumb,” but they question its suitability to the work of bioethics;

The mere difference between acts and omissions—which is often hard to draw in any case—never by itself determines what is morally acceptable. Rather, the acceptability of particular actions or omissions turns on other morally significant considerations, such as the balance of harms and benefits likely to be achieved, the duties owed by others to a dying person, the risks imposed on others in acting or refraining, and the certainty of outcome (1983, p. 61).

Neither actions nor omissions are sufficient to determine whether harm is justified. An adequate moral verdict must account for all salient considerations. While the retrieval of vital organs always entails harm, causing rather than allowing this harm does not necessarily mean that DDR-exempt procurement is unjustified.<sup>M</sup>

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<sup>M</sup> It should be noted that it begs the question to infer that DDR-exempt procurement is ethically wrong *because* it does not adhere to the DDR. Some commentators might counter by claiming the DDR as a core principle of medical ethics, thereby showing that non-adherence to the norm is wrong. However, all core principles in medical ethics are pluralistic, meaning they are non-hierarchical and no principle always supersedes the others. If the DDR is a core principle, it follows that exceptions are permissible in certain circumstances and thus an exception is not necessarily wrong.

## A Framework of Wrongful Harm

The question at the center of this debate is whether there are any situations where the harm of DDR-exempt organ retrieval is ethically justified. I would venture that in most cases, the harm is indefeasible: construed as transplantation's "rule-of-thumb" for the principle of nonmaleficence, the DDR is rather dependable.<sup>N</sup> Killing for organs is wrong in the vast majority of cases. However, much like the cause/allow distinction, the DDR oversimplifies ascriptions of culpability. It presupposes that the distinction between life and death—as the medical profession came to define each—is morally relevant. And at this boundary the heuristic can clash with considered moral judgement, such as when a dying patient with catastrophic brain injury wishes to undergo BDB rather than DCDD. Here, the principle motivating the DDR might be better respected if moral judgement were confined to harm and its justification. As a matter of professional integrity, violations of the DDR are unacceptable; I do believe however that ethical exemptions are permissible in the grey areas.<sup>O</sup>

A framework equipped to analyze these situations might be adapted from Joel Feinberg's canonical scholarship in political philosophy (1984).<sup>P</sup> The principle of nonmaleficence demands the infliction of no harm only when harm is unjustified; as such, only if both of the following criteria are satisfied is an act considered to cause *wrongful harm*:

- (1) The act adversely effects the patient's interests.
- (2) All things considered, the act wrongs the patient.

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<sup>N</sup> This "rule-of-thumb" approach to morality is common in clinical practice. Ruth Macklin, for instance, points out that by following a rule of "always tell the truth," physicians usually show respect for autonomy, but the rule is not required by the principle. In fact, in very specific clinical settings, following the rule is disrespectful to autonomy (1999, p. 113).

<sup>O</sup> Only, of course, if such a proposal were to already be accepted by the medical profession: otherwise an *exemption* from the DDR is no different than a *violation*. Without authorization to deviate from accepted medical practices, the obligations of professionalism outweigh any justification for an "exemption." For reasons I will explain, violations of the DDR cause wrongful harm.

<sup>P</sup> Wrongful harm is the cornerstone of Feinberg's "harm principle," a theory of the moral limits to the criminal law. It advances the landmark work John Stuart Mill in *On Liberty* about "the nature and limits of the power which can be legitimately exercised by society over the individual" (1863). Feinberg's four-book analysis considers if the state's only legitimate reason for restricting the moral autonomy of citizens is to prohibit actions that would wrongfully harm others. To do so he develops a framework for analyzing whether harm is, all things considered, justified. This naturally lends itself to pluralism of medical ethics. Feinberg also provides a nuanced analysis of interests, including which interests are allowed to count as "harm" in a morally-relevant sense. Beauchamp and Childress dismiss the problem in their textbook as "a matter we need not to decide here" (2013, p. 153)

An act that inflicts wrongful harm always has two distinguishing features: it sets back, defeats, thwarts, or otherwise impedes something a patient considers to be in her own interest *and* it is ethically unjustified under the circumstances. Accordingly, if an act sets back the patient's interests but does not violate the clinician's overriding duty to the patient, then the act causes harm but is defensible by virtue of other salient considerations. An act which fails to satisfy one or both of the criteria does not count as a wrongful harm. If a medical intervention would wrongfully harm a patient, its provision is ethically indefensible.

Broadly speaking, interests can be anything in which the patient has a *stake*. The state of her wellbeing is closely tied to the state of whatever her interests are in: she "flourishes or languishes as they flourish or languish" (Feinberg 1984, p. 34). People value and, all else being equal, prefer to advance their interests. The more a person believes her welfare and success rests upon the advancement of an interest, the more it is said to be in that individual's best interest—setbacks to such interests result in harms of a greater relative magnitude. Interests a person would voluntarily undermine to further other, more important interests are said to not overall be in her best interest—setbacks to these are harms with a comparatively smaller magnitude. Respect for persons demands that individuals have authority whenever possible to determine what specifically is in their own interest. Still, welfare interests can generally be safely assumed. Setbacks to welfare interests cause serious harm because they thwart an entire network of interests (p. 37).

Harm must also satisfy the second condition if overall it is ethically unjustified. By virtue of the principle of nonmaleficence all harmful acts have a wrong-making property—its harmfulness is the basis of its moral undesirability. Yet because of the nature of *prima facie* obligations in pluralism, the same act might at the same time have right-making properties, such as respect for autonomy and beneficence. To arrive at the correct moral verdict about the overriding duty to a patient, physicians must use moral judgement and, all things considered, determine which considerations are most salient in that particular situation (Ross 1930). Only setbacks to interests which undermine the overriding duty to the patient are counted as wrongful harms.

The framework can help assess harm in any clinical setting, but its greatest utility is in a context such as organ donation when the principle of nonmaleficence is usually the overriding consideration. Because harm might be at times justified, here it is too simplistic to equate the ideals of *primum non nocere* with a duty to not hinder interests. Considered judgement must attempt to balance multiple normative considerations (including a setback to interests) against a background of a particularly-relevant duty not to harm. The wrongful harm framework asks clinicians to disclose the proposed

harm and, because harm is usually unjustified under similar circumstances, to provide a compelling rationale for undermining the principle of nonmaleficence.

With this framework in mind, return now to the issue of organ donation. As I argued earlier, removing life-sustaining organs before the declaration of death is necessarily harmful. Exemption from the DDR satisfies the first condition. All harms which violate an overriding duty to the patient are immoral, and hence the retrieval of vital organs prior to the declaration of death is impermissible whenever it would wrongfully harm the donor. Only harms which are not justified by other salient considerations should be prohibited on normative grounds. Therefore, exemptions from the DDR should be granted on ethical grounds when the retrieval of organs would do no wrongful harm.

What sort of situation might justify exemption from the DDR? Consider Sal's circumstances. His family considered the certain harm of organ removal before declaration of death and, applying substituted judgement, concluded this is what Sal would have wanted were he able to decide for himself. They believe Sal would have felt it was in his interest to make the best of his misfortune and give as many of his organs as possible to those in dire need. The altruism of this gesture does not mean it will not positively affect his surviving family members for years. If Sal did not receive an exemption, his family would still plan to halt mechanical life-support, thus his interest in not being deprived of the future is no more impeded than were he to undergo DCDD.

Moral reasoning about Sal's circumstances might take the following form. The foremost consideration lessening the stringency of nonmaleficence is the presence of valid consent. Respect for Sal's wishes at the end of his life honors his dignity, thereby promoting the principle of autonomy and justifying some degree of harm. Second, realizing his and his family's interests advances considerations of beneficence, which further counterbalances the proportionality of harm. Finally, under the lamentable circumstances the deprivation of life is unavoidable, but death will thwart Sal's interests regardless of whether he is declared before or after the removal of life-sustaining organs. An exemption would cause no more harm than he otherwise would suffer following cessation of life support. All things considered, then, the principle of nonmaleficence and its corresponding duty not to harm do not constitute the overriding obligation to Sal. While it would cause harm, exemption from the DDR would do no wrongful harm.



## Objections

There are crucial issues in law and public policy which must be addressed before DDR-exempt organ removal can be recommended. I do not satisfactorily address these questions—nor have I attempted to do so—not out of dismissiveness but out of respect for the substantial challenges ahead in each field. My aim was to provide an ethical analysis to precede any such effort.

Along the same lines, commentators might worry about the killing of innocent persons. In this regard, my analysis highlights a few considerations that will be necessary to protect innocent persons from harm. For one, policy makers should organize independent panels to evaluate requests for an exemption. This helps mitigate conflict-of-interest concerns, but primarily an independent panel can help ensure that exemption is only granted on the basis of adequately-considered circumstances. At the present time an exemption from the DDR should not be granted if there is no valid consent; if there is no compelling interest in exemption from the DDR; if there is no dependence on life-sustaining interventions; if there are no plans to terminate further care, or; if exemption would fail to adherence to professionally-accepted standards.

Commentators might still raise concerns about the framework's tolerance for aid-in-dying. For one, anyone who agrees to kill themselves through organ procurement presumably lacks the capacity to make such a decision. Even if a non-dying patient had a valid reason to seek exemption from the DDR (perhaps a teenage child will die without a transplant), some would argue that wrongful harm's deference to autonomy effectively facilitates the suicide of healthy persons. Bioethicist Daniel Callahan might describe this as "self-determination run amok" (Callahan 1992).

Just because a person can consent to harm does not mean they can consent to a harm of any magnitude whatsoever (Feinberg 1986). Exemption from the DDR would rob a healthy person of interests not otherwise thwarted. Especially in matters of life and death, the stringency of the principle of nonmaleficence is inelastic. This magnitude of harm is not counterbalanced by other considerations in the wrongful harm framework. Moreover, the right to self-determination granted under autonomy does not entail an obligation to provide medically-inappropriate care (Brock 1992, p. 11). In the scenario above, a physician is bound by her professional obligations not to honor the principle of autonomy. If the patient is imminently dying, however, her request for an exemption does not prove she lacks capacity to make this decision. As Joel Feinberg points out, this circular justification for prohibiting self-harmful behavior infers the person's irrationality from the nature of her wishes while claiming to prove that her self-harming preference is the result of her irrationality (1984, p. 174). This

catch-22 never demonstrates that the person is actually irrational. The objection then does not show the wrongful harm framework to permit anything which undermines the moral tenants of medicine.

The framework does tolerate one form of aid-in-dying. It should be noted that prospective donors should request an exemption—physicians should not recommend it unprompted. The patient must be competent at the time of the request, and her preference must be voluntary and stable. If her doctor finds exemption appropriate and submits the case for independent review, the facts of the particular case are carefully probed before it is determined that DDR-exempt donation is not wrong. This might deny medically-unstable patients access to exemption. However, strong norms like the ones above can justify aid-in-dying practices by providing moral protections for vulnerable persons (Beauchamp and Childress 2013, p. 184).

Is it still wrong? I offer one final counter-point. Recall my earlier discussion about how the Ad Hoc Committee came to define brain death as true death. There was an open debate at the time about whether life-saving organs should be obtained by killing comatose patients or by moving the goal post and determining that comatose patients cannot be killed—as Miller and Truog write, “The arguments about why these patients should be considered dead have never been fully convincing” (2008, p. 674). If donors who undergo DBD or DCDD are not truly dead, then current practices already violate the professional moratorium on aid-in-dying. This does not imply that transplantation is morally wrong, but certainly that it lacks clarity (Miller, Truog, and Brock 2010).

Previous commentators have sought to develop alternatives to the DDR that rely on considerations of harm. Norman Fost, for instance, argued that the organ donation should explicitly focus on whether organ donation “violates no interest” (1983, p. 728). As Arnold and Youngner point out, however, this approach creates a “problem of judging what constitutes a harm” (1993, p. 271). Instead they argue for an increased emphasis on informed consent so that donors can “define their own threshold for being harmed” (p. 271). Still, autonomy does not always override maleficence, and their framework might enable competent young donors to commit suicide through organ procurement. Miller and Truog argue that the DDR should be replaced with norms better aligned with the medical profession’s ethical commitments (2011). They avoid the previous concern in limiting the initial eligibility to situations where vital-organ removal would cause no harm. For example, presuming there is valid consent, “If the patient is soon to die because life support has been withdrawn, then there is no harm or wrong done in retrieving vital organs prior to death” (2008, p. 41).

However, as I argue throughout this thesis, removing life-sustaining organs causes harm. The same holds true in end-of-life contexts where a competent patient voluntarily elects to forgo life-

sustaining therapy. Such a patient does not jettison her interests only realizable while she remains alive (perhaps she hopes to attend a grandchild's wedding, or to spend time outdoors), but she concludes that, all things considered, they are outweighed by the burdens of therapy. My analysis does not undermine previous insights about alternatives to the DDR. On the contrary, by helping translating *primum non nocere* to the difficult case of organ donation, my wrongful harm framework furthers ethical clarity in an ongoing area of inquiry.

## Conclusion

“First, do no harm” has unique standing in medical ethics. The dictum represents an unassailable moral commitment to society, yet its clinical application is seldom understood. As Louis Lasagna astutely quipped, “To observe this advice literally is to deny important therapy to everyone, since only inert nostrums can be guaranteed to do no harm” (1967). Still, amidst growing power to heal, physicians in their benevolent endeavors cannot not lose track of their proportionate responsibility to safeguard the vulnerable from suffering the perils of medical intervention. The triumph surrounding the world's first successful heart transplant vividly illustrates the moral vulnerabilities inherent to the scarcity of life-sustaining organs. It is for good reason that the principle of nonmaleficence is ascribed heightened stringency in transplant contexts, and historically the dead donor rule symbolized the profession's commitment to individual welfare. More than half a century has passed since the events in Cape Town and yet there is still substantial confusion about the meaning of death. The unbending demands of the dead donor rule have been well described. There must be an honest deliberation as to whether the medical profession ought to continue its support for the norm in its current form lest it give way to ethical dogmatism—perhaps akin to the unexamined plying of, “First, do no harm,” rather than the ideals encapsulated by the credo. Using a framework of wrongful harm I developed to address this question, I argue that there are compelling ethical reasons to modify the rule in order to permit exemptions under a limited set of circumstances. An acceptable degree of harm does not infringe upon medicine's promise to society, *primum non nocere*.

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