Organ Donation after Circulatory Determination of Death: Lessons and Unresolved Controversies

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The several articles in this special issue on organ donation after circulatory determination of death or, as it is often put, donation after cardiac death (DCD), draw lessons from different kinds of experience in order to guide efforts in the U.S. to develop or refine policies for DCD. One lesson comes from a major and, by many measures, successful experimental DCD program in Washington, D.C. in the 1990s. Another lesson comes from European countries that have adopted presumed-consent legislation, a form of “opt out” that facilitates DCD as well as donation after neurological determination of death (DND). Another lesson, from the perspective of critical care medicine in Canada, attends to the implications of viewing a dying patient, undergoing resuscitative procedures, as a potential organ donor. A final lesson sketches implications of legislation and court cases in the U.S., often involving DND, for initiating temporary organ preservation (TOP) in DCD programs before consent has been obtained for organ donation. Some of these lessons are optimistic about the prospects for DCD, especially if certain steps are taken, while others are more cautious, particularly because of the costs and risks involved in DCD.

Altogether these articles help to sharpen and advance the debate about DCD, which has recently received support from several sources, including a report from the Institute of Medicine (IOM) Committee on Increasing the Rates of Organ Donation, entitled Organ Donation: Opportunities for Action, which endorsed additional efforts to tap both controlled and, especially, uncontrolled DCD (uDCD), and additional support from a follow-up meeting that examined opportunities and barriers to uDCD. For the record, I note that I chaired the IOM committee.

This response will focus on lessons and debates about the kinds of consent necessary and sufficient for TOP in the context of DCD and for organ donation itself; on conflicts of obligation, loyalty, and interest in DCD and ways to address those conflicts; and on benefit, cost, risk assessments of uDCD programs, including measures to achieve a more favorable balance of benefits, costs, and risks.

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Kinds of Consent at Different Stages in the Process of uDCD

A question that pervades much of bioethics is: what kind of consent is needed from whom for what? Uncontrolled DCD raises this question in two contexts: preserving organs in situ and removing organs for transplantation. It is important to distinguish consent for organ preservation from consent to organ donation, even though they may be closely related in some circumstances.

Consider, for instance, that an individual has accepted organ donor status by completing a document of gift, such as a donor card, or by registering as a donor. That individual’s otherwise unspecified consent to post-mortem organ donation encompasses or implies consent to the initiation of TOP. (While this certainly holds for post-mortem organ preservation measures, it could, in some conceivable circumstances, even hold for pre-mortem organ preservation measures that would not harm the individual or hasten his or her death.) Even though an individual could consent to DND but not DCD, consent to post-mortem organ donation typically does not distinguish the two.

Suppose, in a system of express consent for organ donation, that a particular individual suffers a cardiac arrest on the streets and his or her donor status is unknown. TOP measures could be ethically justifiable and, as Bonnie, Wright, and Dineen forcefully argue in this issue of JLMF, legally justifiable, while reasonable efforts are undertaken to determine the decedent’s donor status. If the decedent’s donor status cannot be determined, the next of kin has the legal right to make a decision about donation. However, in many, and perhaps most, cases of uDCD, the family is not immediately available. But in the absence of the decedent’s known preferences and without immediate organ preservation measures, both the family’s right and opportunity to donate, and the organs themselves, would be lost.

What is the ethical warrant for undertaking TOP in the absence of evidence of the decedent’s decision to donate his/her organs after death? According to the IOM report, there is evidence that the public believes (and the committee concurred) “that a presumption of consent to use preservation techniques enhances rather than limits autonomy by enabling a decision about whether to donate; absent such presumed permission, the opportunity to donate is irretrievably lost.” Bonnie, Wright, and Dineen also argue that consent for organ preservation can and should be “presumed for a short period of preservation.”

In contrast to both the IOM report and the Bonnie-Wright-Dineen analysis — as well as the analysis offered by Borry et al. — I now have doubts about the language of presumed consent for TOP, absent certain clear legal rules and social practices. Such language may be unnecessary, potentially misleading, and perhaps even risky. First, it is not necessary to justify TOP, in the absence of explicit consent, through the fiction of presumed consent. Indeed, such an attempted justification obscures the central ethical issues. It is sufficient to justify TOP as enhancing rather than limiting autonomy. On the one hand, TOP makes possible efforts to determine the individual’s prior wishes; on the other hand, TOP allows the family an opportunity to make a decision about donation if the decedent’s wishes cannot be determined. The IOM report rightly argues this point, and that should be sufficient without invoking presumed consent. In the absence of a public practice that the decedent understood and chose to follow, there is no valid presumption about the decedent’s wishes — legitimate presumed consent practices presuppose both understanding and voluntariness. Nor is there a valid presumption of the family’s consent, even though, as Light notes, some families who decide not to donate may still be glad to have had the opportunity to make the decision. Indeed, TOP is best understood as a brief, modestly invasive procedure that makes no presumption about the decedent’s or the family’s consent, but that, rather, seeks to determine the individual’s prior preferences and/or to provide an opportunity for the family to give explicit consent or refusal to organ donation.

Another consequentialist rationale also supports the initiation of TOP: Such measures can reasonably be expected to increase the number of organs available through uDCD because some individuals will be determined to have made decisions to donate, and some families will decide to donate. However, in my judgment, these consequentialist reasons would not be sufficient to justify TOP, in the absence of explicit individual or familial consent, if it involved a major intervention into the dying or dead human body.

Bonnie, Wright, and Dineen build a careful and cogent argument that the Uniform Anatomical Gift Act provides the legal authority (“reasonable search”) for TOP while efforts are undertaken to ascertain the individual’s donor status or to locate his/her family for a decision about organ donation, and that, in any event, TOP does not violate any legally protected family interests and thus would not subject professionals and institutions to serious risks of legal liability. Furthermore, in light of this implicit legal authority and de minimis risk of legal liability, Bonnie, Wright, and Dineen argue that the “ethical imperative” to undertake organ preservation should triumph.
However, beyond these limited legal risks, there are other risks to the entire process of organ donation, procurement, and transplantation. Those risks, including the ones emphasized by Doig and Zygun, merit careful attention and, in particular, the development of transparent public processes to address them. Otherwise, mistrust and distrust can and probably will threaten what is already a relatively successful, though fragile, program of obtaining organs, mainly through DND. Bonnie, Wright, and Dineen concede that the “easiest way” to solve the problem of TOP is through legislative action. Not only is this the “easiest way,” it also poses the least risk for the system of donation, procurement, and transplantation and offers the highest probability of success. A transparent public legislative process, specifically addressing the issues and specifically authorizing TOP, as Light reports occurred in the District of Columbia’s experiment, can provide greater ethical legitimacy. This represents a form of community consent through established political-legal procedures without presuming individual or family consent.

Borry et al. characterize proposals for TOP as “presumed consent” or “opting out” — categories that they appear to view as interchangeable. However, opt-out policies are not limited to presumed consent policies. For instance, it would be possible to have a system of routine salvaging or routine removal that also allows individuals and/or their families to opt-out. Such a system would not involve presumed consent.

Presumed consent and routine salvaging/removal presuppose very different views of the locus and basis of dispositional authority over organs after death. A system of routine salvaging/removal recognizes communal ownership of organs after an individual’s death or a social obligation to donate cadaveric organs. By contrast, a system of presumed consent assigns individuals dispositional authority over their organs after their deaths but presumes their consent if they do not register their objections. In addition, these two systems tend to have very different views about the need for public education and for easily accessible, clear, reliable, and non-burdensome ways to opt out. To be ethically valid, presumed consent, as a form of consent, presupposes both understanding and voluntariness. It is consent, silently and passively given.

Borry et al. believe that presumed consent laws and policies would provide a basis for an increase in the number of organs obtained through uDCD as well as DND: “In addition to the introduction of an opting out system at the level of organ preservation, the U.S. would gain by introducing an opting out system at the level of organ donation.” They do not claim that presumed consent policies would be sufficient by themselves. Nevertheless, they fail to consider the analysis and arguments presented by the IOM committee about why presumed consent for organ donation would probably be ineffective and counterproductive in the U.S., even if it could be adopted. The IOM committee’s decision not to recommend presumed consent at this time was based on a contextual ethical analysis and assessment, not an abstract one — it refrained from recommending an approach that would probably not be effective in the U.S. at this time, however appealing it might be in theory or in principle.

The IOM committee also recognized that the opt-in, express consent system in the U.S. works fairly well and can be further improved without a radical change in...
ally involves notification of the family and removal of organs only when the family does not object. This is very similar to the way the opt-in system has operated in the U.S., though several states have now adopted laws that assign the decedent’s decision to donate priority over familial objections.

As part of their argument, Borry et al. quote surveys that indicate widespread support for presumed-consent legislation. However, such surveys are not very helpful for formulating public policy unless they include the public — not only medical professionals — and unless they are also country-specific in view of the variety of social, cultural, and other differences among countries. Against the survey evidence Borry et al. quote, the 2005 National Survey of Organ Donation in the U.S. determined that 43.2% support or strongly support presumed consent legislation, while 56.8% oppose or strongly oppose such legislation. It is also important — and arguably more important — to determine how individuals would (probably) respond under a presumed consent law. In the same 2005 survey, just over 31% indicated that under a presumed consent policy they would register as “non-donors.” Such a high percentage of registered “non-donors” would probably reduce the overall supply of transplantable organs — their registered “non-donation” would block familial donations, the main source of donated organs in the U.S.

Thus, we simply cannot assume that a presumed consent system will be effective in every setting; indeed, it may even be counterproductive in some settings — for instance, where there is mistrust and distrust coupled with unequal access to a decent minimum of health care.

Conflicts of Obligation, Loyalty, and Interest

One widely felt concern about uDCD programs, as Doig and Zygun stress, is their potential to create or exacerbate conflicts of obligation, loyalty, and interest for health care professionals and institutions, thereby fostering mistrust and distrust. This concern focuses to a great extent on the transition from dying patient, who has experienced a cardiac arrest and is undergoing resuscitative efforts, to organ donor. The intermediate steps include the determination of death and the initiation of TOP. Which criteria should be used to demarcate stages in this transition, and which professionals should make which decisions? How can we manage a shift from dying patient under treatment to potential donor being preserved for organ retrieval without compromising important ethical principles and values?

Two important stakeholders in any program of DCD are dying persons undergoing resuscitative measures after cardiac arrest, and sick persons in need of an organ transplant. Their interests may come into conflict. The standard way to avoid or at least to reduce serious conflicts of obligation, loyalty, and interest is to separate roles — for instance, members of the organ recovery or transplant team, who are expected to act on behalf of potential recipients, should not determine when the potential donor is dead. Such a separation has rightly been viewed as indispensable for public trust, which is so essential for organ donation and
A “hands-off” period ensures an appropriate separation in roles. The IOM report notes that some active European protocols require that those making the decision to stop cardiopulmonary resuscitation not be affiliated with the team that will recover the organs. Some protocols, as Borry et al. also note, even require a “hands-off” period of 5 to 10 minutes between resuscitation and organ recovery/transplant teams. While affirming that “a separation between teams is essential,” the IOM report also stresses “the hands-off period could be very brief and may even be unnecessary.”

Focusing on the pilot experiment in Washington, D.C., in the 1990s, Light raises questions about the complete separation of roles:

In our pilot program, the requirement to completely separate the care of the fatally injured patient from the initiation of organ preservation eventually made the RORP protocol unworkable. The manpower required and the attendant expenses were prohibitive. So in my opinion for the uDCD to become a meaningful donor resource the trauma team must be not only allowed but also expected to initiate in situ organ preservation after death has been declared. If authorization for donation is not granted, then in situ preservation is discontinued and the decedent processes are carried out in the usual manner.

Questions about the trauma team’s participation in TOP, after their determination of the patient’s death, need to be resolved for the sake of both professional integrity and public trust, so essential to organ donation, procurement, and transplantation.

In addition to establishing boundaries of role responsibilities, it will be important to establish consistent, public, and transparent criteria based on the best available scientific evidence and clinical judgment, for determining when it is appropriate for the trauma team to stop resuscitative efforts. According to the IOM report, among the several factors that will be important for DCD programs to succeed, Trust in the healthcare system is the prime consideration. Patients and their families must have complete confidence that all emergency and resuscitative efforts will be made and that organ donation will be considered only in the event of the loss of life after every appropriate measure has been attempted.

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**Benefit/Risk/Cost Assessments of Uncontrolled DCD**

Benefit/risk/cost assessments are explicit or implicit in these articles about uDCD. Bonnie, Wright, and Dineen offer a relatively narrow analysis focused mainly on the probable benefits of obtaining additional organs and the risks/costs to medical professionals and institutions. They stress that the benefits of donated organs to patients in need outweigh what is, according to their legal analysis, a de minimis risk of liability. Even though costs were a major factor in the demise of the experimental uDCD program in the District of Columbia, Light appears to hold that the potential benefits of an increase in the number of transplantable kidneys outweigh the costs and risks in a well-designed program of uDCD. Borry et al. appear to hold a similar view, based on European experience. By contrast, Doig and Zygun hold that the anticipated net benefits of uDCD programs are largely speculative and unlikely to be realized in part because these programs carry “considerable risk,” particularly of alienating supporters of DND, i.e., “the public and health professionals who care for the dying but not yet dead patient.” Hence, Doig and Zygun urge “far more caution” than the IOM report and the other articles in this issue.

Even though Doig and Zygun do not directly appeal to the precautionary principle, their argument approximates some versions of that principle, which dictates precautionary action in the face of uncertainties and possibilities of very bad outcomes. Indeed, although they propose conditions that institutions and health care professionals should meet in pursuing uDCD programs, they appear to have serious reservations about undertaking such programs at all. By contrast to the Doig-Zygun position, I would propose a precaution-
ary process; some of its elements appear in the IOM report. The potential benefits of an increased number of transplantable organs, mainly kidneys, for patients in need warrant further efforts to determine whether those benefits can be realized and whether they will outweigh the costs (particularly the costs of developing and maintaining the necessary infrastructure) and the associated risks (particularly to public trust). This precautionary process for DCD programs should be public and transparent, include public and professional education, seek legislative authorization for TOP, develop publically defensible criteria for stopping resuscitative efforts, resolve debates about a “hands-off” period and the separation of roles of trauma teams and organ recovery/transplantation teams, attend to data emerging from further pilot or demonstration experiments, and the like. Some of these measures may increase the chances of success by reducing the threats to public trust. In the final analysis, DCD programs do not stand alone, and their success or failure will depend in part on the larger framework of organ donation, procurement, and transplantation.

References
3. Id., at 152.
6. See IOM, supra note 2, at 28.
10. See IOM, supra note 2, at 152-53.
12. See IOM, supra note 2, at 156.