Introduction:
Organ Donation and Death from Unexpected Circulatory Arrest:
Engaging the Recommendations of the Institute of Medicine

James M. DuBois and Rebecca L. Volpe

This symposium explores the boldest recommendation of the Institute of Medicine’s (IOM) Committee on Increasing Rates of Organ Donation (hereafter Committee), namely, the recommendation that the U.S. consider a new population of potential donors. In its 2006 report, *Organ Donation: Opportunities for Action*, the committee recommended pilot programs in so-called “uncontrolled” donation after a circulatory determination of death (uDCD). Potential uDCD donors have died from an unexpected loss of circulation, either due to sudden cardiac arrest or excessive blood loss following traumatic injury. Because circulation is lost before death is determined and long before organ procurement could begin, potentially transplantable organs will die from oxygen starvation (warm ischemia) unless they are quickly preserved by cooling or other means.

From a “donor management” perspective, uDCD contrasts sharply with the two more common forms of deceased donation involving either so-called “brain-dead” donors or “controlled” DCD donors. Most deceased donors are declared dead using neurological criteria (“brain death” criteria) while circulation and respiration are artificially maintained. In controlled DCD, which is increasingly common in the U.S., circulation and respiration are artificially maintained until shortly before death is determined. In both cases, organ procurement surgery may be planned in advance, and families and donation coordinators usually have hours available to engage in consent discussions. uDCD has sometimes been called “Rapid Organ Recovery” because, in contrast to more common forms of donation, the initial preservation interventions must be made very quickly, often before family members are present to grant permission for organ preservation.

While two previous IOM reports acknowledged the possibility of uDCD (then called “uncontrolled non-heart-beating organ donation”), neither strongly recommended pursuing uDCD, choosing instead to focus on controlled DCD. Similarly, a 2005 U.S. consensus conference encouraged and provided guidelines for controlled DCD, but did not engage the possibility of uDCD. So why did the 2006 IOM report suddenly recommend pursuing uDCD, and what specifically did it recommend?

The 2006 IOM Committee was formed at the request of the Department of Health and Human Services (DHHS) in response to the legislative requirements of the 2004 Organ Donation and Recovery Improvement Act. The Committee’s task was to “conduct a review of proposals and efforts to increase organ donation” while considering the “ethical implications” of these proposals, their possible impact on “public perceptions ... and ethnic minorities” and the “cost-effectiveness, feasibility, and practicality of implementing such proposals.” The Committee rejected several proposals to increase rates of organ donation, most notably proposals to provide financial incentives for donation and to presume consent to donation (whether by shifting to an opt-out system or routine retrieval). Rather than focusing on controversial approaches to increasing rates of donation within the existing population of roughly 10,500

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to 16,800 who are declared dead each year using neurological criteria (currently approximately 94% of all deceased donors), the Committee sought to expand the pool of potential donors. It estimated that of the roughly 335,000 deaths by cardiac arrest each year, at least 22,000 individuals would meet the criteria for uDCD. At a follow-up meeting organized by the IOM and in this symposium, Dr. Jimmy Light observed that this estimation of potential uDCD donors did not include trauma victims (who died of excessive blood loss rather than loss of neurological functions), who chiefly comprised the donors in the Washington Hospital pilot program. Moreover, the Committee observed that outcomes with uDCD kidneys appeared to be nearly identical to those from standard deceased donors. Thus, the Committee argued that the potential positive impact of uDCD on kidney donation is significant enough to warrant demonstration projects.

While the Committee acknowledged that many ethical and policy issues must be resolved at the local level, it presented two sorts of considerations to guide local thinking: first, statements of European protections and procedures; second, statements of protections and procedures that the Committee thought might provide an absolute baseline. The following are some of the stances the Committee adopted toward key ethical and policy issues pertaining to uDCD:

- “Provide excellent emergency and resuscitative care. ... State-of-the-art guidelines must be followed ... The priority is to focus all possible medical care on the individual’s survival.”
- Ensure a separation between resuscitation and organ donation. “Those making the decision to discontinue CPR should not be affiliated with the organ recovery team. ... although a separation between teams is essential, the hands-off period could be very brief and may even be unnecessary.”
- “Ensure the opportunity for donation. ... Donor consent ... should be considered as the necessary documentation for beginning appropriate medical processes for organ donation after death. In cases of death without that documentation, organ preservation methods could be started to allow the family the opportunity to donate their loved one’s organs if they choose to do so.”

The five papers in this symposium engage different aspects of the IOM’s recommendation to pursue uDCD from diverse perspectives.

- “Provide public education. ... a transparent and open process is essential, as is the substantive and ongoing involvement of the community in the planning, development and implementation of a [uDCD] program.”
- “Provide professional education. ... clarifying the elements of high-quality end-of-life care and explaining the steps and protocols needed to implement [uDCD] in all settings. Support for [uDCD] is particularly needed from professional associations.”
- Legal sanctioning. On the question whether organ procurement organizations (OPOs) need legislation permitting organ preservation absent explicit permission, the Committee acknowledged that “... some OPOs may want such legislation to remove all doubt regarding the legal permissibility of the procedure”; however, it also stated that it “is not convinced that such legislation is necessary.” This contrasts with the necessity of “being transparent” and consulting “relevant communities.”

While articulating a strong commitment to avoiding compromises in resuscitation, some of the Committee’s stances are contrary to recommendations of other groups. For example, the Committee went beyond the recommendations of earlier IOM reports on DCD, which hedged on whether one could preserve organs without prior expressed permission, and contradicted the position of the American Medical Association. Similarly, while most European protocols require a hands off period, the Committee believed such might be desirable but is unnecessary if best practices for resuscitation are followed and the resuscitation team is separate from the organ preservation and donation team.

Despite the fact that some of the IOM Committee’s recommendations were contentious, the Health Resource and Service Administration — the branch of DHHS that commissioned the IOM study — followed up on these recommendations by issuing a request for applications to develop uDCD pilot programs, and two such programs were funded in 2007.

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Although uDCD programs have been implemented and found to be successful in other countries (e.g., Spain), some might doubt this sort of program is possible in the U.S. Jimmy Light’s piece in this issue recounts his experience implementing a pilot uDCD program at Washington Hospital Center. Using their three-year experience as the starting point, Light focuses upon the challenges, benefits, and lessons learned from their program. He emphasizes the importance of community education, OPO support, and the need for immediate in-situ preservation of organs. Significantly, Light and his team showed there were as many uDCD candidates as there were potential candidates from traditional brain death, confirming the hypothesis that uDCD was an important potential donor source. While several possible approaches to preserving organs exist — including sustained CPR following death and the use of extracorporeal circulation — the organ cooling approach used by Dr. Light and colleagues is the approach discussed by the IOM.

Pascal Borry, Walter Van Reusel, Leo Roels, and Paul Schotsmans present a European perspective on uDCD and questions of consent. They present data on the European experience with uDCD and discuss ethical guidelines. While agreeing with the IOM that it is ethically appropriate to preserve organs without explicit consent, they argue that the IOM did not go far enough in its recommendations. Specifically, they state that shifting from an opt-in (explicit consent model) of organ donation to an opt-out system (so-called presumed consent model) increases rates of organ donation far more than embracing uDCD alone. They conclude that such an approach “supports organ donation, respects individuals who object to organ donation, relieves families from the burden of decision-making, and can save lives.”

Critical readers will not fail to appreciate the complexity of the issues surrounding uDCD. If such protocols are implemented, many additional lives could be improved and prolonged with transplantations, and many more families will have the opportunity to participate in organ donation — an opportunity many find meaningful or consoling. At the same time, if done poorly (e.g., with inadequate safeguards or insufficient transparency), uDCD could exacerbate mistrust in the medical system and conceivably turn a portion of the public against donation. The topic is important and unlikely to go away.

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Christopher Doig and David Zygun present a series of concerns about uDCD. They fear that uDCD introduces a conflict between a critical care physician’s duty to resuscitate and the duty uDCD would create to identify potential donors. Potentially, the desire to identify organ donors could compromise the qual-
ity of resuscitation provided. They argue that uDCD is premature until further research is conducted to establish best practices for resuscitation, and until national rather than local guidelines for resuscitation are established. They also challenge the IOM’s estimations regarding the potential impact uDCD might have on donation, warning that the public may resist uDCD, and poorly implemented programs could even hurt donation rates.

James Childress, editor of the 2006 IOM report, concludes this symposium by reviewing the major ethical and policy issues engaged by the previous four articles, and generally explaining and defending the rationale the IOM provided for its recommendations. His conclusion reinforces a point strongly made by the IOM committee: “uDCD programs do not stand alone, and their success or failure will depend in part on the larger framework of organ donation, procurement, and transplantation.”

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References
5. Childress and Liverman, supra note 1, at 157.
6. Id., at 152-153.
7. Id., at 157.
8. Id., at 153.
10. Id.
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