Presently, there are more than 94,000 individuals on the U.S. organ transplant waiting list.

Donation after circulatory determination of death (DCDD) is termed “uncontrolled” when death is due to unexpected or sudden circulatory-respiratory arrest. Circulatory determination of death currently accounts for only 5.5 percent of deceased donations.

OVERVIEW OF THE ISSUES

Lewis Goldfrank opened his presentation with an overview of the issues by reminding the group that many people who die never have the opportunity to be organ donors.

In reviewing the common forms of donations, he noted that there are approximately 7,000 living donations of single organs each year. Neurological determination of death accounts for approximately 23,000 transplanted organs annually from just over 7,500 DNDD donors, although the potential exists for 12,000 to 16,000 DNDD donors. Circulatory determination of death currently accounts for only 5.5 percent of deceased donations. Presently, there are more than 94,000 individuals on the U.S. organ transplant waiting list.

Dr. Goldfrank noted the need for clearer terms and definitions, for instance, in the categorization frameworks, such as the Maastricht categories. He stressed the difficulties in defining and distinguishing controlled versus uncontrolled dying. Donation after circulatory determination of death is termed “uncontrolled” when death is due to unexpected or sudden circulatory-respiratory arrest.
Characteristics of controlled and uncontrolled DCDD might include:

Controlled DCDD (Maastricht III):
- On ventilator
- DNR (no attempted resuscitation)
- Located in the intensive care unit
- Timing of death is controlled
- In situ organ preservation unnecessary
- Family consent can be readily obtained before interventions.

Uncontrolled DCDD (Maastricht I, II, IV):
- Not on ventilator
- Resuscitation normally is attempted
- Located in field, emergency department, hospital
- Timing of death is uncontrolled
- In situ organ preservation (cooling) is necessary
- Family consent is difficult to obtain before preservation interventions need to be started.

Dr. Goldfrank presented the standard criteria for terminating advanced cardiac life-support efforts (ACLS). ACLS may end if the patient is unresponsive after basic CPR is provided; ventricular fibrillation is eliminated; advanced airways device is placed; oxygenation/ventilation is achieved; intervention has been sustained for more than 10 minutes; and rhythm appropriate drugs have been administered.

Dr. Goldfrank concluded by outlining the various areas of consideration relevant to uncontrolled DCDD. At the end of the day, what should the professional standards be—professional considerations. What criteria are necessary to respect the dead donor rule—ethical considerations. What criteria are necessary to preserve the public trust that resuscitation is the first priority—public considerations. What legal criteria are compatible with organ donation—legal considerations. And, finally, it is important to determine what research is necessary to advance the field.

**POTENTIAL IMPACT**

**Potential for Increased Organ Donation**

John Gallagher discussed the potential for increased donations following uncontrolled DCDD and introduced the experiences of a hospital in Madrid, Spain that has performed uncontrolled DCDD for more than 15 years. Spanish law allows institution of organ preservation until the next-of-kin either consents to or refuses organ removal. As soon as the patient is pronounced, and following the hands-off period, the transplant team begins cannulation and cooling, obtains blood samples, and assumes care under previously established conditions (e.g., presumed consent, prior community agreement, or enabling legislation). There must be less than 120 minutes of total warm ischemia time (i.e., from the moment of collapse until cannulation and cooling begins). The medical examiner is contacted, depending on local legal requirements. The family is contacted and notified of the death per the institutional protocol; a trained member of the transplant team makes the donation request from the family within four hours. This protocol has yielded a 93 percent consent rate for kidney donation (see Sanchez-Fructuoso et al., 2006, Annals of Internal Medicine 145:157-164).

To obtain an estimate of the number of uncontrolled DCDD donors, Dr. Gallagher used conservative criteria modified from the Madrid experience (see IOM, 2006, p. 139) and applied this information to data obtained from the New York
City PHASE study (Pre-Hospital Arrest Survival Evaluation). The PHASE study was conducted in New York City in the early to mid-1990s to assess survival following out-of-hospital cardiac arrest. Trained paramedic research associates performed immediate post-arrest interviews with out-of-hospital care providers using a validated, standardized data collection instrument. Dr. Gallagher specifically noted that cardiac arrests associated with trauma were excluded from this dataset. Thus, the number of potential uncontrolled DCDDs following out-of-hospital cardiac arrests could be significantly higher if eligible trauma patients were added to this cohort.

The PHASE study gathered data on 3,243 consecutive out-of-hospital cardiac arrests during a six-month period in New York City. Of these, 2,329 met entry criteria as primary cardiac events. In examining the PHASE data, it was determined that 178 of the non-survivors (about 7.6%, 99% confidence interval 6.6–8.7%) met the Modified Madrid Criteria (excluding trauma cases). These criteria included age under 50 years, receipt of CPR within 15 minutes of witnessed collapse, and pronouncement of death within 60 minutes of onset of cardiac arrest. An application of the lower limit of the confidence interval (6.6%) to the American Heart Association estimate of 335,000 out-of-hospital cardiac arrests occurring annually in the United States, suggests the availability of approximately 22,000 potential uncontrolled DCDD donors in the United States each year. These calculations use conservative approximations and are meant to provide a preliminary working estimate of the number of additional potential kidney donors available from this untapped pool of out-of-hospital cardiac arrests.

Dr. Gallagher concluded by noting that outcomes from fifteen years of experience in Madrid indicate that despite the expected delayed graft function seen in most DCDD kidneys, one- and five-year graft survival rates compare favorably with graft survival of kidneys transplanted following neurologic determination of death. Furthermore, one- and five-year graft survival rates for DCDD in the Madrid experience are actually better than for those of DNDD donors over age 60.

Cost-Benefit Analysis – Issues to Consider

David Howard discussed the limited cost-benefit data on kidney transplantation and the lack of data specific to uncontrolled DCDD. One study compared costs between high- and low-risk recipients by donor type: extended criteria donor (ECD) and non-ECD. Costs for patients who received ECD kidneys were higher than for those who received non-ECD kidneys, regardless of the risk status of the recipient. Transplantation was found to be cost-effective for a five-year time horizon in three of the four categories of recipient/donor and for all four categories over 20 years.

Studies that compare the costs of transplantation to the costs of remaining on dialysis are of particular interest. Dr. Howard noted that while ongoing costs for patients on dialysis are higher than costs for patients on maintenance immunosuppressive therapy, mortality rates for patients on dialysis are also higher, so it is not immediately clear that transplantation is cost-saving relative to transplantation in the long-run. Several recent studies have found that transplantation using kidneys from ECDs and transplantation with kidneys from living donors is cost-saving over a 20-year period when compared with the long run costs of remaining on dialysis from the perspective of the Medicare program. A more recent study of the long-run costs incurred by patients with private insurance found that kidney transplantation is cost-increasing: ten-year costs for all transplant patients are $163,474 compared to $146,538 for dialysis recipients. However, kidney transplantation is cost-saving for living donor transplant recipients and patients who are on dialysis largely because patients are transplanted earlier, while healthier, and the donated organs have fewer complications and are frequently a better match.

The cost-benefit analysis of DCDD could be examined by comparing costs for
those who stay on the waiting list and DCDD kidney transplantation; staying on waiting list and non-DCDD kidney transplantation; and so on. A new study is examining UNOS data for one-, three- and five-year outcomes for DCDD and non-DCDD kidney recipients.

Dr. Howard also noted that it is important to consider how this type of donor recovery would affect the OPOs. Economies of scale will be important in terms of instituting programs; the more they can be ramped up quickly, the lower costs will be for the OPOs. It might be necessary to think about providing extra payments and/or incentives to encourage centers to accept DCDD organs.

**INSIGHTS FROM THE WASHINGTON, DC EXPERIENCE: CASE STUDY AND LESSONS LEARNED**

Jimmy Light discussed the Rapid Organ Recovery Program conducted in the late 1990s in Washington, D.C. This program is the most extensive uncontrolled DCDD program conducted in the United States to date. The Rapid Organ Recovery Program focused on trauma deaths in patients with non-survivable brain injury who did not meet neurologic death criteria. For these patients, uncontrolled DCDD provided the organ donation option for the surviving family. (It was noted in passing that the IOM estimation of the potential pool of uncontrolled DCDD donors excluded trauma deaths, and thus was likely a significant underestimation of the actual number of potential donors).

Dr. Light described the system needs for implementing an uncontrolled DCDD process. The program’s protocol and defined roles were developed to ensure that warm ischemia time was less than 45 minutes. Participating staff included family advocates who interfaced with the medical examiner, the homicide team, and the OPO. An on-site preservation team and equipment was used to conduct bedside cannulation and cooling to begin organ preservation in situ. After recovery, kidneys were biopsied and placed on machine preservation and, if the kidneys were satisfactory, then allocation was made based on UNOS (United Network for Organ Sharing) criteria to the most appropriate recipients. Average total ischemia time was about 23 hours, but in two cases was well over 30 hours. Ischemia time should be shorter with current technology.

When the Rapid Organ Recovery Program began, the donor family had to give consent to initiate preservation. However, this could be accomplished in only 10 percent of the potential donors within the 45-minute window. Most families could be contacted within 4 hours, and most of them authorized tissue donation. As a result of these data accumulated over a one year period, the D.C. City Council amended the Uniform Anatomical Gift Act (UAGA) to authorize hospitals to initiate organ preservation procedures in order to provide family members with the option of donation. The changes were as follows:

- In the event that the next-of-kin is not immediately available for consent to be requested, the hospital may use organ preservation and techniques to maintain the viability of the decedent’s organs... in order to preserve the option to consider organ donation.
- Use all available methods to contact the next-of-kin for organ donation; if not reached in a reasonable time, discontinue in situ preservation.
- Individuals and hospitals are immune from liability.
- Decedent/family bears no costs.

Dr. Light noted that the Rapid Organ Recovery Program did not experience pushback from caregivers, probably because the process was implemented slowly.
and concerns were addressed along the way until everyone was comfortable with it. A significant amount of time was devoted to discussions with the general public and media interactions, spearheaded by the director of the family advocates program.

External grant support provided initial funding for the family advocate system and the organ preservation laboratory and helped build institutional support. Dr. Light explained that the existence of funding encouraged the systems change. There would not have been a family advocate program without the external funding, and without the family advocates, there could not have been a Rapid Organ Recovery Program. The main point is that most health care institutions cannot commit the start up funds and resources needed to institute this type of organ and tissue recovery system. Once the system is well entrenched, then recovery and utilization fees should sustain the program.

Dr. Light discussed the process for rapid organ recovery. To achieve optimal kidney preservation it is necessary to get the body to about 15 degrees Celsius as rapidly as possible. The group’s research showed this was not possible with intravascular cooling alone (the technique used in Europe). The D.C. group used modified laproscopy tubes to initiate intraperitoneal cooling and a heat exchanger to supercool the solutions, along with the traditional intravascular cooling with the triple lumen, double balloon catheter. These combined techniques reduced the core temperature to about 15 degrees within about 30 minutes. The mean warm ischemia time (from cardiac arrest to initiating flush) was 28 minutes with a range of 7 to 60 minutes. Mean in situ preservation time (e.g., kidneys preserved in the donor) was 2 hours and 24 minutes, with a range of 1 to 6.5 hours.

The group discussed what Dr. Light had described as the keystone to making organs available: rapid cooling and immediate surgical capacity. In D.C., the team was always on-site, surgical carts were located in all of the intensive care units, and the preservation fluid was always kept cool. The median time of 28 minutes from death to cooling the organs is not possible without trained in-house personnel. Dr. Light’s view is that uncontrolled DCDD is really only feasible in significantly sized trauma units; otherwise, there are too few cases to keep staff at adequate levels and to maintain expertise, assuming that current hypothermic technology is utilized.

The transplanted kidneys had immediate function in nine instances; delayed function in 20; and non-function in two where preservation times exceeded 30 hours and the recipients were higher immune risk. Patient survival and graft survival were equivalent for about 4 years but not as good as expected in later years, perhaps due to ischemic damage. The number of patients was small, however, and their results should not drive the discussion. Selecting appropriate recipients is an important part of getting good results. Recipient selection should be based on physician and patient willingness to accept a DCDD organ with its attendant risks, noted in advance in the patient’s file to speed organ allocation (much as it is done for ECD recipients). High-immune risk or technically difficult recipients should be avoided.

The group discussed whether a controlled DCDD program must be in place in order to start an uncontrolled DCDD program. Dr. Light noted that when they were conducting the uncontrolled DCDD program, the OPO did not have a controlled DCDD program, which made implementing the uncontrolled program more difficult. Dr. Light felt that controlled DCDD should be implemented first, and then expanded to include the uncontrolled DCDD. However, another participant stated that the ethical issues and the support needs vary between the two processes.
ETHICAL ISSUES

Jim DuBois presented the different ethical issues relevant to DCDD under controlled versus uncontrolled situations. In the United States, controlled DCDD raises issues regarding the withdrawal of ventilation, determination of the length of wait-time following circulatory arrest, and the use of heparin. These issues are non-existent with uncontrolled DCDD, as the donor is not on a ventilator, and medical professionals attempt to resuscitate them. It is the timing of the death, and not the process, that is uncontrolled. Dr. DuBois noted that in the United States, the issue of consent is key. On the one hand, there is a strong tradition of not performing medical procedures on the living without their consent, and a strong tradition of allowing families to determine the treatment of the deceased. On the other hand, most people in the nation favor donation; most Americans who sign a donor card assume that they will be donors, but most will not currently have the chance (only 6 of 1,000 deceased individuals have the chance to actually donate). Preservation leaves open the opportunity to exercise autonomy. Increased donation, moreover, saves lives.

Dr. DuBois raised the question, should we make the consent issue moot? In the absence of statutes explicitly permitting preservation, it could be best to start with those individuals who have a donor card and/or have joined registries. First person consent is generally now honored and registries have improved access to consent information. Other consent issues that should be considered include whether we should create opportunities to opt out. There are no good ways to do this right now. When someone does not sign an organ donor card, they are not explicitly saying they do not want to be a donor and their family would be contacted in an uncontrolled situation. People could be given an option to choose: “I want to be a donor,” “please talk to my family,” or “I don’t want to be a donor.” Then, only in the latter situation would the organs not be preserved.

The criteria for uncontrolled DCDD must be trusted by the public at least as much as is the case in DNDD—or the public itself may insist on the implementation of special consent for uncontrolled donation. People need to know they will really be dead before procurement occurs. Issues that complicate uncontrolled donation include trust and resuscitation. People fear that their doctors will not try as hard as possible to save their lives if they are organ donors. Dr. DuBois stated that education is needed to correct this belief. We also need to guarantee gold standards for resuscitation efforts. Europe uses 30 minutes of attempted resuscitation and 10 minutes of a hands-off period. The IOM in the 2006 report did not insist on a hands-off period, but there may be a need for one, even if it is short and primarily symbolic. Health care workers’ views are likely to be more supportive if there was a short transition period between patient and donor status. It is also critically important that the individual who discontinues resuscitation is not affiliated with any donor program. Without public support, organ donation cannot occur.

Dr. DuBois further noted that organ quality must be acceptable. In time, the quality is likely to improve, although research and quality assurance are both necessary. But, if the quality is found to be unequal, extended criteria rules should apply. Special consent would be needed from the potential recipients and special allocation rules implemented.

Uncontrolled DCDD and living donation each have pros and cons as outlined in Dr. DuBois’ presentation. Living donation has lower costs, yields better graft survival and better quality of life, and can greatly expand the pool of donors. The negative issues regarding living donation are that a few healthy donors are going to die, someone is going to be hurt, and there are concerns about coercion. These negative issues led the 2006 IOM committee to explore DCDD more intently.
The group discussed issues of diversity as they affect uncontrolled DCDD, particularly that mistrust of the medical system is exacerbated by disparities and is a factor in organ donation. Barriers to health care services exist, particularly in large cities that have health care disparities, and this reality may drive the success of the program. Dr. DuBois noted that the 2006 IOM committee felt that increasing the pool of organs will help to diminish disparities and is one way to improve the situation. Another participant noted that there is a danger that people will be confused by the problems that have been publicized in whole body donation.

**LEGAL ISSUES**

Richard Bonnie discussed the relevant legal issues, with particular attention to the core issue of preservation without explicit consent. He began by assuming that it is ethically permissible (at the very least), and may be ethically required, to preserve organs for possible donation while seeking explicit consent, as it preserves options and autonomy. The question, Mr. Bonnie noted, is whether “the law” currently impedes this ethically permissible activity, either because it clearly requires explicit consent before preservation can be undertaken or because legal uncertainty about the issue deters doctors and hospitals from undertaking preservation in the absence of explicit consent.

One point is clear, Mr. Bonnie said: A recorded desire by the deceased to be a donor provides sufficient authority to preserve organs for this purpose, even if the practice is also to seek family consent. The uncertainty arises when the deceased person’s wishes are unknown, and family authorization is being sought. In some states and locales, such as Virginia, Washington D.C., and Illinois, statutes explicitly permit preservation activities prior to obtaining consent. Florida also has a “preservation pending consent” law. However, most states do not have such statutes, and whether the law permits preservation pending consent is admittedly uncertain.

The argument that preservation pending consent is not permissible proceeds as follows. The assumption is that as long as a person is alive, he or she has to give explicit consent, so that prerogative goes to the family members when that person dies, and they must give explicit consent. This assumption is an extension of the views about control over the body: that the baton of control passes to the family. So, one legal assumption could be that the law must explicitly say it is acceptable to conduct preservation without explicit consent. Mr. Bonnie contended, however, that this view reflects a misunderstanding of existing law.

Two lines of arguments were outlined by Mr. Bonnie in support of his view that current law authorizes preservation pending family consent. The first is that the authority is implicitly conferred by the UAGA. The Act’s purpose is to facilitate organ donation; it includes many provisions for doing this, such as the requirement that a reasonable search for donation documents be made. Normally (e.g., in a controlled situation) there is time to conduct such a search and contact the family before the individual is deceased. There is implicit authority, then, to preserve the organs while the search for documentation and the family is being conducted. And, the immunity provision protects those who attempt in good faith to comply with spirit and letter of the UAGA. The Act does not preclude preservation. Moreover, organ preservation is arguably analogous to the common practice of maintaining a patient on mechanical ventilation following a neurological determination of death in order to enable a request for donation.

The second argument is that preservation pending consent does not violate family legal rights. Mr. Bonnie noted that there is an exaggerated understanding of families’ legal rights in this area. The family’s legal interest in the body of a deceased
person is neither an extension of the autonomy that the deceased person exercised while he or she was alive, nor a property interest belonging to the family. The families’ right is the right to have possession of the body and make the final disposition of it. It is a very limited right that can be overridden by the state’s interest in, for example, conducting an autopsy. Organ procurement organizations are sometimes told by families that consent for donation is denied because the family has concerns about mutilation. However, the incisions required for organ preservation do not amount to mutilation in a legal sense, Mr. Bonnie observed. This may be less of a legal issue and more of an educational issue around what happens to the body after death.

The group discussion focused in part on the possibilities of regulation rather than legislation. Discussion also revolved around ensuring that correct terms are used. Several participants noted that, in terms of public awareness, people need to be clear that we are talking about cardiac arrests, not heart attacks.

OPPORTUNITIES AND BARRIERS TO UNCONTROLLED DCDD: NATIONAL AND METROPOLITAN PERSPECTIVES

The group met in breakout sessions to consider specific issues and barriers to the implementation of uncontrolled DCDD efforts in Chicago, New York City, and Washington, D.C. A fourth breakout session focused on national policy issues.

Chicago

Members of this breakout session included: Jim DuBois, Michael Harmon, Bernard Heilicser, Stephen Jensik, Mark Kuczewski, and Martin Mozes. Notes from the breakout session highlighted the following areas of the group’s discussion:

- **Obstacles**: Identifying space to be used for these procedures is an unresolved issue, as is preservation. The group felt that re-routing ambulances to just a few organ retrieval centers would be riskier for EMS staff, who would need to travel further through the city than usual. The UNOS allocation criteria were also seen as a barrier and as a disincentive for the OPO. It would be a benefit and an incentive if the OPO could get an exemption for uncontrolled DCDD.

- **Staffing**: The group saw a need for a dedicated staff person to be ready to do the preservation, but felt that there are not enough emergency department staff to conduct preservation. Paraprofessional staff could be used. The group felt that uncontrolled DCDD would result in few changes for emergency medical services (EMS), as pronouncement should occur in the hospital. The only changes for EMS personnel would be that they would not extubate; the donor should remain intubated to aid preservation, and death should be pronounced in the emergency room rather than in the field.

- **Professional support**: The Chicago group emphasized the importance of involving coroners and medical examiners. National criteria/standards would be helpful in encouraging hospitals to become engaged.

- **Community public relations and education**: The group felt that these efforts should occur at the hospital-based level, with the local community. One question that needs to be resolved is whether this education needs to focus on uncontrolled DCDD or whether focus groups and town hall meetings should focus on the trust issues that are connected with organ donation in general.

- **Demonstration projects**: The group identified a cluster of hospitals around Cook County Hospital where this process could be started, with effort. If there cannot be
one person at each hospital, then one person could cover the three sites and triage will be necessary. The suggestion was to begin with patients who were on the organ registry.

- **Terminology**: The term “emergency room organ donation” was suggested by one member of the group, though the group could not agree on a name. Group members did not like the use of abbreviations and felt that avoiding abbreviations will help to educate the public about what this involves and where it happens. One audience participant suggested that no special name is needed, that we should always just refer to “organ donation” and protocols can specify details for specific situations.

**New York City**

Members of this breakout session included: Richard Bonnie, Dolph Chianchiano, Joseph Cooke, Nancy Dubler, Van Dunn, John Gallagher, Lewis Goldfrank, Eric Grossman, Brad Kaufman, Ginny McBride, Tia Powell. The New York group’s discussion generated a “to do” list that includes legal counsel letters, a demonstration project letter, pre-hospital demonstration EMS involvement, and seeking a grant from HRSA. Specific discussion points included:

- **Logistics**: The group suggested using existing trauma centers and leveraging underutilized trauma teams. The group emphasized that it will be necessary to obtain the buy-in from transplant surgeons, and to work with EMS to modify post-resuscitation and transport protocols.
- **Finance**: Financial issues discussed by the group included the costs of personnel, family advocates, operating room equipment, and hospital time. It was noted that an upcoming Health Resources and Services Administration (HRSA) grant might help cover some of these costs.
- **Legislation**: The New York group wants to seek an opinion letter from the general counsel of the Health and Hospital Corporation so they can move ahead with a demonstration project without necessitating specific legislation.
- **Research**: The group emphasized the importance of integrating uncontrolled DCDD into current research efforts to improve resuscitation.
- **Communications and public involvement**: The group focused much of its discussion on how to engage the community and develop trust in uncontrolled DCDD. It is important to gain buy-in from those entities providing medical care to the community. The New York group intends to reach out to key individuals and organizations and noted that community planning boards are good routes for education and information. It will also be important to work with leaders and change agents in the community, such as religious groups and African American women.
- **Messaging**: Professional advice and analysis will be critical to developing an effective message. The group felt that a public campaign is needed to emphasize that the goal is to save lives with this form of organ donation. It will be important to demonstrate, across the spectrum of care, that the focus is on preventing disease and saving lives, and that only when resuscitation fails does donation become the priority.
- **Stakeholder analysis**: The group felt that stakeholders include patients, families, recipients, transplant surgeons, trauma surgeons who will retrieve organs, emergency physicians, EMS staff, and hospital staff.

**Washington, D.C.**

Notes from the breakout session highlighted the following areas of the group’s discussion:

- **Infrastructure, challenges and barriers**: The group felt that Washington, D.C. is at a high state of readiness with the resources, desire and experience to conduct uncontrolled DCDD. Use of the regional trauma center infrastructure and routing pre-hospital triage through the trauma centers rather than the emergency departments was discussed. Issues regarding initiation of preservation and operating room availability were deemed to be manageable. Community input is strong and the OPO is now interested in working on this issue. Implementing a new uncontrolled DCDD initiative will require some re-engineering and new resources, but the group felt that it is possible.

- **Professional support**: There is a need for trauma surgeons to initiate preservation activities as an extension of end of life care after death has been declared. This simple change preserves the donation option for families, and buys time to assemble organ preservation and recovery teams. Staff will need to be re-educated, but the group felt that it could be done with the structure and protocol used before, with the assistance of family advocates, and with the advent of better preservation solutions and devices. Professional support is likely to be enhanced by the increases in donations.

- **Impact**: The potential impact on emergency departments is unknown; it will be necessary to look at how EMS triages and to create systems that triage likely patients and route them to trauma centers. The group emphasized the importance of being clear about the space needs that will be required, and taking into consideration any resulting strain on the system.

- **Terminology**: The group suggested using a process similar to the last time that Washington, D.C. conducted this process and gather community input on the program/process’ name. Something that references organ donation would be most clear to the public. It is probably worth the effort to generate a program name that is unique and clear. The group also thought that one term for uncontrolled DCDD should be used across the United States rather than varying by location and that the Organ Procurement and Transplantation Network (OPTN) should take on this task.

**National Policy Group**

Members of this breakout session included: James Burdick, Jim Childress, Frank Delmonico, Richard Durbin, David Howard, Howard Nathan, Alan Rubenstein, Paul Schwab, and Jim Warren. Notes from the breakout session highlighted the following areas of the group’s discussion:

- **Stakeholders**: There is a need to educate medical professionals on this issue. The group thought it might be useful for the Joint Commission to draft a focus paper on uncontrolled DCDD, like the one it created earlier on organ donation. Surgeons have concerns about outcomes and the cost of keeping the recipients in the hospital for a longer period of time. There is a new push to gather outcome data about organs that a center rejected, and provide this back to the center as a way to help staff assess their decision-making when rejecting an organ. Recipient selection is an issue: it is anticipated that organs from uncontrolled DCDD donors will not go to high-risk patients; recipient selection will help address issues of cost.

- **Change in practice**: With controlled DCDD, there was already an end-of-life care system in place, and the mindset of providers was established. Uncontrolled DCDD requires a change in practice. The practice has not been set yet and in some cases a staff person is being asked to functionally change what they do in a situation.

- **Risk management**: The group felt that a large issue for hospitals will be risk management and cost-benefits. It may be cost-beneficial in practical and medical
terms, but hospitals may still worry about potential lawsuits.

- **Pilot studies**: The group considered the advantages of implementing a pilot study on uncontrolled DCDD in a state or area with both first person consent and a donor registry. People think they are going to be a donor when they get their card, and most would be astonished to learn that it is not necessarily going to happen—depending on how they die.

### NEXT STEPS IN IMPLEMENTING UNCONTROLLED DCDD PROGRAMS

The group reconvened to hear the reports from the breakout sessions and to focus on next steps for uncontrolled DCDD in the United States. Dr. DuBois noted that although some obstacles had been noted in the groups’ discussions, there are many opportunities and much interest in pursuing the implementation of pilot programs on uncontrolled DCDD. The group discussed whether a national consensus conference or a national taskforce on uncontrolled DCDD is needed, but it was agreed that the present meeting and the 2006 IOM report provided sufficient basis for local efforts, and that local buy-in is perhaps more urgently needed. However, it is important for key national organizations to demonstrate their support (e.g., American Society of Transplant Surgeons [ASTS], OPTN) for uncontrolled DCDD. The group also discussed whether uncontrolled DCDD should be promoted by the HRSA Breakthrough Collaborative. However, it was observed that the Collaborative’s purpose is to promote data-supported best practices, and uncontrolled DCDD is still in its infancy and requires demonstration projects and data.

HRSA funding options were discussed that include clinical intervention grants focused on examining technical factors to increase donation. This grant program could be an appropriate mechanism to fund demonstration projects. The group suggested beginning with programs in states that have organ donor registries. Success in locating individual hospitals that are enthusiastic about involvement will be another critical element.

The group agreed that there is a better foundation for uncontrolled DCDD efforts than there was a decade ago. Ongoing discussions and efforts by participants of this meeting and others in their cities and organizations will be essential in advancing the implementation of uncontrolled DCDD programs and increasing the number of organ donors.
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